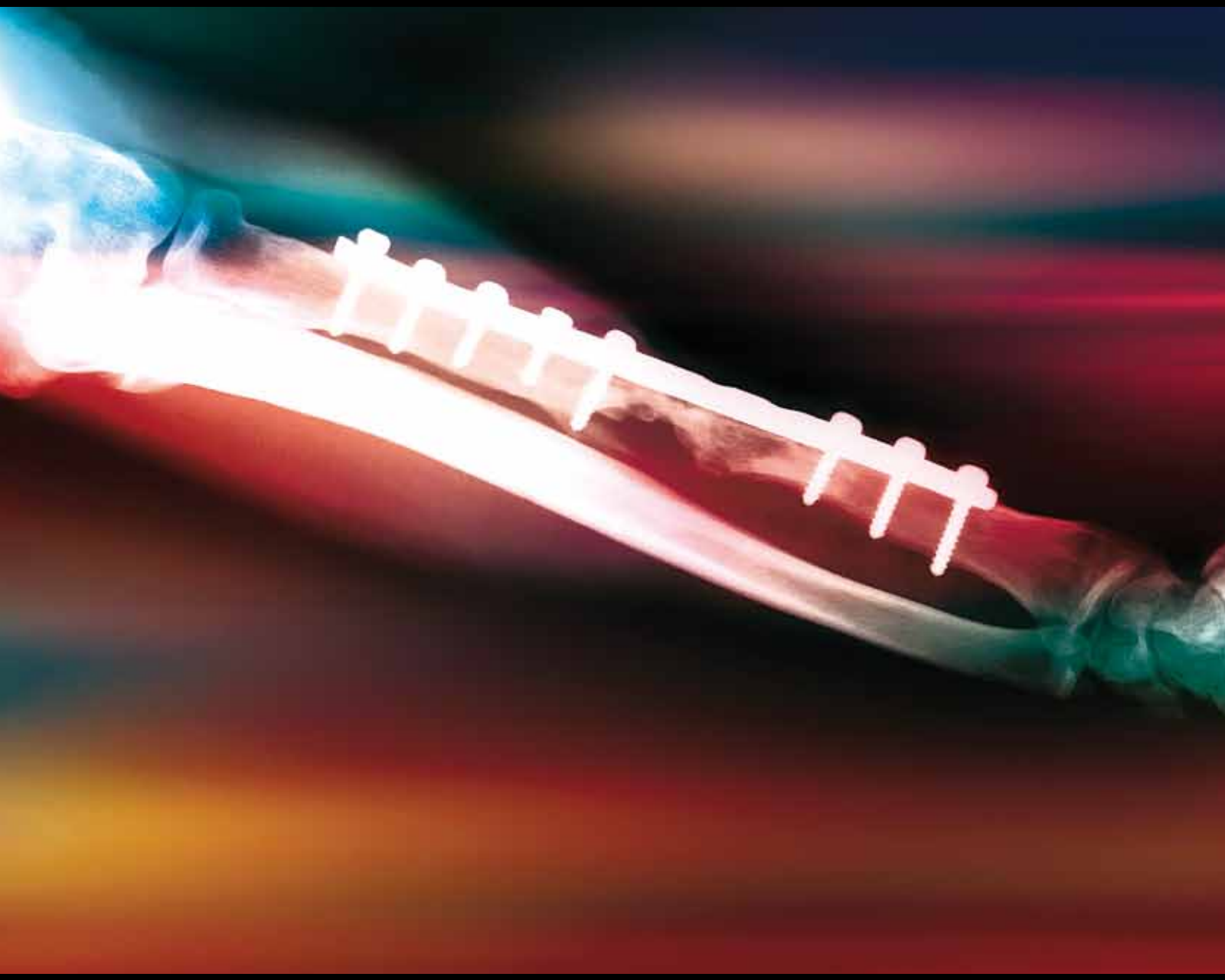
Advances in Orthopedics

Posterior Transpedicular Dynamic Systems in the Treatment of Chronic Lumbar Instability

Guest Editors: Ali Fahir Ozer, Vijay K. Goel, Ahmet Alanay, Mehdi Sasani, Tunc Oktenoglu, and Deniz Erbulut



Posterior Transpedicular Dynamic Systems in the Treatment of Chronic Lumbar Instability

Advances in Orthopedics

Posterior Transpedicular Dynamic Systems in the Treatment of Chronic Lumbar Instability

Guest Editors: Ali Fahir Ozer, Vijay K. Goel, Ahmet Alanay, Mehdi Sasani, Tunc Oktenoglu, and Deniz Erbulut

Editorial Board

Contents

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 432520, 2 pages
http://dx.doi.org/10.1155/2013/432520

Editorial

Posterior Transpedicular Dynamic Systems in the Treatment of Chronic Lumbar Instability

Ali Fahir Ozer,[1] Vijay K. Goel,[2] Ahmet Alanay,[3] Mehdi Sasani,[4] Tunc Oktenoglu,[4] and Deniz Erbulut[5]

[1] *Department of Neurosurgery, Koc University Medical School, Sariyer, 34450 Istanbul, Turkey*
[2] *Engineering Center for Orthopaedic Research Excellence (E-CORE), Departments of Bioengineering and Orthopaedic Surgery, Colleges of Engineering and Medicine, University of Toledo, Toledo, OH 43606, USA*
[3] *Departments of Orthopaedics and Traumatology, Bilim University, Faculty of Medicine, Istanbul Spine Center, Florence Nightingale Hospital, Sisli, 34403 Istanbul, Turkey*
[4] *Department of Neurosurgery, American Hospital, Nisantasi, 34365 Istanbul, Turkey*
[5] *Departments of Mechanical Engineering and Neurosurgery, Koc University, Sariyer, 34450 Istanbul, Turkey*

Correspondence should be addressed to Ali Fahir Ozer; alifahirozer@gmail.com

Received 22 April 2013; Accepted 22 April 2013

Dynamic stabilization is a new concept and a new technology in spinal stabilization. There are a lot of debates on this topic and most of the criticisms may be true; however, it should be kept in mind that every technology develops from necessity. If fusion could solve all the problems, scientists would not try to develop other solutions.

Posterior dynamic stabilization is a hopeful technology and we believe that tremendous innovative surgical techniques and surgical instruments will develop in near future. We expect that we will open new horizons in your minds when you are considering treatment plans about your patients which need lumbar stabilization procedures. In this special issue, you will find several examples of dynamic stabilization surgeries for different spinal diseases. Clinical results were also given with expanded review of the relevant literature.

The papers in this journal also open a new window about treatment of lumbar disc herniations. Type 2 and type 4 disc herniations, according to the Carragee classification, treated with dynamic stabilization instead of subtotal discectomy were discussed by A. F. Ozer et al.

You will find manuscripts in this special issue regarding recurrent disc herniations, painful black discs, degenerative spondylolisthesis, and painful Modic degenerations with degenerative disc disease treated with posterior dynamic stabilization surgery. We believe that dynamic systems will be discussed more intensely in the treatment of degenerative disc and bony pathologies in the lumbar spine.

There are a lot of biomechanical and clinical studies about dynamic stabilization systems of the lumbar spine. Recently, finite element studies also have been published frequently concerning these systems. D. U. Erbulut et al. have performed an excellent review on biomechanics of posterior dynamic stabilization systems, and readers will learn too much from this paper in this special issue.

We know that load sharing of the spinal column is an important biomechanical factor which may directly affect a patient's pain level, fusion success, and future disease progression, following spine surgery. In this journal, there is also a well-written research about load-sharing and regional load distribution of the interbody area investigating comparisons with between rigid rods, semirigid PEEK rods, and semirigid dynamic posterior instrumentation with flexion-extension dampening materials.

There is a very important paper about adult's degenerative scoliosis which concluded that pedicle screw-based dynamic stabilization can be used in elderly patients with mild degenerative lumbar scoliosis because this is a less invasive surgery with short operative duration, moderate blood loss, and low adverse event rates. Moreover, they also reported scoliosis

curve stabilization, at an average followup of more than 5 years.

It was believed that fusion is a gold standard for low back pain treatment so far. However, there have been several complications reported clinically. These complications mainly are related to pseudoarthrosis and adjacent segment degeneration due to high stiffness at the stabilized segment. As an alternative treatment, nonfusion stabilization systems became more and more popular in order to preserve mobility of a motion segment and eliminate adjacent segment phenomena. You will see research studies emphasizing the benefits of dynamic stabilization system to prevent pseudoarthrosis and adjacent segment disease in this issue.

The posterior transpedicular dynamic stabilization method is a very good surgical procedure in the patients with segmental instability. When we consider the biomechanical problems including widening of neutral zone and weakness of parts which stabilize the spine, one can easily understand the effectiveness of dynamic systems in treating patients who have lumbar segmental instability.

There are also reports about the benefits of interspinous spacers and the results in terms of pain control, motion preservation, and prevention of adjacent segment degeneration. The authors in this journal recommend its use in treatment as well as in prevention of adjacent segment disease specifically in young patients where spinal fusion for early degenerative disease is needed.

We know that dynamic stabilization of the lumbar spine not only stops the degeneration process but also starts the regeneration. L.-Y. Fay et al. reported the rehydration of intervertebral disc after dynamic system surgery using MRI evaluation. These papers prove radiological improvement of the disc tissue after this surgery.

Ali Fahir Ozer
Vijay K. Goel
Ahmet Alanay
Mehdi Sasani
Tunc Oktenoglu
Deniz Erbulut

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 745610, 9 pages
http://dx.doi.org/10.1155/2013/745610

Research Article

The Comprehensive Biomechanics and Load-Sharing of Semirigid PEEK and Semirigid Posterior Dynamic Stabilization Systems

D. K. Sengupta,[1] Brandon Bucklen,[2] Paul C. McAfee,[3] Jeff Nichols,[2] Raghavendra Angara,[2] and Saif Khalil[2]

[1] *Dartmouth-Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756, USA*
[2] *Globus Medical, Inc., Valley Forge Business Center, 2560 General Armistead Avenue, Audubon, PA 19403, USA*
[3] *Towson Orthopaedic Associates, P.A.—Scoliosis and Spine Center, O'Dea Medical Arts Building, Suite 104, 7505 Osler Drive, Towson, MD 21204, USA*

Correspondence should be addressed to Brandon Bucklen; bbucklen@globusmedical.com

Received 1 June 2012; Accepted 30 January 2013

Academic Editor: Ali Fahir Ozer

Alternatives to conventional rigid fusion have been proposed for several conditions related to degenerative disc disease when nonoperative treatment has failed. Semirigid fixation, in the form of dynamic stabilization or PEEK rods, is expected to provide compression under loading as well as an intermediate level of stabilization. This study systematically examines both the load-sharing characteristics and kinematics of these two devices compared to the standard of internal rigid fixators. Load-sharing was studied by using digital pressure films inserted between an artificially machined disc and two loading fixtures. Rigid rods, PEEK rods, and the dynamic stabilization system were inserted posteriorly for stabilization. The kinematics were quantified on ten, human, cadaver lumbosacral spines (L3-S1) which were tested under a pure bending moment, in flexion-extension, lateral bending, and axial rotation. The magnitude of load transmission through the anterior column was significantly greater with the dynamic device compared to PEEK rods and rigid rods. The contact pressures were distributed more uniformly, throughout the disc with the dynamic stabilization devices, and had smaller maximum point-loading (pressures) on any particular point within the disc. Kinematically, the motion was reduced by both semirigid devices similarly in all directions, with slight rigidity imparted by a lateral interbody device.

1. Introduction

Conventional instrumentation to achieve fusion in the lumbar spine utilizes rigid rods and pedicle screws [1–3]. Rigid rod fixation is criticized to reduce load-sharing and inhibit fusion mass formation because of the stress-shielding effect [4]. Not only does load-sharing influence fusion, but it may also affect a patient's pain level, adjacent segment kinematics, and the potential for device failure following spine surgery [2]. Semirigid instrumentations, such as polyetheretherketone (PEEK) rods and titanium rods with helical grooves, are designed to increase load-sharing in attempt to induce compression on the bone graft and promote bone remodeling as first credited by Wolff [4]. There is certainly evidence of osteoblastic response to mechanical activation, in various forms, as well as increases in bone formation rate following bouts of loading [5, 6]. Semirigid PEEK instrumentation attempts to allow loading through the anterior column, but most studies show the stiffness of these constructs to be relatively high [7].

One hypothesized benefit of a dynamic device is to restore the loading of the damaged disc to similar thresholds as a normal disc would tolerate. For example, with damage comes reduced proteoglycan content, overload of the annulus, change in homogeneity of material properties, depressurization of the nucleus, and inability of the disc to hydrophilically retain water [3, 8]. Normal physiological loads on a damaged disc will produce stress concentrations

higher and more disparate than a corresponding healthy disc. Therefore, one goal of semirigid stabilization should be to reduce and redistribute these loads off the disc to some degree, while trying to maintain a similar loading as what a healthy disc would experience, all in the presence of fusion.

Dynamic stabilization systems may be used as a load-sharing device, to mechanically stimulate bone cells toward fusion. The purpose of the device is to act as semirigid instrumentation, with the ability to dampen the loads as the spine moves. Design of posterior dynamic stabilization devices (PDSs) is very difficult for the reason that every diseased disc is not diseased in the same way and to the same extent as one another. How much offloading is ideal remains a matter of debate. Sengupta et al. suggest that pain alleviation is determined by the uniformity of loading on the disc space, as a fully healthy disc is expected to act as a uniform load bearing structure [3, 8].

In this study, the authors are interested in evaluating the load-sharing and kinematic properties of the spectrum of surgical options, from rigid, using titanium rods, to semirigid, using PEEK rods, to PDS, using polymer-based posterior dampeners. The goal was to quantify load-sharing as well as to determine the distribution of these loads within the interbody space.

2. Materials and Methods

There are two arms to this study. The first arm is determining the load-sharing through the anterior column as determined by the type of posterior instrumentation. The second arm is determining the kinematic range-of-motion as determined by the type of posterior instrumentation. Due to difficulty in measuring regional loading through an intervertebral disc *in vivo* or *in vitro*, mechanical testing was conducted on a spine model with a flat disc surface, as to accommodate a pressure sensor on the disc. The range-of-motion characterization was carried out on human cadaveric spines.

2.1. Load-Sharing

2.1.1. Testing Fixtures and Protocol. Tests were performed on lumbar spine models, prepared according to the ASTM F1717 standard corpectomy model (modified with a construct height of 28 mm from top screw to bottom screw) using ultrahigh molecular weight polyethylene (UHMWPE) blocks. The load-sharing of the vertebral disc was simulated through controlled mechanical testing using a MTS Bionix Servohydraulic Test System (Eden Prairie, MN) with an MTS 661.18 Force Transducer, 2.5 kN maximum. Prior to testing, each construct was soaked in a saline (0.9%) bath at body temperature (37°C) for 1 hour. An axial compressive bending load was applied to the construct at a rate of 10 mm/min in ambient air until 320 N was reached. The moment arm was chosen so that the bending moment, with respect to the posterior instrumentation, in maximum flexion was 12.8 Nm resulting in a 0.04 m moment arm. The constructs were subjected to cyclical loading for three cycles, and the data were captured from the third cycle.

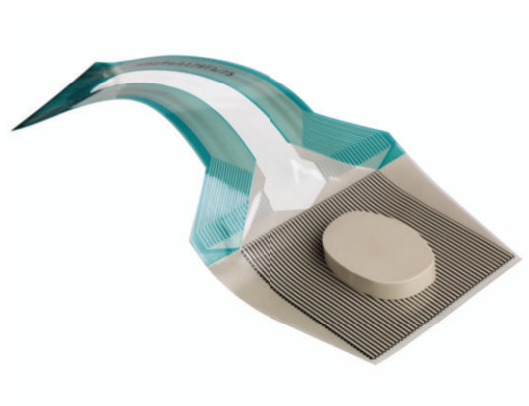
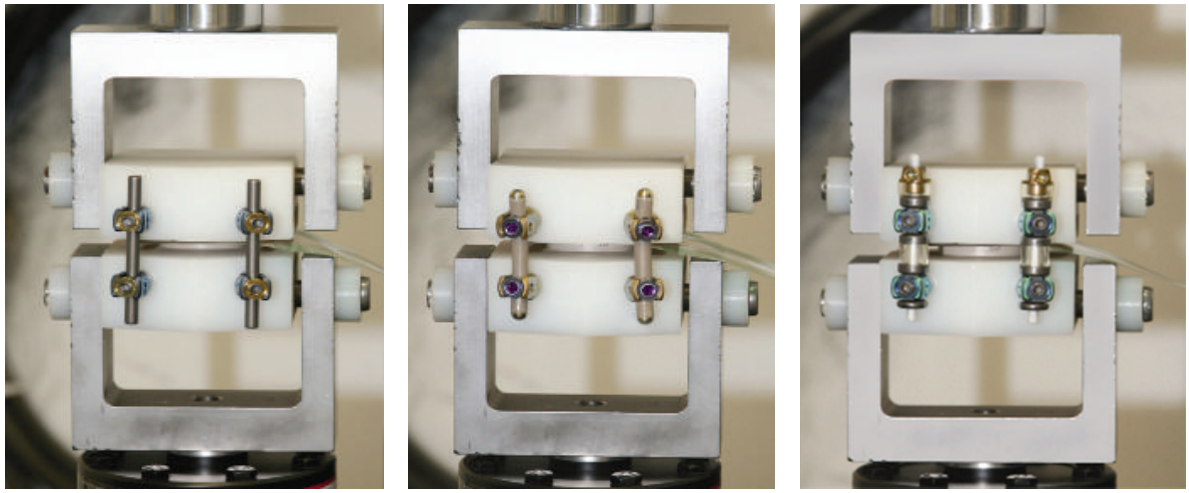


Figure 1: Tekscan pressure film used to measure contact pressures on the spacer. Note that during testing the film was placed above the spacer.

The anterior column load was measured using Tekscan pressure mapping software (I-Scan Pressure Measurement System, Boston, MA) and a digital pressure film (Model 5051) placed between the endplate of the polyethylene vertebral body and the modified interbody spacer device (CONTINENTAL, Globus Medical, Audubon, PA) to detect contact pressures. The pressure film consists of a square grid of 44 × 44 sensor cells with a row and column width of 0.03 inches. Each cell registers the force passing through it. Based on the known area of each cell, the software postprocesses pressure as well as other parameters involving regional data averaging.

The spacer was machined from PEEK, and two windows (in the shape of bone graft windows) were milled to a depth of 3 mm on the bottom surface (to ensure consistent location), while the top surface of the spacer remained flat (test surface) (Figure 1). The top surface of the spacer was tested via a profilometer to ensure no preexisting roughness which could cause pressure artifacts. Solid rigid polyurethane foam (Sawbones, density 20 pcf, Vashon, WA) which contained a boss of the same window shape as the spacer was inserted into the bottom test block (UHMWPE). The windows were used to secure a press fit of the spacer onto the bottom polyurethane foam insert, so that the spacer would not move throughout the testing. A flat polyurethane foam insert was used in the upper test block (UHMWPE). The sequence of load transfer was therefore through the MTS machine, upper test block, upper polyurethane foam insert, pressure film, spacer, lower polyurethane foam insert, and lower test block. The pressure film was placed between the spacer and upper polyurethane foam block, according to Figure 2. A fixed clearance was introduced to ensure consistency in the location of first contact. The clearance between the interbody spacer and upper test fixture was chosen at 400 μm and was measured on all four sides, prior to testing.

2.1.2. Posterior Stabilization. Three different posterior instrumentation systems representing rigid (titanium rods, REVERE, Globus Medical, Audubon, PA), semirigid (PEEK rods, LEGACY, Medtronic, Memphis, TN), and semirigid



(a) (b) (c)

Figure 2: Testing constructs loaded in fixtures. Left to right: rigid rods, PEEK rods, and posterior dynamic stabilization. The pressure film can be seen above the spacer.

(dynamic stabilization, TRANSITION, Globus Medical, Audubon, PA) stabilization methods were tested. The pedicle screws were placed with the tulip heads nearly flush with respect to the UHMWPE test blocks with just enough space for polyaxial head toggle. The PDS device, TRANSITION Stabilization System, was evaluated (Figure 3), and it requires some explanation. The device consists of titanium spools over a polyethylene terephthalate (PET) cord which are dropped in between pedicle screws of adjacent levels. A polycarbonate urethane (PCU) polymer spacer surrounds the cord and fits between the spools which is used to buffer compressive forces. The PCU spacer between the pedicle screws is compressible, to allow normal extension with a soft end point, and the PCU bumper is compressible, allowing a dampened flexion motion. A PET cord which is not attached directly to the pedicle screw head but imbedded within titanium spools allows small interpedicular distance (IPD) changes.

Prior to testing, the pressure mapping system was calibrated using loads of 50% and 100% of the maximum load (320 N) without posterior instrumentation in place, in order to correlate the raw sensor readings to standardized pressure units (pounds per square inch). Five samples were tested. Each sample was prepared by assembling the posterior instrumentation on the test fixtures with appropriate test clearance. Following testing, the assembly was deconstructed, soaked in saline, and subsequently reconstructed with the next sample. Data was recorded from the pressure film in real time during the three loading and unloading cycles and saved as a sequence of image files. Data analysis and postprocessing was completed on the pressure profile of the image slice corresponding to the maximum load of 320 N for the last cycle.

2.1.3. Data Analysis. The total force passing through the spacer (i.e., pressure film) was used to estimate load-sharing between the anterior and posterior column. The load passing through the spacer represented anterior column load-sharing, while the remaining load was assumed to pass through the posterior instrumentation and represented posterior column loading. Subsequent analysis involved splitting the anterior column spacer area into four distinct regions, hereafter referred to as bounding boxes: anterior, posterior, left, and right, according to the symmetrical midlines of the spacer itself (see Figure 4). For each bounding box, the following quantities were tabulated: total force, box pressure, and peak (maximum) box pressure. The total force is the sum of the forces in the rectangular bounding box. Box pressure is the sum of the forces in the rectangular bounding box

Figure 3: The TRANSITION Stabilization System. The cephalad bumper shown in neutral and flexed positions.

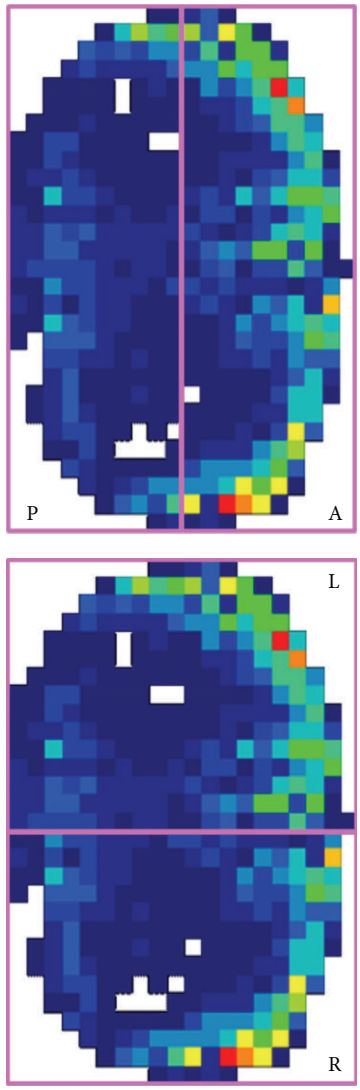


Figure 4: Pressure area division by bounding box: anterior (A), posterior (P), left (L), and right (R).

divided by the area of the bounding box. Peak box pressure is the maximum localized pressure in that bounding box. Statistical comparisons were made using two-tailed student's t-tests assuming equal variance, with a probability of type I error, $\alpha = 0.05$ ($n = 5$).

2.2. Kinematics

2.2.1. Specimen Preparation and Test Constructs. Ten human cadaver lumbosacral spines (L3-S1) were tested under a pure moment of 7 N-m, using a 6-degree-of-freedom spine tester in flexion-extension (FE), lateral bending (LB), and axial rotation (AR). The spines were fixed proximally at L3 and distally at S1 in a three-to-one mixture of Bond Auto Body Filler and fiberglass resin (Bondo Mar-Hyde Corp., Atlanta, GA). The specimens were divided into two groups of five, according to the type of semirigid fixation applied. Each type of transpedicular semirigid instrumentation utilized pedicle screws of a different design and could not be reused on the same specimen without sacrificing screw purchase. Posterior fixation was tested with and without a lateral interbody spacer (TransContinental, Globus Medical) and in the injured state following a lateral discectomy (Figures 5 and 6). Results are presented as a percentage of intact range-of-motion (ROM).

2.2.2. Test Setup and Data Analysis. The spine was affixed to a six-degree-of-freedom (6DOF) testing apparatus via magnetization, and pure unconstrained bending moments will be applied in the physiologic planes of the spine at room temperature using a multidirectional hybrid flexibility protocol [9]. The 6DOF machine applies unconstrained loading through three cephalad stepper motors placed in each of the three physiological rotation axes. Moreover, the supports are mounted on air bearings to provide near frictionless resistance to the natural kinematics of the spine. Plexiglass markers, each having three infrared light-emitting diodes, were secured rigidly to each vertebral body via bone screws to track its motion with the Optotrak Certus (NDI, Inc., Waterloo, Canada) motion analysis system. The location of the markers (denoting a rigid body) were aligned approximately sagitally along the curvature of the spine. The Optotrak Certus software superimposes the coordinate systems of two adjacent vertebral bodies in order to inferentially determine the relative Eularian rotations in each of the three planes.

Data analysis was conducted using independent single factor ANOVA, with both groups combined. The data was first normalized to intact motion and underwent a log transformation to remove unequal variances. The Student-Newman-Keuls post hoc test was applied to all eight comparison groups at a level-1 alpha value of 0.05.

3. Results

3.1. Load-Sharing. A representative example of the recorded data is shown in Figure 7 (during maximum applied loading) for each type of posterior fixation. TekScan software postprocesses the output of each sensor cell into color-coded regions from low to high for easy visualization. A three-dimensional view is useful to assess the distribution and locations of maximum pressure.

The force through the entire spacer was used to determine the percentage of anterior and posterior columns loading as a fraction of the applied load (Figure 8). All load not passing through the pressure film (located in the anterior column) was considered to pass through the posterior instrumentation (located in the posterior column). No energy dissipation due to friction or any form was considered. Anterior column load-sharing was 55%, 59%, and 75%, for rigid rods, PEEK rods, and posterior dynamic stabilization, respectively. The posterior dynamic stabilization system transferred statistically more load than rigid or PEEK rods. Rigid and PEEK rods did not statistically differ from each other in their ability to transfer load through the anterior column. Moreover, of the three instrumentation types tested, the dynamic stabilization most closely approximated the load-sharing of the intact

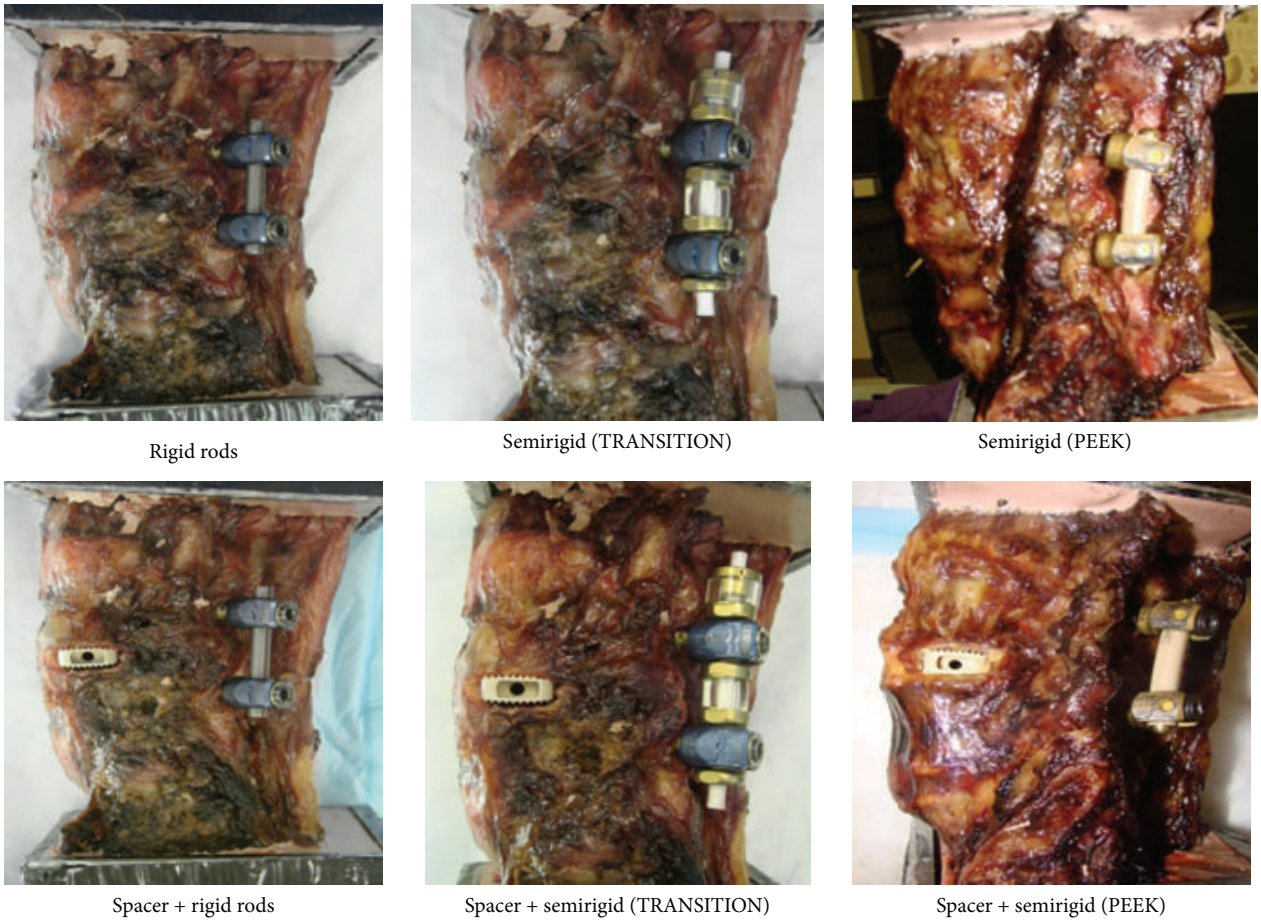


Figure 5: Select test images from flexibility testing, showing rigid and semirigid devices.

lumbar spine as an 80%–20% distribution in the anterior-posterior column as described by White and Panjabi, 1990 [10]. It should be noted that posterior elements and their contribution toward the load-sharing could not be included in the mechanical model.

3.1.1. Regional Loading. The spacer area was divided into bounding boxes describing anterior, posterior, left, and right regions. The average (Figure 9) and peak (Figure 10) pressures in each bounding box are reported. The reader should note the distinction between anterior and posterior bounding boxes (Figure 4) and the anterior and posterior columns loading as described previously.

In all types of fixation, the average anterior box pressure was larger than the posterior box pressure, and left and right pressures were similar (Figure 9). The disparity between anterior and posterior pressures was largest for PEEK rod instrumentation (63 PSI) and smallest for posterior dynamic instrumentation (29 PSI). The regional pressure profile created by PEEK rods was similar to that of rigid rods, except that PEEK had a higher anterior pressure. In all cases, posterior dynamic stabilization resulted in statistically higher average pressure readings, in the posterior, left, and right sides of the spacer, than the other posterior fixation groups. The PEEK rods were the only constructs to result in a statistical difference in left versus right box pressures.

In all types of fixation, the peak anterior box pressure was larger than the peak posterior box pressure, and there were no statistical differences between left and right pressures (Figure 10). The disparity between anterior and posterior peak pressures was largest for PEEK rod instrumentation (312 PSI) and smallest for posterior dynamic instrumentation (65 PSI). The maximum pressure across the entire spacer (denoted by "max" in Figure 10) was the largest for PEEK rods (316 PSI), followed by rigid rods (233 PSI), and smallest for posterior dynamic instrumentation (193 PSI). All three instrumentation types were statistically different.

3.2. Kinematics. As per Figure 11, in the without-interbody group, rigid rods achieved the highest level of fixation (FE: 25%, LB: 33%, AR: 52%), with both semirigid systems demonstrating equivalence (TRANSITION; FE: 34%, LB: 54%, AR: 82%; PEEK Rods; FE: 35%, LB: 51%, AR: 65%). The addition of a lateral interbody spacer provided much stability, similar to that of semirigid instrumentation without interbody, in all three loading modes. In the interbody group, rigid rods achieved the highest level of fixation (FE: 16%, LB: 23%, AR: 40%) compared to the semirigid systems

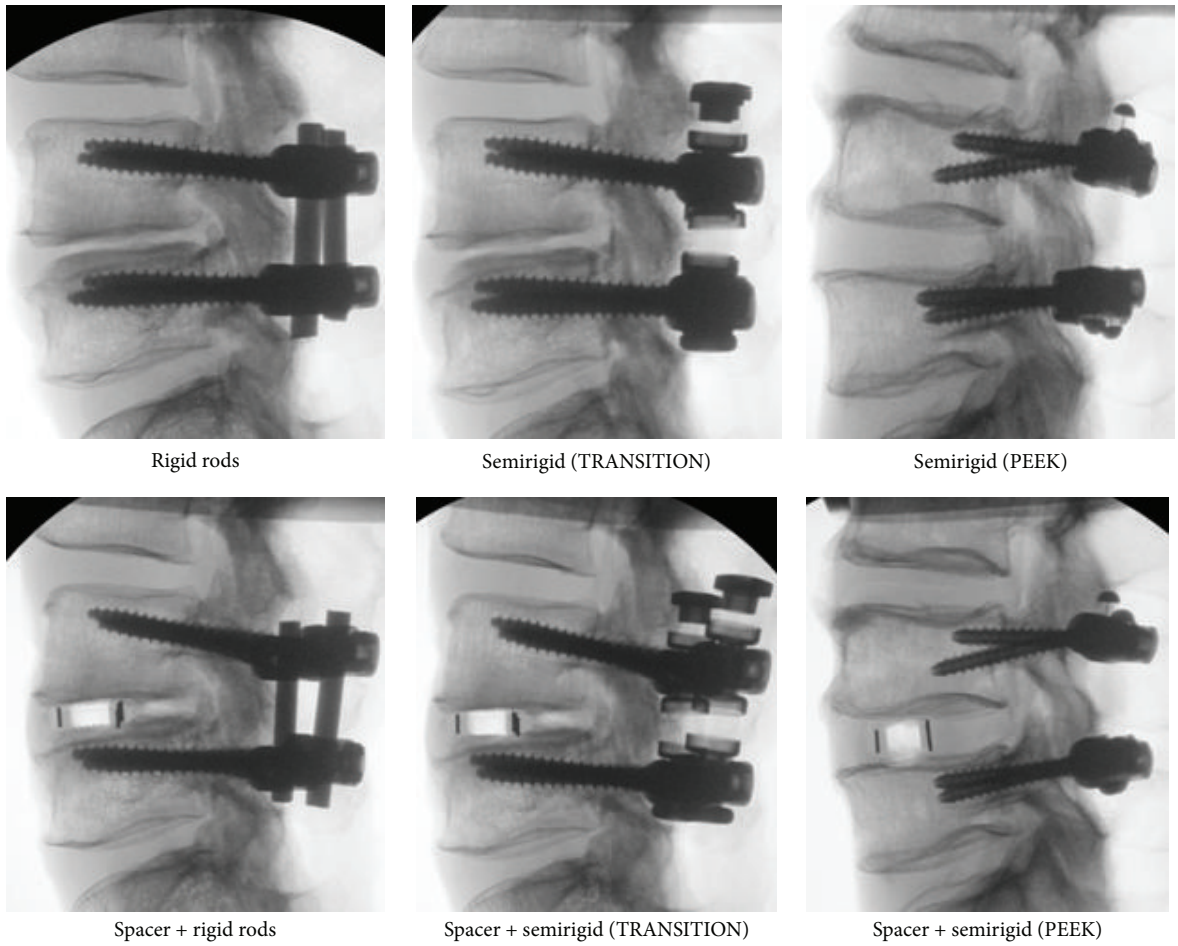


Figure 6: Select radiographs from flexibility testing, showing rigid and semirigid devices.

(TRANSITION FE: 20%, LB: 30%, AR: 48%; PEEK Rods FE: 18%, LB: 30%, AR: 47%). Semirigid systems led to gradual decrease of stiffness of 10%, 20%, and 20% in FE, LB, and AR, respectively, when compared to rigid systems without interbody. With the addition of a lateral interbody device, range-of-motion of semirigid systems was reduced by 16%, 22%, and 26%. There were no detectable differences between the semirigid devices tested.

4. Discussion

The stiffness of the spine after surgery is a combination of the applied instrumentation and fusion mass. With difficulty in predicting the contribution of the fusion mass, this study investigated the rigidity of posterior instrumentation imparted on the spine and the allowable anterior load-sharing. The benefits of semirigid systems may further contribute to the stiffness of the fusion mass, but could not be evaluated.

The hypothesis was that anterior column load-sharing would be higher for posterior dynamic stabilization (PDS) and PEEK rods than rigid systems. According to Sengupta et al., load-sharing and uniformity of loading are two important factors responsible for mechanical back pain, when occurring abnormally [3, 8]. Load-sharing at the index level is useful to promote fusion by stimulating bone cells to form new bone in the graft space. Most patients complain of acute or short bouts of pain, which could be triggered with peak contact pressures (abnormal load-sharing) or nonuniform pressures on a compromised disc. Load-sharing influences adjacent level motion, which has been considered as contributing to adjacent level disease. While previous biomechanical studies have described the relationship between adjacent level problems and kinematic behavior of PDS devices, there is no reported study that investigated load-sharing, which may prove to be clinically as important as global range-of-motion—though consistent clinical evidence is even lacking for motion [11, 12]. In this study, anterior column load-sharing was improved by the use of a semirigid posterior dynamic stabilization device when compared to semirigid PEEK or rigid fixation. The anterior-posterior column distribution was 55%–45%, 59%–41%, and 75%–25%, for rigid rods, PEEK rods, and posterior dynamic stabilization, respectively. The PDS device approximated the 80%–20% distribution of the normal spine as outlined by White and Panjabi, 1990 [10]. No statistical difference in anterior column loading existed between PEEK or rigid rods,

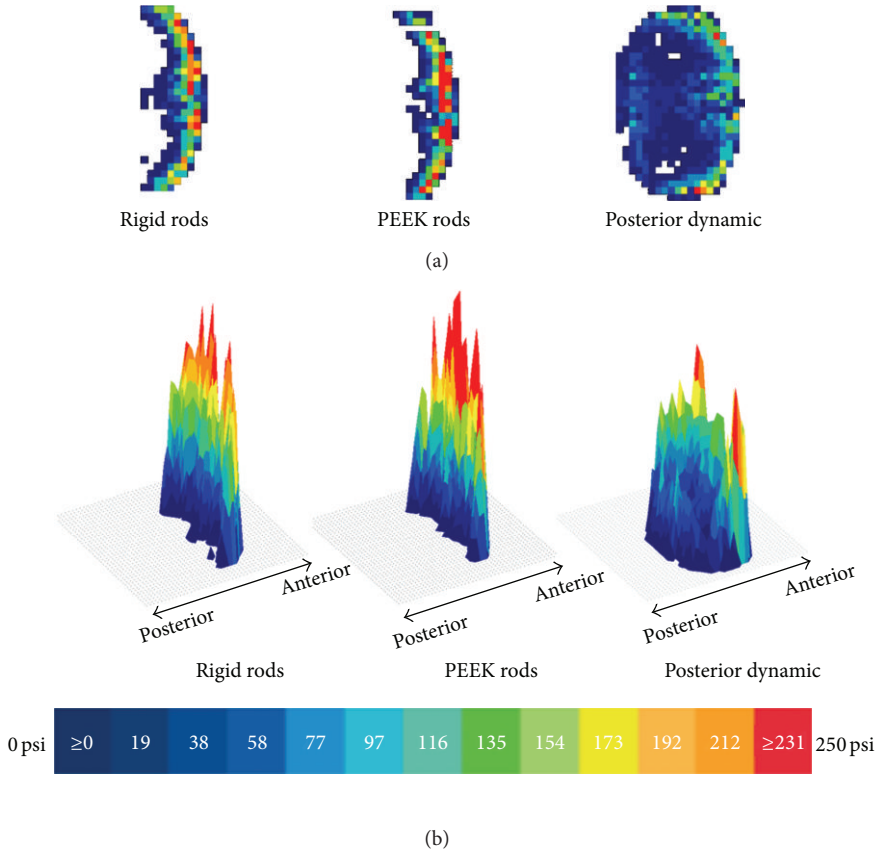


Figure 7: Example of pressure film data showing pressure contact area of spacer with blue colors representing low pressures and red colors representing high pressures, in two dimensions (a) and three dimensions (b) for each posterior instrumentation type.

but the PDS device provided statistically more load through the anterior column than both systems.

The load distribution across the interbody spacer area proved to be more uniform with posterior dynamic stabilization when compared to semirigid PEEK or rigid fixation as evidenced by Figures 5, 7, and 8. With rigid and PEEK rods, only nominal load was transferred to the posterior aspects of the spacer. PEEK rods consistently demonstrated larger average and maximum pressures on the anterior region of the spacer, when compared to PDS or rigid fixation. Dynamic stabilization and rigid rods have similar pressures on the anterior region of the spacer but differ dramatically in the posterior, left, and right portions of the spacer, which are much more uniform and statistically higher for PDS when compared to rigid rods. It should be noted, due to the predefined clearance of 400 μm, that load was first transmitted to the anterior portion of the spacer, to ensure consistency of testing.

Another difference between the PDS design and conventional designs is that the PDS device in this study utilized a PET cord which was not attached directly to the pedicle screw head but imbedded within titanium spools which allow some travel or sliding to compress and engage the soft bumper. This effect may have helped to redistribute the loads. This redistribution seems very evident in Figure 5, where the PDS device shows more coverage and symmetry in loading. Additionally, the repeatability of the testing was high across all five samples.

Peak or maximum pressures are of great concern and may be mechanically induced pain generators even during normal loading. Ideally, a PDS device would reduce abnormally high pressures as well as reduce disparities between different portions of the interbody space. While total load-sharing with the PEEK device is marginally improved compared to rigid rods, the disparity between anterior and posterior regions of PEEK is the least favorable, with a 312 psi difference. The PDS device has a more favorable profile of maximum pressures which are lower in magnitude and more equally distributed across different regions (largest regional difference 65 psi). Statistically speaking, PEEK rods produced the highest maximum pressures, while the PDS device produced the least.

There are very few literature studies which looked at load-sharing in posterior dynamic stabilization devices, of which the data from the current study could be compared. Analytical finite element studies on L3-L4 spinal segment showed that axial forces across the anterior column would be 29%, 67%, and 59% of the applied loading for rigid rods, PEEK rods, and PDS, respectively[4]. However, the PDS device examined was a nitinol rod, which could not be compared to the current device or conventional devices. The data from this study shows higher overall load transfer, with minimal differences in rigid and PEEK rods. Their data show a stark

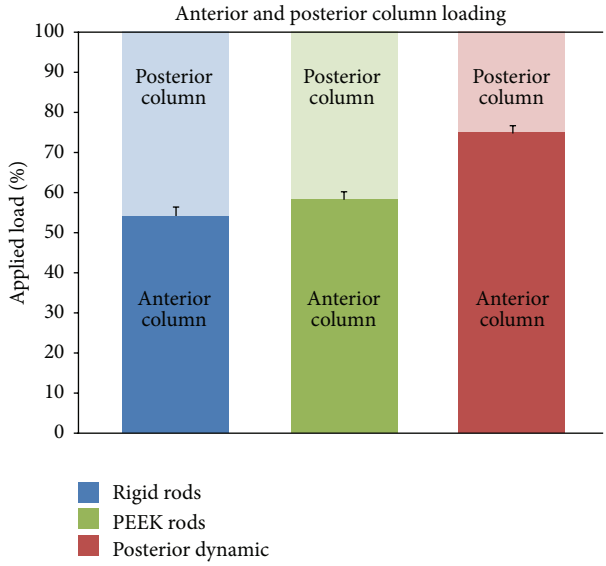


Figure 8: Anterior and posterior columns load-sharing. The bars represent standard deviations in measured anterior column load.

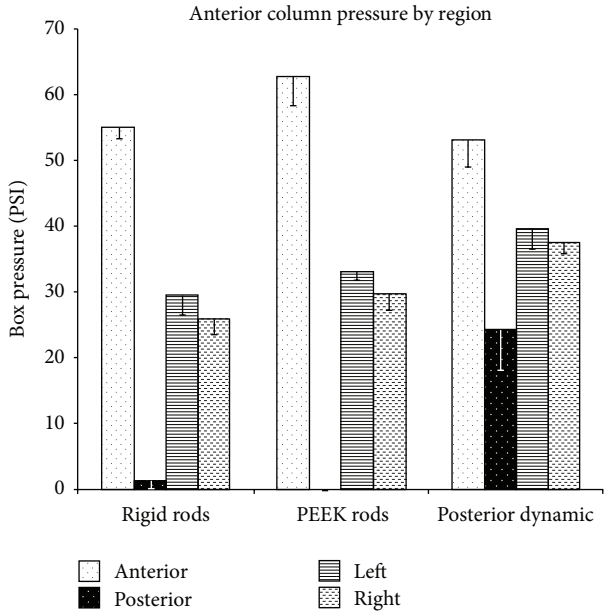


Figure 9: Average box pressure of the anterior, posterior, left, and right portions of the spacer as measured through the pressure film (according to Figure 4).

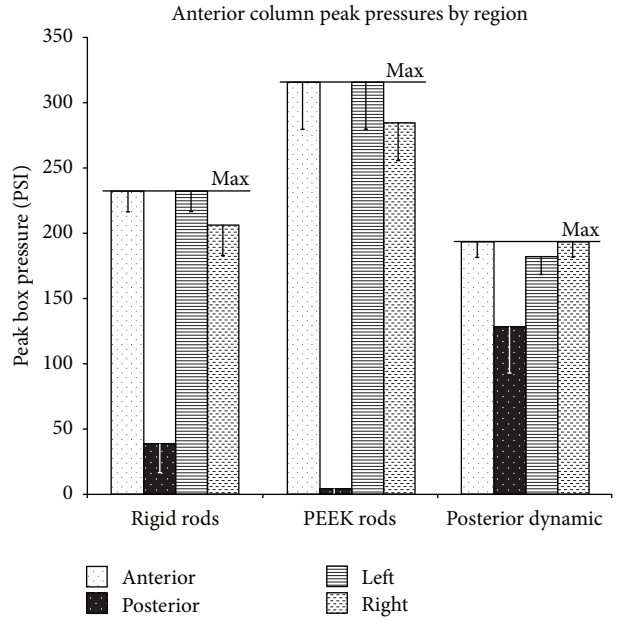


Figure 10: Peak (or maximum) box pressure of the anterior, posterior, left, and right portions of the spacer as measured through the pressure film (according to Figure 4).

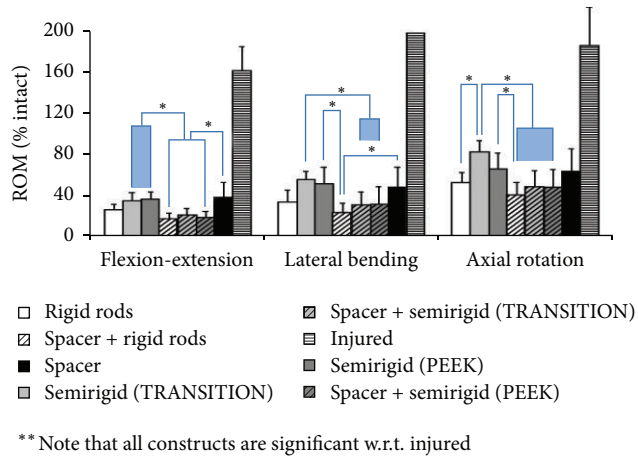


Figure 11: The biomechanical flexibility results normalized to intact motion (100%) by mode. Statistical indicators are shown with asterisks.

improvement in anterior column load-sharing for PEEK rods which was not observed in the present study.

The kinematics of the two semirigid systems investigated was very similar. There was not much difference in the response of the spine to either device, with or without interbody fusion—in terms of motion output. Nevertheless, as mentioned, there were clear differences in load-sharing. Rigid and semirigid PEEK instrumentation formed concentrated pressures on the area of first contact, while the semirigid dynamic stabilization system redistributed load away from the initial contact point. Ultimately with the PDS device, the total force through the spacer was larger, but the maximum pressures were reduced. PEEK rods appear to provide some benefit in terms of total force transmission through the interbody space, albeit statistically insignificant, but like rigid rods suffer from very nonuniform regions of loading across the spacer area.

5. Conclusion

Load-sharing of the spinal column is an important biomechanical factor which may directly affect a patient's pain level,

fusion success, and future disease progression, following spine surgery. In this study, load-sharing and regional load distribution of the interbody area were compared between rigid rods, semirigid PEEK rods, and semirigid dynamic posterior instrumentation with flexion-extension dampening materials. Despite similarities in motion characteristics between PEEK rods and PDS systems, the overall load-sharing was highest for the PDS device, with marginal differences between rigid and semirigid PEEK instrumentation. The PDS system reduced regional pressure gradients and was more uniform in the anterior, posterior, left, and right interbody spaces when compared to the other instrumentation types. The semirigid PEEK rods had the least uniform distribution in contact pressure. The outcomes reported here are encouraging for the use of PDS devices, but more clinical evaluation is needed to understand how load-sharing properties relate to clinical outcomes.

References

[1] N. Boos and J. K. Webb, "Pedicle screw fixation in spinal disorders: a European view," *European Spine Journal*, vol. 6, no. 1, pp. 2–18, 1997.

[2] P. A. Cripton, G. M. Jain, R. H. Wittenberg, and L. P. Nolte, "Load-sharing characteristics of stabilized lumbar spine segments," *Spine*, vol. 25, no. 2, pp. 170–179, 2000.

[3] R. C. Mulholland and D. K. Sengupta, "Rationale, principles and experimental evaluation of the concept of soft stabilization," *European Spine Journal*, vol. 11, supplement 2, pp. S198–S205, 2002.

[4] Y. H. Ahn, W. M. Chen, K. Y. Lee, K. W. Park, and S. J. Lee, "Comparison of the load-sharing characteristics between pedicle-based dynamic and rigid rod devices," *Biomedical Materials*, vol. 3, no. 4, Article ID 044101, 2008.

[5] P. A. Kokkinos, I. K. Zarkadis, D. Kletsas, and D. D. Deligianni, "Effects of physiological mechanical strains on the release of growth factors and the expression of differentiation marker genes in human osteoblasts growing on Ti-6Al-4V," *Journal of Biomedical Materials Research A*, vol. 90, no. 2, pp. 387–395, 2009.

[6] M. J. Patel, H. C. Kyungh, M. C. Sykes, R. Talish, C. Rubin, and H. Jo, "Low magnitude and high frequency mechanical loading prevents decreased bone formation responses of 2T3 preosteoblasts," *Journal of Cellular Biochemistry*, vol. 106, no. 2, pp. 306–316, 2009.

[7] A. Rohlmann, N. K. Burra, T. Zander, and G. Bergmann, "Comparison of the effects of bilateral posterior dynamic and rigid fixation devices on the loads in the lumbar spine: a finite element analysis," *European Spine Journal*, vol. 16, no. 8, pp. 1223–1231, 2007.

[8] D. K. Sengupta, "Dynamic stabilization devices in the treatment of low back pain," *Neurology India*, vol. 53, no. 4, pp. 466–474, 2005.

[9] M. M. Panjabi, "Hybrid multidirectional test method to evaluate spinal adjacent-level effects," *Clinical Biomechanics*, vol. 22, no. 3, pp. 257–265, 2007.

[10] A. White and M. Panjabi, "Physical properties and functional biomechanics of the spine," in *Clinical Biomechanics of the Spine*, chapter 1, Lippincott Williams & Wilkins, Philadelphia, Pa, USA, 1990.

[11] W. Schmoelz, J. F. Huber, T. Nydegger, L. Claes, and H. J. Wilke, "Influence of a dynamic stabilisation system on load bearing of a bridged disc: an in vitro study of intradiscal pressure," *European Spine Journal*, vol. 15, no. 8, pp. 1276–1285, 2006.

[12] W. Schmoelz, J. F. Huber, T. Nydegger, Dipl-Ing, L. Claes, and H. J. Wilke, "Dynamic stabilization of the lumbar spine and its effects on adjacent segments: an in vitro experiment," *Journal of Spinal Disorders and Techniques*, vol. 16, no. 4, pp. 418–423, 2003.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 365059, 7 pages
http://dx.doi.org/10.1155/2013/365059

Clinical Study

Adult's Degenerative Scoliosis: Midterm Results of Dynamic Stabilization without Fusion in Elderly Patients—Is It Effective?

Mario Di Silvestre, Francesco Lolli, Tiziana Greggi, Francesco Vommaro, and Andrea Baioni

Spine Surgery Department, Istituti Ortopedici Rizzoli, Via Pupilli 1, 40136 Bologna, Italy

Correspondence should be addressed to Mario Di Silvestre; mario.disilvestre@ior.it

Received 25 July 2012; Revised 2 January 2013; Accepted 3 January 2013

Academic Editor: Vijay K. Goel

Study Design. A retrospective study. *Purpose*. Posterolateral fusion with pedicle screw instrumentation used for degenerative lumbar scoliosis can lead to several complications. In elderly patients without sagittal imbalance, dynamic stabilization could represent an option to avoid these adverse events. *Methods*. 57 patients treated by dynamic stabilization without fusion were included. All patients had degenerative lumbar *de novo* scoliosis (average Cobb angle 17.2°), without sagittal imbalance, associated in 52 cases (91%) with vertebral canal stenosis and in 24 (42%) with degenerative spondylolisthesis. Nineteen patients (33%) had previously undergone lumbar spinal surgery. *Results*. At an average followup of 77 months, clinical results improved with statistical significance. Scoliosis Cobb angle was 17.2° (range, 12° to 38°) before surgery and 11.3° (range, 4° to 26°) at last follow-up. In the patients with associated spondylolisthesis, anterior vertebral translation was 19.5% (range, 12% to 27%) before surgery, 16.7% (range, 0% to 25%) after surgery, and 17.5% (range, 0% to 27%) at followup. Complications incidence was low (14%), and few patients required revision surgery (4%). *Conclusions*. In elderly patients with mild degenerative lumbar scoliosis without sagittal imbalance, pedicle screw-based dynamic stabilization is an effective option, with low complications incidence, granting curve stabilization during time and satisfying clinical results.

1. Introduction

Degenerative lumbar scoliosis, also described as *de novo* or "primary degenerative scoliosis" [1] is a frequent disease. Its incidence is reported to be from 6% to 68% [2–5] and increases with age [6]. These curves are located at thoracolumbar or lumbar level and need to be distinguished from degenerated preexisting idiopathic scoliosis; in fact, *de novo* scoliosis is developing after skeletal maturity without previous history of scoliosis. A recent prospective study [3] investigated 60 adults aged 50–84 years, without previous scoliosis. within 12 years, 22 cases (36.7%) developed *de novo* scoliosis with a mean angle of 13°. A previous study reported a similar incidence: Robin et al. [7] followed 160 adults with a straight spine for more than 7 years and found 55 cases of *de novo* scoliosis (34.4%). Decreased bone density was initially considered to be the cause of *de novo* lumbar scoliosis [2]. At present, asymmetric degenerative changes of the disc, vertebral body wedging, and facet joint arthritis are held to be the predominant causes [1, 3, 7–9], disc degeneration appearing to be the starting point [3, 8]. Lumbar *de novo* scoliosis is frequently associated with degenerative spondylolisthesis and stenosis [6, 10, 11].

The surgical treatment of these deformities included more often a posterolateral fusion with pedicle screw instrumentation in addition to decompression of neural elements [1, 12–15]. In most series, the incidence of complications is high [1, 13–15]. The impact of different factors on the complications rate remains unclear and there are conflicting results in the literature [13–21]. However, older age (over 65 years), medical comorbidities, increased blood loss, and number of levels fused seem to play an important role. Among these, excessive intraoperative blood loss seems to be the most significant risk factor for early perioperative complications [14]. Accordingly, in elderly patients, the surgery should be the least aggressive possible, and the length of the surgical procedure should be

considered very carefully [20]. A surgical treatment based on decompression alone presented poor results, related to progression of symptoms and deformity [22]. At the same time, adding an arthrodesis to the decompression procedure increases the operative time and blood loss and consequently can increase the complications rate [13, 16, 21].

The use of dynamic stabilization without fusion can represent an option for treatment of mild degenerative lumbar scoliosis without sagittal imbalance. In a previous study [23], we analyzed the outcomes of dynamic stabilization for these deformities, using Dynesys implants (Zimmer Spine, Minneapolis, MN) as an alternative to fusion in elderly patients. The purpose of the present paper is to assess the midterm results of a larger series of patients over 65 years, in order to determine complications and to evaluate clinical outcomes.

2. Materials and Methods

A retrospective data base review was performed to identify all patients affected by degenerative lumbar "*de novo*" scoliosis (Aebi's classification type I [1]), who had been surgically treated by dynamic fixation (Dynesys system) without fusion at our department between January 2002 and December 2006.

Inclusion criteria were (1) minimum age at surgery of 65 years; (2) Cobb angle more than 10° before surgery; (3) no improvement after conservative treatment; (4) minimum-5-year followup.

Exclusion criteria were (1) fixed sagittal imbalance; (2) scoliosis Cobb angle more than 40° before surgery; (3) previous lumbar fusion or stabilization surgery.

An independent spine surgeon reviewed all the selected patients' medical records and X-rays. Inpatient and outpatient charts were used for collecting demographic data, preoperative data (location of pain, neurologic symptoms, and previous surgeries), perioperative data (blood loss, surgical duration, hospital stay, and any medical and surgical-related complication), and postoperative data, including revision surgeries.

2.1. Questionnaires. Clinical outcome was assessed by means of the Oswestry Disability Index (ODI), Roland Morris Disability Questionnaire (RMDQ), and separate visual analog scales (VAS) for back and leg pain, completed by patients preoperatively, in the early postoperative period and at last followup. Radiographic evaluation included preoperative CT and MRI of the lumbar spine, as well as pre-operative, post-operative and followup standing plain radiographs. Overall measures from the radiographs included Cobb angle of the lumbar curve, lumbar lordosis (T12-S1) and thoracolumbar junction alignment (T10-L2), apical vertebral lateral displacement, and anterior vertebral translation measurements for spondylolisthesis. Instrumentation loosening or breakage and degenerative alterations of adjacent levels were also investigated.

2.2. Statistical Evaluation. The clinical and radiologic results were analyzed using t-test. Results are expressed as the mean (range), with a P value < 0.05 considered as being statistically significant.

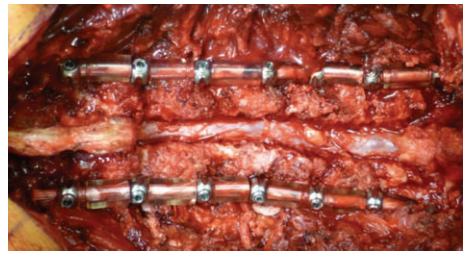


Figure 1: Multisegmental dynamic stabilization with decompressive laminectomy.

2.3. Surgical Treatment. All surgeries were performed by four experienced spine surgeons of our department. Preventive antibiotics were routinely started 12 hours before surgery and continued for an average of 9 days (range, 8 to 11 days). The patients were treated under general anesthesia in the prone position.

Initially, in cases with associated stenosis of the vertebral canal, patients' hips were flexed at an angle of 90° to facilitate decompression of the stenotic levels. Stenosis was treated by laminectomy: the decompression was extended to the lateral recess, and foraminotomy was performed without interrupting the isthmus.

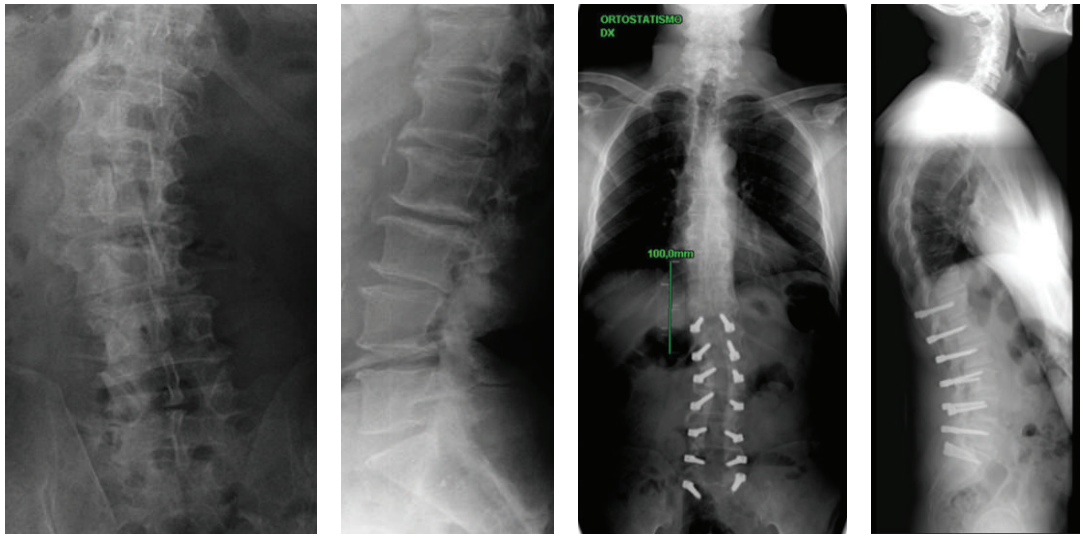
After decompression, the patients' position was modified to obtain the maximum lumbar lordosis, and stabilization was performed.

Dynesys implants were used for dynamic fixation. Dynesys implants consist of titanium alloy pedicle screws (Protasul 100), polyethylene-terephthalate cords (Sulene-PET), and polycarbonate urethane spacers (Sulene-PCU), which fit between the pedicle screw heads (Figure 1). The pedicle screws used in lumbar, thoracolumbar vertebrae, and in the sacrum were 7.2 mm diameter screws. The pedicle entry point was lateral, at the basis of the transverse process. The screws were inserted as deep as possible. So as not to compromise the bone purchase of the screws, given their conical core, we avoided removing and reinserting them in the same hole. Each of the polycarbonate urethane spacers was cut to the desired length and threated with a polyester cord, which was stretched between and fixed to two adjacent screw heads. Larger spacers were used on the concave side and shorter on the convex side of the scoliosis curve.

Redon drains were applied and maintained for a mean of 3.7 days (range: 3 to 4 days).

3. Results

3.1. Preoperative Data. One hundred twenty-five consecutive patients were assessed for eligibility: 68 were excluded. Reasons were incomplete radiographic documentation (n = 4), previous spinal fusion or instrumentation (n = 16), scoliosis Cobb angle >40° (n = 20), fixed sagittal imbalance (n = 25), and age <60 years (n = 3).



(a) (b) (c) (d)

Figure 2: A 73-year-old woman. Degenerative lumbar scoliosis with good sagittal balance ((a)-(b)), associated with stenosis of the vertebral canal. Treatment: T12-S1 dynamic stabilization and decompressive laminectomy. Five-year postoperative radiographs showing stable scoliosis correction with maintained sagittal balance ((c)-(d)).

A total of 57 patients were included in the study and reviewed at a mean followup time of 77 months (range: 61 to 91 months) (Table 1). There were 12 men (22%) and 45 women (78%), with a mean age of 68.4 years (range: 66 to 78). At the time of surgery, all 57 patients reported leg pain; 47 (82%) also had neurogenic claudication, and 42 (73%) had back pain. All patients had failed to respond to conservative treatment conducted for at least 12 months.

Average BMI was 26.4 (range: 21 to 36). There were 1.8 ± 0.7 comorbidities per patient, including diabetes mellitus in 25 patients, heart disease in 12, arterial hypertension in 38, liver disease in 13, and pulmonary disease in 16 cases. All patients had degenerative lumbar *de novo* scoliosis (with an average Cobb angle of 17.2°), associated in 52 cases (91%) with vertebral canal stenosis. Twenty-four patients (42%) also presented with degenerative spondylolisthesis, at L2-L3 level in 2 cases, at L3-L4 in 12 cases, at L4-L5 in 7 cases, and at L5-S1 in 3 cases (3 patients had spondylolisthesis at two levels): the mean slippage was 18.9% (range: 12% to 27%). Nineteen patients (33%) had previously undergone lumbar spinal surgery, including decompressions and/or discectomies (seven patients had had 2 previous operation, five had had 2 operations, and 2 patients had had three).

Table 1: Demographic data.

Parameters	Value
Age (yrs)	68.4
Female gender (%)	78%
Comorbidities	1.8 ± 0.7
Deg. spondylolisthesis	42%
Stenosis	91%
Prev. spinal surgery	33%
Leg pain	100%
Back pain	73%
Claudicatio	82%

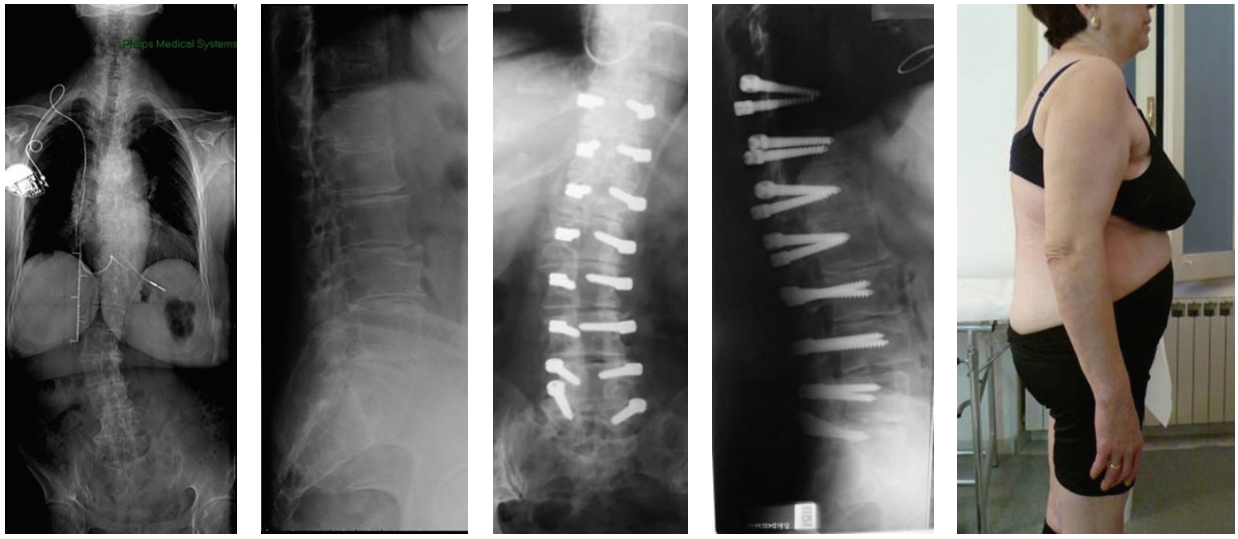
3.2. Perioperative Data. All patients had dynamic stabilization without fusion (Figures 2 and 3). Three levels were stabilized in 31 patients (54%: L1-L4 in 6, L2-L5 in 16, and L3-S1 in 9), four levels in 11 patients (19%: L1-L5 in 7, L2-S1 in 4), five levels in 5 cases (8%: T12-L5 in 3, L1-S1 in 2), six levels in 8 patients (15%: T12-S1), and seven levels in 2 patients (4%: T11-S1).

In 52 patients (91%), the stabilization was combined with decompressive laminectomy of 2 levels in 7 cases (14%: L2-L3 in 3, L3-L4 in and 2, L4-L5 in 2), of 3 levels in 14 cases (27%: L2-L4 in 7, L3-L5 in 7), of 4 levels in 13 cases (25%: L2-L5 in 6, L3-S1 in 7 cases), of 5 levels in 10 cases (19%: L1-L5 in 6, L2-S1 in 4), and of 6 levels in 8 cases (15%: T12-L5 in 6, L1-S1 in 2). If present, the associated spondylolisthesis was always included in the stabilization construct.

Mean operating time was 170 minutes (range: 120 to 210 minutes), mean hospital stay was 6.8 days (range: 6 to 9 days) and mean blood loss was 650 cc (range: 200 to 700 cc). Patients were returned to the upright position at 2.6 days postoperatively (range, 2 to 4 days), with a lumbar orthosis, which was prescribed for 1 month.

3.3. Clinical Outcome (See Table 2). The mean preoperative ODI score was 51.6% (range, 28 to 80), mean postoperative score was 27.2 (range, 0 to 66), and the final followup score was 27.7 (range, 0 to 70) ($P < 0.05$), with a mean final improvement of 51.6% (range, 12% to 100%) ($P < 0.05$).

The mean preoperative RMDQ score was 12.4 of 24 (range, 7 to 22), mean postoperative score was 6.0



(a) (b) (c) (d) (e)

Figure 3: A 71-year-old woman. Degenerative lumbar scoliosis associated with stenosis of the vertebral canal: good sagittal balance ((a), (b)). Treatment: T11-S1 dynamic fixation and decompressive laminectomy. Six-year and 9 months postoperative radiographs showing stable scoliosis correction with maintained sagittal balance ((c), (d), and (e)).

Table 2: Clinical outcome.

	Preop	FU	% corr.	P value
ODI	51.6 (28 to 80)	27.7 (0 to 70)	51.6 (12 to 100)	<0.05
RMDQ	12.4 (7 to 22)	6.3 (0 to 20)	58.8 (9.1 to 100)	<0.05
VAS "leg score"	67.5 (30 to 100)	41.6 (2 to 90)	51.1 (10 to 96.4)	<0.05
VAS "back score"	66.7 (30 to 100)	33.8 (2 to 79)	57.4 (20 to 97)	<0.05

Mean value (range: minimum to maximum).

(range: 0 to 19), and final followup score was 6.3 (range, 0 to 20) ($P < 0.05$), with a mean final improvement of 58.8% (range: 9.1% to 100%) ($P < 0.05$).

The mean leg pain VAS decreased from a preoperative score of 67.5 (range: 30 to 100) to a mean postoperative score of 40.1 (range: 2 to 90) and to a score of 41.6 (range: 2 to 90) at the last followup ($P < 0.05$), with a mean final improvement of 51.1% (range, 10% to 96.4%) ($P < 0.05$). The mean back pain VAS decreased from a preoperative score of 66.7 (range: 30 to 100) to a postoperative score of 33.1 (range: 2 to 75) and to a score of 33.8 (range: 2 to 79) at last followup ($P < 0.05$), with a mean final improvement of 57.4% (range: 20% to 97.0%) ($P < 0.05$).

3.4. Radiologic Outcome (See Table 3). The average scoliosis Cobb angle was 17.2° (range: 12° to 38°) before surgery, 11.0° (range, 4° to 26°) after surgery and remained stable, and 11.3° (range: 4° to 26°), at last followup ($P < 0.05$). Lumbar lordosis was −30.6° (range: 3° to −39°) before surgery, −36.8° (range: −12° to −57°) after surgery, and −35.8° (range: −10° to −55°) at last followup ($P < 0.05$), with a mean final improvement of 6.4% (range: 0% to 17%) ($P < 0.05$).

Thoracolumbar junction alignment (TLJA) (T10-L2) was −2.8° before surgery (range: −25° to 23°), −0.2° (range: −18° to 25°) after surgery, and −0.4° (range: −18° to 25°) at last followup.

Apical vertebra lateral listhesis (AVLL) was 1.2 cm (range: 0.2 to 2.0 cm) before surgery, 0.8 cm (range: 0.2 to 1.1 cm) after surgery, and 0.8 cm (range: 0.3 to 1.2 cm) at last followup ($P < 0.05$), with a mean final correction of 30.7% (range: 0% to 44.4%) ($P < 0.05$).

In the patients with associated spondylolisthesis, anterior vertebral translation was 19.5% (range: 12% to 27%) before surgery, 16.7% (range: 0% to 25%) after surgery, and 17.5% (range: 0% to 27%) at followup ($P < 0.05$), for a 14.9% mean correction (range: 0 to 100%) ($P < 0.05$).

3.5. Complications (See Table 4). No neurological complications were observed in any patient: 8 overall complications (14%) occurred.

Six patients (10%) had minor complications. These included two cases of ileus (4%) and two urinary tract infection (4%), which resolved after medical treatment. Another patient (2%) had transient postoperative delirium, which spontaneously resolved after 3 days. One patient (2%) developed dyspnea after surgery, requiring 5 days of recovery in the Intensive Care Unit for complete resolution.

Two patients (4%) had major complications that required revision surgery. One patient (2%) developed severe postoperatative sciatica, resistant to medication without neurological deficit, due to a misplaced screw on L5; revision surgery for replacement of the screw was performed 5 days after

Table 3: Radiologic outcome*.

	Preop	FU	% corr	*P* value
Scoliosis (°)	17.2° (12 to 38)	11.3° (4 to 26)	37.3% (13.3 to 61.5)	<0.05
Lordosis	−30.6° (3 to −39)	−35.8° (−10 to −55)	6.4% (0 to 17)	<0.05
TLJA	−2.8° (−25 to 23)	−0.4° (−18 to 25)	n.a.	n.a.
AVLL (cm)	1.2 (0.2 to 2)	0.8 (0.3 to 1.2)	30.7 (0 to 44.4)	<0.05
AVT (%)	19.5% (12 to 27)	17.5% (0 to 27)	14.9% (0 to 100)	<0.05

Mean value (range, minimum to maximum).
TLJA: thoracolumbar junction alignment (T10-L2).
AVLL: apical vertebra lateral listhesis.
AVT: anterior vertebral translation.
n.a.: not available.

Table 4: Complications.

Complications	Percentage
Overall	**8 (14%)**
Minor	**6 (10%)**
Ileus	2 (4%)
Urinary tract infection	2 (4%)
Transient delirium	1 (2%)
Dyspnea	1 (2%)
Major	**2 (4%)**
Misplaced screw	1 (2%)
Lower junctional disc degeneration	1 (2%)

the first operation, with complete resolution of the sciatica. Another patient (2%) developed persistent leg pain, resistant to medication without neurological deficit, 28 months after surgery, due to disc degeneration at the lower junctional level; revision surgery was performed 32 months after the first operation, with decompression and extension of fixation from L5 to S1.

No screw loosening or breakage was observed at followup. However, asymptomatic radiolucent lines up to 2 mm around the thread of pedicle screws in the sacrum without screw loosening were found in 5 patients (9%) at last followup.

4. Discussion

The surgical treatment of degenerative lumbar scoliosis in elderly patients presents demanding aspects. The main goals of surgery are pain relief and improvement in quality of life. Some correction of the deformity is desirable, but this is not the most important issue and it is essential to limit the aggressiveness of the surgical procedure as much as possible [10]. Posterolateral fusion with pedicle screw instrumentation in addition to laminectomy [10, 13–15] is the most commonly used procedure. Unfortunately, a high incidence of complications has been reported in older patients [14, 15, 18–20]. Notably, age has been correlated with an increased incidence of complications, with a 20% rate of major complications over 80 years of age [18]. Furthermore, excessive blood loss and the number of levels fused have been found to be associated with higher complication rates [14].

Less invasive than posterior fusion, pedicle screw-based dynamic stabilization without arthrodesis might be a useful alternative in elderly patients with mild degenerative lumbar scoliosis without sagittal imbalance. Previously, our series of degenerative scoliosis patients often associated with lumbar stenosis has shown that it can prevent progression of scoliosis and postoperative instability, even after laminectomy [23]. In that report, operative duration time was short, blood loss was reduced, and there was no screw loosening or breakage at followup. The present study confirms at midterm followup these results with limited blood loss and short operative time. Moreover, dynamic fixation provided substantial stability by preserving against further scoliosis progression or translation of associated spondylolisthesis, despite use of decompressive laminectomy. By applying asymmetric spacers, larger on the concave side and shorter on the convex side of scoliosis, it was possible to obtain a mild reduction of the scoliosis Cobb angle, albeit less than with fusion constructs, reported in the literature [13–15]. There was no case of screw loosening or breakage during followup. In five of the patients (9%), asymptomatic radiolucent lines up to 2 mm did appear around the thread of pedicle screws in S1 at last X-rays control; however, it was not observed a screw mobilization or a loss of scoliosis correction and the patients were asymptomatic, so we did not classify these cases as "unstable". The overall complication rate was low (14%) with an even markedly lower incidence of major complications (14%).

A frequent complication observed in elderly patients after posterior fusion is adjacent segment disease, which generally occurs proximal to posterior instrumentation and has been reported primarily after short lumbar fusion [15]. Proximal adjacent disease appears to develop more frequently when stopping fusion from T11 to L1 compared with extending it to T10 [14, 24]. In older patients, the advantage for a "short" posterior fusion is obvious, even if the instrumentation should not stop at a junctional zone or adjacent to a rotatory subluxation, spondylolisthesis, or a segment with significant spinal stenosis, because this may lead to spinal instability. In a recent study, Cho et al. [15] compared the results of short posterior fusion, within the deformity, versus long fusion, extended above the upper end vertebra, for degenerative lumbar scoliosis in patients whose mean age was 65.5 years. In this series, there was a trade-off in complications between short fusion and long fusion; whereas all cases of proximal adjacent segment disease developed in the short fusion group,

long fusion induced excessive intraoperative blood loss, which was closely related to the development of perioperative complications.

In our series, elderly patients received a short instrumentation, extended up to T11 at most. Only one patient (2%) required subsequent surgery for adjacent segment deasese and a distal junctional disc degeneration 32 months after surgery. At present, there is no consensus on whether or not dynamic instrumentation protects adjacent levels more than fusion. A study concluded that dynamic stabilization can prevent degeneration of the adjacent segment [25]. However, the results of the study of Schnake et al. [26] after Dynesys instrumentation in cases with degenerative spondylolisthesis did not support this theory. The authors found signs of adjacent degeneration in 29% of the patients after 2 years. Although longer followup studies are necessary for definitive conclusions, the theoretical protective effect of dynamic stabilization against adjacent segment degeneration is consistent with our findings, with a 5-year minimum followup.

In different series [13–15], posterior fusion obtained a significative scoliosis correction. In our series there was a scoliosis stabilization at a followup of more than 5 years. However, in *de novo* scoliosis patients the goal of treatment is less for the amount of correction of the curve than its stability over time. The same could be said for final lumbar lordosis; dynamic fixation maintained a stable and satisfying lumbar lordosis at followup. The patient's position on the operating table was always assessed to maintain or to increase the lumbar lordosis. All cases included in this study presented preoperatively a satisfying sagittal balance. In cases of sagittal imbalance, it is very difficult to achieve normal lumbar lordosis by dynamic stabilization or posterior fusion alone. Different surgical techniques such as corrective osteotomy should be considered preoperatively in these patients.

Finally, it's important to underline that, at followup (Table 2) dynamic fixation achieved clinically significant improvement in ODI, RMDQ, and VAS scores.

5. Conclusions

The present series must be interpreted in the context of its limitations (the retrospective nature of the review and the fact that patients were not randomized). However, this series of patients is consecutive and they received surgical treatment in the same institution.

In elderly patients with mild degenerative lumbar scoliosis without sagittal imbalance, pedicle screw-based dynamic stabilization permitted to maintain a satisfying balanced spine at follow-up: this procedure resulted less invasive with short operative duration and limited blood loss and low adverse event rates.

Dynamic fixation achieved scoliosis curve stabilization, at an average followup of more than 5 years. Furthermore, functional outcomes resulted were satisfying at last control.

Acknowledgment

The work should be attributed to the Spine Surgery Department, Istituto Ortopedico Rizzoli, Bologna, Italy.

References

[1] M. Aebi, "The adult scoliosis," *European Spine Journal*, vol. 14, no. 10, pp. 925–948, 2005.

[2] D. W. Vanderpool, J. I. James, and R. Wynne-Davies, "Scoliosis in the elderly," *Journal of Bone and Joint Surgery. American*, vol. 51, no. 3, pp. 446–455, 1969.

[3] T. Kobayashi, Y. Atsuta, M. Takemitsu, T. Matsuno, and N. Takeda, "A prospective study of de novo scoliosis in a community based cohort," *Spine*, vol. 31, no. 2, pp. 178–182, 2006.

[4] F. Schwab, A. Dubey, L. Gamez et al., "Adult scoliosis: prevalence, SF-36, and nutritional parameters in an elderly volunteer population," *Spine*, vol. 30, no. 9, pp. 1082–1085, 2005.

[5] S. L. Weinstein and I. V. Ponseti, "Curve progression in idiopathic scoliosis," *Journal of Bone and Joint Surgery. American*, vol. 65, no. 4, pp. 447–455, 1983.

[6] J. W. Pritchett and D. T. Bortel, "Degenerative symptomatic lumbar scoliosis," *Spine*, vol. 18, no. 6, pp. 700–703, 1993.

[7] G. C. Robin, E. Y. Span, and R. Steinberg, "Scoliosis in the elderly. A follow-up study," *Spine*, vol. 7, no. 4, pp. 355–359, 1982.

[8] Y. Murata, K. Takahashi, E. Hanaoka, T. Utsumi, M. Yamagata, and H. Moriya, "Changes in scoliotic curvature and lordotic angle during the early phase of degenerative lumbar scoliosis," *Spine*, vol. 27, no. 20, pp. 2268–2273, 2002.

[9] M. Benoist, "Natural history of the aging spine," *European Spine Journal*, vol. 12, no. 2, pp. S86–S89, 2003.

[10] A. Ploumis, E. E. Transfledt, and F. Denis, "Degenerative lumbar scoliosis associated with spinal stenosis," *Spine Journal*, vol. 7, no. 4, pp. 428–436, 2007.

[11] H. Liu, H. Ishihara, M. Kanamori, Y. Kawaguchi, K. Ohmori, and T. Kimura, "Characteristics of nerve root compression caused by degenerative lumbar spinal stenosis with scoliosis," *Spine Journal*, vol. 3, no. 6, pp. 524–529, 2003.

[12] E. D. Simmons, "Surgical treatment of patients with lumbar spinal stenosis with associated scoliosis," *Clinical Orthopaedics and Related Research*, no. 384, pp. 45–53, 2001.

[13] L. Y. Carreon, R. M. Puno, J. R. Dimar, S. D. Glassman, and J. R. Johnson, "Perioperative complications of posterior lumbar decompression and arthrodesis in older adults," *Journal of Bone and Joint Surgery. American*, vol. 85, no. 11, pp. 2089–2092, 2003.

[14] K. J. Cho, S. I. Suk, S. R. Park et al., "Complications in posterior fusion and instrumentation for degenerative lumbar scoliosis," *Spine*, vol. 32, no. 20, pp. 2232–2237, 2007.

[15] K. J. Cho, S. I. Suk, S. R. Park et al., "Short fusion versus long fusion for degenerative lumbar scoliosis," *European Spine Journal*, vol. 17, no. 5, pp. 650–656, 2008.

[16] R. A. Deyo, M. A. Ciol, D. C. Cherkin, J. D. Loeser, and S. J. Bigos, "Lumbar spinal fusion: a cohort study of complications, reoperations, and resource use in the Medicare population," *Spine*, vol. 18, no. 11, pp. 1463–1470, 1993.

[17] G. S. Shapiro, G. Taira, and O. Boachie-Adjei, "Results of surgical treatment of adult idiopathic scoliosis with low back pain and spinal stenosis: a study of long-term clinical radiographic outcomes," *Spine*, vol. 28, no. 4, pp. 358–363, 2003.

[18] C. S. Raffo and W. C. Lauerman, "Predicting morbidity and mortality of lumbar spine arthrodesis in patients in their ninth decade," *Spine*, vol. 31, no. 1, pp. 99–103, 2006.

[19] M. D. Daubs, L. G. Lenke, G. Cheh, G. Stobbs, and K. H. Bridwell, "Adult spinal deformity surgery: complications and outcomes in patients over age 60," *Spine*, vol. 32, no. 20, pp. 2238–2244, 2007.

[20] M. Y. Wang, B. A. Green, S. Shah, S. Vanni, and A. D. Levi, "Complications associated with lumbar stenosis surgery in patients older than 75 years of age," *Neurosurgical Focus*, vol. 14, no. 2, p. e7, 2003.

[21] R. J. Benz, Z. G. Ibrahim, P. Afshar, and S. R. Garfin, "Predicting complications in elderly patients undergoing lumbar decompression," *Clinical Orthopaedics and Related Research*, no. 384, pp. 116–121, 2001.

[22] E. N. Hanley, "The indications for lumbar spinal fusion with and without instrumentation," *Spine*, vol. 20, no. 24, pp. 143S–153S, 1995.

[23] M. Di Silvestre, F. Lolli, G. Bakaloudis, and P. Parisini, "Dynamic stabilization for degenerative lumbar scoliosis in elderly patients," *Spine*, vol. 35, no. 2, pp. 227–234, 2010.

[24] H. Shufflebarger, S. I. Suk, and S. Mardjetko, "Debate: determining the upper instrumented vertebra in the management of adult degenerative scoliosis: stopping at T10 versus L1," *Spine*, vol. 31, no. 19, pp. S185–S194, 2006.

[25] T. M. Stoll, G. Dubois, and O. Schwarzenbach, "The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system," *European Spine Journal*, vol. 11, no. 2, pp. S170–S178, 2002.

[26] K. J. Schnake, S. Schaeren, and B. Jeanneret, "Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis," *Spine*, vol. 31, no. 4, pp. 442–449, 2006.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 806267, 6 pages
http://dx.doi.org/10.1155/2013/806267

Clinical Study

Dynamic Stabilisation in the Treatment of Degenerative Disc Disease with Modic Changes

Olcay Eser,[1] Cengiz Gomleksiz,[2] Mehdi Sasani,[3] Tunc Oktenoglu,[3] Ahmet Levent Aydin,[4] Yaprak Ataker,[5] Tuncer Suzer,[3] and Ali Fahir Ozer[6]

[1] *Department of Neurosurgery, School of Medicine, Afyon Kocatepe University, Afyonkarahisar, Turkey*
[2] *Department of Neurosurgery, Ordu Medical Park Hospital, Ordu, Turkey*
[3] *Department of Neurosurgery, American Hospital, Istanbul, Turkey*
[4] *Neurosurgery Department, Istanbul Physical Therapy and Rehabilitation Hospital, Istanbul, Turkey*
[5] *Physical Therapy and Rehabilitation Department, American Hospital, Istanbul, Turkey*
[6] *Department of Neurosurgery, School of Medicine, Koc University, Rumelifeneri Yolu Sarıyer, Istanbul 34450, Turkey*

Correspondence should be addressed to Ali Fahir Ozer; alifahirozer@gmail.com

Received 20 July 2012; Accepted 18 April 2013

Academic Editor: Deniz Erbulut

Objective. Posterior dynamic stabilization is an effective alternative to fusion in the treatment of chronic instability and degenerative disc disease (DDD) of the lumbar spine. This study was undertaken to investigate the efficacy of dynamic stabilization in chronic degenerative disc disease with Modic types 1 and 2. Modic types 1 and 2 degeneration can be painful. Classic approach in such cases is spine fusion. We operated 88 DDD patients with Modic types 1 and 2 via posterior dynamic stabilization. Good results were obtained after 2 years of followup. *Methods*. A total of 88 DDD patients with Modic types 1 and 2 were selected for this study. The patients were included in the study between 2004 and 2010. All of them were examined with lumbar anteroposterior (AP) and lateral X-rays. Lordosis of the lumbar spine, segmental lordosis, and ratio of the height of the intervertebral disc spaces (IVSs) were measured preoperatively and at 3, 12, and 24 months after surgery. Magnetic resonance imaging (MRI) analysis was carried out, and according to the data obtained, the grade of disc degeneration was classified. The quality of life and pain scores were evaluated by visual analog scale (VAS) score and Oswestry Disability Index (ODI) preoperatively and at 3, 12, and 24 months after surgery. Appropriate statistical method was chosen. *Results*. The mean 3- and 12-month postoperative IVS ratio was significantly greater than that of the preoperative group ($P < 0.001$). However, the mean 1 and 2 postoperative IVS ratio was not significantly different ($P > 0.05$). Furthermore, the mean preoperative and 1 and 2 postoperative angles of lumbar lordosis and segmental lordosis were not significantly different ($P > 0.05$). The mean VAS score and ODI, 3, 12, and 24 months after surgery, decreased significantly, when compared with the preoperative scores in the groups ($P = 0.000$). *Conclusion*. Dynamic stabilization in chronic degenerative disc disease with Modic types 1 and 2 was effective.

1. Introduction

Chronic low back pain (LBP) has been one of the most common causes of disability in adults and is a very important disease for early retirement in industrialized societies. Degenerative disc disease (DDD) is the most frequent problem in patients with LBP. The prevalence of Modic changes among patients with DDD of the lumbar spine varies between 19% and 59%. Type 1 and 2 Modic changes are more common than type 3 and mixed changes [1–13].

Degenerative vertebral endplate and subchondral bone marrow changes were first noted on magnetic resonance imaging (MRI) by Roos et al. in 1987 [1]. A formal classification was subsequently provided by Modic et al. in 1988, based on a study of 474 patients, most of whom had chronic LBP [2]. They were found to be associated with DD [1–3]. Three different types have been described [2, 3]. Type I lesions (low T1 and high T2 signals) are assumed to indicate an ongoing active degenerative process. Type II lesions (high T1 and T2 signals) are thought to manifest a

more stable and chronic degeneration. Type III lesions (low T1 and T2 signals) are associated with subchondral bone sclerosis. Modic changes are interesting because an association between Modic changes and LBP symptoms has been shown recently in population-based cohorts [10, 12, 14].

Kjaer et al. suggested that Modic changes constitute the crucial element in the degenerative process around the disk in relation to LBP and clinical findings [14]. They demonstrated that DDD on its own was a fairly quiet disorder, whereas DDD with Modic changes was much more frequently associated with clinical symptoms. Most authors agree that among Modic changes, type 1 changes are those that are most strongly associated with symptomatic LBP [5, 7, 12, 13]. Braithwaite et al. suggested that vertebral endplate could be a possible source of discogenic LBP [4]. Therefore, Modic changes appear to be a relatively specific but insensitive sign of a painful lumbar disc in patients with discogenic LBP.

Buttermann et al. suggested that abnormal endplates associated with inflammation are a source of pain, and treating endplates directly with anterior fusion may be a preferred treatment for this subset of degenerative patients [15]. Chataigner et al. suggested that anterior fusion is effective for the treatment of LBP due to DDD when associated with vertebral plate changes [16]. Fritzell et al. reported that posterior lumbar fusion in patients with severe chronic LBP can diminish pain and decrease disability more efficiently than commonly used nonsurgical treatment, through a prospective multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group [17]. Kwon et al. suggested that PLIF procedures in which TFC is used in patients with Modic types 1 and 2 showed an acceptably high success and fusion rate [18].

Segmental fusion operations are performed frequently as treatment for DDD with Modic types 1 and 2. Nevertheless, fusion also carries various risks such as adjacent segment degeneration, bone graft donor place pain, and pseudoarthrosis [19–22]. Dynamic stabilization controls abnormal movements in an unstable, painful segment and facilitates healthy load transfer, preventing degeneration of the adjacent segment [23]. Recently, several clinical studies reported that dynamic stabilization yielded good clinical results and represented a safe and effective alternative technique to spine arthrodesis in selected cases of degenerative lumbar spine instability [24–26].

The purpose of the current study was to assess the efficacy of dynamic stabilization in DDD with Modic types 1 and 2.

2. Materials and Methods

A total of 88 DDD patients with Modic types 1 and 2 were selected for this study. The patients were included in the study between 2004 and 2010. Among them, 70 patients showed Modic type 1 (80%) and 18 patients exhibited Modic type 2 (20%). The study patients consisted of 30 males and 58 females, with a mean age of 45 years (range: 25–65 years). All the patients received surgery, with 59 patients at L4-5 level (67%), 22 patients at L5-S1 level (25%), and 7 patients at L3-4 level (8%). Furthermore, 23 patients had (26 %) grade 3 and 65 patients had (74%) grade 4 disc degeneration.

Patients were informed about the operation. All the patients completed the consent forms. The patients had leg and/or chronic LBP, and those who had previously undergone spinal surgery were excluded. We also excluded patients with spinal tumor, infection, spondylolisthesis, traumatic vertebral fracture, scoliosis, and serious systemic disease. Patients were diagnosed to have DDD with Modic changes on MRI. All patients were examined with lumbar anteroposterior (A-P) and lateral X-rays. *Cosmic* (Ulrich GmbH & Co. KG, Ulm, Germany) and *Safinaz* (Medikon *AS*, Turkey) dynamic pedicle screws and rigid rod system were used together with the microdiscectomy procedure in all patients.

2.1. Evaluation of Quality and Pain Scores. The quality of life and pain scores were evaluated using visual analog scale (VAS) score (0, no pain; 10, worst pain) and Oswestry Disability Index (ODI) both preoperatively and at 3, 12, and 24 months after surgery (Table 2).

2.2. Radiological Analysis. The patients underwent preoperative MRI and/or computed tomography (CT). Furthermore, all patients had AP and lateral standing X-rays of the lumbar spine preoperatively and at 3 (1 postoperative), 12 (2 postoperative), and 24 months (3 postoperative) after surgery. Lordosis of the lumbar spine (L1-S1) was measured as the angle between the lines drawn on lateral standing X-rays from the lower endplate of L1 and upper endplate of S1. Segmental lordosis of the operative level (or levels) was measured as the angle between lines drawn from the upper and lower endplates of the vertebrae across which instrumentation spanned preoperatively as well as 3, 12, and 24 months after surgery. The ratio of the height of the intervertebral disc spaces (IVSs) to the vertebral body height was measured and compared preoperatively and postoperatively. The IVS ratio was calculated as the mean anterior and posterior intervertebral disc height divided by the vertebral height of the rostral vertebra of the motion segment.

2.3. MRI Evaluation. Lumber sagittal MRI was performed with a slice of 5 mm thickness. A T2-weighted image with a repetition of 2500 msec and an echo time of 90 msec of the lumbar spine was taken for all the participants. The signal intensity of nucleus pulposus of the discs L2-L3, L3-L4, L4-L5, and L5-S1 was evaluated independently by three radiologists. The grade of disc degeneration was determined according to Schneiderman's classification: Grade 1, normal signal intensity; Grade 2, heterogeneous decreased signal intensity; Grade 3, diffuse loss of signal; Grade 4, signal void. MRI analysis was carried out, and according to the data obtained, the grade of disc degeneration was classified as mild (Grades 1-2), and severe (Grades 3-4).

In this study, before surgery, endplate abnormalities were divided into Modic type 1 signals (low intensity on T1-weighted spin-echo images and high intensity on T2-weighted spin-echo images) and Modic type 2 signals (high intensity on both T1- and T2-weighted spin-echo images).

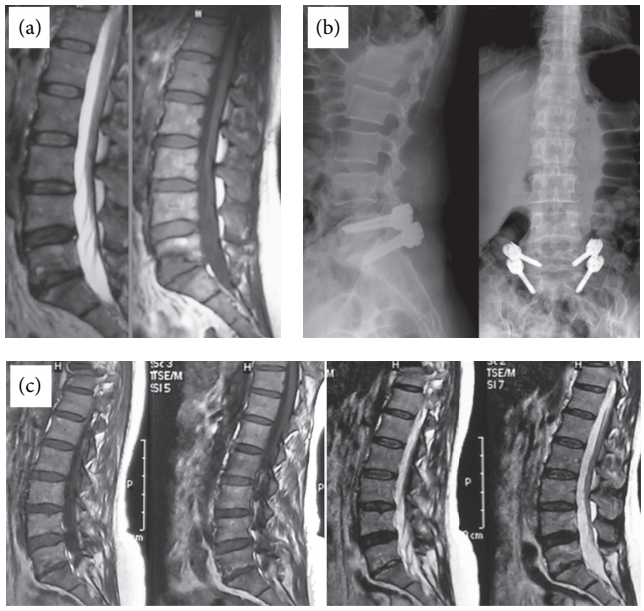


Figure 1: A 43-year-old female patient complained of severe back pain, particularly when standing or walking. (a) T1- and T2-weighted images showing hypointense corpus changes in upper and lower endplates. (b) Dynamic stabilization carried out with Safinaz screws. (c) T1- and T2-weighted MR images showing degenerative changes that shifted to Modic type 3, 2 years later.

2.4. Operative Technique. All patients were taken into the operating room under general anesthesia in the prone position. Prophylactic antibiotics were given to all of them before the operation. All operations were performed using operational microscopy and standard surgical technique. The level of operation was determined via intraoperative fluoroscopy. When the interlaminar level with disc herniation was approached from the medial aspect, laminotomy was widened with the help of a high-speed drill. After identifying the correct nerve root, free disc fragments under the nerve root and passageway were removed. Decompression was completed by performing the required laminotomy. After carrying out the microdecompression procedure, we also executed posterior dynamic transpedicular stabilization from the same incision with the help of lateral intraoperative fluoroscopy using Wiltse approach via inside lateral paravertebral muscle. The dynamic pedicle hinged screws used in our cases were Cosmic (Ulrich Gmbh & Co. KG, Ulm, Germany) and Safinaz (Medikon, Turkey), in combination with rigid rods (Figure 1).

2.5. Statistical Methods. Kolmogorov-Smirnov test was used for homogeneity of the groups to comply with the normal distribution test. Friedman and Wilcoxon test was used for statistical analysis.

3. Results

In Table 1, the median, minimum and maximum range, Lumbar lordosis, α angle, and IVS value are given. The mean 1, 2, and 3 postoperative IVS ratio was significantly greater than that of the preoperative group ($P < 0.001$, Table 1). However, the mean 1 and 2 postoperative IVS ratio was not significantly different ($P > 0.05$). The mean preoperative and 1, 2, and 3 postoperative angles of lumbar lordosis and segmental lordosis were not significantly different ($P > 0.05$). Furthermore, the mean lumbar lordosis preoperative and 1, 2, and 3 postoperative values were not significantly different ($P > 0.05$).

All cases of Modic type 1 degeneration upgraded to type 2 or 3 degeneration after 24 months without pain.

From Table 2, it can be noted that the mean VAS pain score and ODI score 3, 12, and 24 months after surgery decreased significantly, when compared with the preoperative scores in the groups ($P = 0.000$). Furthermore, 24 months after surgery, the mean VAS score and ODI score decreased significantly, when compared with preoperative scores and postoperative 3- and 12-month scores in the groups ($P = 0.000$).

4. Discussion

Abnormalities of the vertebral endplate and vertebral bone marrow were described by Modic et al. [2]. Abnormalities associated with decreased signal intensity on T1-weighted spin-echo images (Modic type 1) correlated with segmental hypermobility and LBP [3]. Fayad et al. found that patients with chronic LBP and predominantly type 1 inflammatory Modic changes had better short-term relief of symptoms following intradiscal steroid injection than those with predominantly type 2 changes, which further supports the inflammatory nature of Modic type 1 changes and the role of inflammation in the generation of LBP [27]. Two recent publications suggest a possible relationship between bone marrow abnormalities revealed by MRI and discogenic pain [4, 28]. In these studies, moderate and severe types 1 and 2 endplate abnormalities were considered abnormal, and all the tested discs caused concordant pain on provocation [6]. Ohtori et al. reported that endplate abnormalities in patients with discogenic pain are related to inflammation and axonal growth into the abnormal bone marrow induced by cytokines, such as tumor necrosis factor-α [29]. Thus, tumor necrosis factor-α expression and sensory nerve in-growth in abnormal endplates may be a cause of LBP [29].

It has been reported that Modic type 1 change is associated with pathology, including disruption and fissuring of the endplate with regions of degeneration and regeneration and vascular granulation tissue [2, 5]. In addition, an increased amount of reactive woven bone as well as prominent osteoclasts and osteoblasts has been observed [2]. It has been reported that there were increases in the amount of cytokines and the density of sensory nerve fibers in the endplate and bone marrow in Modic type 1 change, when compared with normal subjects, strongly suggesting that the endplates and vertebral bodies are the sources of pain [29, 30]. These reports suggest that Modic type 1 signal shows an active inflammatory stage [2, 5, 29, 30]. In contrast, type 2 changes were found to be associated with fatty degeneration of the red marrow and its replacement by yellow marrow. Thus, it

Table 1: Results of radiological lumbar lordosis, α angle, and intervertebral space (IVS).

	Preop	Postop (3 months)	Postop (12 months)	Postop (24 months)	P value
Lumbar lordosis (LL)					
Median	44.85	43.45	43.86	43.56	0.059
Min–max	14–72	18–70	18–71	17–69	
α angle					
Median	10.17	9.98	9.93	10.06	0.685
Min–max	1–30	0–33	0–31	2–32	
Intervertebral space (IVS)					
Median	0.28	0.27	0.28	0.28	0.029
Min–max	0-0	0-0	0-0	0-0	

Friedman test (mean and P value); Wilcoxon Signed Ranks Test IVS (preop 3 months: $P < 0.005$, preop 12 months: $P < 0.004$, and preop 24 months: $P < 0.005$).

Table 2: Comparison of the outcomes of visual analog scale (VAS) and Oswestry Disability Index (ODI) scores in the groups. Both groups exhibited significant reduction in pain over time.

	Mean	Comparison		P value
Visual analog scale (VAS)	Preop: 7.20 3 months: 2.70 12 months: 1.53 24 months: 0.95	Preop: 3 months Preop: 12 months Preop: 24 months 3–12 months	3–24 months 12–24 months	0.000
Oswestry Disability Index (ODI)	Preop: 65.90 3 months: 22.80 12 months: 11.10 24 months: 4.94	Preop: 3 months Preop: 12 months Preop: 24 months 3–12 months	3–24 months 12–24 months	0.000

Friedman test (mean and P value); Wilcoxon Signed Ranks Test.

had been concluded that type 1 changes correspond to the inflammatory stage of DDD and indicate an ongoing active degenerative process, whereas type 2 changes represent the fatty stage of DDD and are related to a more stable and chronic process.

In the study by Toyone et al. [5], 70% of the patients with type 1 Modic changes and 16% of those with type 2 changes were found to have segmental hypermobility, defined as a sagittal translation of 3 mm or more on dynamic flexion-extension films [5]. In a study assessing osseous union following lumbar fusion in 33 patients, Lang et al. found that all 19 patients with solid fusion had type 2 Modic changes, whereas 10 of the 14 patients with nonunion had type 1 changes [31, 32]. They suggested that Modic type 1 in patients with unstable fusions might be related to reparative granulation tissue, inflammation, edema, and hyperemic changes. They concluded that the persistence of type 1 Modic changes after fusion suggests pseudoarthrosis. Similarly, Buttermann et al. observed that nonfusion was associated predominantly with the persistence of type 1 Modic changes [15]. There are patients having very low back pain Modic type 1 and in addition patients with unbearable pain will spend for the failed fusion surgery. For this reason, we performed dynamic stabilization in Modic type 1 and 2 patients.

Hinged screw systems have been used for posterior dynamic stabilization in the current series. The advantages of this system are as follows. (i) These systems stabilize the spine and restore the neutral zone [33–35]. (ii) They provide a simple surgery, when compared with anterior, posterior, or combined fusion surgery. (iii) These types of dynamic systems allow performing lumbar lordosis during the surgery. (iv) Pseudoarthrosis rate is high in cases with fusion surgery [16, 31]. (v) The clinical experience demonstrated good results in the literature [36, 37].

Chataigner et al. studied 56 patients who underwent anterior procedures with bone grafting for LBP [16]. Their best results were obtained in patients with Modic type 1 lesions. The results were poorer in patients who had black discs without endplate involvement or Modic type 2 lesions. Among five nonunions, three requiring posterior revision surgery were observed in Modic type 2 changes. Anterior surgery, with disc herniation associated with Modic type 1 or 2 as the basis for the implementation of changes, is difficult. Because these patients for the treatment of disc herniation and discectomy ago posterior made, then the patients given the same or a different session, the anterior position to apply the anterior fusion surgery. Anterior surgery is time consuming and is an intervention method with a high likelihood of complications. For these patients instead of an application, we propose a posterior dynamic stabilization.

Kwon et al. studied the long-term efficacy of PLIF with a threaded fusion cage based on vertebral endplate changes in DDD [18]. They found that the fusion rate was 80.8% for patients with Modic type 1 changes, 83.6% with Modic type 2

changes, and 54.5% with Modic type 3 changes. Furthermore, the nonfusion rate was 20%. This ratio is higher for patients with Modic type 1 as a high proportion of patients continue to complain about pain and do not see the benefits of treatment. Vital et al. assessed the clinical and radiological outcomes following instrumented posterolateral fusion in 17 patients with chronic LBP and type 1 Modic changes [32]. Six months later, all type 1 changes had converted, with 76.5% being converted to type 2 changes and 23.5% back to normal, and clinical improvement was seen in all patients. They concluded that fusion accelerates the course of type 1 Modic changes probably by correcting the mechanical instability, and that these changes appear to be a good indicator of satisfactory surgical outcome after arthrodesis.

The natural course of the signal anomalies reported by Modic et al. was subsequently followed up by the same authors [2]. Five of the six type 1 lesions were replaced by type 2 signal anomalies over 14–36 months. The type 2 lesions remained stable over 2-3 years of follow-up evaluation. Lang et al. showed that the persistence of Modic type 1 signal after arthrodesis suggests pseudoarthrosis [31]. Toyone et al. concluded that Modic type 1 signal is associated with instability, requiring arthrodesis more commonly than Modic type 2 change, which can accompany nerve-root compromise [5].

In brief, we can state that Modic type 1 changes are associated with instability and painful disorders connected with instability. In such cases, posterior dynamic stabilization could be an effective and alternative treatment modality.

References

[1] A. de Roos, H. Kressel, C. Spritzer, and M. Dalinka, "MR imaging of marrow changes adjacent to end plates in degenerative lumbar disk disease," *The American Journal of Roentgenology*, vol. 149, no. 3, pp. 531–534, 1987.

[2] M. T. Modic, P. M. Steinberg, J. S. Ross, T. J. Masaryk, and J. R. Carter, "Degenerative disk disease: assessment of changes in vertebral body marrow with MR imaging," *Radiology*, vol. 166, no. 1, pp. 193–199, 1988.

[3] M. T. Modic, T. J. Masaryk, J. S. Ross, and J. R. Carter, "Imaging of degenerative disk disease," *Radiology*, vol. 168, no. 1, pp. 177–186, 1988.

[4] I. Braithwaite, J. White, A. Saifuddin, P. Renton, and B. A. Taylor, "Vertebral end-plate (Modic) changes on lumbar spine MRI: correlation with pain reproduction at lumbar discography," *European Spine Journal*, vol. 7, no. 5, pp. 363–368, 1998.

[5] T. Toyone, K. Takahashi, H. Kitahara, M. Yamagata, M. Murakami, and H. Moriya, "Vertebral bone-marrow changes in degenerative lumbar disc disease: an MRI study of 74 patients with low back pain," *Journal of Bone and Joint Surgery B*, vol. 76, no. 5, pp. 757–764, 1994.

[6] D. Weishaupt, M. Zanetti, J. Hodler et al., "Painful lumbar disk derangement: relevance of endplate abnormalities at MR imaging," *Radiology*, vol. 218, no. 2, pp. 420–427, 2001.

[7] D. Mitra, V. N. Cassar-Pullicino, and I. W. Mccall, "Longitudinal study of vertebral type-1 end-plate changes on MR of the lumbar spine," *European Radiology*, vol. 14, no. 9, pp. 1574–1581, 2004.

[8] G. Schmid, A. Witteler, R. Willburger, C. Kuhnen, M. Jergas, and O. Koester, "Lumbar disk herniation: correlatlon of histologic findings with marrow signal intensity changes in vertebral endplates at MR imaging," *Radiology*, vol. 231, no. 2, pp. 352–358, 2004.

[9] M. Karchevsky, M. E. Schweitzer, J. A. Carrino, A. Zoga, D. Montgomery, and L. Parker, "Reactive endplate marrow changes: a systematic morphologic and epidemiologic evaluation," *Skeletal Radiology*, vol. 34, no. 3, pp. 125–129, 2005.

[10] P. Kjaer, C. Leboeuf-Yde, L. Korsholm, J. S. Sorensen, and T. Bendix, "Magnetic resonance imaging and low back pain in adults: a diagnostic imaging study of 40-year-old men and women," *Spine*, vol. 30, no. 10, pp. 1173–1180, 2005.

[11] M. Kuisma, J. Karppinen, J. Niinimäki et al., "A three-year follow-up of lumbar spine endplate (Modic) changes," *Spine*, vol. 31, no. 15, pp. 1714–1718, 2006.

[12] M. Kuisma, J. Karppinen, J. Niinimäki et al., "Modic changes in endplates of lumbar vertebral bodies: prevalence and association with low back and sciatic pain among middle-aged male workers," *Spine*, vol. 32, no. 10, pp. 1116–1122, 2007.

[13] H. B. Albert and C. Manniche, "Modic changes following lumbar disc herniation," *European Spine Journal*, vol. 16, no. 7, pp. 977–982, 2007.

[14] P. Kjaer, L. Korsholm, T. Bendix, J. S. Sorensen, and C. Leboeuf-Yde, "Modic changes and their associations with clinical findings," *European Spine Journal*, vol. 15, no. 9, pp. 1312–1319, 2006.

[15] G. R. Buttermann, K. B. Heithoff, J. W. Ogilvie, E. E. Transfeldt, and M. Cohen, "Vertebral body MRI related to lumbar fusion results," *European Spine Journal*, vol. 6, no. 2, pp. 115–120, 1997.

[16] H. Chataigner, M. Onimus, and A. Polette, "Surgery for degenerative lumbar disc disease. Should the black disc be grafted?" *Revue de Chirurgie Orthopedique et Reparatrice de l'Appareil Moteur*, vol. 84, no. 7, pp. 583–589, 1998.

[17] P. Fritzell, O. Hägg, P. Wessberg, and A. Nordwall, "2001 Volvo award winner in clinical studies: lumbar fusion versus nonsurgical treatment for chronic low back pain. A multicenter randomized controlled trial from the Swedish lumbar spine study group," *Spine*, vol. 26, no. 23, pp. 2521–2534, 2001.

[18] Y. M. Kwon, D. K. Chin, B. H. Jin, K. S. Kim, Y. E. Cho, and S. U. Kuh, "Long term efficacy of posterior lumbar interbody fusion with standard cages alone in lumbar disc diseases combined with modic changes," *Journal of Korean Neurosurgical Society*, vol. 46, no. 4, pp. 322–327, 2009.

[19] M. D. Rahm and B. B. Hall, "Adjacent-segment degeneration after lumbar fusion with instrumentation: a retrospective study," *Journal of Spinal Disorders*, vol. 9, no. 5, pp. 392–400, 1996.

[20] J. Zucherman, K. Hsu, G. Picetti, A. White, G. Wynne, and L. Taylor, "Clinical efficacy of spinal instrumentation in lumbar degenerative disc disease," *Spine*, vol. 17, no. 7, pp. 834–837, 1992.

[21] M. Putzier, S. V. Schneider, J. F. Funk, S. W. Tohtz, and C. Perka, "The surgical treatment of the lumbar disc prolapse: nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone," *Spine*, vol. 30, no. 5, pp. E109–E114, 2005.

[22] J. C. Banwart, M. A. Asher, and R. S. Hassanein, "Iliac crest bone graft harvest donor site morbidity: a statistical evaluation," *Spine*, vol. 20, no. 9, pp. 1055–1060, 1995.

[23] D. K. Sengupta, "Dynamic stabilization devices in the treatment of low back pain," *Neurology India*, vol. 53, no. 4, pp. 466–474, 2005.

[24] T. Kaner, M. Sasani, T. Oktenoglu, M. Cosar, and A. F. Ozer, "Utilizing dynamic rods with dynamic screws in the surgical treatment of chronic instability: a prospective clinical study," *Turkish Neurosurgery*, vol. 19, no. 4, pp. 319–326, 2009.

[25] G. S. Sapkas, G. S. Themistocleous, A. F. Mavrogenis, I. S. Benetos, N. Metaxas, and P. J. Papagelopoulos, "Stabilization of the lumbar spine using the dynamic neutralization system," *Orthopedics*, vol. 30, no. 10, pp. 859–865, 2007.

[26] O. Ricart and J. M. Serwier, "Dynamic stabilisation and compression without fusion using Dynesys for the treatment of degenerative lumbar spondylolisthesis: a prospective series of 25 cases," *Revue de Chirurgie Orthopedique et Reparatrice de l'Appareil Moteur*, vol. 94, no. 7, pp. 619–627, 2008.

[27] F. Fayad, M. M. Lefevre-Colau, F. Rannou et al., "Relation of inflammatory modic changes to intradiscal steroid injection outcome in chronic low back pain," *European Spine Journal*, vol. 16, no. 7, pp. 925–931, 2007.

[28] H. S. Sandhu, L. P. Sanchez-Caso, H. K. Parvataneni, F. P. Cammisa, F. P. Girardi, and B. Ghelman, "Association between findings of provocative discography and vertebral endplate signal changes as seen on MRI," *Journal of Spinal Disorders*, vol. 13, no. 5, pp. 438–443, 2000.

[29] S. Ohtori, G. Inoue, T. Ito et al., "Tumor necrosis factor-immunoreactive cells and PGP 9.5-immunoreactive nerve fibers in vertebral endplates of patients with discogenic low back pain and modic type 1 or type 2 changes on MRI," *Spine*, vol. 31, no. 9, pp. 1026–1031, 2006.

[30] M. F. Brown, M. V. J. Hukkanen, I. D. McCarthy et al., "Sensory and sympathetic innervation of the vertebral endplate in patients with degenerative disc disease," *Journal of Bone and Joint Surgery B*, vol. 79, no. 1, pp. 147–153, 1997.

[31] P. Lang, N. Chafetz, H. K. Genant, and J. M. Morris, "Lumbar spine fusion: assessment of functional stability with magnetic resonance imaging," *Spine*, vol. 15, no. 6, pp. 581–588, 1990.

[32] J. M. Vital, O. Gille, V. Pointillart et al., "Course of Modic 1 six months after lumbar posterior osteosynthesis," *Spine*, vol. 28, no. 7, pp. 715–720, 2003.

[33] C. Schilling, S. Krüger, T. M. Grupp, G. N. Duda, W. Blömer, and A. Rohlmann, "The effect of design parameters of dynamic pedicle screw systems on kinematics and load bearing: an in vitro study," *European Spine Journal*, vol. 20, no. 2, pp. 297–307, 2011.

[34] W. Schmoelz, J. F. Huber, T. Nydegger, Dipl-Ing, L. Claes, and H. J. Wilke, "Dynamic stabilization of the lumbar spine and its effects on adjacent segments: an in vitro experiment," *Journal of Spinal Disorders and Techniques*, vol. 16, no. 4, pp. 418–423, 2003.

[35] H. Bozkuş, M. Şenoğlu, S. Baek et al., "Dynamic lumbar pedicle screw-rod stabilization: in vitro biomechanical comparison with standard rigid pedicle screw-rod stabilization—laboratory investigation," *Journal of Neurosurgery: Spine*, vol. 12, no. 2, pp. 183–189, 2010.

[36] A. F. Ozer, N. R. Crawford, M. Sasani et al., "Dynamic lumbar pedicle screw-rod stabilization: two year follow-up and comparison with fusion," *Open Orthopaedics*, vol. 4, pp. 137–141, 2010.

[37] T. Oktenoglu, A. F. Ozer, M. Sasani et al., "Posterior dynamic stabilization in the treatment of lumbar degenerative disc disease: 2-year follow-up," *Minimally Invasive Neurosurgery*, vol. 53, no. 3, pp. 112–116, 2010.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 437570, 8 pages
http://dx.doi.org/10.1155/2013/437570

Research Article

Intervertebral Disc Rehydration after Lumbar Dynamic Stabilization: Magnetic Resonance Image Evaluation with a Mean Followup of Four Years

Li-Yu Fay,[1,2,3] Jau-Ching Wu,[1,2,3] Tzu-Yun Tsai,[4,5] Tsung-Hsi Tu,[1,2] Ching-Lan Wu,[6] Wen-Cheng Huang,[1,2] and Henrich Cheng[1,2,3]

[1] *Department of Neurosurgery, Neurological Institute, Taipei Veterans General Hospital, Taipei 11217, Taiwan*
[2] *School of Medicine, National Yang-Ming University, Taipei 11221, Taiwan*
[3] *Institute of Pharmacology, National Yang-Ming University, Taipei 11221, Taiwan*
[4] *Department of Ophthalmology, National Taiwan University Hospital, College of Medicine, National Taiwan University, Taipei 10002, Taiwan*
[5] *Department of Ophthalmology, New Taipei City Hospital, New Taipei City 241, Taiwan*
[6] *Department of Radiology, Taipei Veterans General Hospital, Taipei 11217, Taiwan*

Correspondence should be addressed to Jau-Ching Wu; leofay1978@gmail.com

Received 7 July 2012; Accepted 27 March 2013

Academic Editor: Mehdi Sasani

Objective. To compare the clinical and radiographic outcomes in patients of different ages who underwent the Dynesys stabilization. *Methods.* This retrospective study included 72 patients (mean age 61.4 years) with one- or two-level lumbar spinal stenosis who underwent laminectomy and the Dynesys (Zimmer Spine, Minneapolis) dynamic stabilization system. Thirty-seven patients were younger than 65-year old while the other 35 were older. Mean followup was 46.7 months. Pre- and postoperative radiographic and clinical evaluations were analyzed. *Results.* The mean calibrated disc signal (CDS) at the index level was significantly improved from 60.2 ± 25.2 preoperatively to 66.9 ± 26.0 postoperatively ($P > 0.001$). Screw loosening occurred in 22.2% of patients and 5.1% of screws. The improvement in CDS at index level was seen to be significant in younger patients but not in older patients. Overall, the mean visual analogue scale (VAS) of back pain, VAS of leg pain, and the Oswestry disability index (ODI) scores improved significantly after operation. There were no significant differences in pre- and postoperative VAS and ODI and screw loosening rates between the younger and older patients. *Conclusions.* There is significant clinical improvement after laminectomy and dynamic stabilization for symptomatic lumbar spinal stenosis. Intervertebral disc rehydration was seen in younger patients.

1. Introduction

Instrumented spinal fusion is the treatment of choice for degenerative spondylosis with instability refractory to conservative treatment [1, 2]. Spine surgeons have also used modern biologics such as recombinant human bone morphogenetic protein-2 to increase the rate of spinal fusion in selected patients [3–7]. However, using biologics to enhance spinal fusion has been sometimes reported with complications postoperatively and during followup. Moreover, even autograft has been repeatedly reported with adverse events, such as donor site morbidity. Not to mention that loss of segmental motion and subsequent adjacent segmental degeneration have also been concerned for the spinal fusion surgery [8–10].

In the recent years, there is the emerging option of dynamic stabilization to spare spinal fusion and still yield satisfactory outcomes in the surgical management of lumbar spondylosis and back pain. Fischgrund and colleagues reported application of the Dynesys (Zimmer Spine, Minneapolis, USA), a pedicle-based lumbar dynamic stabilization system, as an effective alternative to treat lumbar spondylosis in 1994 [11–16]. Theoretically Dynesys can unload the intervertebral disc while providing a restricted range of motion

and thus alleviates symptoms in the indexed level of spine. Although its long-term effect on the adjacent segment is still uncertain, there are reports demonstrating improved clinical outcomes with acceptably low rate of screw loosening when Dynesys is used in degenerative disc diseases (DDD), lumbar stenosis, and some spondylolisthesis [13, 17]. Despite the common nature of spondylosis in the diseases treated, quite some disparity exists among these patients, who have variable age and bone quality that could affect the screw anchoring in the nonfused constructs. However, there is a paucity of data addressing the differences of age and clinical outcomes in these patients treated by dynamic stabilization with Dynesys.

This study aims to compare the clinical and radiographic outcomes in patients of different ages who underwent surgical decompression and Dynesys stabilization. This is the first study focusing on the discrepancies between the elderly and the younger patients. The pre- and postoperative magnetic resonance imaging (MRI) especially of each patient were compared to evaluate the condition of the discs at the index segments. All clinical data was prospectively collected and outcomes were measured by standardized parameters with more than two years of followup.

2. Methods

2.1. Patient Enrollment. From September 2007 to August 2009, the study enrolled 88 consecutive patients who underwent surgical decompression and dynamic stabilization with Dynesys (Zimmer Spine, Minneapolis, MN) in the authors' service. The clinical and radiological data were collected prospectively and then analyzed retrospectively. Three experienced spine surgeons performed all operations in a very similar fashion by the same technique.

The inclusion criteria were the patients who had lumbar DDD with persistent symptoms such as intermittent claudication, low back pain, buttock pain, leg pain, or any combination of the above. Each patient underwent preoperative MRI to confirm the diagnosis and had failed medical treatment for longer than 12 weeks. The exclusion criteria were degenerative scoliosis, prior lumbar surgery, disc diseases requiring discectomies, and spondylolisthesis worse than grade II. Patients with psychiatric disorders, cerebral vascular accidents, coexisting cervical or thoracic myelopathy, or neoplasms were also excluded. Among the 88 patients enrolled in this cohort, 72 completed the follow up for more than 24 months and were thus analyzed. These patients were divided into two groups according to the age at operation: young age (<65 years) and old age (≧65 years).

2.2. Operative Technique. Patients were placed in prone position under general anesthesia. Fluoroscopy was used routinely before sterilization to confirm the treated level and keep the lumbar spine in a neutral lordotic curve. Prophylactic antibiotics were infused thirty minutes before incision. After midline incision by subperiosteal dissection, the laminae and spinous process were exposed. The facet joints capsules were preserved intact. Standard total laminectomies and foraminotomies with resection of hypertrophic spur and ligamentum flavum were performed carefully to preserve the complex structure of the facet joints. The exiting and traversing nerve roots were probed through to confirm the adequate decompression without any bony fragment. Bilateral fascial incisions were made by subdermal dissection through the same wound. Along the Wiltse and Spencer intermuscular plane, the titanium alloy screws were placed transpedicularly without destruction of the facet joints [18]. The modular spacers were cut appropriately and the tension cords were assembled to reach 300 N for dynamic stabilization. Fluoroscope was used to assure the correct position of each screw. Drainage catheters were left and the wound was closed layer by layer.

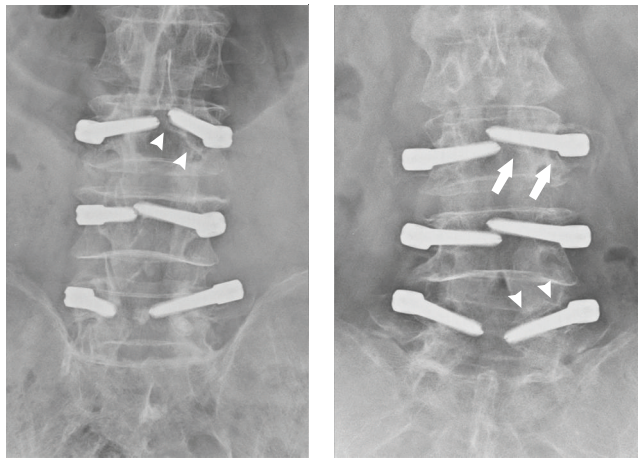
2.3. Clinical Assessment. The Oswestry disability index (ODI) scale was used for functional assessment. The 0–10 visual analogue scale (VAS) was used for back and leg pain evaluation. The patients themselves completed the ODI and VAS questionnaire preoperatively and at 1.5-, 3-, 6-, 12-, and 24-month followup regularly. Preoperative scores were compared to postoperative scores.

2.4. Radiographic Assessment. Standard anterior/posterior and lateral radiographs, computed tomography (CT), and magnetic resonance imaging (MRI) studies were routinely performed in preoperative assessment. Radiographs were taken regularly at 1.5-, 3-, 6-, 12-, and 24-month followup.

The presence of "halo zone sign" or "double halo sign" on anteroposterior radiographs was defined as screw loosening during followup (Figure 1). CT was used to determine questionable screw loosening. The halo zone sign was defined as a radiolucent zone alone the screws with 1 mm in width and in any length. The double halo sign was further defined as a radiolucent zone with a radiopaque rim alone the screws.

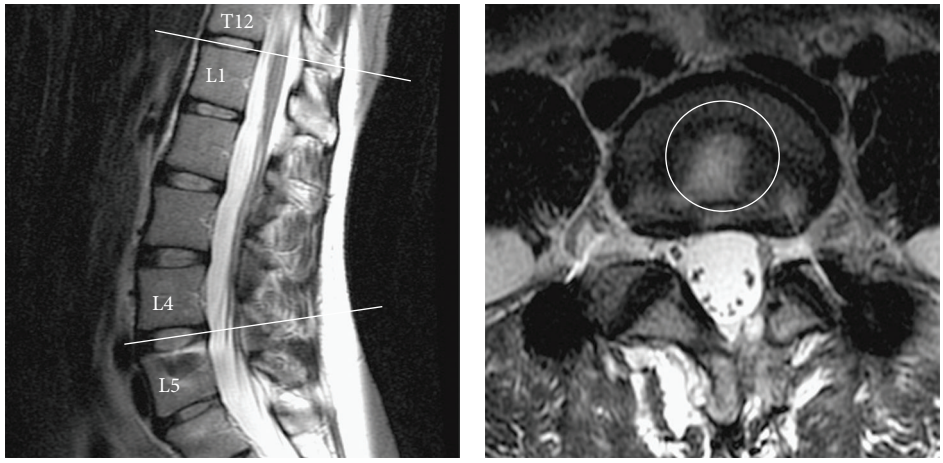
Pre- and post-operative MRI images were compared focusing on the condition of the discs, including the indexed and adjacent segments. Due to the lack of an absolute unit of measuring the signal intensities on MRI, for example, the Hounsfield unit used in computed tomography to describe radiodensity, these signals of the same patient are difficult to compare. Ideally the pre- and post-operative MRI studies need to be taken by the very same MRI machine to unify the signal intensity references. We tried to allocate the same MRI machine to each patient; however, not every patient achieved the goal. To address this issue, the digital signal in central intervertebral disc of the levels T12-L1 in T2-weighted image (T2WI) was designated as a reference (Figure 2). The signal intensity in the center of the discs in the lumbar spine of each patient was recorded and compared to each patient's own signal intensity recorded at the levels of T12-L1 in T2-weighted MRI (T2WI). The ration differences of signal intensity were calculated and defined as the calibrated disc signal (CDS). The pre- and post-operative CDS of bridged levels were thus all compared and analyzed.

2.5. Statistical Analysis. Clinical and radiographic assessments were compared and analyzed using Student's t-test, chi-square, and Mann-Whitney U test, where appropriate. All



(a) (b)

Figure 1: Anteroposterior radiographs. (a) A 61-year-old female who underwent Dynesys stabilization at 12-month postoperation. The double halo sign indicated loosening of the left L3 pedicle screw. (b) A 75-year-old male who underwent Dynesys stabilization, at 2-year postoperation. The double halo sign indicated screw loosening of the left L5 and the halo sign indicated screw loosening of the left L3 screws. Arrowhead, double halo sign; arrow, halo sign.



(a) (b)

Figure 2: MRI T2-weighted image of a 34-year-old female. (a) Sagittal view. (b) Axial view. The axial view of each disc was retrieved in correspondence with the center of each disc in sagittal view. A circle of one centimeter in radius, region of interest (ROI), was drawn in the geometrical center of each disc. The mean signal intensity of ROI was then measured and recorded. The mean signal intensity of ROI of each level (e.g., L4-5) divided with reference level (i.e., T12-L1) was called CDS.

data analysis was processed with the statistical software, SPSS version 17.0 (SPSS, Inc., Chicago, IL). Statistical significance was set at P value < 0.05.

3. Results

Of the 88 consecutive patients with lumbar spondylosis who underwent 1- or 2-level dynamic stabilization with the Dynesys system, 72 patients (81.8%), in whom 370 screws were placed, completed the clinical and radiological evaluations for at least 24 months postoperatively. There were 37 men (51.4%) and 35 women (48.6%) whose mean age was 61.4 ± 11.3 (31–82) years at the time of surgery (Table 1).

The mean followup duration was 46.7 ± 7.8 (33–58) months. In the 72 patients, 31 (43.1%) underwent a 1-level and 41 (56.9%) underwent a 2-level stabilization. The distributions of index levels were as follows: 3 (4.2%) at L3-4; 23 (31.9%) at L4-5; 5 (6.9%) at L5-S1; 1 (1.4%) at L2-3-4; 33 (45.8%) at L3-4-5; and 7 (9.7%) at L4-5-S1 (Table 2).

Overall there were 15 (20.8%) patients diagnosed of type 2 (diabetes mellitus) DM and 9 (12.5%) patients of hypertension. There were more diabetic patients in older age group (34.3%) than in young age group (8.1%) in current study ($P = 0.006$). The hypertensive patients in both groups had similar prevalence rates (10.8% versus 14.3%, $P = 0.656$) (Table 3).

Table 1: Clinical and demographic characteristics ($n = 72$).

Characteristic	Value
Gender	
Male	37 (51.4%)
Female	35 (48.6%)
Age (years) mean	61.4 ± 11.3 (31–82)
Follow-up (months) mean	46.7 ± 7.8 (33–58)
Number of instrumented levels	
1-level	31 (43.1%)
2-levels	41 56.9%)

Table 2: Distribution of treated levels.

Instrumentation	Level	Number of patients
1-level ($n = 31$)	L3-4	3 (4.2%)
	L4-5	23 (31.9%)
	L5-S1	5 (6.9%)
2-levels ($n = 41$)	L2-3-4	1 (1.4%)
	L3-4-5	33 (45.8%)
	L4-5-S1	7 (9.7%)

3.1. Clinical Outcomes. The overall mean VAS for back pain improved with statistical significance, from 6.3 ± 3.3 preoperatively to 2.8 ± 2.9 postoperatively ($P < 0.001$). There was significant improvement in both the young age group (6.1 ± 3.4 preoperatively to 2.9 ± 2.9 postoperatively; $P < 0.001$) and the old age group (6.4 ± 3.1 preoperatively to 2.7 ± 2.9 postoperatively; $P < 0.001$) (Table 3). There were no significant differences in pre- and postoperative VAS between the young and old age groups ($P = 0.811$ and $P = 0.754$, resp.) (Figure 1).

The overall mean VAS for leg pain improved with statistical significance, from 7.0 ± 2.7 preoperatively to 2.6 ± 3.2 postoperatively ($P < 0.001$). There was significant improvement in both the young age group (6.7 ± 3.0 preoperatively to 2.7 ± 3.1 postoperatively; $P < 0.001$) and the old age group (7.4 ± 2.3 preoperatively to 2.4 ± 3.2 postoperatively; $P < 0.001$) (Table 3). There were no significant differences in pre- and postoperative VAS between the young and old age groups ($P = 0.497$ and $P = 0.474$, resp.) (Figure 1).

The overall ODI functional scores significantly improved from 51.1 ± 19.6 preoperatively to 23.4 ± 21.4 postoperatively ($P < 0.001$). The young age group specifically improved from 50.4 ± 21.3 preoperatively to 21.8 ± 22.0 postoperatively ($P < 0.001$) and the old group from 51.7 ± 17.8 preoperatively to 25.2 ± 20.8 postoperatively ($P < 0.001$) (Table 3). There were no significant differences in pre- and postoperative ODI scores between the young and old groups ($P = 0.612$ and $P = 0.291$, resp.) (Figure 1).

3.2. Radiographic Outcome of Screw Loosening. There was screw loosening in 16 out of 72 patients (22.2% per patient) and 19 out of 370 screws (5.1% per screw). Specifically, there were 8 of 37 patients (21.6%) and 9 of 188 screws (4.8%) found loosened in the young age group. In contrast, there were 8 of 35 patients (22.9%) and 10 of 182 screws (5.5%) found loosened in the old age group. There was no statistically significant difference found between the two groups in the rates of screw loosening per patient or per screw ($P = 0.900$, $P = 0.739$, resp.) (Table 4).

Table 3: Comparison between young age and old age.

Variables	Total	Age		P values
		<65-year old	≧65-year old	
Number of patients	72	37	35	
Age (years)	61.4 ± 11.3	53.0 ± 9.0	70.3 ± 4.8	<0.001*
Gender				
Male	37	23 (62.2%)	14 (40.0%)	0.060
Female	35	14 (37.8%)	21 (60.0%)	
Number of instrumented levels				
One	31	17 (45.9%)	14 (40.0%)	0.611
Two	41	20 (54.1%)	21 (60.0%)	
Mean pre-op scores				
VAS back pain	6.3 ± 3.3	6.1 ± 3.4	6.4 ± 3.1	0.811
VAS leg pain	7.0 ± 2.7	6.7 ± 3.0	7.4 ± 2.3	0.497
ODI (%)	51.1 ± 19.6	50.4 ± 21.3	51.7 ± 17.8	0.612
Mean 24-month post-op scores				
VAS back pain	2.8 ± 2.9	2.9 ± 2.9	2.7 ± 2.9	0.754
VAS leg pain	2.6 ± 3.2	2.7 ± 3.1	2.4 ± 3.2	0.474
ODI (%)	23.4 ± 21.4	21.8 ± 22.0	25.2 ± 20.8	0.291
Serum glucose status				
Type 2 DM	15	3 (8.1%)	12 (34.3%)	0.006*
Euglycemia	57	34 (91.9%)	23 (65.7%)	
Blood pressure				
Hypertensive	9	4 (10.8%)	5 (14.3%)	0.656
Normotensive	63	33 (89.2%)	30 (85.7%)	

Mean values are presented ± SD.
*$P < 0.05$, statistically significant.
DM: diabetes mellitus.
VAS: visual analogue scale.
ODI: Oswestry disability index.

3.3. Radiographic Outcome of Bridged Disc Signal. The mean overall CDS at bridged level improved (i.e., increased) with statistical significance, from 60.2 ±25.2 preoperatively to 66.9 ± 26.0 postoperatively ($P = 0.014$). There was significant increase in the young age group (58.9 ± 24.7 preoperatively to 67.6 ± 28.7 postoperatively; $P = 0.013$) (Figure 3). However, the change in the old age group was not significant (62.1 ± 26.1 preoperatively to 65.9 ± 22.2 postoperatively; $P = 0.366$). There were no significant differences in pre- and post-operative bridged level CDS between the young and old age groups ($P = 0.732$ and $P = 0.800$, resp.) (Table 4).

Table 4: Comparison of disc signal change between young age and old age.

Variables	Total	Age		P values
		<65-year old	≧65-year old	
Number of patients	72	37	35	
Screw loosening per patient				
Yes	16	8 (21.6%)	8 (22.9%)	0.900
No	56	29 (78.4%)	27 (77.1%)	
Screw loosening per screw				
Yes	19	9 (4.8%)	10 (5.5%)	0.739
No	351	179 (95.2%)	172 (94.5%)	
CDS of bridged disc				
Pre-op	60.2 ± 25.2	58.9 ± 24.7	62.1 ± 26.1	0.732
Post-op	66.9 ± 26.0**	67.6 ± 28.7**	65.9 ± 22.2	0.800

Mean values are presented ± SD.
**$P < 0.05$, the post-op value compared with the pre-op value demonstrated significant difference.
CDS: calibrated disc signal.

4. Discussion

The current study collected total 72 patients with lumbar spondylosis who underwent decompression and dynamic stabilization. A total 370 screws of Dynesys were placed during the operations. In a mean follow-up period of 46.7 months, the results of both the young age (<65 years old, $n = 37$) and the old age (≧65 years old, $n = 35$) groups demonstrated satisfactory improvement in clinical outcomes. The overall screw loosening rate was 22.2% per patient (16 in 72 patients) and 5.1% per screw (19 in 370 screws). The rate of screw loosening was slightly higher in the old age patients. Regarding disc signal, in the overall CDS of bridged discs, the change significantly improved from 60.2±25.2 preoperatively to 66.9 ± 26.0 postoperatively ($P = 0.014$). However, the change in the young age group (58.9 ± 24.7 to 67.6 ± 28.7, $P = 0.013$) appeared to be more obvious than in the old age group (62.1 ± 26.1 to 65.9 ± 22.2, $P = 0.366$).

Using the 10% difference as minimal clinically important difference (MCID) of the ODI defined by Hägg et al., and the 1.2 unit improvement of VAS reported by Copay et al., overall there were 68.1% (49/72) of patients had MCID of VAS back pain, 84.7% (61/72) had MCID of VAS leg pain, and 81.9% (59/72) had MCID of ODI [19, 20]. Therefore, a significant number of patients had clinically significant improvement in the present series at a mean followup of 47 months.

According to the population projections of the United Nations, the number of elderly patients (older than 65 years) in the world will increase from 8 to 14 percent and the percentage will increase far more to 25 percent in more developed nations between 2010 and 2040. Low back pain and lumbar spondylosis is a common problem in the elderly patients which may greatly affect their quality of life. Pain, numbness, claudication, and risk to fall are the frequent symptoms of the patients. The prevalence of lumbar spondylosis will increase as the population ages [21, 22]. Conservative treatment such as medication, physical therapy, or manual therapy may be the first-line treatment for most patients and surgical intervention can still achieve satisfactory improvement in selected patients refractory to conservative treatment [23]. Weinstein et al. conducted a cohort study, spine patient outcome research trial (SPORT), to analyze the pain improvement and functional outcomes. They enrolled a randomized cohort of 304 patients and an observational cohort of 303 patients for analysis. They concluded that patients with degenerative spondylolisthesis and spinal stenosis treated surgically, decompression with or without fusion, would maintain greater pain relief and functional improvement [24].

Regarding the influence of age, Deyo et al. reported that complications associated with procedures were primarily related to patients' age [25]. The mortality and morbidity, length of hospitalization, and hospital charge all increased with the ages of the patients. Wang et al. conducted a retrospective study to analyze the clinical outcomes and complications associated with lumbar stenosis surgery in elderly patients (>75 years) in 2003. Eighty-eight patients older than 75 years of age who underwent lumbar spondylosis surgery were collected and fifty-two (59.1%) patients received spinal fusion. Among them, 76% experienced complete or partial improvement of back pain, 85% experienced complete or partial relief of leg pain, and 61% of 33 patients with preoperative gait disturbance experienced at least one point on the ambulatory scale. They concluded that lumbar spinal surgery could be conducted safely and with satisfactory outcomes as in young age patients [26]. For more complicated spinal degeneration, Daubs et al. surveyed forty-six patients older than 60 years of age in 2007. These elderly patients with mean age of 67 years underwent spinal deformity surgery to perform thoracic or lumbar arthrodesis procedures of 5 levels or more. The overall complication rate is 37%, including dura tear in 4, iliac vein injury in 4, misplaced pedicle screw in 1, and nerve root injury in 1 patient. The overall mean ODI improvement is 24 points which is statistically significant ($P < 0.001$). They concluded that increasing age was a predicting factor for complication. However, the presence of complications had no association with final clinical outcomes [27].

Dynamic stabilization, Dynesys, is an alternative surgical treatment for lumbar spondylosis. It aims to change the mechanical loading of lumbar spinal segments. Several studies have proved the safety and efficacy of dynamic stabilization but there were only few series involving the Dynesys in the elderly patients [12, 13, 15, 16, 28–30]. Di Silvestre et al. reported that to use this pedicle screw-based system in elderly patients with degenerative scoliosis was able to achieve significant improvement of clinical outcome at last followup. In twenty-nine elderly patients, with mean age of 68.5 years, 51.6% of them had improvement in

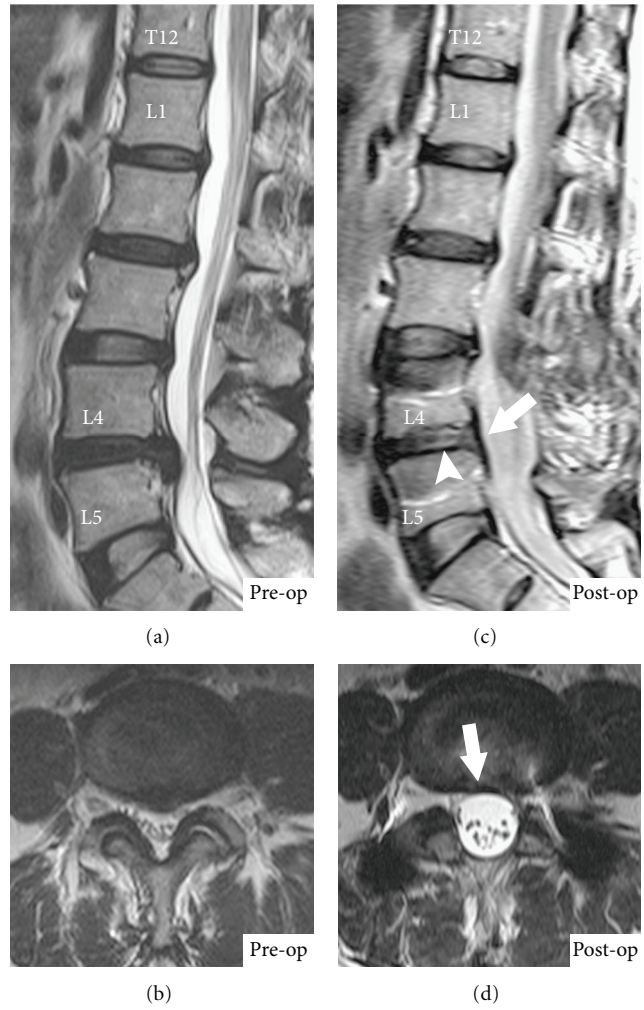


Figure 3: MRI T2-weighted image of a 56-year-old female. ((a) and (c)) Sagittal view. ((b) and (d)) Axial view. The significant increase in CDS was seen in L4-5 level (preoperative 0.44 to postoperative 0.92) at 24-month followup. Meanwhile, the signal intensity of T12-L1 demonstrated to be similar brightness. Arrow, reduced bulging disc after stabilization; arrowhead, significant increase in CDS.

ODI and 58.2% had improvement in Roland Morris score. The mean improvement was 51.7% and 57.8% in VAS for back and leg pain, respectively. The scoliosis and associated spondylolisthesis remained stable at the last followup [31]. Wu et al. conducted a study to investigate risk factor and outcomes associated with screw loosening of Dynesys. They collected 126 patients with more than 24-month followup. Besides diabetes mellitus, they concluded that old age was identified as major risk factors for screw loosening. Screw loosening can be asymptomatic to clinical outcomes [17].

However, there was no comparative study to discuss the outcomes between young and elderly patients. To date, there is a paucity of long-term data for the application of Dynesys in the elderly patients. The current retrospective study specifically aimed to compare the cohort of young to old age patients with lumbar spondylosis who underwent dynamic stabilization. Regarding the low back pain, the prevalence may be quite high and it may be often underestimated due to inconsistent study design and definition. Cho et al. reported the lifetime prevalence of low back pain was as high as 53.8% in the Asian population [22]. In our study, between the young and elderly patients, the preoperative VAS for back pain was the same (6.1 ± 3.4 versus 6.4 ± 3.1, $P = 0.811$). After decompression and Dynesys implant, they both had significant improvement. Regarding the improvement of VAS back pain, 64.9% (24/37) of patients in young age group had MCID and 71.4% (25/35) of patients in old age group had MCID. The treatment of back pain in elderly seems to be as effective as in young patients. The results of VAS leg pain were similar to back pain. Between the two groups, the preoperative VAS for leg pain was the same (6.7 ± 3.0 versus 7.4 ± 2.3, $P = 0.497$). After surgery, 78.4% (29/37) of patients in young age group had MCID and 91.4% (32/35) of patients in old age group had MCID. The elderly group seemed to have much better result than the young age group.

The preoperative ODI scores were similar between the two groups (50.4 ± 21.3 versus 51.7 ± 17.8, $P = 0.612$). Thirty in 37 (81.1%) young patients and 29 in 35 (82.9%) old patients had MCID in ODI. Both groups had significant improvement after surgery.

Ko et al. reported the screw loosening rate was 19.7% per patient and 4.6% per screw at last followup in 2010. They collected 71 patients with a mean age of 59.2 years and concluded that screw loosening was not associated with clinical outcomes. Most patients with screw loosening were more than 55-year old [13]. Later Wu et al. conducted a study of 126 patients with 658 screws in 2011 and they reported the screw loosening rate as 19.8% per patient and 4.7% per screw. The patients with screw loosening may be asymptomatic at last followup as 37 months long. They concluded that hyperglycemia and old age may be the risk factors of screw loosening [17]. In current study the overall screw loosening rate was 22.2% per patient and 5.1% per screw which were similar to previous studies. The screw loosening rate in the old age group was higher than the young age group in per patient (22.9% versus 21.6%) and per screw (5.5% versus 4.8%). Even the difference did not reach statistically significant but the result was consistent with previous reports. The smaller patient numbers and uncertain cut value of age both could affect the P value. Further study with larger number of patients will be required for this question.

In concern of the bridged disc degeneration, Kumar et al. collected 32 patients with lumbar spondylosis who underwent Dynesys stabilization and completed 2-year follow-up MRI in 2008. Till now, there were only few in vivo reports to discuss disc change. By using Woodend scores to define the degeneration classification, they found that there was a significant increase in the scores from preoperative 1.95 to postoperative 2.52 ($P < 0.001$) at the treated levels. The data demonstrated progressive disc degeneration at bridged level after dynamic stabilization. The authors concluded that the degeneration may be due to natural disease progression [32]. Regarding this topic, Vaga et al. collected ten patients with low back pain who underwent Dynesys and analyzed the quantification of glycosaminoglycan (GAG) concentration by MRI at followup. The GAG was increased in 61% of bridged level discs and the result suggested that dynamic stabilization was able to stop or partially reverse the degeneration. Interestingly they thought Pfirrmann grading, even achieved excellent intra- and interobserver agreement, is not sensitive enough to detect the disc change in their study [33]. In 2001, Pfirrmann et al. conducted a study for classification of lumbar disc degeneration. They collected 60 patients with 300 intervertebral discs for analysis. They have established a reliable classification on routine T2-weighted MRI [34]. However, the same protocol for MRI evaluation was not practicable in routine clinical followup. Our study evaluated the disc signal on T2WI series in pre- and post-operative imaging study. Regarding the different MRI machines at each study, we used the CDS which referred to compare the target disc signal with the least mobile level. The significant increase in bridged level CDS, which was consistent to Vaga's report, represented the Dynesys to stop and reverse the disc degeneration. In detail, the young patients had much more improvement than the old patients had.

There were limitations to this study. The cohort composition was not strictly uniform. The old age patients had much higher prevalence of type 2 diabetes which may have some influence on the outcomes. Smoking habit, osteoporosis profile, and body mass index may also have some adverse effect on the outcomes. There were also two iatrogenic dura tear in the old age group (5.7%), but no related symptom was recorded. No other complications (i.e. wound infection) or reoperations have happened to date in the current series.

5. Conclusions

There was significant clinical improvement after laminectomy and dynamic stabilization with the Dynesys for symptomatic lumbar spinal stenosis in both the young and old age patients. The screw loosening rate was slightly higher in the old age patients. Disc degeneration may stop or reverse in the young age patients but not for the elderly patients. Further studies are needed to evaluate the regenerative effect of dynamic stabilization on the intervertebral discs.

Disclosure

No funds were received in support of this work and no benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this paper.

References

[1] S. D. Glassman, L. Y. Carreon, M. Djurasovic et al., "Lumbar fusion outcomes stratified by specific diagnostic indication," *Spine Journal*, vol. 9, no. 1, pp. 13–21, 2009.

[2] A. R. Vaccaro and S. R. Garfin, "Internal fixation (pedicle screw fixation) for fusions of the lumbar spine," *Spine*, vol. 20, no. 24, pp. 157S–165S, 1995.

[3] V. Arlet, L. Jiang, T. Steffen, J. Ouellet, R. Reindl, and M. Aebi, "Harvesting local cylinder autograft from adjacent vertebral body for anterior lumbar interbody fusion: surgical technique, operative feasibility and preliminary clinical results," *The European Spine Journal*, vol. 15, no. 9, pp. 1352–1359, 2006.

[4] K. H. Bridwell, T. A. Sedgewick, M. F. O'Brien, L. G. Lenke, and C. Baldus, "The role of fusion and instrumentation in the treatment of degenerative spondylolisthesis with spinal stenosis," *Journal of Spinal Disorders*, vol. 6, no. 6, pp. 461–472, 1993.

[5] Z. Ghogawala, E. C. Benzel, S. Amin-Hanjani et al., "Prospective outcomes evaluation after decompression with or without instrumented fusion for lumbar stenosis and degenerative Grade I spondylolisthesis," *Journal of Neurosurgery*, vol. 1, no. 3, pp. 267–272, 2004.

[6] H. N. Herkowitz and L. T. Kurz, "Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective study comparing decompression with decompression and intertransverse process arthrodesis," *Journal of Bone and Joint Surgery A*, vol. 73, no. 6, pp. 802–808, 1991.

[7] A. R. Vaccaro, D. G. Anderson, T. Patel et al., "Comparison of OP-1 putty (rhBMP-7) to iliac crest autograft for posterolateral lumbar arthrodesis: a minimum 2-year follow-up pilot study," *Spine*, vol. 30, no. 24, pp. 2709–2716, 2005.

[8] J. C. Banwart, M. A. Asher, and R. S. Hassanein, "Iliac crest bone graft harvest donor site morbidity: a statistical evaluation," *Spine*, vol. 20, no. 9, pp. 1055–1060, 1995.

[9] A. Çakmak, A. Gyedu, I. Kepenekçi, C. Özcan, and A. E. Ünal, "Colon perforation caused by migration of a bone graft following a posterior lumbosacral interbody fusion operation: case report," *Spine*, vol. 35, no. 3, pp. E84–E85, 2010.

[10] M. D. Rahm and B. B. Hall, "Adjacent-segment degeneration after lumbar fusion with instrumentation: a retrospective study," *Journal of Spinal Disorders*, vol. 9, no. 5, pp. 392–400, 1996.

[11] J. S. Fischgrund, M. Mackay, H. N. Herkowitz, R. Brower, D. M. Montgomery, and L. T. Kurz, "Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective, randomized study comparing decompressive laminectomy and arthrodesis with and without spinal instrumentation," *Spine*, vol. 22, no. 24, pp. 2807–2812, 1997.

[12] D. Grob, A. Benini, A. Junge, and A. F. Mannion, "Clinical experience with the dynesys semirigid fixation system for the lumbar spine: surgical and patient-oriented outcome in 50 cases after an average of 2 years," *Spine*, vol. 30, no. 3, pp. 324–331, 2005.

[13] C. C. Ko, H. W. Tsai, W. C. Huang et al., "Screw loosening in the Dynesys stabilization system: radiographic evidence and effect on outcomes," *Neurosurgical Focus*, vol. 28, no. 6, article E10, 2010.

[14] S. Schaeren, I. Broger, and B. Jeanneret, "Minimum four-year follow-up of spinal stenosis with degenerative spondylolisthesis treated with decompression and dynamic stabilization," *Spine*, vol. 33, no. 18, pp. E636–E642, 2008.

[15] K. J. Schnake, S. Schaeren, and B. Jeanneret, "Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis," *Spine*, vol. 31, no. 4, pp. 442–449, 2006.

[16] T. M. Stoll, G. Dubois, and O. Schwarzenbach, "The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system," *The European Spine Journal*, vol. 11, no. 2, pp. S170–S178, 2002.

[17] J. C. Wu, W. C. Huang, H. W. Tsai, C. C. Ko, C. L. Wu, T. H. Tu et al., "Pedicle screw loosening in dynamic stabilization: incidence, risk, and outcome in 126 patients," *Neurosurgical Focus*, vol. 31, no. 4, article E9, 2011.

[18] L. L. Wiltse and C. W. Spencer, "New uses and refinements of the paraspinal approach to the lumbar spine," *Spine*, vol. 13, no. 6, pp. 696–706, 1988.

[19] A. G. Copay, S. D. Glassman, B. R. Subach, S. Berven, T. C. Schuler, and L. Y. Carreon, "Minimum clinically important difference in lumbar spine surgery patients: a choice of methods using the Oswestry Disability Index, Medical Outcomes Study questionnaire Short Form 36, and Pain Scales," *Spine Journal*, vol. 8, no. 6, pp. 968–974, 2008.

[20] O. Hägg, P. Fritzell, and A. Nordwall, "The clinical importance of changes in outcome scores after treatment for chronic low back pain," *The European Spine Journal*, vol. 12, no. 1, pp. 12–20, 2003.

[21] H. B. Bressler, W. J. Keyes, P. A. Rochon, and E. Badley, "The prevalence of low back pain in the elderly: a systematic review of the literature," *Spine*, vol. 24, no. 17, pp. 1813–1819, 1999.

[22] N. H. Cho, Y. O. Jung, S. H. Lim, C. K. Chung, and H. A. Kim, "The prevalence and risk factors of low back pain in rural community residents of Korea," *Spine*, vol. 37, no. 24, pp. 2001–2010, 2012.

[23] K. M. Backstrom, J. M. Whitman, and T. W. Flynn, "Lumbar spinal stenosis-diagnosis and management of the aging spine," *Manual Therapy*, vol. 16, no. 4, pp. 308–317, 2011.

[24] J. N. Weinstein, J. D. Lurie, T. D. Tosteson et al., "Surgical compared with nonoperative treatment for lumbar degenerative spondylolisthesis: four-year results in the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts," *Journal of Bone and Joint Surgery A*, vol. 91, no. 6, pp. 1295–1304, 2009.

[25] R. A. Deyo, D. C. Cherkin, J. D. Loeser, S. J. Bigos, and M. A. Ciol, "Morbidity and mortality in association with operations on the lumbar spine. The influence of age, diagnosis, and procedure," *Journal of Bone and Joint Surgery A*, vol. 74, no. 4, pp. 536–543, 1992.

[26] M. Y. Wang, B. A. Green, S. Shah, S. Vanni, and A. D. Levi, "Complications associated with lumbar stenosis surgery in patients older than 75 years of age," *Neurosurgical Focus*, vol. 14, no. 2, article e7, 2003.

[27] M. D. Daubs, L. G. Lenke, G. Cheh, G. Stobbs, and K. H. Bridwell, "Adult spinal deformity surgery: complications and outcomes in patients over age 60," *Spine*, vol. 32, no. 20, pp. 2238–2244, 2007.

[28] M. Putzier, S. V. Schneider, J. F. Funk, S. W. Tohtz, and C. Perka, "The surgical treatment of the lumbar disc prolapse: nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone," *Spine*, vol. 30, no. 5, pp. E109–E114, 2005.

[29] W. C. Welch, B. C. Cheng, T. E. Awad et al., "Clinical outcomes of the Dynesys dynamic neutralization system: 1-year preliminary results," *Neurosurgical Focus*, vol. 22, no. 1, article E8, 2007.

[30] C. C. Würgler-Hauri, A. Kalbarczyk, M. Wiesli, H. Landolt, and J. Fandino, "Dynamic neutralization of the lumbar spine after microsurgical decompression in acquired lumbar spinal stenosis and segmental instability," *Spine*, vol. 33, no. 3, pp. E66–E72, 2008.

[31] M. di Silvestre, F. Lolli, G. Bakaloudis, and P. Parisini, "Dynamic stabilization for degenerative lumbar scoliosis in elderly patients," *Spine*, vol. 35, no. 2, pp. 227–234, 2010.

[32] A. Kumar, J. Beastall, J. Hughes et al., "Disc changes in the bridged and adjacent segments after Dynesys dynamic stabilization system after two years," *Spine*, vol. 33, no. 26, pp. 2909–2914, 2008.

[33] S. Vaga, M. Brayda-Bruno, F. Perona et al., "Molecular MR imaging for the evaluation of the effect of dynamic stabilization on lumbar intervertebral discs," *The European Spine Journal*, vol. 18, no. 1, supplement, pp. S40–S48, 2009.

[34] C. W. A. Pfirrmann, A. Metzdorf, M. Zanetti, J. Hodler, and N. Boos, "Magnetic resonance classification of lumbar intervertebral disc degeneration," *Spine*, vol. 26, no. 17, pp. 1873–1878, 2001.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 753470, 13 pages
http://dx.doi.org/10.1155/2013/753470

Review Article

Dynamic Stabilization for Challenging Lumbar Degenerative Diseases of the Spine: A Review of the Literature

Tuncay Kaner[1] and Ali Fahir Ozer[2]

[1] *Department of Neurosurgery, School of Medicine, Istanbul Medeniyet University, 34730 Istanbul, Turkey*
[2] *Department of Neurosurgery, School of Medicine, Koc University, 34365 Istanbul, Turkey*

Correspondence should be addressed to Ali Fahir Ozer; alifahirozer@gmail.com

Received 30 November 2012; Accepted 7 March 2013

Academic Editor: Mehdi Sasani

Fusion and rigid instrumentation have been currently the mainstay for the surgical treatment of degenerative diseases of the spine over the last 4 decades. In all over the world the common experience was formed about fusion surgery. Satisfactory results of lumbar spinal fusion appeared completely incompatible and unfavorable within years. Rigid spinal implants along with fusion cause increased stresses of the adjacent segments and have some important disadvantages such as donor site morbidity including pain, wound problems, infections because of longer operating time, pseudarthrosis, and fatigue failure of implants. Alternative spinal implants were developed with time on unsatisfactory outcomes of rigid internal fixation along with fusion. Motion preservation devices which include both anterior and posterior dynamic stabilization are designed and used especially in the last two decades. This paper evaluates the dynamic stabilization of the lumbar spine and talks about chronologically some novel dynamic stabilization devices and thier efficacies.

1. Introduction

Today, low back pain is one of the most important problem in decreasing the quality of life as a result of lumbar disc degeneration [1–4]. It is thought that the origin of low back pain results from degenerative intervertebral disc and facet joints. Segmental instability significantly contributed to lower back pain. Instability associated with intervertebral disc degeneration is represented first by Knutsson in 1944 [5]. Knutsson also described the abnormal flexion-extention slipping in X-ray along with disc degeneration and told that segmental instability should be if sagittal slipping is greater than 3 mm in dynamic X-ray. Degeneration process of the lumbar spine and pathology of discogenic pain were described by Kirkaldy-Willis and Farfan in 1982 [2]. They explained that degenerative instability of the spine began primarily with disc degeneration which contains dehydration of intervertebral disc along with decrease in tension of the annulus fibrosis. It is followed by decrease of disc height, and then this process continues with hypertrophy of the facet joint and ligamentum flavum. At the end spinal stenosis and degenerative spondylolisthesis, which have caused low back pain, occur. Besides, Frymoyer and Selby revealed the concept of primary and secondary instabilities and put the degenerative disc disease, degenerative spondylolisthesis, and degenerative scoliotic deformities into the group of primary instability [6, 7]. Panjabi also well defined the term instability that leads to a pain, pathological movement, deformities, and neurological inability [8]. Afterwards, Benzel splitted the chronic instability to two groups which were glacial instability and dysfunctional segmental motion [9]. According to Benzel the commonest sample for glacial instability is spondylolisthesis which has been seen as degenerative, isthmic, and iatrogenic and for dysfunctional segmental motion is degenerative disc disease.

Within last century the surgical treatment of disc-related pain began with discectomies and decompressions. First lumbar discectomy surgery has been performed by Mixter and Barr in 1934 [10]. However, they could not obtain the relief of chronic low back pain after their disc excision operation. Afterwards, radical discectomies and subtotal discectomies have been performed commonly, but good clinical

results have not been obtained, and lower back pain and continuous sciatica as high as 40% insisted [11–14]. Insisting low back pain and sciatica after discectomy procedures have been engaged to segmental instability, and the concept of chronic and degenerative instability has been suggested and then developed within years [2, 5–9]. Some studies showed that decompression with fusion (posterolateral or interbody) meaningfully improved patient outcome compared to decompression alone [15–18]. Fusion was carried out to cease the motion for stopping the pain in degenerative disorders of the lumbar spine [19], but every time the achievement could not been arrived because to fuse the moving spine was hard [20, 21]. Later, internal fixation systems have been discovered by pioneers like Harrington, Dick, Magerl, and Roy Camille and commonly used with fusion [22–24]. Rigid pedicle screw fixation of spine improves the ratio of successful fusions according to some biomechanical studies [25].

Rigid internal fixation and fusion have been currently the mainstay for surgical treatment of degenerative diseases of the spine over the last 4 decades. In all over the world the common experience was formed about fusion surgery. Although successful radiological results up to 100% associated with fusion reported, this results were not compatible with successful clinical outcome regarding pain alleviation [15, 26, 27]. Satisfactory results of lumbar spinal fusion appear completely incompatible and ranged from 16% to 95% with an average of 70% according to a meta-analysis study evaluated systematically [28]. Rigid spinal implants along with fusion also cause increased stresses of the adjacent segments, and adjacent segment degeneration, which is well known, is formed [29–34]. In addition fusion surgery has some important disadvantages such as donor site morbidity including pain, wound problems, infections because of longer operating time, pseudarthrosis, and fatigue failure of implants [35–38].

The search for alternative spinal implants was supported with time on unsatisfactory outcomes of rigid internal fixation along with fusion. The main aim was to avoid the opposed effects of rigid implants on the stabilized and adjacent segments, to prevent the implant failure and to provide reduced-stress shielding, and finally to develop a system that permits increased load sharing and controlled motion without cutting off the stability [39]. İntervertebral disc actually has a isotropic architecture like a fluid-filled ball, but it changes as intervertebral disc is degenerated. Isotropic properties and load transmission of the intervertebral disc alter depending on disc degeneration [40, 41]. The "stone-in-the-shoe" phenomenon explains the postural pain pattern in patients suffering from lumbar disc degeneration because pattern of loading is related to pain generation in the degenerated spine which alters one patient to another [41, 42]. Dynamic stabilization intends to eliminate the pain by delivering the weight with more physiological load transmission between anterior and posterior components of the spine while attempting to maintain the motion and to control abnormal movement in the spinal segment [42, 43] (Figure 1). It is supposed that soft or semirigid stabilization systems restore normal functions of the spine unit and protect the adjacent segments [43, 44]. Dynamic stabilization of spine has been classified by several authors [4, 45, 46]. Today in market different both anterior and posterior dynamic stabilization devices of spine are found. Various biomechanical and clinical studies were done about dynamic stabilization systems of spine. Recently finite element studies have begun more and more on these systems. Some clinical studies concerning dynamic screws and dynamic rods have been revealed [37, 44, 47–49]. Recently it is thought how we can do the dynamic stabilization systems which is close to more physiological pattern.

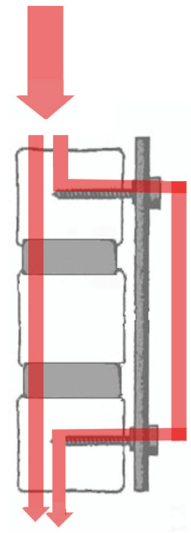


Figure 1: Posterior dynamic stabilization provides more physiological load transmission between anterior and posterior components of the spine.

Figure 2: Cosmic posterior dynamic system.

2. Indications of Dynamic Stabilization of Spine

Strempel et al. revealed the indications for dynamic stabilization with cosmic (semirigid posterior dynamic system including dynamic screw and rigid rod) [50] (Figure 2). These are symptomatic lumbar stenosis, chronically recurrent

lumbago in the case of discogenic pain and facet syndrome, recurrent disc herniation, in combination with a spondylodesis, and extention of an existing spondylodesis in the case of a painful adjacent level degeneration. Strempel suggested that cosmic posterior dynamic stabilization should only be used for a maximum of three segments.

Khoueir et al. revealed the indications for posterior dynamic stabilization in 2007 [45]. The indications included controlled motion in the iatrogenically destabilized spine, increased anterior load sharing to augment interbody fusion, protection and restoration of degenerated facet joints and intervertebral discs, in combination with anterior motion preservation for 360 circumferential motion segment reconstruction, adaptation of stabilization techniques to the aging spine, and the prevention of fusion-related sequelae.

Kaner et al. described a new classification system about dynamic stabilization of spine [4]. They reported the indications related to posterior dynamic stabilization systems. They included degenerative spinal instability (disc degeneration, facet degeneration, and degenerative spondylolisthesis), iatrogenic instability following discectomy/decompressive laminectomy, increased anterior load shared to augment interbody fusion, stabilization of a painful adjacent segment degeneration, adjacent to fusion, complement TDR to achieve anterior disc replacement, and second recurrent of a disc herniation. Lomber disc herniations which were graded III and IV are based on Carrage Classification system [51]. The reherniation rate is quite high in these groups (%27) and if surgery is supported with a dynamic system, reherniation rate significantly decreases [51, 52]. They also reported the indications related to interspinous distraction devices which are central spinal canal stenosis with neurogenic claudication, foraminal stenosis with radicular symptoms, and facet joint disease, in one- or two-level stenosis in patients over 50 years. As third the indications related to anterior disc prosthesis are patients between 18–60 ages (optimally below age 50 years), single level or two levels, pain due to symptomatic degenerative disc disease, absence of facet joint degeneration changes, existence of intervertebral disc height of at least 4 mm, nonradicular leg pain or back pain, postlaminectomy syndrome, and patient with positive discogram [4].

3. Anterior Dynamic Stabilization

3.1. Anterior Disc Prosthesis. Lumbar degenerative disc disease is the commonest indication of lumbar disc prosthesis. Patients selected for anterior disc prosthesis should be proven to have discogenic pain or segmental instability, or both, without advanced degenerative arthritis. However, spinal pathology should be demonstrated by routine radiological evaluations including upright X-rays, magnetic resonance imaging (MRI), and provocative discography. A lumbar disc prosthesis may be used to restore discogenic instability and improve the discogenic pain after discectomy procedure or at places of previous discectomy.

The history of arthroplasty of spine begins with Paul Harmon, from 1959 to 1961. He used vitallium balls through an anterior approach to stabilize vertebral segments to assist fusion and realized that some of them could be work well as stand-alone stabilizers (the first disc arthroplasty) [53]. Second specialist who is Ulf Fernstrom, from 1962 to 1972, used the steel ball arthroplasty of the spine via posterior lumbar approach [53]. The first published article about disc arthroplasty belongs to Fernström in 1966 [54]. Later Reitz and Joubert (1964) [55] and Mc Kenzie (1971) [56] used steel ball arthroplasties. These specialists imagined and tried earlier disc arthroplasty procedures and motion preservation surgery. In this surgeries ball has an extremely low surface contact area on initial implantation which may lead to subsidence. Pain, disc height loss, loss of motion, and many times fusion were seen in many cases depending on subsidence. The usage of Fernstrom has been left afterwards. The first modern prosthesis, CHARITE, was designed and first implanted by Büttner-Janz et al. in 1984 [57]. First Charite disc prosthesis had a polymer core which is either floating, unconstrained, and between two concave end plates. Within years Charite III (DePuy Spine) was accepted in its final form and certified by the FDA in October of 2004 [58] (Figure 3). Today it is widely used clinically. The semiconstrained disc prosthesis design, ProDisc (Synthes), was implanted first by Rousseau et al. in 1990 [59] (Figure 4). CHARITE and ProDisc artificial disc prostheses have the architecture of hard plates/hard core designs. There are several artificial disc prosthesis having different design. These are hard plates/soft core, screw-In dowel,

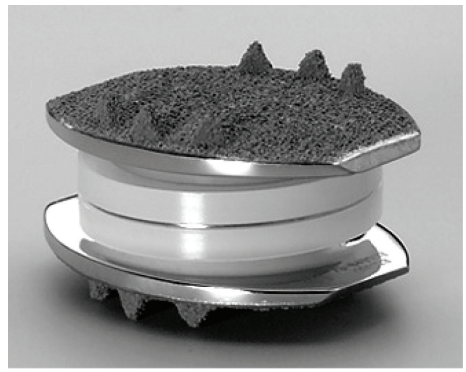


Figure 3: Charite III artificial lumbar disc prosthesis.

Figure 4: ProDisc artificial lumbar disc prosthesis.

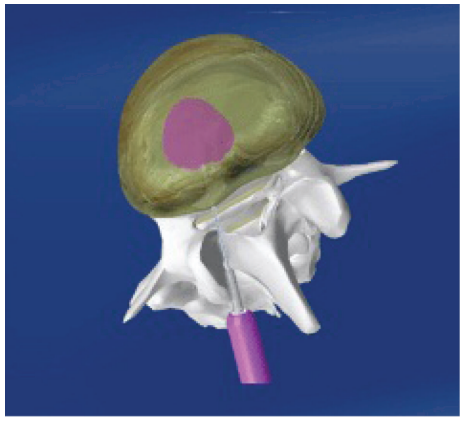


Figure 5: Nucleus replacement, NuCore and BioDisc.

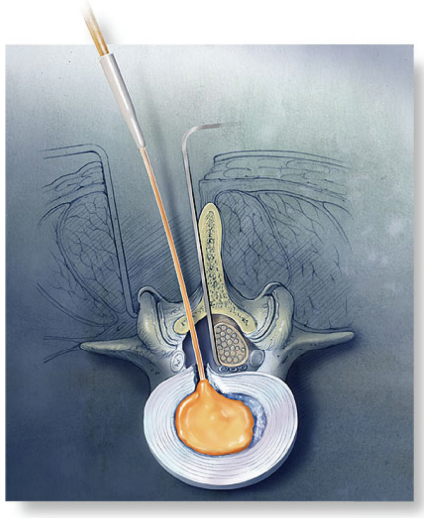


Figure 6: Nucleus replacement, NuCore and BioDisc.

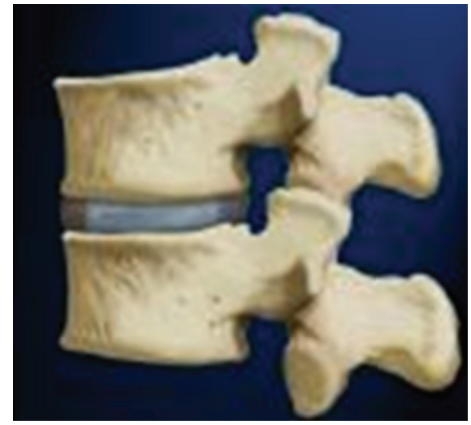


Figure 7: Nucleus replacement, DASCOR.

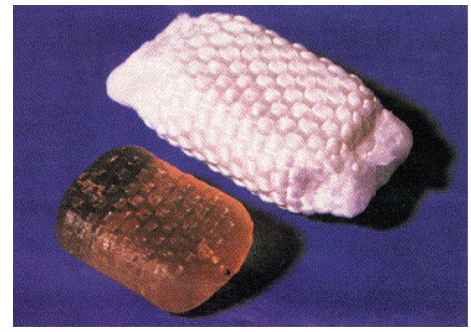


Figure 8: Nucleus replacement, PDN SOLO.

spring and piston, and complex mechanical/vertebral body replacement [60]. Lumbar disc prosthesis is recommended, L4-L5 and L5-S1 disc levels, but especially L4-L5 disc level is ideal for maintaining the motion. This approach is more logical with regard to the philosophy of motion preservation. Satisfactory outcomes are seen after anterior disc prosthesis if it covers surgical indications. Some studies also revealed good clinical results [61, 62].

3.2. Nucleus Replacement. Subcategories of nucleus replacement was classified by Büttner-Janz, and this classification has been made according to following different criteria [63]. Group A includes injectable, in situ materials, and divided 2 subgroup; (1) *Uncontained* (a) hydrogel adhesive: NuCore and BioDisc (Figures 5 and 6), (b) nonhydrogel nonadhesive: Sinux, (2) *Contained* (a) nonhydrogel: Dascor (Figure 7), PNR, and PDR. Group B includes the preformed implants and divided 2 subgroup; (1) *Nonarticulating* (a) hydrogel: PDN-SOLO (Figure 8), Hydraflex, Neudisc, and Aquarella, (b) nonhydrogel: Newcleus, Neodisc, and Regain, (2) *Articulating* (a) same material of components: NUBAC (Figure 9). Prosthetic disc nucleus (PDN-Raymedica, Inc., Minneapolis, MN) was first implanted in 1996 [64]. This device consists of a polymeric hydrogel pellet surrounded by a high-tenacity polyethylene jacket. The aim was cushioning the intervertebral space for maintaining the function, high and flexibility of the normal disc. It is transformed from the stiff PDN to PDN-SOLO. HydraFlex (Raymedica, Inc., Minneapolis, MN) is the last form of PDN [64]. There are some clinical studies regarding PDN, but the results of studies are not good [65, 66]. It is used limitedly today [4].

NuCore is an injectable nucleus which is adhesive and protein polymer. NuCore is injected percutaneously into the nucleus pulposus as computed tomography guided [63]. NuCore is one of the least stiff materials in this group.

Kaner et al. [4] classified the nucleus replacements in two fashions: (1) nucleus pulposus alternatives that contained the PDN (PDN-Solo, Raymedica, LLC), Nubac (Invibio, Greenville, NC, USA), Daskor (Disc dynamics, Inc., Eden Prairie, Minn), and Neudisc (Replication Medical Inc., New Brunswick, NJ) and (2) Nucleous Pulposus Supports Biodisc (Cryolife, Inc., Kennesaw, Ga), NuCore IDN (Spine Wave Inc., Shelton, Conn), and Gelifex (Gelifex, Inc., Philadelphia, Pa).

Figure 9: Nucleus replacement, NUBAC.

Figure 10: The picture of Henry Graf which used the Graf ligament system.

4. Posterior Dynamic Stabilization

Henry Graf used the Graf ligament system (Sem Co., Montrouce, France) which has been called and designed by him as first posterior dynamic stabilization device (Figures 10 and 11). Graf ligament was developed by Henry Graf opposite to fusion surgeries. This system uses braided polyester bands looped around the screws instead of rods for providing stability while allowing movement. Henry Graf believed that fusion surgeries had some disadvantages and complications when it was used in degenerative diseases of the spine and that Graf ligament would be enough for conditions of the degenerative or chronic instability not overt instability. He suggested that supporting posterior extension band was pretty good in the treatment of degenerative diseases of the lumbar spine. Graf arrived at the achievement with his posterior extention band named Graf ligament as a novel alternative treatment opposite to fusion surgery of the lumbar spine. The concept of Graf's ligament gained popularity primarily in Europe. Graf ligament as posterior extention band was used in condition of chronic instability resulted from degenerative diseases of the lumbar spine. This concept was supported and used [67–71] and found inconvenient [72, 73] by some surgeons in time. Criticism of Graf ligament focused especially on these concerns which are ligament loosening, foramen narrowing, and flat back.

Kanayama et al. reported 10 year follow-up results of posterior dynamic stabilization using Graf artificial ligament [71]. This report was a retrospective long-term study. In this study 56 consecutive patients had artificial Graf ligament, but 43 patients that suffered from degenerative spondylolisthesis (23 patients), disc herniation with flexion instability (13 patients), lumbar spinal stenosis with flexion instability (4 patients), and degenerative scoliosis (3 patients) had sufficient clinical and radiological followup. Patients suffering from degenerative spondylolisthesis and flexion instability improved significantly from symptoms due to low back pain and sciatica, but patients suffering from degenerative scoliosis and/or laterolisthesis had poor clinical improvement. Their long-term results showed that Graf ligamentoplasty was an effective treatment choice for low-grade spondylolisthesis, and flexion instability; however, it has some limitations to correct deformity and is not advocated for the treatment of degenerative scoliosis and/or laterolisthesis.

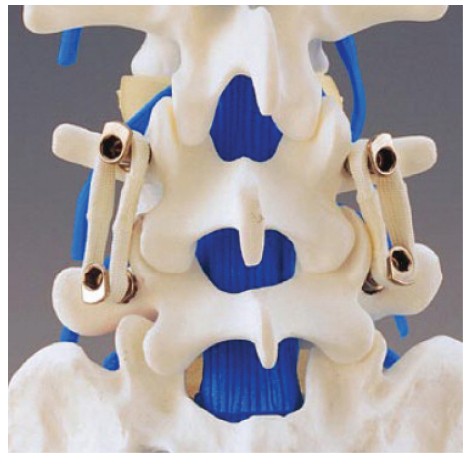


Figure 11: Graf ligament system.

Choi et al. [74] reviewed retrospectively 43 patients treated with Graf ligamentoplasty for degenerative lumbar stenosis. This study had 8 years follow-up time. They observed angular instability, translational instability, and adjacent segment instability in upper and lower segments, respectively, 28%, 7%, 42%, and 30%. This study shows that Graf ligament can be altered by degeneration of the disc and facet joints at instrumented segments. However, the adjacent segment can be affected because of abnormal load transmission in Graf ligamentoplasty.

Dynesys posterior dynamic stabilization system (Zimmer Spine, Inc., Warsaw, IN) is pedicle screw-based system for dynamic stabilization of lumbar spinal segments and was performed first 1994 [64, 75] (Figure 12). Dynesys has cords of polyethylene terephthalate with a tube made from polycarbonate urethane slid over them and fixed to two adjacent pedicle screws [4, 64]. In Dynesys appropriate length spacer is used to control the degree of distraction and compression on the related segment in contrast to Graft soft stabilization system. Therefore Foramen narrowing and flat back syndrome were avoided by using the spacers in Dynesys dynamic system. Dynesys approved by FDA in 2004 for posterior stabilization system as an adjunct to fusion of the lumbar spine [4, 46]. Dynesys was planned to neutralize abnormal forces and restored without pain function to the spinal segments while protecting adjacent segments [46, 76]. Plenty of studies were reported about Dynesys posterior dynamic stabilization system [18, 43, 76–84].

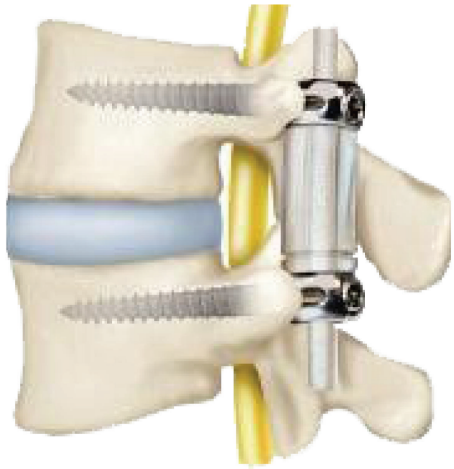


Figure 12: Dynesys posterior dynamic stabilization system.

Stoll et al. [78] reported 83 consecutive patients who operated because of lumbar spinal stenosis, degenerative disc disease, disc herniation, and revision surgery. The mean follow-up time was 38.1 months. Their implant-related complications were two screw displacement and screw loosening on radiograph. The one patient of screw displacement was reoperated because of root compression and improved. Just one patient was reoperated because of the loosening of two bilateral screws, and screws were removed and have not been put again. Besides there were 9 complications unrelated to the implant. Seven patients had adjacent segment degeneration and have been reoperated. Mean Oswestry score was 55.4% preoperatively and went down to 22.9% postoperatively. This improvement was found statistically meaningful ($P < 0.01$). Authors suggested in this study that Dynesys was less invasive and theoretically produced less degeneration of adjacent segments.

Putzier et al. [77] reported the compared nucleotomy procedure for the surgical treatment of the lumbar disc prolapse without or with posterior dynamic stabilization with Dynesys. 84 patients underwent nucleotomy procedure and Dynesys was carried out to 35 of them. There were MODIC 1 disc degeneration signs in all patients. The mean follow-up duration was 34 months. This study showed that the patients with additional stabilization with Dynesys revealed meaningful less signs of progressive degeneration.

Schaeren et al. reported 26 consecutive patients suffering from lumbar spinal stenosis and degenerative spondylolisthesis [85]. They performed decompression and posterior dynamic stabilization with Dynesys. Their mean follow-up duration was 52 months. Patients were evaluated clinically and radiographically during followup. Patients satisfaction was obtained high as 95%. Implant failure screw loosening was observed in 3 patients in 2 years after operation; however, nobody was reoperated related for that. 2 of these patients were asymptomatic and other had low back pain. They observed one instability related to a screw breakage in a patient and adjacent segment degeneration in 9 patients (47%) after four years.

Schnake et al. [18] reported in their prospective clinical study a total of 26 patients with lumbar spinal stenosis with degenerative spondylolisthesis who underwent interlaminar decompression and dynamic stabilization with the Dynesys posterior dynamic system. They concluded that Dynesys maintains enough stability to prevent further progression of instability. Otherwise they mentioned that Dynesys stabilization system does not need using bone Grafting.

Some studies were done regarding the effects of Dynesys on adjacent segments. Schmoelz et al. [86] reported in an in vitro study that Dynesys provided substantial stability while allowing more movement in the stabilized segment in degenerative spinal disorders, and therefore it is considered as an alternative method to fusion surgery. On the other hand, adjacent segments appear to be not influenced by the stiffness of the fixation procedure. Cakir et al. researched adjacent segment mobility after rigid and semirigid instrumentations of the lumbar spine [81]. They study included 26 patients with low back pain and neurogenic claudication due to L4-L5 degenerative instability and spinal stenosis. Patients operated either with decompression and Dynesys posterior stabilization ($n = 11$) or with decompression and fusion ($n = 15$). Range of motion was evaluated at L4-L5 which is index level and adjacent segments which are L3-L4 and L5-S1. They obtained that monosegmental dynamic stabilization along with Dynesys has no beneficial effect on adjacent segment mobility compared with monosegmental fusion and instrumentation. Kumar et al. [80] reported in their prospective case series including 32 patients who underwent just posterior dynamic stabilization with Dynesys ($n = 20$) and additional fusion at one or more levels that disc degeneration at the bridged and adjacent segment seems to continue despite Dynesys dynamic stabilization.

Grob et al. [79] revealed the clinical experience with Dynesys stabilization system. This study was composed of retrospective 50 consecutive case series. All of them instrumented with Dynesys. 31 patients were followed-up with questionnaire at least 2 years. Their result showed that quality of life and improvements in functional capacity were just moderate. Around 50% patients stated that the operation helped or helped a lot. There was no superiority of Dynesys system compared with fusion surgery.

Cosmic semirigid posterior dynamic system is composed of dynamic screw and rigid rod. Dynamic screw was first used and accepted as a new concept by Strempel in 1999 [47]. Strempel built a dynamic screw with a hinge placed between the head and body of the screw (Cosmic, Ulrich AG, Germany) [47, 50, 87]. Posterior dynamic transpedicular hinged-screw along with rigid rod system enables potential sagittal movement between the screw head and the screw body. This system allows limited motion, which occurs between hinged screw head and the longitudinally placed rod, during flexion-extention behavior of the spine. Cosmic transpedicular dynamic system provides the load sharing on bridged segment, and part of the load placed on the spine is transferred by the system, hereby the effect of the stress shielding on the bones reduced [50, 86, 87]. Bozkuş et al. showed that dynamic stabilization provides a stability that is similar to that provided by rigid systems and that

Figure 13: Saphinas dynamic screw.

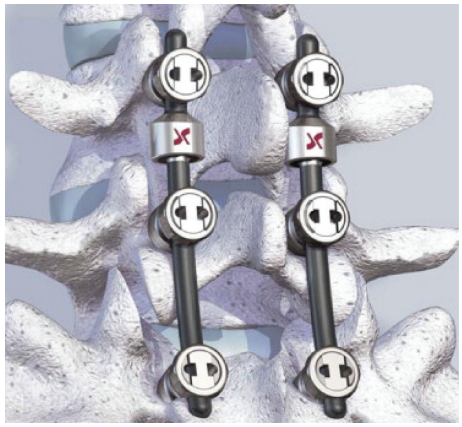


Figure 14: The Isobar TLL dynamic rod.

the hinged-dynamic screws allow less stress shielding than standard rigid screws in their in vitro biomechanical study which had used the dynamic/hinged pedicular screw-rod system [88]. Another hinged transpedicular screw-rigid rod system is from Turkey and its name is Safinas Dynamic Screw (Medikon, Turkey) (Figure 13). Safinas hinged screw works similarly to cosmic screw and allows the limited motion in flexion and extention behavior of the spine, but it controls displacement rotation and translation. There are some both clinical [37, 44, 47–50, 52, 66, 89] and biomechanical [25, 39, 86, 88] studies about dynamic screw-rod stabilization system.

Kaner et al. [37] reported the compared study of dynamic stabilization with cosmic dynamic screw-rod and posterior rigid transpedicular stabilization with fusion to treat degenerative spondylolisthesis. This clinical and radiological studies were conducted between 2004 and 2007 and contained totally 46 patients. Twenty-six patients operated via cosmic posterior dynamic stabilization were followed-up at average of 38 months, and fusion group with rigid stabilization that included twenty patients was followed-up at average of 44 months. There were similar results in both groups as a result of VAS, Oswestry, the measurements of lumbar lordosis and segmental lordosis angle after two years of followup. On the other hand, intervertebral space ratios in the cosmic

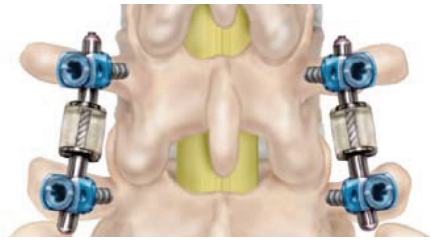


Figure 15: The rod of the CD Horizon Agile.

posterior dynamic stabilization group were obtained to be statistically meaningful higher than those in the fusion group. In conclusion of this study it was thought that the disc distance is maintained and disc degeneration is slowed down after using posterior dynamic transpedicular stabilization.

Another compared study of safinas lumbar pedicular dynamic screw-rod and fusion was done by Ozer et al. [48]. Equivalent relief of pain and maintenance of sagittal balance were seen compared with safinas lumbar pedicular dynamic screw-rod and standard rigid screw-rod fixation.

The Isobar TLL Dynamic Rod (Scient'x, Maitland, FL) is composed of TiAlV alloy and attached between rigid screws (monoaxial or polyaxial) [64] (Figure 14). The Isobar semi-rigid spinal system (Scient'X's Isobar) received FDA clearance for using as an adjunct to lumbar fusions in November 1999. Isobar TLL semirigid rod allows some limited movement in fusion place. It is aimed by manufacturer that it can promote fusion ratio on the instrumented segment and decrease adjacent segment degeneration via protecting the adjacent disc from excessive stress [90]. Zhang et al. studied the effectiveness of ISOBAR TTL semirigid dynamic stabilization system in treatment of lumbar degenerative disease [91]. This study was done between 2007 and 2011 on 38 patients which are treated because of lumbar degenerative disease. The mean follow-up duration in this study was 27.8 months. The results of this study showed that Isobar TLL had reliable fixation, and no loosening, breakage, and adjacent segment degeneration. Authors suggested that Isobar TLL had good short-term effectiveness in treatments of lumbar degenerative disease. Another biomechanical study using cadaveric human lumbar spine reported that Isobar TLL device may stabilize only the anterior colon [92].

The rod of the CD Horizon Agile (Medtronic Sofamor Danek, Memphis, TN) is dynamic stabilization device [4, 64] and was used as single level and adjacent to fusion (Hybrid) in two forms (Figure 15). It was developed for using along with rigid rods in 2007 [44]. Dynamic Agile rod was deformed due to overloading and stress in clinical usage in time. As a result it has been removed from the market and terminated of its production [44]. It is the first study that has been done utilizing dynamic rods with dynamic screws in treatment of chronic instability [44]. CD Horizon Agile used Safinas dynamic screws, and good clinical results were observed in this clinical study [44].

NFlex (N spine, Inc., San Diego, CA) is a dynamic stabilization system [64] (Figure 16). It is composed of two parts: polyaxial rigid screw and titanium and polycarbonate

Figure 16: NFlex dynamic stabilization system.

urethane rod. NFlex is first implanted in 2006. A multicenter study was performed related to NFlex dynamic stabilization system [93]. In this retrospective study 72 consecutive patients who have degenerative diseases of the spine underwent surgery with NFlex dynamic system. Mean followup was 25,6 months. VAS and Oswestry disability index of the patients were improved obviously after operations. Just three implant-related complications were observed. This study showed that NFlex dynamic system seems to improve pain and functional scores and may be considered a good alternative to rigid fusion [93].

AXIENT dynamic stabilization system (Innovative Spinal Technologies, Mansfield, MA) is composed of rigid pedicle screws and articulates CoCr sliding rods with a part for depressing during extention which is made of carbonate urethane [64]. This system permits segmental motion provided to avoid excessive motion in flexion, extention, and axial rotation.

Accuflex rod system (Globus Medical Inc.) is a semirigid rod which has been situated between rigid rods. Accuflex system obtained FDA clearance in 2005 as a single-level tool to stabilize lumbar interbody fusion [46]. A clinical study was done related to Accuflex rod system. This study reported that Accuflex semirigid system showed clinical benefits and ceased the degenerative process in 83% of the patients although high incidence of implant failure (22.22%) was observed [94].

CD Horizon legacy peek rod (Medtronic, Safamor Danek, Memphis, TN) has been introduced to the market as a semirigid alternative to titanium rods (Figure 17). FDA clearance has been got in June 2005. In a biomechanical study Gornet et al. reported that peek rod system provided intervertebral stability comparable to currently marketed titanium lumbar fusion constructs [95]. Ormond et al. studied retrospective 42 case series from 2007 to 2009 for degenerative lumbar disease and performed them posterior lumbar fusion using PEEK rods [96]. They observed that 8 of 42 patients with PEEK rods underwent reoperation. Reoperations included

Figure 17: CD horizon legacy peek rod.

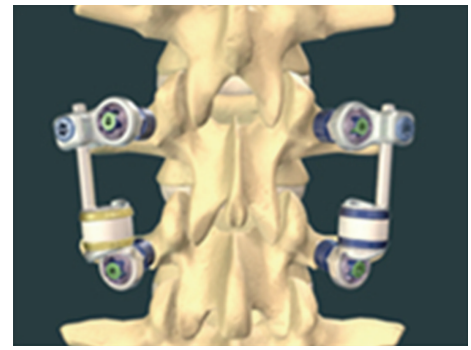


Figure 18: The Stabilimax NZ which is a pedicle-based posterior dynamic system.

adjacent segment degeneration (5/8) and nonunion with cage migration (3/5). In conclusion authors reported that PEEK rods demonstrated similar fusion and reoperation rate in comparison with other instrumentation modalities.

The Stabilimax NZ (Applied Spine Technologies, New Haven, CT) is a pedicle-based posterior dynamic system which was developed and designed to specifically address pathological alterations in the neutral zone by Panjabi [97, 98] (Figure 18). Its indications include moderate to severe degenerative lumbar spinal stenosis and discogenic low back pain. The Stabilimax NZ is composed of a system of ball and socket joints to decrease the load on the pedicle screw and double connecting springs [46, 97, 98].

5. Total Facet Replacement Systems

Total facet replacement systems are designed to totally restore facet joints functionally. The degeneration of facet joints generally results from intervertebral disc degeneration, because of this reason facetogenic pain can occur along with severe disc degeneration, and it may be used in significant facet and intervertebral disc degeneration either alone or with total disc arthroplasty [45]. Total facet replacement systems can be used at the situation of reconstruction of the spine due to iatrogenic facetectomy [45, 64]. There are

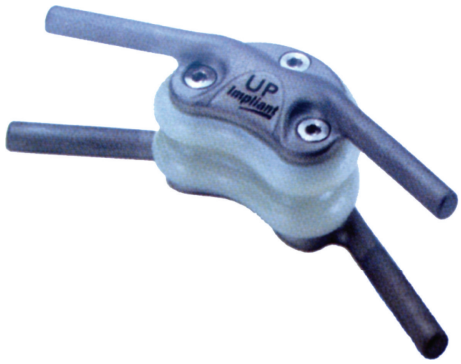


Figure 19: The total posterior arthroplasty system (TOPS).

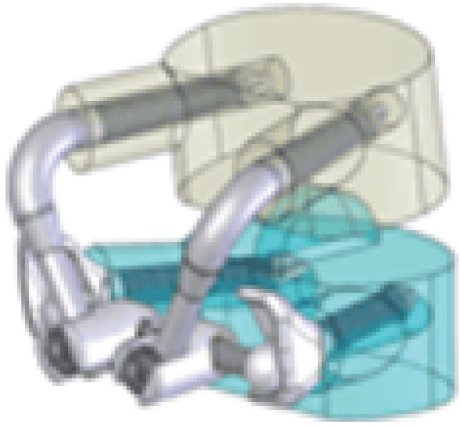


Figure 20: The total facet arthroplasty system (TFAS).

some total facet replacement systems such as the total facet arthroplasty system (TFAS), the total posterior arthroplasty system (TOPS) (Figure 19) and anatomic facet replacement system (AFRS) [4, 45, 46, 64]. TFAS (Archus Orthopedics, Inc., Redmond, WA) completely restores the total joints and is totally made of metal [64] (Figure 20). It is nonfusion spinal implant and is developed for severe facet degeneration with lumbar spinal stenosis. It needs total laminectomy and facet resection for the implantation of TFAS. TOPS (Impliant Spine, Princeton, NJ) is composed of metal and plastic material and a pedicle screw-based systems [45, 46, 64]. Posterior facets and lamina are resected totally, and nonfusion TOPS device, which enables physiologic range of motion, is implanted. It is thought that TOPS preserves motion, prevents abnormal load sharing at both adjacent and treated segments, and restores the neutral zone [99]. Nowadays there are several clinical and biomechanical studies on total facet replacement systems, and similar facet replacement systems having the same properties have been developed for clinical usage [45].

6. Posterior Interspinous Spacer Devices

Lumbar interspinous spacer devices have recently been popular for alternative treatment of lumbar degenerative diseases. Interspinous spacer devices are used in lumbar spine from L1 to L5 for treatment of central spinal canal stenosis with neurogenic claudication, foraminal stenosis, facet joint disease, and the dorsal disc anloading in extention [4, 64]. One of the first interspinous spacer devices has been developed for lumbar stabilization in 1986 and was called as wallis system [100]. Wallis system (Abbott Spine, Inc., Austin, TX) consists of two parts: these are PEEK and two woven polyester bands (Figure 21). The first implant was developed, and in 2002 a second generation of the wallis implant has been produced [64, 101]. Senegas et al. who developed the wallis device reported the clinical evaluation of the wallis interspinous spacer device with a 13-year mean followup. They reported 107 patients who filled out the health questionnaires. All patients had schedule for fusion surgery because of lumbar canal stenosis and lumbar disc herniation, or both. While 87 patients have still interspinous spacer today, other 20 patients experienced implant removing and had reoperation as fusion. They concluded that wallis provided good clinical results at last 13 years and 80% of patients were protected from fusion surgery and living now with posterior dynamic stabilization. Some similar systems have been produced and offered to the market. Some of them are Coflex (Paradigm Spine, LLC, New York, NY) (Figure 22), the device for intervertebral assisted motion (DIAM) (Medtronic Sofamor Danec, Memphis, TN) (Figure 23), the Fulcrum-assisted soft stabilization (FASS), The superion spacer (VertiFlex Inc., San Clemente, CA), and X-STOP (Kyphon, Inc., Sunnyvale, CA) (Figure 24) [4, 64, 101]. Kabir et al. [102] studied on a systematic review of clinical and biomechanical evidence about lumbar interspinous spacers. They reported that the biomechanical studies with all the devices showed that interspinous spacer devices have a beneficial effect on the kinematics of the degenerative spine. They also mentioned that Lumbar interspinous spacer devices may have a potential beneficial effect in selected group of patients with degenerative disease of the lumbar spine. A new biomechanical study about X-STOP showed that implantation of the X-Stop devices can effectively distract the interspinous process space at the diseased level without causing apparent kinematic changes at the adjacent segments during the studied postures [103]. In other study being randomized, controlled, prospective multicenter trial Zucherman et al. suggested that the X-STOP provides a conservative yet effective treatment for patients suffering from lumbar spinal stenosis and the X-STOP may

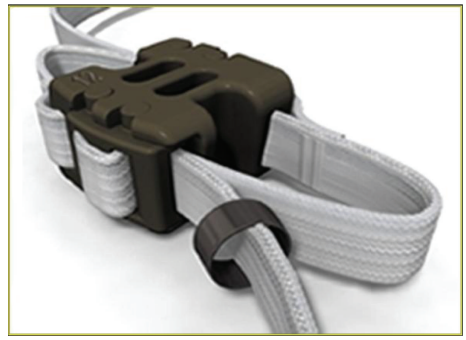


Figure 21: Wallis posterior interspinous spacer device.

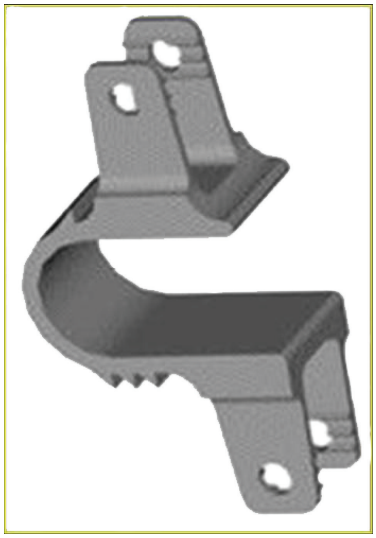


Figure 22: Coflex posterior interspinous spacer device.

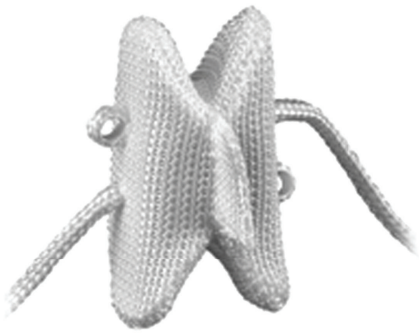


Figure 23: The device for intervertebral assisted motion (DIAM).

be alternative treatment to both decompressive spine surgery and conservative treatment [104].

7. Conclusion

Nowadays in market different both anterior and posterior dynamic stabilization devices of the lumbar spine are found. Various both biomechanical and clinical studies have been made about dynamic stabilization systems of the lumbar spine. Recently finite element studies also have been begun more and more on these systems. Dynamic stabilization systems of lumbar spine on rigid stabilization have some advantages such as increased load sharing and controlled motion without cutting off the stability which could be an important factor in decreasing adjacent segment degeneration, but this matter has not been yet proved clearly. In the future it needs prospective compared clinical studies for providing the benefit of dynamic stabilization systems.

Figure 24: X-STOP posterior interspinous spacer device.

Conflict of Interests

None of the authors has a secondary interest such as financial gain and a conflict of interest with the mentioned commercial identities in this manuscript.

References

[1] A. C. Schwarzer, C. N. Aprill, R. Derby, J. Fortin, G. Kine, and N. Bogduk, "The relative contributions of the disc and zygapophyseal joint in chronic low back pain," *Spine*, vol. 19, no. 7, pp. 801–806, 1994.

[2] W. H. Kirkaldy-Willis and H. F. Farfan, "Instability of the lumbar spine," *Clinical Orthopaedics and Related Research*, vol. 165, pp. 110–123, 1982.

[3] S. D. Kuslich, C. L. Ulstrom, and C. J. Michael, "The tissue origin of low back pain and sciatica: a report of pain response to tissue stimulation during operations on the lumbar spine using local anesthesia," *Orthopedic Clinics of North America*, vol. 22, no. 2, pp. 181–187, 1991.

[4] T. Kaner, M. Sasani, T. Oktenoglu, and A. F. Ozer, "Dynamic stabilization of the spine: a new classification system," *Turkish Neurosurgery*, vol. 20, no. 2, pp. 205–215, 2010.

[5] F. Knutsson, "The instability associated with disc degeneration in the lumbar spine," *Acta Radiologica*, vol. 25, pp. 593–609, 1944.

[6] J. W. Frymoyer, "Segmental instability," in *The Adult Spine*, J. W. Frymoyer, Ed., pp. 1873–1891, Raven Press, New York, NY, USA, 1991.

[7] J. W. Frymoyer and D. K. Selby, "Segmental instability: rationale for treatment," *Spine*, vol. 10, no. 3, pp. 280–286, 1985.

[8] M. M. Panjabi, "Clinical spinal instability and low back pain," *Journal of Electromyography and Kinesiology*, vol. 13, no. 4, pp. 371–379, 2003.

[9] E. C. Benzel, "Stability and instability of the spine," in *Biomechanics of Spine Stabilization*, pp. 29–43, AANS, New York, NY, USA, 2001.

[10] W. J. Mixter and J. S. Barr, "Rupture of the intervertebral disc with involvement of the spinal canal," *The New England Journal of Medicine*, vol. 211, pp. 210–215, 1934.

[11] H. Striffeler, U. Groger, and H. J. Reulen, "''Standard'' microsurgical lumbar discectomy vs. ''Conservative'' microsurgical

discectomy; a preliminary study," *Acta Neurochirurgica*, vol. 112, no. 1-2, pp. 62–64, 1991.

[12] W. Caspar, B. Campbell, D. D. Barbier, R. Kretschmmer, and Y. Gotfried, "The Caspar microsurgical discectomy and comparison with a conventional standard lumbar disc procedure," *Neurosurgery*, vol. 28, no. 1, pp. 78–87, 1991.

[13] P. A. Vaughan, B. W. Malcolm, and G. L. Maistrelli, "Results of L4-L5 disc excision alone versus disc excision and fusion," *Spine*, vol. 13, no. 6, pp. 690–695, 1988.

[14] R. W. Hu, S. Jaglal, T. Axcell, and G. Anderson, "A population-based study of reoperations after back surgery," *Spine*, vol. 22, no. 19, pp. 2265–2271, 1997.

[15] K. H. Bridwell, T. A. Sedgewick, M. F. O'Brien, L. G. Lenke, and C. Baldus, "The role of fusion and instrumentation in the treatment of degenerative spondylolisthesis with spinal stenosis," *Journal of Spinal Disorders*, vol. 6, no. 6, pp. 461–472, 1993.

[16] R. J. Nasca, "Rationale for spinal fusion in lumbar spinal stenosis," *Spine*, vol. 14, no. 4, pp. 451–454, 1989.

[17] H. L. Feffer, S. W. Wiesel, J. M. Cuckler, and R. H. Rothman, "Degenerative spondylolisthesis: to fuse or not to fuse," *Spine*, vol. 10, no. 3, pp. 287–289, 1985.

[18] K. J. Schnake, S. Schaeren, and B. Jeanneret, "Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis," *Spine*, vol. 31, no. 4, pp. 442–449, 2006.

[19] R. B. Cloward, "The treatment of ruptured lumbar intervertebral discs by vertebral body fusion. I. Indications, operative technique, after care," *Journal of Neurosurgery*, vol. 10, no. 2, pp. 154–168, 1953.

[20] T. Andersen, F. B. Christensen, E. S. Hansen, and C. Bünger, "Pain 5 years after instrumented and non-instrumented posterolateral lumbar spinal fusion," *European Spine Journal*, vol. 12, no. 4, pp. 393–399, 2003.

[21] A. F. DePalma and R. H. Rothman, "The nature of pseudarthrosis," *Clinical Orthopaedics and Related Research*, vol. 59, pp. 113–118, 1968.

[22] P. R. Harrington, "The history and development of Harrington instrumentation," *Clinical Orthopaedics*, vol. 93, pp. 110–112, 1973.

[23] R. Roy-Camille, M. Roy-Camille, and C. Demeulenaere, "Osteosynthesis of dorsal, lumbar, and lumbosacral spine with metallic plates screwed into vertebral pedicles and articular apophyses," *La Presse Medicale*, vol. 78, no. 32, pp. 1447–1448, 1970.

[24] W. Dick, P. Kluger, F. Magerl, O. Woersdörfer, and G. Zäch, "A new device for internal fixation of thoracolumbar and lumbar spine fractures: the 'fixateur interne'," *Paraplegia*, vol. 23, no. 4, pp. 225–232, 1985.

[25] J. L. Scifert, K. Sairyo, V. K. Goel et al., "Stability analysis of an enhanced load sharing posterior fixation device and its equivalent conventional device in a calf spine model," *Spine*, vol. 24, no. 21, pp. 2206–2213, 1999.

[26] N. Boos and J. K. Webb, "Pedicle screw fixation in spinal disorders: a European view," *European Spine Journal*, vol. 6, no. 1, pp. 2–18, 1997.

[27] K. C. Booth, K. H. Bridwell, B. A. Eisenberg, C. R. Baldus, and L. G. Lenke, "Minimum 5-year results of degenerative spondylolisthesis treated with decompression and instrumented posterior fusion," *Spine*, vol. 24, no. 16, pp. 1721–1727, 1999.

[28] J. A. Turner, M. Ersek, L. Herron, and R. Deyo, "Surgery for lumbar spinal stenosis: attempted meta-analysis of the literature," *Spine*, vol. 17, no. 1, pp. 1–8, 1992.

[29] P. V. Mummaneni, R. W. Haid, and G. E. Rodts, "Lumbar interbody fusion: state-of-the-art technical advances," *Journal of Neurosurgery*, vol. 101, no. 1, pp. 24–30, 2004.

[30] J. Glaser, M. Stanley, H. Sayre, J. Woody, E. Found, and K. Spratt, "A 10-year follow-up evaluation of lumbar spine fusion with pedicle screw fixation," *Spine*, vol. 28, no. 13, pp. 1390–1395, 2003.

[31] P. Fritzell, O. Hagg, D. Jonsson, and A. Nordwall, "Swedish Lumbar Spine Study Group. Cost effectiveness of lumbar fusion and nonsurgical treatment for chronic low back pain in the Swedish lumbar spine study: a multicenter, randomized, controlled trial from the Swedish lumbar spine study group," *Spine*, vol. 29, no. 4, pp. 421–434, 2004.

[32] P. C. McAfee, I. D. Farey, C. E. Sutterlin, K. R. Gurr, K. E. Warden, and B. W. Cunningham, "The effect of spinal implant rigidity on vertebral bone density: a canine model," *Spine*, vol. 16, no. 6, pp. S190–S197, 1991.

[33] T. R. Lehmann, K. F. Spratt, J. E. Tozzi et al., "Long-term follow-up of lower lumbar fusion patients," *Spine*, vol. 12, no. 2, pp. 97–104, 1987.

[34] M. D. Rahm and B. B. Hall, "Adjacent-segment degeneration after lumbar fusion with instrumentation: a retrospective study," *Journal of Spinal Disorders*, vol. 9, no. 5, pp. 392–400, 1996.

[35] E. M. Younger and M. W. Chapman, "Morbidity at bone graft donor sites," *Journal of Orthopaedic Trauma*, vol. 3, no. 3, pp. 192–195, 1989.

[36] J. C. Banwart, M. A. Asher, and R. S. Hassanein, "Iliac crest bone graft harvest donor site morbidity: a statistical evaluation," *Spine*, vol. 20, no. 9, pp. 1055–1060, 1995.

[37] T. Kaner, S. Dalbayrak, T. Oktenoglu, M. Sasani, A. L. Aydin, and F. O. Ozer, "Comparison of posterior dynamic and posterior rigid transpedicular stabilization with fusion to treat degenerative spondylolisthesis," *Orthopedics*, vol. 33, no. 5, 2010.

[38] J. L. West, J. W. Ogilvie, and D. S. Bradford, "Complications of the variable screw plate pedicle screw fixation," *Spine*, vol. 16, no. 5, pp. 576–579, 1991.

[39] H. Z. Xu, X. Y. Wang, Y. L. Chi et al., "Biomechanical evaluation of a dynamic pedicle screw fixation device," *Clinical Biomechanics*, vol. 21, no. 4, pp. 330–336, 2006.

[40] D. S. McNally and M. A. Adams, "Internal intervertebral disc mechanics as revealed by stress profilometry," *Spine*, vol. 17, no. 1, pp. 66–73, 1992.

[41] R. P. Nockels, "Dynamic stabilization in the surgical management of painful lumbar spinal disorders," *Spine*, vol. 30, no. 16, pp. S68–S72, 2005.

[42] D. K. Sengupta, "Dynamic stabilization devices in the treatment of low back pain," *Neurology India*, vol. 53, no. 4, pp. 466–474, 2005.

[43] M. Bothmann, E. Kast, G. J. Boldt, and J. Oberle, "Dynesys fixation for lumbar spine degeneration," *Neurosurgical Review*, vol. 31, no. 2, pp. 189–196, 2008.

[44] T. Kaner, M. Sasani, T. Oktenoglu, M. Cosar, and A. F. Ozer, "Utilizing dynamic rods with dynamic screws in the surgical treatment of chronic instability: a prospective clinical study," *Turkish Neurosurgery*, vol. 19, no. 4, pp. 319–326, 2009.

[45] P. Khoueir, K. A. Kim, and M. Y. Wang, "Classification of posterior dynamic stabilization devices," *Neurosurgical Focus*, vol. 22, no. 1, article E3, 2007.

[46] C. M. Bono, M. Kadaba, and A. R. Vaccaro, "Posterior pedicle fixation-based dynamic stabilization devices for the treatment of degenerative diseases of the lumbar spine," *Journal of Spinal Disorders and Techniques*, vol. 22, no. 5, pp. 376–383, 2009.

[47] T. Oktenoglu, A. F. Ozer, M. Sasani et al., "Posterior dynamic stabilization in the treatment of lumbar degenerative disc disease: 2-year follow-up," *Minimally Invasive Neurosurgery*, vol. 53, no. 3, pp. 112–116, 2010.

[48] A. F. Ozer, N. R. Crawford, M. Sasani et al., "Dynamic lumbar pedicle screw-rod stabilization: two-year follow-up and comparison with fusion," *The Open Orthopaedics Journal*, vol. 4, pp. 137–141, 2010.

[49] T. Kaner, M. Sasani, T. Oktenoglu et al., "Minimum two-year follow-up of cases with recurrent disc herniation treated with microdiscectomy and posterior dynamic transpedicular stabilisation," *The Open Orthopaedics Journal*, vol. 4, pp. 120–125, 2010.

[50] A. V. Strempel, D. Moosmann, C. Stoss, and A. Martin, "Stabilisation of the degenerated lumbar spine in the nonfusion technique with cosmic posterior synamic system," *The Wall Street Journal*, vol. 1, no. 1, pp. 40–47, 2006.

[51] E. J. Carragee, M. Y. Han, P. W. Suen, and D. Kim, "Clinical outcomes after lumbar discectomy for sciatica: the effects of fragment type and anular competence," *Journal of Bone and Joint Surgery A*, vol. 85, no. 1, pp. 102–108, 2003.

[52] T. Kaner, M. Sasani, T. Oktenoglu, M. Cosar, and A. F. Ozer, "Clinical outcomes after posterior dynamic transpedicular stabilization with limited lumbar discectomy: carragee classification system for lumbar disc herniations," *SAS Journal*, vol. 4, no. 3, pp. 92–97, 2010.

[53] A. H. McKenzie, "The basis for motion preservation surgery: lessons learned from the past," in *Motion Preservation Surgery of the Spine*, J. J. Yu, R. Bertagnoli, P. C. McAfee, and H. S. An, Eds., pp. 3–10, Saunders Elsevier Press, Philadelphia, Pa, USA, 2008.

[54] U. Fernström, "Arthroplasty with intercorporal endoprothesis in herniated disc and in painful disc," *Acta Chirurgica Scandinavica, Supplement*, vol. 357, pp. 154–159, 1966.

[55] H. Reitz and M. J. Joubert, "Replacement of cervical intervertebral disc with a metal prosthesis," *South African Medical Journal*, vol. 38, pp. 881–884, 1964.

[56] A. H. Mc Kenzie, "Steel ball arthroplasty of lumbar discs," *Journal of Bone and Joint Surgery*, vol. 54, article 266, 1972.

[57] K. Büttner-Janz, K. Schellnack, and H. Zippel, "Biomechanics of the SB Charite lumbar intervertebral disc endoprosthesis," *International Orthopaedics*, vol. 13, no. 3, pp. 173–176, 1989.

[58] R. D. Guyer, P. C. McAfee, S. H. Hochschuler et al., "Prospective randomized study of the Charité artificial disc: data from two investigational centers," *Spine Journal*, vol. 4, no. 6, pp. 252–259, 2004.

[59] M. A. Rousseau, D. S. Bradford, R. Bertagnoli, S. S. Hu, and J. C. Lotz, "Disc arthroplasty design influences intervertebral kinematics and facet forces," *Spine Journal*, vol. 6, no. 3, pp. 258–266, 2006.

[60] R. K. Sethi, L. N. Metz, and D. S. Bradford, "History and evolution of motion preservation," in *Motion Preservation Surgery of the Spine*, J. J. Yu, R. Bertagnoli, P. C. McAfee, and H. S. An, Eds., pp. 11–20, Saunders Elsevier Press, Philadelphia, Pa, USA, 2008.

[61] M. Sasani, T. Öktenoğlu, K. Tuncay, N. Canbulat, S. Carilli, and F. A. Özer, "Total disc replacement in the treatment of lumbar discogenic pain with disc herniation: a prospective clinical study," *Turkish Neurosurgery*, vol. 19, no. 2, pp. 127–134, 2009.

[62] J. C. Le Huec, H. Mathews, Y. Basso et al., "Clinical results of Maverick lumbar total disc replacement: two-year prospective follow-up," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 315–322, 2005.

[63] K. Büttner-Janz, "Percutaneous application of nucleus replacements," in *Proceedings of the 2nd International Congress, Biotechnologies for Spinal Surgery (BIOSPINE '07)*, Leipzig, Germany, September 2007.

[64] K. Büttner-Janz, "Classification of spine arthroplasty devices," in *Motion Preservation Surgery of the Spine*, J. J. Yu, R. Bertagnoli, P. C. McAfee, and H. S. An, Eds., pp. 21–35, Saunders Elsevier Press, Philadelphia, Pa, USA, 2008.

[65] L. Pimenta, *PDN at 5 Years Follow-Up*, Spine Arthroplasty Society, Montreal, Canada, 2006.

[66] M. Sasani, A. L. Aydin, T. Oktenoglu et al., "The combined use of a posterior dynamic transpedicular stabilization system and a prosthetic disc nucleus device in treating lumbar degenerative disc disease with disc herniations," *SAS Journal*, vol. 2, no. 3, pp. 130–136, 2008.

[67] A. Gardner and K. C. Pande, "Graf ligamentoplasty: a 7-year follow-up," *European Spine Journal*, vol. 11, no. 2, pp. S157–S163, 2002.

[68] M. Kanayama, T. Hashimoto, and K. Shigenobu, "Rationale, biomechanics, and surgical indications for graf ligamentoplasty," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 373–377, 2005.

[69] M. Kanayama, T. Hashimoto, K. Shigenobu et al., "Adjacent-segment morbidity after Graf ligamentoplasty compared with posterolateral lumbar fusion," *Journal of Neurosurgery*, vol. 95, no. 1, pp. 5–10, 2001.

[70] A. Onda, K. Otani, S. Konno, and S. Kikuchi, "Mid-term and long-term follow-up data after placement of the Graf stabilization system for lumbar degenerative disorders," *Journal of Neurosurgery: Spine*, vol. 5, no. 1, pp. 26–32, 2006.

[71] M. Kanayama, T. Hashimoto, K. Shigenobu, D. Togawa, and F. Oha, "A minimum 10-year follow-up of posterior dynamic stabilization using graf artificial ligament," *Spine*, vol. 32, no. 18, pp. 1992–1996, 2007.

[72] M. Rigby, G. Selmon, M. Foy, and A. Fogg, "Graf ligament stabilisation: mid- to long-term follow-up," *European Spine Journal*, vol. 10, no. 3, pp. 234–236, 2001.

[73] Z. Askar, D. Wardlaw, T. Muthukumar, F. Smith, D. Kader, and S. Gibson, "Correlation between inter-vertebral disc morphology and the results in patients undergoing Graf ligament stabilisation," *European Spine Journal*, vol. 13, no. 8, pp. 714–718, 2004.

[74] Y. Choi, K. Kim, and K. So, "Adjacent segment instability after treatment with a graf ligament at minimum 8 years' followup," *Clinical Orthopaedics and Related Research*, vol. 467, no. 7, pp. 1740–1746, 2009.

[75] G. Dubois, B. de Germay, N. S. Schaerer, and P. Fennema, "Dynamic neutralization: a new concept for restabilization of the spine," in *Lumbal Segmental Instability*, M. Szpalski, R. Gunzburg, and M. H. Pope, Eds., pp. 233–240, Lippincott Williams and Wilkins, Philadelphia, Pa, USA, 1999.

[76] O. Schwarzenbach, U. Berlemann, T. M. Stoll, and G. Dubois, "Posterior dynamic stabilization systems: DYNESYS," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 363–372, 2005.

[77] M. Putzier, S. V. Schneider, J. F. Funk, S. W. Tohtz, and C. Perka, "The surgical treatment of the lumbar disc prolapse:

nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone," *Spine*, vol. 30, no. 5, pp. E109–E114, 2005.

[78] T. M. Stoll, G. Dubois, and O. Schwarzenbach, "The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system," *European Spine Journal*, vol. 11, no. 2, pp. S170–S178, 2002.

[79] D. Grob, A. Benini, A. Junge, and A. F. Mannion, "Clinical experience with the dynesys semirigid fixation system for the lumbar spine: surgical and patient-oriented outcome in 50 cases after an average of 2 years," *Spine*, vol. 30, no. 3, pp. 324–331, 2005.

[80] A. Kumar, J. Beastall, J. Hughes et al., "Disc changes in the bridged and adjacent segments after Dynesys dynamic stabilization system after two years," *Spine*, vol. 33, no. 26, pp. 2909–2914, 2008.

[81] B. Cakir, C. Carazzo, R. Schmidt, T. Mattes, H. Reichel, and W. Käfer, "Adjacent segment mobility after rigid and semirigid instrumentation of the lumbar spine," *Spine*, vol. 34, no. 12, pp. 1287–1291, 2009.

[82] S. Vaga, M. Brayda-Bruno, F. Perona et al., "Molecular MR imaging for the evaluation of the effect of dynamic stabilization on lumbar intervertebral discs," *European Spine Journal*, vol. 18, no. 1, pp. S40–S48, 2009.

[83] B. Cakir, M. Richter, K. Huch, W. Puhl, and R. Schmidt, "Dynamic stabilization of the lumbar spine," *Orthopedics*, vol. 29, no. 8, pp. 716–722, 2006.

[84] O. Ricart and J. M. Serwier, "Dynamic stabilisation and compression without fusion using Dynesys for the treatment of degenerative lumbar spondylolisthesis: a prospective series of 25 cases," *Revue de Chirurgie Orthopedique et Reparatrice de l'Appareil Moteur*, vol. 94, no. 7, pp. 619–627, 2008.

[85] S. Schaeren, I. Broger, and B. Jeanneret, "Minimum four-year follow-up of spinal stenosis with degenerative spondylolisthesis treated with decompression and dynamic stabilization," *Spine*, vol. 33, no. 18, pp. E636–E642, 2008.

[86] W. Schmoelz, U. Onder, A. Martin, and A. von Strempel, "Non-fusion instrumentation of the lumbar spine with a hinged pedicle screw rod system: an in vitro experiment," *European Spine Journal*, vol. 18, no. 10, pp. 1478–1485, 2009.

[87] A. Strempel, A. Neekritz, P. Muelenaere et al., "Dynamic versus rigid spinal implants," in *Lumbar Spinal Stenosis*, R. Gunzburg and M. Szpalski, Eds., pp. 275–285, Lippincott-Williams and Wilkins, Philadelphia, Pa, USA, 2000.

[88] H. Bozkuş, M. Senoğlu, S. Baek et al., "Dynamic lumbar pedicle screw-rod stabilization: in vitro biomechanical comparison with standard rigid pedicle screw-rod stabilization—laboratory investigation," *Journal of Neurosurgery: Spine*, vol. 12, no. 2, pp. 183–189, 2010.

[89] T. Kaner, M. Sasani, T. Oktenoglu, A. L. Aydin, and A. F. Ozer, "Clinical outcomes of degenerative lumbar spinal stenosis treated with lumbar decompression and the Cosmic "semi-rigid" posterior system," *SAS Journal*, vol. 4, no. 4, pp. 99–106, 2010.

[90] D. Avasthi, *Juxtafusional Outcomes with the Dynamic Posterior Lumbar Instrumentation*, World Spine III, Rio de Jeneiro, Brasil, 2005.

[91] L. Zhang, X. Shu, Y. Duan, G. Ye, and A. Jin, "Effectiveness of ISOBAR TTL semi-rigid dynamic stabilization system in treatment of lumbar degenerative disease," *Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi*, vol. 26, no. 9, pp. 1066–1070, 2012.

[92] S. N. Sangiorgio, H. Sheikh, S. L. Borkowski, L. Khoo, C. R. Warren, and E. Ebramzadeh, "Comparison of three posterior dynamic stabilization devices," *Spine*, vol. 36, no. 19, pp. E1251–E1258, 2011.

[93] J. D. Coe, S. H. Kitchel, H. J. Meisel, C. H. Wingo, S. E. Lee, and T.-A. Jahng, "NFlex dynamic stabilization system: two-year clinical outcomes of multi-center study," *Journal of Korean Neurosurgical Society*, vol. 51, no. 6, pp. 343–349, 2012.

[94] A. Reyes-Sánchez, B. Zárate-Kalfópulos, I. Ramírez-Mora, L. M. Rosales-Olivarez, A. Alpizar-Aguirre, and G. Sánchez-Bringas, "Posterior dynamic stabilization of the lumbar spine with the Accuflex rod system as a stand-alone device: experience in 20 patients with 2-year follow-up," *European Spine Journal*, vol. 19, no. 12, pp. 2164–2170, 2010.

[95] M. F. Gornet, F. W. Chan, J. C. Coleman et al., "Biomechanical assessment of a PEEK rod system for semi-rigid fixation of lumbar fusion constructs," *Journal of Biomechanical Engineering*, vol. 133, no. 8, Article ID 081009, 2011.

[96] D. R. Ormond, L. Albert Jr., and K. Das, "Polyetheretherketone (PEEK) rods in lumbar spine degenerative disease: a case series," *Journal of Spinal Disorders & Techniques*, 2012.

[97] J. J. Yue, G. Malcolmon, and J. P. Timm, "The stabilimax NZ posterior lumbar dynamic stabilization system," in *Motion Preservation Surgery of the Spine*, J. J. Yu, R. Bertagnoli, P. C. McAfee, and H. S. An, Eds., pp. 476–482, Saunders Elsevier Press, Philadelphia, Pa, USA, 2008.

[98] J. J. Yue, J. P. Timm, M. M. Panjabi, and J. Jaramillo-de la Torre, "Clinical application of the Panjabi neutral zone hypothesis: the Stabilimax NZ posterior lumbar dynamic stabilization system," *Neurosurgical focus*, vol. 22, no. 1, p. E12, 2007.

[99] L. T. Khoo, L. Pimenta, and R. Diaz, "TOPS: total posterior facet replacement and dynamic motion segment stabilization system," in *Motion Preservation Surgery of the Spine*, J. J. Yu, R. Bertagnoli, P. C. McAfee, and H. S. An, Eds., pp. 551–564, Saunders Elsevier Press, Philadelphia, Pa, USA, 2008.

[100] J. Sénégas, "Mechanical supplementation by non-rigid fixation in degenerative intervertebral lumbar segments: the wallis system," *European Spine Journal*, vol. 11, no. 2, pp. S164–S169, 2002.

[101] K. M. Shibata and D. H. Kim, "Historical review of Spinal artroplasty and dynamic stabilization," in *Dynamic Reconstruction of the Spine*, D. H. Kim, F. P. Cammisa Jr., and R. G. Fessler, Eds., pp. 3–15, Thieme Medical Publishers, New York, NY, USA, 2006.

[102] S. M. R. Kabir, S. R. Gupta, and A. T. H. Casey, "Lumbar interspinous spacers: a systematic review of clinical and biomechanical evidence," *Spine*, vol. 35, no. 25, pp. E1499–E1506, 2010.

[103] Z. Wan, S. Wang, M. Kozánek et al., "Biomechanical evaluation of the x-stop device for surgical treatment of lumbar spinal stenosis," *Journal of Spinal Disorders & Techniques*, vol. 25, no. 7, pp. 374–378, 2012.

[104] J. F. Zucherman, K. Y. Hsu, C. A. Hartjen et al., "A multi-center, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results," *Spine*, vol. 30, no. 12, pp. 1351–1358, 2005.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 738252, 9 pages
http://dx.doi.org/10.1155/2013/738252

Research Article

Does Semi-Rigid Instrumentation Using Both Flexion and Extension Dampening Spacers Truly Provide an Intermediate Level of Stabilization?

Dilip Sengupta,[1] Brandon Bucklen,[2] Aditya Ingalhalikar,[2] Aditya Muzumdar,[2] and Saif Khalil[2]

[1] *Dartmouth-Hitchcock Medical Center, Orthopedics, One Medical Center Drive, Lebanon, NH 03756-0001, USA*
[2] *Globus Medical Inc., Valley Forge Business Center, 2560 General Armistead Avenue, Audubon, PA 19403, USA*

Correspondence should be addressed to Brandon Bucklen; bbucklen@globusmedical.com

Received 17 May 2012; Accepted 4 February 2013

Academic Editor: Vijay K. Goel

Conventional posterior dynamic stabilization devices demonstrated a tendency towards highly rigid stabilization approximating that of titanium rods in flexion. In extension, they excessively offload the index segment, making the device as the sole load-bearing structure, with concerns of device failure. The goal of this study was to compare the kinematics and intradiscal pressure of monosegmental stabilization utilizing a new device that incorporates both a flexion and extension dampening spacer to that of rigid internal fixation and a conventional posterior dynamic stabilization device. The hypothesis was the new device would minimize the overloading of adjacent levels compared to rigid and conventional devices which can only bend but not stretch. The biomechanics were compared following injury in a human cadaveric lumbosacral spine under simulated physiological loading conditions. The stabilization with the new posterior dynamic stabilization device significantly reduced motion uniformly in all loading directions, but less so than rigid fixation. The evaluation of adjacent level motion and pressure showed some benefit of the new device when compared to rigid fixation. Posterior dynamic stabilization designs which both bend and stretch showed improved kinematic and load-sharing properties when compared to rigid fixation and when indirectly compared to existing conventional devices without a bumper.

1. Introduction

Fusion using rigid pedicle screw-rod instrumentation is a conventional surgical treatment for mechanical back pain due to disc degeneration when nonoperative treatment has failed. In spite of this standard, it is associated with implant-related failures such as screw breakage or loosening. Screw breakage or loosening have been reported in the literature to range from 1% to 11.2% of the screws inserted [1–7]. It has been shown to be affected by a number of factors such as screw design, the number of levels fused, anterior column load-sharing, bone density, the presence of pseudoarthrosis, and its use in burst fractures [3, 4, 8–10]. While in multilevel fusion, bone density and burst fracture applications are more related to patient pathology and indications; all other factors are more dependent on implant design and biomechanics. Anterior column load-sharing is negatively affected by the absence of interbody support and higher stiffness of posterior fixation devices [3, 11]. Adjacent segment degeneration (ASD) has also been recognized as a potential long-term complication of rigidly instrumented fusion [12–17]. While there is some debate surrounding the causality of the disease (whether it is mechanical factors or a natural degenerative progression), a review of 271 articles found a higher rate of symptomatic ASD in 12%–18% of patients fused with rigid transpedicular instrumentation. In spite of these disadvantages, it is proven that implant rigidity is required to achieve successful fusion.

The challenge for surgeons, biomechanists, and engineers has been to determine and develop an optimally stiff device that will provide enough rigidity across a destabilized

spinal segment while simultaneously sharing load with the fusion mass. Posterior fixation devices have evolved from larger diameters and stiffer materials (6.5 mm cobalt chromium/stainless steel) to smaller diameters and less stiff or semi-rigid materials (5.5 mm poly ether ether ketone (PEEK)), respectively. Semi-rigid fixation or dynamic stabilization devices such as PEEK rods, titanium rods with helical grooves, and polymeric spacers with an interwoven cord tethered between pedicle screws have been designed to increase load-sharing in an attempt to induce compression on the bone graft and accentuate the concept of bone remodeling as first credited by Wolff [18]. Examples of such devices are Isobar TTL (Scient'x, Maitland, FL), a metal rod with disc springs, the CD Horizon Legacy PEEK rod (Medtronic Sofamor Danek, Memphis, TN), and Dynesys Dynamic Stabilization System (Zimmer, Warsaw, IN) consisting of a polymeric dampener and posterior tensioning cord. Semi-rigid fixation devices attempt to offload adjacent levels, but most studies show the stiffness of these constructs to be too high to have much of an effect on adjacent level loading [18–21]. These devices have also been clinically recommended for stabilization and modulation of the load distribution across mildly degenerated discs in an attempt to alleviate discogenic back pain and potentially enable regeneration of disc cells [22, 23].

In this particular study, the TRANSITION Stabilization System (Globus Medical, Inc., Audubon, PA) was utilized as the method of semi-rigid stabilization. The device was designed to bend and stretch by incorporating two polymeric spacers: one strategically placed above the cranial pedicle screw and the other between the pedicle screws, to allow a resistance to flexion, and a natural compression across the joint, respectively. We hypothesize that the compressibility across the surgical level may have implications on both the index and adjacent levels, but to what degree remains unknown.

The aim of this study was to evaluate the implanted and adjacent level kinematics and load-sharing effects of the human lumbosacral spine implanted with a semi-rigid fixation device, TRANSITION, compared to rigid fixation, and the historical performance of conventional semi-rigid devices. In this study, the injury model of the motion segment was created by a decompression involving facetectomy.

2. Materials and Methods

2.1. Specimen Preparation. All spines were radiographed to ensure the absence of fractures, deformities, and any metastatic disease. The spines were stripped of paravertebral musculature while preserving the spinal ligaments, joints, and disk spaces. Subsequently, they were mounted at L1 rostrally and S1 caudally in a three-to-one mixture of Bond Auto Body Filler and fiberglass resin (Bondo MarHyde Corp., Atlanta, GA). The spine was then affixed to a six degree-of-freedom (6-DOF) testing apparatus, and pure unconstrained bending moments were applied in the physiological planes of the spine at room temperature using a multidirectional hybrid flexibility protocol [24]. The 6-DOF machine applied

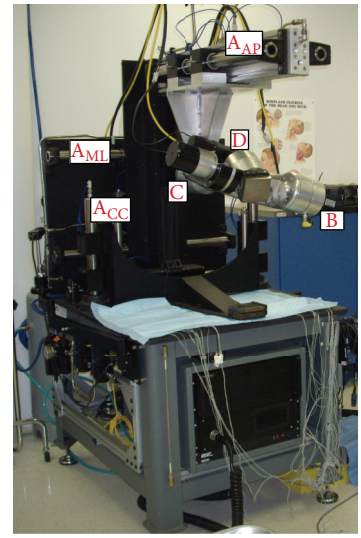


Figure 1: Six degree-of-freedom testing apparatus, allowing unconstrained motion and rotations. Three motors, each placed in a physiological rotation direction providing pure rotations, while translational guide rails allow the forces to redistribute according to the kinematic properties of the spine. A_{AP}: guide rail with air bearings (anterior-posterior), A_{ML}: guide rail with air bearings (medial-lateral), A_{CC}: guide rail with air bearings (cephalad-caudal), B: flexion-extension motor, C: lateral bending motor, and D: axial rotation motor.

unconstrained loading through the application of three cephalad stepper motors placed in each of the three physiological rotation axes (Figure 1). Moreover, the supports were mounted on air bearings to provide near frictionless resistance to the natural kinematics of the spine. Plexiglas markers, each having three infrared light-emitting diodes, were secured rigidly to each vertebral body via bone screws to track its motion with Optotrak Certus (NDI, Inc. Waterloo, Canada) motion analysis system. The location of the markers (denoting a rigid body) was approximately aligned sagitally along the curvature of the spine. The Optotrak Certus software was able to superimpose the coordinate systems of two adjacent vertebral bodies in order to inferentially determine the relative eulerian rotations in each of the three planes.

2.2. Device Descriptions. The semi-rigid device which can both bend and stretch (TRANSITION) is composed of titanium, polycarbonate urethane (PCU), and polyethylene terephthalate (PET) (Figure 2). Essentially, instead of a rod, a PCU spacer is placed between the pedicle screws, while a central PET cord, which runs from top to bottom, provides resistance to stretching (namely flexion). The cord is not tethered to the screws, like conventional devices, but is passed through spools which are the attachment point of the pedicle screws. The spools are 5.5 mm thick at the portion which fits into the pedicle screw. Above the cranial pedicle screw is another PCU spacer which is compressed when the cord is in tension (flexion). The rigid rods tested were standard

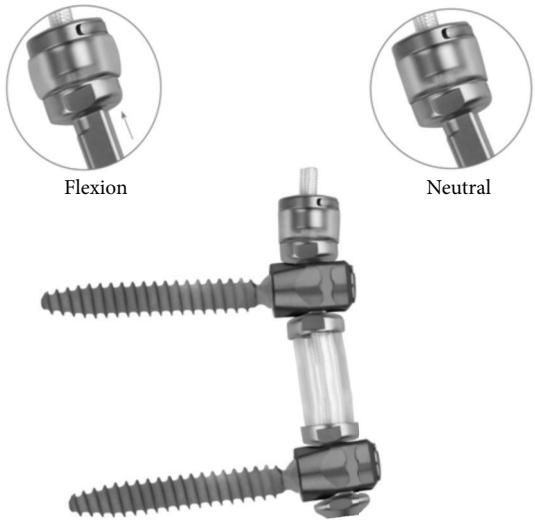


Figure 2: The TRANSITION Stabilization System. The cephalad bumper shown in neutral and flexed position.

5.5 mm diameter titanium rods (REVERE Stabilization System, Globus Medical). Both devices were locked in place through the same screws, having the same tulip, and same locking caps. Comparisons to historical controls or so-called conventional dynamic stabilization devices are primarily focused on Dynesys Dynamic Stabilization System (Zimmer, Warsaw, IN) but could also include Isobar TTL (Scient'x, Maitland, FL), CD Horizon Legacy PEEK rod (Medtronic Sofamor Danek, Memphis, TN), or others. Dynesys has been by far the most extensively studied, biomechanically and clinically.

2.3. Test Groups. Nine intact fresh human cadaver lumbosacral spines (L1-S1) were tested by applying a pure moment of ±8 Nm, according to the test standards for lumbar spine [25]. The specimens consisted of 6 males and 3 females, with an average age of 53 ± 10 years. The hybrid protocol for testing adjacent level effects was applied, as described by Panjabi [24]. Initially, the total L1-S1 range of motion (ROM) was determined in an individual intact specimen. In all subsequent tests for the respective specimen, the displacement of the spine was ranged to the intact total ROM values in flexion (F), extension (E), lateral bending (LB), and axial rotation (AR). A series of three load/unload cycles were performed for each motion with data analysis based on the final cycle. The first five specimens were tested for unilateral facetectomy and unilateral stabilization of L4-L5 segment in the following sequence (Figure 3): (1) intact; (2) unilateral facetectomy (UF); (3) UF and unilateral TRANSITION PDS device (UF + UT); and (4) UF and bilateral TRANSITION PDS device (UF + BT). All the nine specimens (including the previous five unilateral models) were tested for bilateral facetectomy and bilateral stabilization at the L4-L5 segment in the following sequence: (1) intact; (5) bilateral facetectomy (BF); (6) BF and bilateral TRANSITION PDS device (BF + BT); and (7) BF and bilateral rigid fixation (pedicle screws and titanium rod, REVERE Stabilization System, Globus Medical) with interbody spacer (Sustain-O, Globus Medical) (BF + S + R). The numbers in parenthesis indicate the construct number identifying the test condition, in the rest of this paper. Disc pressure was measured using miniature pressure transducers (width = 1.5 mm; height = 0.3 mm, Precision Measurement Co., Ann Arbor, MI) inserted at the adjacent levels, in the posterior half of the disc space, confirmed by sagittal radiographs [26]. The transducers were configured using C-DAQ (National Instruments, Austin, TX) data acquisition module.

2.4. Data Interpretation. Several comparisons were made to evaluate any statistical differences between constructs 1 and 7. The unilateral model (constructs 1, 2, 3, and 4) was evaluated separately from the bilateral model (constructs 1, 5, 6, and 7). Statistical comparisons were completed using a single factor, repeated measures analysis of variance (ANOVA). In all cases to alleviate inhomogeneity of variance, log transforms in the form of $\log_{10}$ (rawdata + 1) were applied to the raw data. Comparisons were made with a probability of type I error, $\alpha = 0.05$, using Tukey's *post hoc* comparison for equal sample size ($n = 5$ unilateral and $n = 9$ bilateral). Intradiscal pressure (IDP) profiles were normalized according to the neutral zone "base pressure" such that the only changes between the base pressure and the pressure at maximum displacement were recorded according to Schmoelz et al. [13]. When the percentage change is discussed, unless otherwise stated, the percentages are calculated through differences in normalized ROM of surgical groups, when normalized to the intact spine motion (100%).

3. Results

3.1. Unilateral Model. The range of motion (ROM) was determined for each surgical construct of the unilateral injury model (Figure 4), and *post hoc* comparisons were tabulated. Unilateral facetectomy (UF) did not cause any significant destabilization in flexion, extension, or lateral bending but increased rotation significantly (124% of intact; $Q > Q_{.05}$, $7.9 > 4.2$). The stabilization of the unilateral injury with a unilateral TRANSITION (UF + UT) resulted in the reduction of motion which was significant in flexion and axial rotation (*F*: 58% of injury, $Q > Q_{.05}$, $4.4 > 4.2$; AR: 87% of injury, $Q > Q_{.05}$, $5.7 > 4.2$) but insignificant in extension (*E*: 62% of injury) and lateral bending (LB: 65% of injury). The stabilization of the unilateral injury with a bilateral TRANSITION (UF + BF) resulted in the reduction of motion which was significant in flexion, lateral bending, and axial rotation (*F*: 52% of injury, $Q > Q_{.05}$, $5.4 > 4.2$; LB: 57% of injury, $Q > Q_{.05}$, $5.1 > 4.2$; AR: 85% of injury, $Q > Q_{.05}$, $6.0 > 4.2$) but insignificant in extension (*E*: 65% of injury). With respect to intact, the stabilization with a unilateral TRANSITION (UF + UT) resulted in the reduction of motion which was significant in flexion (*F*: 56% of intact, $Q > Q_{.05}$, $4.6 > 4.2$) but insignificant in extension (*E*: 72% of intact), lateral bending (LB: 67% of intact), and axial rotation (AR: 108% of intact). With respect to intact, stabilization with a bilateral TRANSITION (UF + BF) resulted in reduction of

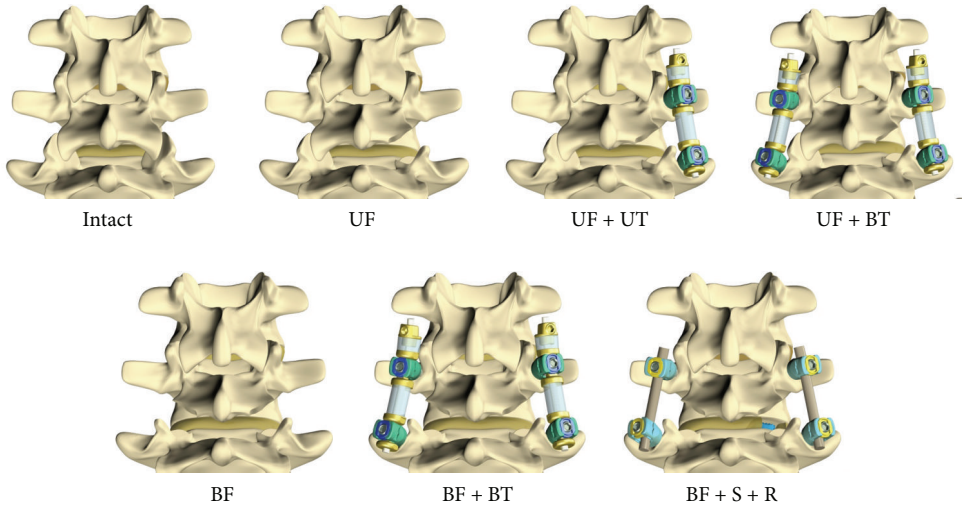


Figure 3: Surgical testing sequence. (1) Intact; (2) unilateral facetectomy (UF); (3) UF and unilateral TRANSITION device (UF + UT); (4) UF and bilateral TRANSITION device (UF + BT); (5) bilateral facetectomy (BF); (6) BF and bilateral TRANSITION device (BF + BT); (7) BF and bilateral rigid fixation with interbody spacer (BF + S + R).

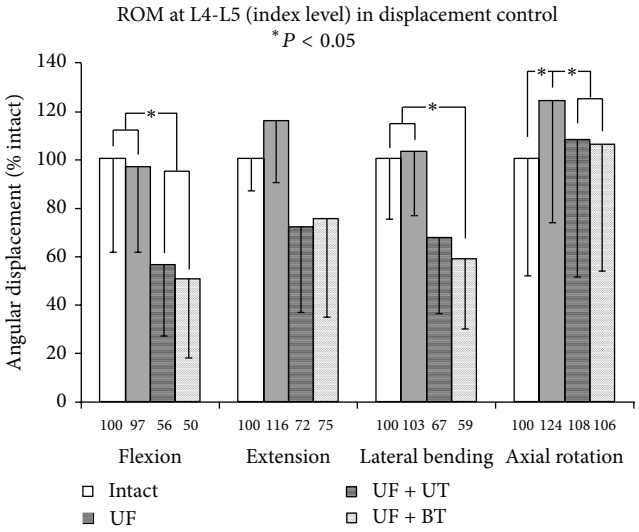


Figure 4: Index surgical level results of multidirectional flexibility testing for constructs 1, 2, 3, and 4 (unilateral model).

motion which was significant in flexion and lateral bending (F: 50% of intact, $Q > Q_{.05}$, 5.6 > 4.2; LB: 59% of intact, $Q > Q_{.05}$), but insignificant in extension (E: 75% of intact) and axial rotation (AR: 106% of intact).

Increased motion due to the UF injury was expected to lead to reduced motions at the immediate adjacent levels in a displacement control protocol (Table 1). This was generally true (especially for L3-L4), but the reduced motions were small and insignificant, except in axial rotation. The stabilization with the PDS system reduced ROM at L4-L5, and, as expected, produced larger ROM at the adjacent levels, which reached significance (with respect to injury) only in lateral bending (L3-L4: UF + UT, 107% of injured, $Q > Q_{.05}$, 4.7 > 4.2; L3-L4: UF + BT, 108% of injured, $Q > Q_{.05}$, 5.3 > 4.2; L5-S1: UF + UT, 110% of injured $Q > Q_{.05}$, 4.5 > 4.2; L5-S1: UF + BT, 112% of injured, $Q > Q_{.05}$, 5.2 > 4.2) and axial rotation (L3-L4: UF + UT, 104% of injured, $Q > Q_{.05}$, 4.6 > 4.2; L3-L4: UF + BT, 106% of injured, $Q > Q_{.05}$, 5.6 > 4.2). There were few differences between unilateral stabilization (UF + UT) and bilateral stabilization (UF + BT) on adjacent level motion.

With respect to intact, adjacent level motion was significantly increased in lateral bending at L5-S1 by both PDS constructs (UF + UT: 114% of intact, $Q > Q_{.05}$, 6.4 > 4.2; UF + BT: 116% of intact, $Q > Q_{.05}$, 7.1 > 4.2).

Intradiscal pressure measurements of adjacent levels (Table 1) showed greater differences between intact and injury groups than what was seen kinematically. Therefore, even small changes in kinematics may translate to large changes in load-sharing properties. Statistically, in lateral bending, unilateral injury stabilized with a bilateral TRANSITION (UF + BT) was the only construct to produce significantly more adjacent level pressure than the corresponding level of the unilaterally injured spine (L3-L4: 131% of injured, $Q > Q_{.05}$, 7.5 > 4.2) and the intact spine (L3-L4: 127% of intact, $Q > Q_{.05}$, 5.7 > 4.2). With respect to the intact spine, both unilateral TRANSITION (UF + UT) and bilateral TRANSITION (UF + BT) produce significantly more adjacent level pressure in flexion (L5-S1: UF + UT, 161% of intact, $Q > Q_{.05}$, 4.7 > 4.2; L3-L4: UF + BT, 220% of intact, $Q > Q_{.05}$, 5.7 > 4.2; L5-S1: UF + BT, 207% of intact, $Q > Q_{.05}$, 6.7 > 4.2).

3.2. Bilateral Model. The range of motion (ROM) was determined for each surgical construct of the bilateral injury model (Figure 5), and *post hoc* comparisons were tabulated. Destabilization after BF increased the ROM in all directions, but this reached statistical significance only in axial rotation (AR: 168% of intact, $Q > Q_{.05}$, 8.0 > 3.9). Again, in flexion and lateral bending, similar statistical trends were seen, revealing that BF + BT provided significant stabilization with respect

Table 1: Unilateral model (construct 1, 2, 3, and 4) adjacent level ROM and pressure. Brackets show which construct groups are significant.

	Intact [1]	UF [2]	UF + UT [3]	UF + BT [4]
ROM (% of intact)				
Flexion				
L3-L4	Mean 100 (SD 23) [4]	Mean 101 (SD 20)	Mean 109 (SD 24)	Mean 111 (SD 27) [1]
L5-S1	Mean 100 (SD 32)	Mean 98 (SD 26)	Mean 107 (SD 41)	Mean 108 (SD 35)
Extension				
L3-L4	Mean 100 (SD 11)	Mean 91 (SD 12)	Mean 101 (SD 16)	Mean 98 (SD 9)
L5-S1	Mean 100 (SD 26)	Mean 118 (SD 28)	Mean 133 (SD 43)	Mean 126 (SD 35)
Lateral bending				
L3-L4	Mean 101 (SD 16)	Mean 98 (SD16) [3, 4]	Mean 105 (SD 17) [2]	Mean 106 (SD 20) [2]
L5-S1	Mean 100 (SD 28) [3, 4]	Mean 104 (SD 29) [3, 4]	Mean 114 (SD 31) [1, 2]	Mean 116 (SD 31) [1, 2]
Axial rotation				
L3-L4	Mean 100 (SD 31) [2, 3, 4]	Mean 89 (SD 29) [1, 3, 4]	Mean 93 (SD 28) [1, 2]	Mean 94 (SD 28) [1, 2]
L5-S1	Mean 100 (SD 22)	Mean 99 (SD 25)	Mean 110 (SD 27)	Mean 109 (SD 26)
Pressure (% of intact)				
Flexion				
L3-L4	Mean 100 (SD 42) [4]	Mean 144 (SD 33)	Mean 166 (SD 38)	Mean 220 (SD 76) [1]
L5-S1	Mean 100 (SD 58) [3, 4]	Mean 141 (SD 62)	Mean 161 (SD 53) [1]	Mean 207 (SD 82) [1]
Extension				
L3-L4	Mean 100 (SD 21)	Mean 74 (SD 26)	Mean 78 (SD 31)	Mean 99 (SD 24)
L5-S1	Mean 100 (SD 84)	Mean 103 (SD 78)	Mean 120 (SD 89)	Mean 113 (SD 96)
Lateral bending				
L3-L4	Mean 100 (SD 54) [4]	Mean 97 (SD 59) [4]	Mean 109 (SD 66) [4]	Mean 127 (SD 76) [1, 2, 3]
L5-S1	Mean 100 (SD 78)	Mean 90 (SD 70)	Mean 90 (SD 65)	Mean 94 (SD 70)
Axial rotation				
L3-L4	Mean 100 (SD 44)	Mean 92 (SD 33)	Mean 110 (SD 36)	Mean 81 (SD 21)
L5-S1	Mean 100 (SD 33)	Mean 85 (SD 35)	Mean 100 (SD 45)	Mean 87 (SD 33)

to intact (F: 44% of intact, $Q > Q_{.05}$, 15.1 > 3.9; LB: 58% of intact, $Q > Q_{.05}$, 7.8 > 3.9) and BF (F: 42% of injury, $Q > Q_{.05}$, 16.2 > 3.9; LB: 56% of injury, $Q > Q_{.05}$, 8.3 > 3.9). In extension, the bilateral injury produced larger motions (119%) when compared to intact.

The trend of index level motion follows the model BF + S + R < BF + BT < BF, where all constructs were statistically different than one another. The stabilization with TRANSITION PDS device reduced the ROM values, which were, in terms of intact, 44% ($Q > Q_{.05}$, 15.1 > 3.9), 62% ($Q > Q_{.05}$, 4.2 > 3.9), 58% ($Q > Q_{.05}$, 7.8 > 3.9), and 125% ($Q < Q_{.05}$, 3.3 < 3.9), while rigid fixation resulted in ROM values of 31% ($Q > Q_{.05}$, 19.5 > 3.9), 29% ($Q > Q_{.05}$, 8.7 > 3.9), 34% ($Q > Q_{.05}$, 13.6 > 3.9), and 77% ($Q < Q_{.05}$, 3.8 < 3.9) in *F*, *E*, LB, AR, respectively. Compared to the BF, and stabilization with TRANSITION PDS device reduced the ROM values, which were, in terms of injury, 42% ($Q > Q_{.05}$, 16.2 > 3.9), 52% ($Q > Q_{.05}$, 5.5 > 3.9), 56% ($Q > Q_{.05}$, 8.3 > 3.9), and 74% ($Q > Q_{.05}$, 4.7 > 3.9), while rigid fixation resulted in ROM values of 30% ($Q > Q_{.05}$, 20.6 > 3.9), 24% ($Q > Q_{.05}$, 10.0 > 3.9), 33% ($Q > Q_{.05}$, 14.1 > 3.9), and 46% ($Q > Q_{.05}$, 11.9 > 3.9) in *F*, *E*, LB, and AR, respectively.

Increased motion due to the BF injury at the index level is expected to lead to reduced motions at the immediate adjacent levels in a displacement control protocol (Figures 6 and 7). This was generally correct, but the reduced motions

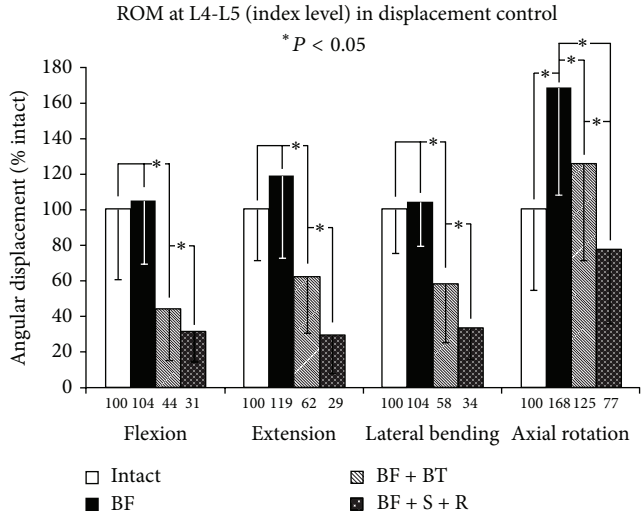


Figure 5: Index surgical level results of multidirectional flexibility testing for constructs 1, 4, 5, and 6 (bilateral model).

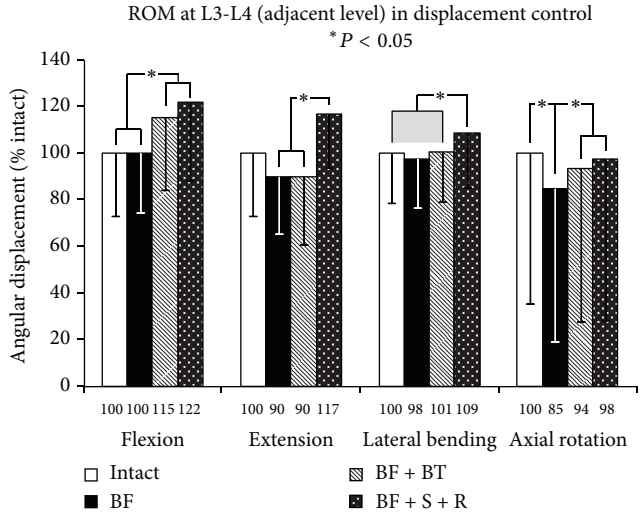


Figure 6: Cranial adjacent level results of multidirectional flexibility testing for constructs 1, 5, 6, and 7.

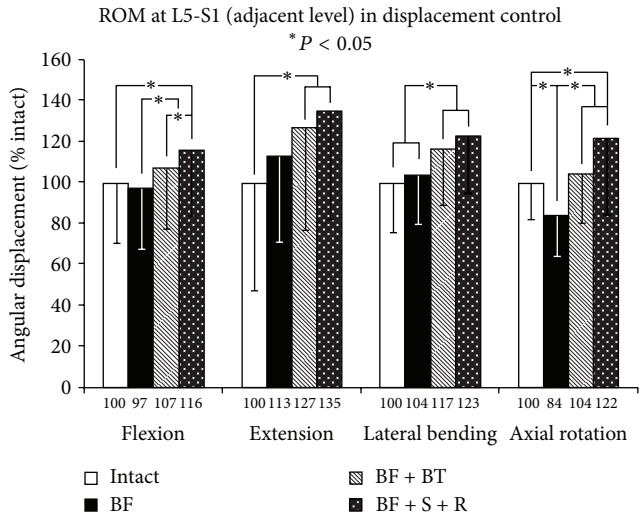


Figure 7: Caudal adjacent level results of multidirectional flexibility testing for constructs 1, 5, 6, and 7.

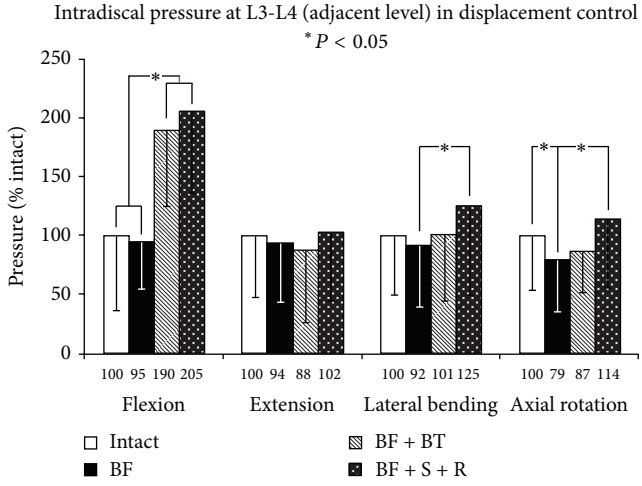


Figure 8: Cranial adjacent level intradiscal pressures of multidirectional flexibility testing for constructs 1, 5, 6, and 7.

were small and insignificant, except for axial rotation where BF was significantly less than intact ($P < 0.05$) (except for L5-S1). The stabilization at L4-L5 increased the ROM at both the adjacent levels and the trend followed the model BF + S + R ≥ BF + BT ≥ BF for all loading modes at both L3-L4 and L5-S1, indicating the utility of semi-rigid stabilization to offset adjacent level effects caused by rigid instrumentation. Nevertheless, this trend was not always large enough to warrant significance.

The load-bearing effect at the adjacent levels, as measured by intradiscal pressure, (Figures 8 and 9) demonstrated very similar trends to ROM, that is, the IDP was decreased or unchanged after facetectomy at the L4-L5 level and increased with PDS stabilization, with an even greater increase with rigid stabilization. The increase in adjacent segment pressure after rigid stabilization was more pronounced at the cranial (L3-L4) level than the caudal (L5-S1) level, reaching a significant level, with respect to injury in flexion (209% of injured, $Q > Q_{.05}$, 7.6 > 3.9), lateral bending (136% of injured, $Q > Q_{.05}$, 5.5 > 3.9), and axial rotation (144% of injured, $Q > Q_{.05}$, 5.4 > 3.9) at L3-L4, but only in flexion (192% of injured, $Q > Q_{.05}$, 7.2 > 3.9) at L5-S1. While adjacent segment ROM changes were more pronounced in rotation, the increase in adjacent segment pressure was most noticeable in flexion. At the cranial adjacent level (L3-L4), while the ROM in flexion was increased to 122% after rigid fixation, the corresponding disc pressure was increased to 205% of the intact value. The stabilization with PDS also significantly increased the adjacent segment pressures in flexion, but the increase was smaller (190%) than with rigid fixation ($P < 0.05$). Therefore, though a strong relationship exists between ROM and IDP changes at the adjacent segments, it shows a nonlinear phenomenon in flexion. Additionally, though the use of the particular PDS device reduced the adjacent level pressure, it did not restore it near the intact value in flexion. Whether this would translate into potential alleviation of adjacent level stresses needs to be corroborated with clinical evidence. The remaining ROM and IDP trends are very similar, though higher variation (standard deviations) in the measurement of pressure resulted in very little significance and no significance between BF + BT and BF + S + R in any loading mode.

4. Discussion

Conventional rigid fusion in the surgical treatment for chronic low back pain has some negative side effects such as the potential for adjacent segment degeneration and screw loosening. The concept of semi-rigid or dynamic stabilization has evolved to possibly prevent such degeneration, if it is not a function of natural disease progression, mainly through the reduction of stress at the adjacent segments. Soft-stabilization devices were developed to permit load-sharing with the anterior column to accomplish solid fusion and, at the same time, provide a softer posterior implant stiffness.

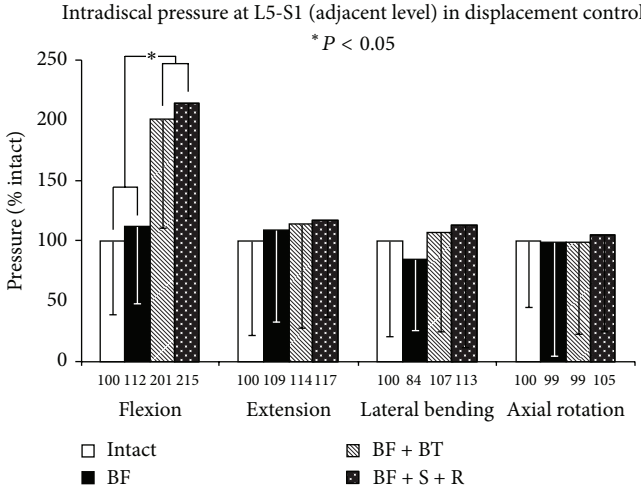


Figure 9: Caudal adjacent level intradiscal pressures of multidirectional flexibility testing for constructs 1, 5, 6, and 7.

Consequently, semi-rigid instrumentation is expected to lower screw breakage associated with transmission of forces through posterior instrumentation as opposed to through the anterior column. While there is some disparity between the potential uses of PDS systems (whether they are for reducing adjacent level degeneration or for promoting fusion through load-sharing), the ubiquitousness of such systems cannot be ignored. Their prevalence currently has more to do with dissatisfaction with conventional fusion than a proven efficacy. This study attempts to characterize the biomechanical efficacy of a select system. The clinical efficacy has yet to be determined. It remains to be seen if "soft fusion" can be achieved and if, in the presence of boney ingrowth with weaker mechanical properties, adjacent level effects can be ameliorated.

The purpose of this study was to evaluate the stability of using a posterior dynamic stabilization (PDS) device which differs from conventional PDS devices in two ways: (1) by the addition of both flexion and extension dampening materials; and (2) by the addition of titanium spools (attached to the screw heads) which slide along the PET cord. The primary aim was to compare this device to rigid fixation with pedicle screws and rods. The hypothesis is that the new PDS design will load-share with the surgical level more effectively, therefore minimizing the over-load effect of the adjacent levels compared to the conventional rigid and PDS devices.

Both the PDS and rigid devices produced significant stabilization, but a consistent and significant trend of increased flexibility was observed in all loading modes for BF + BT (TRANSITION) when compared to BF + S + R (rigid). TRANSITION led to ROM values which were, in terms of intact, 44%, 62%, 58%, and 125% in *F*, *E*, LB, and AR, respectively, while rigid fixation resulted in ROM values of 31%, 29%, 34%, and 77%. Gédet et al. reported (load control protocol using a follower load and partial injury including a 25% nucleotomy) that Dynesys system provided stabilization when compared to intact values of ~20%, 40%, 40%, and 100% for *F*, *E*, LB, and AR, respectively [27]. The data from the current study showed a higher ROM baseline because of the facetectomy as opposed to nucleotomy as the injury model but the stabilization effect followed a similar pattern. A separate study, investigating Dynesys in a more severe injury model without axial preload, revealed that PDS restored motion to ~20%, 100%, 27%, and 130% of the intact values [14]. While it is difficult to directly compare the magnitudes reported in the literature sources to the current data, due to differences in test protocols, injury models, and the use of follower loads, the pattern in data is still comparable.

The PDS device used in this study resulted in kinematic and load-sharing trends which appear different when compared to trends observed in conventional PDS designs within the literature [13, 14]. The majority of data in the literature show Dynesys behaves more rigid in flexion, almost comparable to rigid fixation, and less rigid in extension. On the contrary, the data from the present study show a more uniform rigidity in ROM across flexion, extension, and lateral bending. This inference is only based on indirect comparisons. In terms of load-sharing effect, the literature showed Dynesys responds to extension by total load-bearing of the implant, resulting in negative pressure in the disc at the index level [13]. This study cannot comment on load-sharing at the index level because the rigid rod construct was tested with an interbody spacer, precluding the simultaneous use of a pressure transducer. Comparisons of this construct with the PDS construct would not have been possible; therefore, both were excluded. Nevertheless, the adjacent level effects consistently reveal that the hypermobility of rigid fixation was reduced via TRANSITION. Moreover, the amount of reduction was uniform across the loading modes, not favoring extension over flexion. In rotation, more motion was allowed and not limited through the bumper mechanism. Yet, rotation itself is much less of a problem in a degenerated lumbar spine and is infrequently diagnosed as a cause of pain.

In a finite element study by Schmidt et al., the authors predicted the performance of PDS devices in different loading modes, as a function of polymer properties [28]. The material properties of posterior instrumentation were input in the analysis in terms of the bending stiffness and axial stiffness, axial stiffness referring to purely compressing the polymer spacer and bending stiffness similar to folding the spacer. The difference in bending stiffness between a PCU spacer and rigid rod is expected to be larger than their difference in axial stiffness. In that study, the authors concluded that, in each loading mode, the resulting ROM of an L4-L5 segment with posterior instrumentation involved a combination of both bending and axial stiffness. However, in flexion-extension, the relationship was mostly determined through axial stiffness, while in lateral bending and axial rotation, both stiffness parameters played a role. Extrapolating these results to PDS findings helps explain the relative rigidity of PDS devices in flexion-extension, which, despite a polymer spacer, are significantly stabilized with respect to intact values. Moreover, their findings predict that materials with high bending flexibility, such as PCU, would respond with increased motion in lateral bending and axial rotation. These conclusions are consistent with the results reported here as well as other studies. In this

study, the extra polymeric material added through the spacer and bumper can be expected to add to the overall flexibility of conventional PDS devices, especially in lateral bending and axial rotation.

The PDS test device reduced adjacent level hypermobility caused by rigid fixation. The trend of adjacent level motions followed the model BF + S + R ≥ BF + BT ≥ BF for all loading modes at both L3-L4 and L5-S1, indicating the utility of semi-rigid stabilization to offset adjacent level effects. While this trend is encouraging to alleviate adjacent level stresses, its clinical relevance needs to be proven. The question "How much is off-loading ideal?" remains to be answered. Nevertheless, the new PDS device produced significantly smaller motions than rigid fixation at the adjacent levels, in flexion (only at L5-S1), extension (only at L3-L4), and lateral bending (only at L3-L4).

Intradiscal pressure measurements at the adjacent level reflected the same trends as the ROM, but, in flexion, the relationship between ROM and IDP was nonlinear. For example, a 22% increase in L3-L4 level motion caused by L4-L5 rigid fixation, resulted in 105% increase in the IDP value. Moreover, the stabilization with PDS device (BF + BT) was not able to restore these large pressure that increases to near the intact value. If adjacent level disease is indeed related to a physiological imbalance in load-sharing and kinematics of segments juxtaposed to the fusion site, then the role of motion versus pressure on the rate of disease progression needs to be determined. Since these factors are nonlinearly related, restricting the motion may not be sufficient at buffering the load-sharing effects on the adjacent level.

There were certain limitations in this study. One objective was to relate the biomechanical differences observed between this study and those found on the widely studied conventional device, Dynesys. The ideal way to evaluate the difference was to compare TRANSITION versus Dynesys directly. In the current study, this comparison was indirect from the literature data. The reason behind this was that testing TRANSITION and Dynesys on the same specimen was not possible because the pedicle screws are different in the two systems, and the reinsertion of the pedicle screws in the same specimens introduces unacceptable errors because of loosening at the screw-bone interface. Removing the bumper alone from the TRANSITION does not make it comparable to Dynesys. The second limitation of this study was the bilateral facetectomy injury model, which may not be the most common scenario of a decompression clinically. However, facetectomy produced considerable instability, possibly more than what can be achieved by nucleotomy alone. The injury model was chosen because of the benefit of having a greater degree of instability (or worst-case scenario). Thirdly, testing pedicle screws and rods without an interbody device would have provided some information in the comparison of rigid rods and TRANSITION. Nevertheless, the authors were predominately interested in seeing the maximum change in the rigidity between interbody fusion with internal fixation and semi-rigid posterolateral fusion. Lastly, there is a certain amount of error introduced via suboptimal device placement which can occur via difficulty in the anatomy, irregular curvatures, or even screw placement. The PDS device considered made use of individually sized PCU spacers which were trialed to appropriate length. The implants are also pre-assembled with a constant tension of 220 N, so there should never be a case where one side of the disc space is artificially tensioned more than the other. Therefore, device placement was not separately considered in the analysis of variance.

5. Conclusion

The semi-rigid fixation/dynamic stabilization device investigated in this study, which utilized posteriorly placed flexion and extension dampening materials, was able to reduce the motion ($P < 0.05$) at the surgical level in all modes, and the reduction in motion was significantly less in comparison to rigid internal fixation. The adjacent levels were off-loaded by the dynamic stabilization device, in terms of both motion and intradiscal pressure, though the effect was often insignificant. The new dynamic device provides more uniform reduction of motion at the surgical level in all directions, especially in flexion, as well as permits more uniform load-sharing when compared to conventional systems like Dynesys. The disc, which is a uniform load-bearing structure of homogeneous material properties, may, likewise, benefit from a device with uniform rigidity.

Acknowledgments

The authors would like to thank Kurt Faulhaber for his contribution to the artwork in Figure 3. The authors acknowledge the funding and materials provided by Globus Medical, Inc., specifically for their Research Department.

References

[1] S. H. Davne and D. L. Myers, "Complications of lumbar spinal fusion with transpedicular instrumentation," *Spine*, vol. 17, supplement 6, pp. S184–S189, 1992.

[2] S. I. Esses and D. A. Bednar, "The spinal pedicle screw: techniques and systems," *Orthopaedic Review*, vol. 18, no. 6, pp. 676–682, 1989.

[3] P. C. Jutte and R. M. Castelein, "Complications of pedicle screws in lumbar and lumbosacral fusions in 105 consecutive primary operations," *European Spine Journal*, vol. 11, no. 6, pp. 594–598, 2002.

[4] J. E. Lonstein, F. Denis, J. H. Perra, M. R. Pinto, M. D. Smith, and R. B. Winter, "Complications associated with pedicle screws," *Journal of Bone and Joint Surgery A*, vol. 81, no. 11, pp. 1519–1528, 1999.

[5] H. Pihlajamäki, P. Myllynen, and O. Böstman, "Complications of transpedicular lumbosacral fixation for non-traumatic disorders," *Journal of Bone and Joint Surgery B*, vol. 79, no. 2, pp. 183–189, 1997.

[6] A. D. Steffee and J. W. Brantigan, "The variable screw placement spinal fixation system: report of a prospective study of 250 patients enrolled in Food and Drug Administration clinical trials," *Spine*, vol. 18, no. 9, pp. 1160–1172, 1993.

[7] J. L. West III, J. W. Ogilvie, and D. S. Bradford, "Complications of the variable screw plate pedicle screw fixation," *Spine*, vol. 16, no. 5, pp. 576–579, 1991.

[8] H. Daniaux, P. Seykora, A. Genelin, T. Lang, and A. Kathrein, "Application of posterior plating and modifications in thoracolumbar spine injuries: indication, techniques, and results," *Spine*, vol. 16, supplement 3, pp. S125–S133, 1991.

[9] K. R. Gurr and P. C. McAfee, "Cotrel-Dubousset Instrumentation in adults. A preliminary report," *Spine*, vol. 13, no. 5, pp. 510–520, 1988.

[10] H. J. Hehne, K. Zielke, and H. Bohm, "Polysegmental lumbar osteotomies and transpedicled fixation for correction of long-curved kyphotic deformities in ankylosing spondylitis: report on 177 cases," *Clinical Orthopaedics and Related Research*, vol. 258, pp. 49–55, 1990.

[11] P. Enker and A. D. Steffee, "Interbody fusion and instrumentation," *Clinical Orthopaedics and Related Research*, no. 300, pp. 90–101, 1994.

[12] B. Cakir, C. Carazzo, R. Schmidt, T. Mattes, H. Reichel, and W. Käfer, "Adjacent segment mobility after rigid and semirigid instrumentation of the lumbar spine," *Spine*, vol. 34, no. 12, pp. 1287–1291, 2009.

[13] W. Schmoelz, J. F. Huber, T. Nydegger, L. Claes, and H. J. Wilke, "Influence of a dynamic stabilisation system on load bearing of a bridged disc: an in vitro study of intradiscal pressure," *European Spine Journal*, vol. 15, no. 8, pp. 1276–1285, 2006.

[14] W. Schmoelz, J. F. Huber, T. Nydegger, Dipl-Ing, L. Claes, and H. J. Wilke, "Dynamic stabilization of the lumbar spine and its effects on adjacent segments: an in vitro experiment," *Journal of Spinal Disorders and Techniques*, vol. 16, no. 4, pp. 418–423, 2003.

[15] B. C. Cheng, J. Gordon, J. Cheng, and W. C. Welch, "Immediate biomechanical effects of lumbar posterior dynamic stabilization above a circumferential fusion," *Spine*, vol. 32, no. 23, pp. 2551–2557, 2007.

[16] J. Beastall, E. Karadimas, M. Siddiqui et al., "The dynesys lumbar spinal stabilization system: a preliminary report on positional magnetic resonance imaging findings," *Spine*, vol. 32, no. 6, pp. 685–690, 2007.

[17] K. S. Delank, E. Gercek, S. Kuhn et al., "How does spinal canal decompression and dorsal stabilization affect segmental mobility? A biomechanical study," *Archives of Orthopaedic and Trauma Surgery*, vol. 130, no. 2, pp. 285–292, 2010.

[18] R. C. Huang, T. M. Wright, M. M. Panjabi, and J. D. Lipman, "Biomechanics of nonfusion implants," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 271–280, 2005.

[19] S. Schaeren, I. Broger, and B. Jeanneret, "Minimum four-year follow-up of spinal stenosis with degenerative spondylolisthesis treated with decompression and dynamic stabilization," *Spine*, vol. 33, no. 18, pp. E636–E642, 2008.

[20] K. J. Schnake, S. Schaeren, and B. Jeanneret, "Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis," *Spine*, vol. 31, no. 4, pp. 442–449, 2006.

[21] A. Rohlmann, N. K. Burra, T. Zander, and G. Bergmann, "Comparison of the effects of bilateral posterior dynamic and rigid fixation devices on the loads in the lumbar spine: a finite element analysis," *European Spine Journal*, vol. 16, no. 8, pp. 1223–1231, 2007.

[22] D. K. Sengupta and H. N. Herkowitz, "Degenerative spondylolisthesis: review of current trends and controversies," *Spine*, vol. 30, supplement 6, pp. S71–S81, 2005.

[23] D. K. Sengupta and R. C. Mulholland, "Fulcrum assisted soft stabilization system: a new concept in the surgical treatment of degenerative low back pain," *Spine*, vol. 30, no. 9, pp. 1019–1030, 2005.

[24] M. M. Panjabi, "Hybrid multidirectional test method to evaluate spinal adjacent-level effects," *Clinical Biomechanics*, vol. 22, no. 3, pp. 257–265, 2007.

[25] V. K. Goel, M. M. Panjabi, A. G. Patwardhan, A. P. Dooris, and H. Serhan, "Test protocols for evaluation of spinal implants," *Journal of Bone and Joint Surgery A*, vol. 88, supplement 2, pp. 103–109, 2006.

[26] P. A. Cripton, G. A. Dumas, and L. P. Nolte, "A minimally disruptive technique for measuring intervertebral disc pressure in vitro: application to the cervical spine," *Journal of Biomechanics*, vol. 34, no. 4, pp. 545–549, 2001.

[27] P. Gédet, D. Haschtmann, P. A. Thistlethwaite, and S. J. Ferguson, "Comparative biomechanical investigation of a modular dynamic lumbar stabilization system and the dynesys system," *European Spine Journal*, vol. 18, no. 10, pp. 1504–1511, 2009.

[28] H. Schmidt, F. Heuer, and H. J. Wilke, "Which axial and bending stiffnesses of posterior implants are required to design a flexible lumbar stabilization system?" *Journal of Biomechanics*, vol. 42, no. 1, pp. 48–54, 2009.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 637362, 7 pages
http://dx.doi.org/10.1155/2013/637362

Clinical Study

The Interspinous Spacer: A New Posterior Dynamic Stabilization Concept for Prevention of Adjacent Segment Disease

Antoine Nachanakian, Antonios El Helou, and Moussa Alaywan

Department of Neurosurgery, Saint George Hospital University Medical Center and Balamand University, Youssef Sursock Street, Rmeil, Beirut 11 00 2807, P.O. Box 166378, Lebanon

Correspondence should be addressed to Antoine Nachanakian; nachanakian@gmail.com

Received 19 February 2013; Accepted 27 March 2013

Academic Editor: Mehdi Sasani

Introduction. Posterior Dynamic stabilization using the interspinous spacer device is a known to be used as an alternative to rigid fusion in neurogenic claudication patients in the absence of macro instability. Actually, it plays an important in the management of adjacent segment disease in previously fused lumbar spine. *Materials and Method*. We report our experience with posterior dynamic stabilization using an interspinous spacer. 134 cases performed in our institution between September 2008 and August 2012 with different lumbar spine pathologies. The ages of our patients were between 40 and 72 years, with a mean age of 57 years. After almost 4 years of follow up in our patient and comparing their outcome to our previous serious we found that in some case the interspinous distracter has an important role not only in the treatment of adjacent segment disease but also in its prevention. *Results and Discussion*. Clinical improvement was noted in ISD-treated patients, with high satisfaction rate. At first, radicular pain improves with more than 3/10 reduction of the mean score on visual analog scale (VAS). In addition, disability score as well as disc height and lordotic angle showed major improvement at 3 to 6 months post operatively. And, no adjacent segment disease was reported in the patient operated with interspinous spacer. *Conclusion*. The interspinous spacer is safe and efficient modality to be used not only as a treatment of adjacent segment disease but also as a preventive measure in patients necessitating rigid fusion.

1. Introduction

Spinal disorders are among the most common health complaints affecting a large portion of the population in developed and developing countries [1]. Spinal disorders can be treated medically at first and the majority of patients will respond to the latter, whereas others will need surgical treatment for their spinal disease. And though, degenerative disease of the spinal cord became a serious problem with the aging of the population and its management is in continuous evolution.

Spinal stenosis manifested by back or radicular pain and nonresponding to conservative management or evolution to neurogenic claudication necessitates surgical procedure. The management of this pathology changed over time and in case decompressive surgery was not sufficient or the spinal segments degenerated later on, a rigid fusion was used. Rigid fusion was efficient and provided better outcome compared to decompression alone, but it could not resolve the problem of disc degeneration without evident radicular compression [2]. And, overtime, with millions of segmental fusion done, a new pathology known as adjacent segment disease was described. From this evidence for adjacent-segment degeneration emerged the concept of dynamic or nonfusion stabilization of the lumbar spine [3]. The dynamic stabilization hardware functions as shock absorbent at the level above a fused segment and reduces the pressure leading to further degeneration in the spinal cord [4].

Posterior dynamic stabilization was born from the need of normalization of the intersegmental motion [5] and in contrast to the traditional fusion surgery it does not eliminate the mobility of the fused segment [6]. While both procedures treat the microinstability, posterior dynamic stabilization does it in a more physiological manner. By restoring normal motion, mobility is theoretically preserved rather than eliminated, and the forces acting above and below the construct are

altered to a lesser extent, reducing the potential undesirable effects of fusion [7].

Interspinous process spacers have been introduced as a possible alternative to spinal decompression and fusion for the treatment of neurogenic intermittent claudication (NIC) and discogenic lower back pain [8]. The interspinous devices work as a shock absorbent device. In addition to intervertebral height restoration, it improves central canal and foraminal stenosis. Interspinous Distracter (ISD) is designed to stabilize the motion segment after neural elements decompression in lumbar stenosis, tolerating flexion and extension in this segment thus preserving the adjacent segment from deterioration [5–8].

2. Methods

Our experience is based on 134 cases performed between September 2008 and August 2012 with different lumbar spine pathologies (Table 1). The ages of our patients were between 40 and 72 years, with a mean age of 57 years. All patients were treated with Interspinous Distracter (ISD).

2.1. Inclusion Criteria. At the beginning of our usage of ISD, patients were eligible for enrolment if they had the following:

(i) degenerative disk disease and subsequent bilateral foraminal stenosis (Figure 1),

(ii) foraminal-canalar stenosis, due to ligamentum flavum hypertrophy, declared symptoms consisting of neurogenic claudication,

(iii) suspended vertebra shown on X-ray which is due to facet degenerative disease,

(iv) facet joint syndrome.

Then with the development of the techniques and the follow-up results, two indications were added to the above mentioned criteria:

(i) adjacent segment syndrome (Figure 2) which refers to degenerative changes that occur in the mobile segment next to spinal fusion,

(ii) degenerated disc at a level superior to the one necessitating posterior rigid fusion.

After several procedures with successful results in management of adjacent segment syndrome and to avoid later hospitalization and added surgical procedure in previously operated patients with spinal fusion, we started to use ISD as prevention to avoid adjacent segment disease.

2.2. Exclusion Criteria. Patients were excluded in cases of more than 2 adjacent levels disease, in the absence of the spinous processes due to previous surgery or fractures, in the presence of spondylolysthesis, and, when severe osteoporosis exists in the lumbar region (T score < -2.5 in the lumbar region).

Table 1: Number of cases in correlation with disease and sex.

Number of cases	Pathology	Male/female ratio
36	Biforaminal stenosis	24/12
15	Ligamentum flavum hypertrophy	8/7
6	Suspended vertebrae	4/2
3	Facet syndrome	0/3
47	Adjacent syndrome	28/19
27	Adjacent syndrome prevention	12/15

2.3. Preoperative Evaluation. The patients completed the visual analogue scale (VAS) for pain and Oswestry disability index (ODI).

At first, paraclinical evaluation included plain lumbar film, lumbar MRI or CT, and osteodensitometry. Then MRI along with dynamic lumbar X-ray was used and osteodensitometry was done in postmenopause female patients.

The global and segmental lordotic angles (stabilized segments, above and below adjacent segments) were measured using Cobb's method on lateral neutral position lumbosacral spine X-ray.

The segmental lordotic angles (stabilized segments and adjacent segments) were measured from between the upper end plates of the corresponding segments.

2.4. Operative Procedure

2.4.1. Preparation. The procedure is done under general anesthesia. All patients were operated in a prone position, avoiding hyperlordosis for a better interspinous distraction.

2.4.2. Product Used. Different interspinous spacers' types are used in our institution.

2.4.3. The Instrument Used. A set of lumbar laminectomy is used. In addition, a set of interspinous spacer measurer is utilized to define the depth and width of the spacer to be used.

2.4.4. Surgical Note. The level of the procedure is localized under fluoroscopy after positioning. Surgical exposure is done similar to any lumbar laminectomy procedure. For the insertion of the ISD the interspinous ligament as well as the ligamentum flavum was resected.

After ISD insertion, the depth between it and the dural sac is assessed by 3 mm hook.

In cases where the disc is protruded/herniated, medial discectomy was not done. In cases where degenerative or congenital spondylolysthesis is present, rigid fusion of the spondylotic level was done. The insertion of ISD at the level above was done in patients older than 55 years. In patients younger than 55 years, the decision was made for each case separately. If the level adjacent to the fusion is not degenerated, this level is spared and the ISD is inserted at the level above; whereas if the disc at the adjacent level is degenerated, ISD is used at the latter mentioned level (Figure 3).

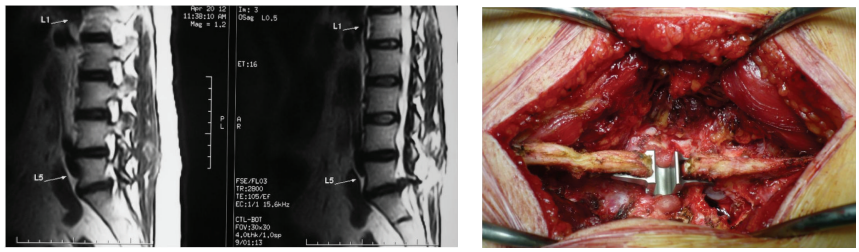


Figure 1: On the left, sagittal T2W image MRI of Lumbosacral spine showing extruded L5-S1 disc with degenerated L4-L5 disc. On the right, preoperative view of the same patient showing left L5-S1 laminotomy for disc excision and L4-L5 interspinous distractor.

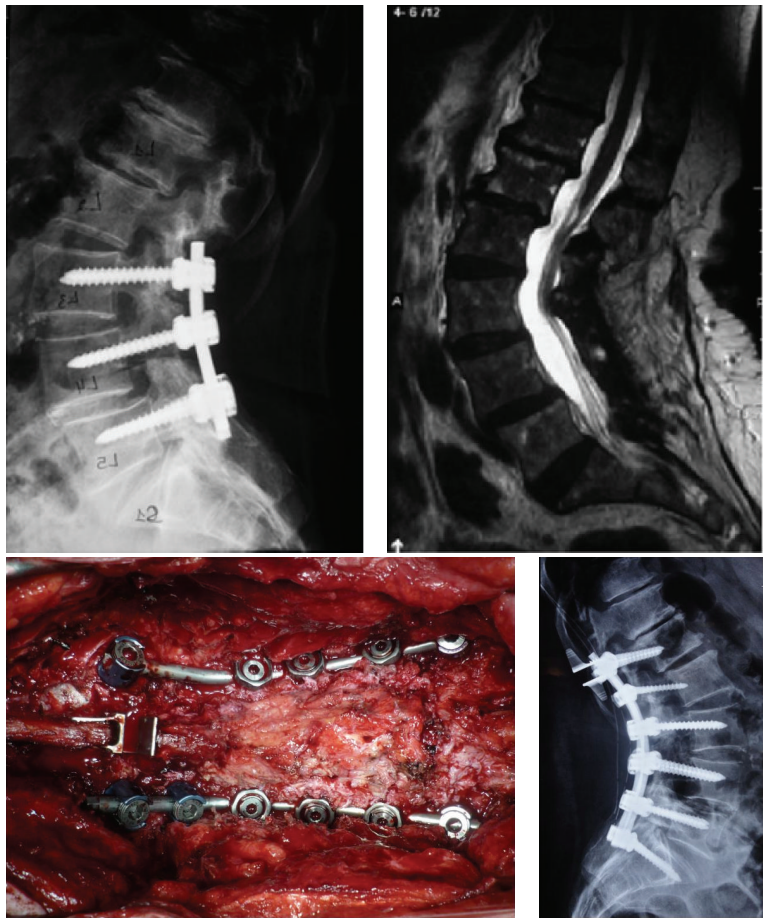


Figure 2: Above preoperative spine X-ray with previous instrumented level on the right. On the left, degenerated segments at L1-L2 and L2-L3 levels. Below preoperative view showing the extended fusion from L1 to S1 with Th12-L1 interspinous spacer.

Regular closure of layers and placing of deep hemovac drain ended the surgery.

2.5. Follow-Up Evaluation

2.5.1. Immediate Postoperative Care. The patient is out of bed the day after surgery and discharged on day 3 after surgery or on day 2 when drain was not inserted. All patients wear a lumbar brace, for a period of one month during their daily activities.

2.5.2. Late Postoperative Evaluation. The following data were collected: VAS, ODI, pain medication, complications, and patient satisfaction.

Control lumbosacral X-ray is done in 2 views to evaluate the created distraction.

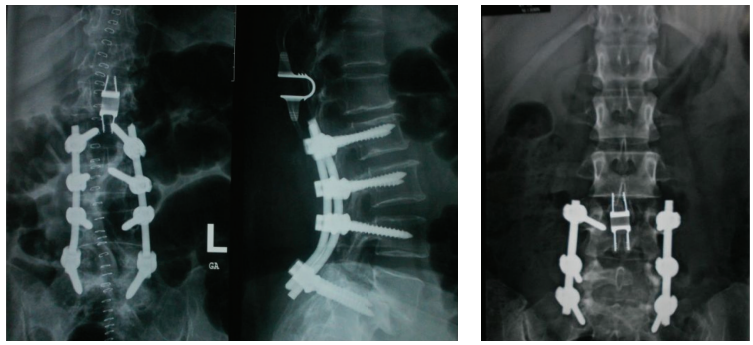


Figure 3: Postoperative spine X-ray, on the right, showing multiple level fusions with ISD 1 level skipping the adjacent segment. On the left, ISD used at the level adjacent to the rigid fusion.

The plain radiographs (anteroposterior and lateral standing in neutral position) are obtained at day 1, day 90, and day 180 postoperatively. Disc height and Cobb's angle are measured and compared to the preoperative values.

2.6. Complications. In general, materials are well tolerated. The rate of complications is between 1% and 10% in all series. Two sets of complications exist: the early and the delayed.

Early complications include device dislocation/malposition, spinous process fractures, erosion of the spinous process, infection, hematoma, and neurological sequelae.

One case of migration was observed in one series [4]. There were no broken or permanently deformed implants in all series.

In our series, no cases of fracture of the superior spinous process occurred. In our experience, we do osteodensitometry for all patients to assess bone density preoperatively. During operation, we avoid bone erosions of the adjacent spinous processes.

We had one case of recurrent neurological symptoms, and ISD was removed. Microsurgical decompression and posterolateral fusion were done. To avoid this type of complications, a complete posterior decompression through ligamentum flavum excision and discectomy in the presence of herniated disc should be done.

Selection of patients without spondylolysthesis is mandatory to avoid posterolateral fusion later on. And in the presence of spondylotic segment, rigid fusion with insertion of ISD at the superior adjacent level protects from recurrence of neurological symptoms as well as from later adjacent segment disease.

2.7. Statistical Analysis. The clinical and radiologic results were analyzed using t-test; a P value of less than 0.05 is considered statistically significant. All analyses were carried out using SPSS Ver. 16.00 (IL, Chicago, Inc.).

3. Results

3.1. Pain Assessment. Overall improvement was noted in ISD-treated patients, with considerable satisfaction in 89% of patients on average.

The patients at first reported an improvement of their radicular pain with a mean reduction of 3.4/10 on visual analog scale (VAS) (scale for 0: absent pain to 10: severe intolerable pain necessitating intravenous treatment).

In the preoperative period, radicular pain had a mean score of 8.6/10 on VAS (5–10). Whereas in the immediate post-op period, the pain mean score was 4.3/10 on VAS (1–7).

Patients achieved maximum improvement after an average period of 6 months, with a mean score of 1.8/10 on VAS (0–5), and up to 83% of patients were pain free (Figure 4).

3.2. Disability Assessment. The Oswestry low back disability questionnaire score (ODI) improved from a mean of 68.1% in the pre-op period (23%–91%) to 17.8% at 3 months (0%–52%) and <10% at a 6-month followup ($P < 0.05$) (Figure 5).

3.3. Disc Height. The preoperative disc height was measured by MRI, with a mean of 1.2 cm (0.4–1.6 cm) and intervertebral space on lateral X-ray view measured manually had a mean of 1.3 cm (0.7–1.6 cm). Whereas, in post-op evaluation only spine X-ray was done (due to the elevated cost of MRI) and the mean measured intervertebral space was 1.75 cm (1.2–2.4 cm).

Radiologic changes, on lateral views in neutral position in lumbosacral spine X-ray, in the disk height of the stabilized segment, were increased significantly from preoperative to immediate postoperative evaluation ($P < 0.05$). This increase persisted at 3-month followup ($P < 0.05$) (Figure 6).

3.4. Segmental Lordotic Angles. The range of motion measured by the segmental lordotic angle in stabilized segment decreased postoperatively ($3.78 \pm 3.1^{\circ}$) compared to the preoperative measured values ($5.26 \pm 3.68^{\circ}$). This change was not statistically significant ($P = 0.4$).

Although adjacent segment ROM showed a decrease on post-op X-ray, there was no statistical significance (Figure 6).

3.5. Operative Characteristics. The prominent characteristic of this surgery is a low level of postoperative pain. And so, the decompression is done by removal of ligamentum flavum and the reestablishment of the dynamics of the spine plays a

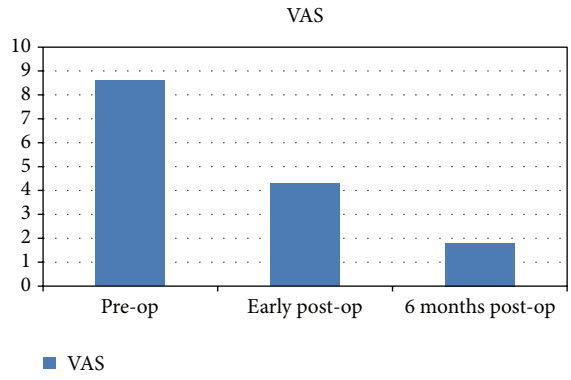


Figure 4: Comparative chart of mean VAS from preoperative period, early postoperative, and at 6-month follow up.

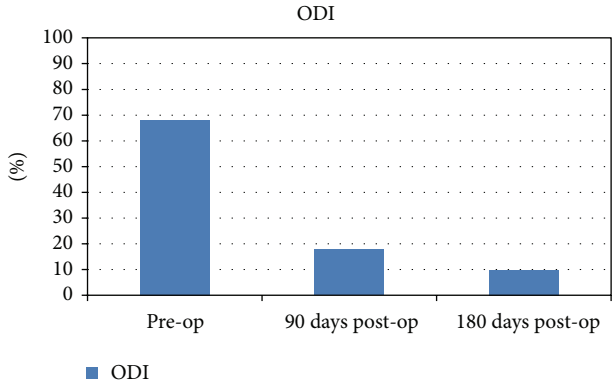


Figure 5: Oswestry low back disability score comparing pre-op evaluation to 3 months and 6 months post-op evaluation.

major role in the resolution of back pain. Restoration of the height of the intervertebral disc relieves the pressure on the sinuvertebral nerve which plays a major role in decreasing paraspinal muscles spasm despite the back pain.

In addition, the amount of blood loss with ISD procedure (49.2 cc ± 24.8) compared to rigid stabilization (184.3 cc ± 67.8) was found to be reduced ($P < 0.005$).

4. Discussion

Rigid spinal fusion is a mandatory procedure for the management of lumbar instability although it could be associated with different types of complications such as device failure, osteoporosis, and spinal deformity by changing the spinal mechanical activities, leading to adjacent segment disease [9]. The fusion technique shifts the center of rotation of vertebral body over the disc leading to an increase in the stress on the facets and/or disc of the adjacent mobile segment. The increase of stress induces several changes in the mobility of the adjacent segment and elevation of intradiscal pressure [10]. And so, it can lead to disc degeneration which precedes the facet degeneration [11].

Some authors do not agree with the theory of adjacent segment degeneration and in a prospective study conducted

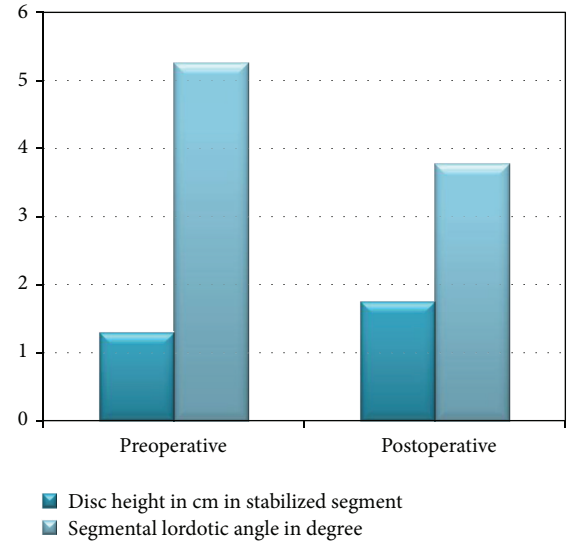


Figure 6: Comparative chart between preoperative and postoperative radiological changes.

in Spain, disc degeneration post lumbar fusion appeared homogeneously at several levels cephalad to fusion and seemed to be determined more by individual characteristics than by fusion itself [12].

In our experience, after a long followup period, we have remarked that adjacent segment disease is a serious problem that causes refractory pain to medical treatment, which necessitated long segment fusion which leads to limitation of back motion and spinal deformities [13]. In addition, the refractory pain to medical treatment has high cost both on individual and national levels.

To avoid these adverse effects, the achievement of ideal mobility is important. Thus, dynamic stabilization devices would appear to represent a notable technological advantage.

Posterior dynamic stabilization is done to decrease and/or avoid the harmful effects of rigid fusion, like listhesis, instability, hypertrophic facet joint arthritis, herniated nucleus pulposus, and stenosis.

Several studies comparing interspinal distractor or dynamic pedicular system to posterior lumbar interbody fusion (PLIF) were conducted and showed promising results [14, 15]. We did not try dynamic pedicular system since we had satisfactory results with the interspinous spacer.

The interspinous dynamic stabilization system, with preservation of the disc and facet, creates a favorable environment in the motion segment by reducing the loading on these joints and allowing more normal motion.

The clinical outcomes of patients in our study improved significantly during the follow-up period, not only at 3 and 6 months, but also in the early post-op period.

The system increased the distraction posteriorly and improved the anterior disc space height and articular process pressure which decreased the stenosis, liberated the nerve roots and the foramina [14], and reduced neural pain transmission via the dorsal root ganglia despite decreased overall painful stimuli and transmission [16].

The followup with serial X-rays showed no evidence of osteophytes at articular facets level as noted in rigid fixation. We conclude that ISD not only decreases the load on the facets, but also impairs osteophytes formation. Decreasing the load in addition to the impairment of osteophytes formation is an additional proof that posterior dynamic stabilization is an effective method to treat and to prevent adjacent segment disease. It also shows that this type of fusion not only preserves normal motion, but it prevents further degenerative process by maintaining patient's own lumbar kinematics and reducing instability.

In late postoperative X-ray followup of the patients examined, a mineralization of the spinous process in contact with the implant was found, in particular at its base which appears to absorb high stresses due to lordosis, and this finding was described 10 years ago [17].

Our results concerning disc height and segmental lordotic angles correlate with other studies done in China and Turkey [15, 18]. This means that the ISD is useful regardless of ethnic origin.

Rigid stabilization was found to decrease fiber strain of the intervertebral disc and transfer the load to the rod, changing all the biomechanics of the spinal cord; whereas ISD keeps the natural fiber strain in a physiological manner which was proved by the pre- and postoperative disc height [16].

The ISD system slightly limits the bulging of the disc at the lateral and posterolateral site. This could be due to the decompression effect at the posterior elements by the implant [19]. Compared to rigid stabilization surgery, ISD insertion is associated with less blood loss and shorter surgical time and hospital stay. These criteria have a high impact on postoperative pain, recovery period, and the overall quality of life [20].

5. Conclusion

Interspinous spacer insertion after excision of ligamentum flavum showed excellent results in terms of pain control, motion preservation, and prevention of adjacent segment degeneration in previously stabilized lumbar spine segments. It provides restoration of disc height, reduction of vertebral slip and leads to physiological condition concerning disc bulging. We highly recommend its use in treatment as well as in prevention of adjacent segment disease specifically in young patients where spinal fusion for early degenerative disease is needed.

References

[1] C. S. Chen, C. K. Cheng, C. L. Liu, and W. H. Lo, "Stress analysis of the disc adjacent to interbody fusion in lumbar spine," *Medical Engineering and Physics*, vol. 23, no. 7, pp. 483–491, 2001.

[2] M. Kanayama, T. Hashimoto, K. Shigenobu et al., "Adjacent-segment morbidity after Graf ligamentoplasty compared with posterolateral lumbar fusion," *Journal of Neurosurgery*, vol. 95, no. 1, pp. 5–10, 2001.

[3] S. D. Christie, J. K. Song, and R. G. Fessler, "Dynamic interspinous process technology," *Spine*, vol. 30, no. 16, pp. S73–S78, 2005.

[4] D. Adelt, J. Samani, W.-K. Kim et al., "Coflex Interspinous Stabilisation: clinical and Radiographic results from an international multicenter retrospective study," *Paradigm Spine Journal*, no. 1, pp. 1–4, 2007.

[5] D. L. Kaech, C. Fernandez, and P. Haninec, "Preliminary experience with the interspinous U device," *Rachis*, vol. 13, pp. 303–304, 2001.

[6] D. L. Kaech, C. Fernandez, D. Lombardi-Weber et al., "The interspinous U: a new restabilization device for the lumbar spine," *Spinal Restabilization Procedures*, vol. 30, pp. 355–362, 2000.

[7] D. L. Kaech and J. R. Jinkins, "The interspinous "U": a new restabilization device for the lumbar spine Spinal Restabilization Procedures," *Elsevier Science B.V.*, pp. 355–362, 2002.

[8] C. Bowers, A. Amini, A. T. Dailey, and M. H. Schmidt, "Dynamic interspinous process stabilization: review of complications associated with the X-Stop device," *Neurosurgical Focus*, vol. 28, no. 6, p. E8, 2010.

[9] D. K. Resnick, T. F. Choudhri, A. T. Dailey et al., "Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 5: correlation between radiographic and functional outcome," *Journal of Neurosurgery. Spine*, vol. 2, no. 6, pp. 658–661, 2005.

[10] M. N. Kumar, A. Baklanov, and D. Chopin, "Correlation between sagittal plane changes and adjacent segment degeneration following lumbar spine fusion," *European Spine Journal*, vol. 10, no. 4, pp. 314–319, 2001.

[11] J. S. Mehta, S. Kochhar, and I. J. Harding, "A slip above a slip: retrolisthesis of the motion segment above a spondylolytic spondylolysthesis," *European Spine Journal*, vol. 21, no. 11, pp. 2128–2133, 2012.

[12] F. Pellisé, A. Hernández, X. Vidal, J. Minguell, C. Martínez, and C. Villanueva, "Radiologic assessment of all unfused lumbar segments 7.5 years after instrumented posterior spinal fusion," *Spine*, vol. 32, no. 5, pp. 574–579, 2007.

[13] A. Nachanakian, A. El Helou, and M. Alaywan, *Posterior Dynamic Stabilization: The Interspinous spacer, Low Back Pain Pathogenesis and Treatment*, Edited by Y. Sakai, InTech, 2012.

[14] S.-W. Yu, C.-Y. Yen, C.-H. Wu, F.-C. Kao, Y.-H. Kao, and Y.-K. Tu, "Radiographic and clinical results of posterior dynamic stabilization for the treatment of multisegment degenerative disc disease with a minimum follow-up of 3 years," *Archives of Orthopaedic and Trauma Surgery*, vol. 132, pp. 583–589, 2012.

[15] T. Cansever, E. Civelek, S. Kabatas, C. Yılmaz, H. Caner, and M. N. Altinörs, "Dysfunctional segmental motion treated with dynamic stabilization in the lumbar spine," *World Neurosurgery*, vol. 75, no. 5-6, pp. 743–749, 2011.

[16] F. Heuer, H. Schmidt, W. Käfer, N. Graf, and H.-J. Wilke, "Posterior motion preserving implants evaluated by means of intervertebral disc bulging and annular fiber strains," *Clinical Biomechanics*, vol. 27, pp. 218–225, 2012.

[17] K. E. Swanson, D. P. Lindsey, K. Y. Hsu, J. F. Zucherman, and S. A. Yerby, "The effects of an interspinous implant on intervertebral disc pressures," *Spine*, vol. 28, no. 1, pp. 26–32, 2003.

[18] Y. H. Jia and P. F. Sun, "Preliminary evaluation of posterior dynamic lumbar stabilization in lumbar degenerative disease in Chinese patients," *Chinese Medical Journal*, vol. 125, no. 2, pp. 253–256, 2012.

[19] W. Schmoelz, S. Erhart, S. Unger, and C. Alexander, "Disch: biomechanical evaluation of a posterior non-fusion instrumentation of the lumbar spine," *European Spine Journal*, vol. 21, pp. 939–945, 2012.

[20] B. Cakir, B. Ulmar, H. Koepp, K. Huch, W. Puhl, and M. Richter, "Posterior dynamic stabiliziation as on alternative for instrumented fusion in the treatment of degenerative lumbar instability with spinal stenosis," *Zeitschrift fur Orthopadie und Ihre Grenzgebiete*, vol. 141, no. 4, pp. 418–424, 2003.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 270565, 6 pages
http://dx.doi.org/10.1155/2013/270565

Clinical Study

A Novel Approach to the Surgical Treatment of Lumbar Disc Herniations: Indications of Simple Discectomy and Posterior Transpedicular Dynamic Stabilization Based on Carragee Classification

A. F. Ozer,[1] F. Keskin,[2] T. Oktenoglu,[3] T. Suzer,[3] Y. Ataker,[4] C. Gomleksiz,[5] and M. Sasani[3]

[1] *Neurosurgery Department, Koç University School of Medicine, Rumelifeneri Yolu Sarıyer, 34450 Istanbul, Turkey*
[2] *Neurosurgery Department, Necmettin Erbakan University Meram Medical Faculty Hospital, 42080 Konya, Turkey*
[3] *Neurosurgery Department, American Hospital, 34365 Istanbul, Turkey*
[4] *Physical Therapy and Rehabilitation Department, American Hospital, 34365 Istanbul, Turkey*
[5] *Neurosurgery Department, Mengücek Gazi Training and Research Hospital, School of Medicine, Erzincan University, 24100 Erzincan, Turkey*

Correspondence should be addressed to A. F. Ozer; alifahirozer@gmail.com

Received 30 January 2013; Accepted 7 March 2013

Academic Editor: Deniz Erbulut

Surgery of lumbar disc herniation is still a problem since Mixter and Barr. Main trouble is dissatisfaction after the operation. Today there is a debate on surgical or conservative treatment despite spending great effort to provide patients with satisfaction. The main problem is segmental instability, and the minimally invasive approach via microscope or endoscope is not necessarily appropriate solution for all cases. Microsurgery or endoscopy would be appropriate for the treatment of Carragee type I and type III herniations. On the other hand in Carragee type II and type IV herniations that are prone to develop recurrent disc herniation and segmental instability, the minimal invasive techniques might be insufficient to achieve satisfactory results. The posterior transpedicular dynamic stabilization method might be a good solution to prevent or diminish the recurrent disc herniation and development of segmental instability. In this study we present our experience in the surgical treatment of disc herniations.

1. Introduction

The surgical treatment of lumbar disc herniation is performed when the conservative treatment is recalcitrant and only ten percent of all lumbar disc herniations cases are candidates to surgery [1]. The main problem with the surgery is that the lumbar pain of the patients does not necessarily relieved following surgery and even they might become worse. For this reason, there are serious anxiety and suspicion against the surgical treatment of lumbar disc herniations. This phenomenon is also valid for some spine surgeons who will perform the operation. Even on their own series of Mixter and Barr, who first performed the discectomy of lumbar disc herniations, the success and failure rates compete head to head [2]. Later Caspar and Yasargil introduced the microscope into the disc surgery and allowed minimal anatomic damage; however, no significant rise was achieved in satisfactory results [3, 4].

Carragee et al. revealed that the occurrence of disc herniation, the type of surgery, and the rates of reherniation are in a close relation with the defect on posterior annulus [5]. Lumbar disc herniation is not a separate illness but a part of a degenerative process, so the treatment should be designed in this manner. It is known that if the defect on the annulus is small, annulus has capacity to repair itself after fragmentectomy with both operative techniques: endoscopy and microdiscectomy. On the other hand, if the defect is large, problem arises at that time [6, 7].

In this paper, we discussed our results in the light of literature. We evaluated the role of load sharing principle with

application of posterior transpedicular dynamic stabilization (PTDS) in lumbar disc herniation cases with large annulus defect, instead of performing radical discectomy.

2. Materials and Methods

This is a prospective study held between 2008 and 2012. Totally 98 patients were included in the study who did not respond to conservative treatment and minimal invasive pain procedure that was applied at a minimum of 6 weeks. Conservative treatment includes back exercises program and medicine. Epidural steroid injection and anauloplasty with laser were also performed for some of these cases as a minimal invasive pain procedure. Five surgeons performed the operations. The patients included for the study met the following inclusion criteria: (1) the findings of neurologic examination concordant with the patient's sciatica, (2) one level lumbar disc herniation determined with MR, (3) the surgical procedure applied electively, and (4) not having a spine operation before. Additionally, the patients with infection, instability, scoliosis, and malignancy are excluded from the study. The type of the operation to be applied was told to all the patients and the consent of patients was taken. Before the operation, magnetic resonance imaging was done to all cases and the deformation of annulus was evaluated with MR study and under the surgical microscope in operation. Patients were divided into four groups according to the classification of Carragee et al. [5] with a slight modification. In regard to achieving low recurrence notes, we accepted annulus defect as 4 mm difference from Carragee:

(i) Type I: there is no significant defect on annulus (Figure 1),

(ii) Type II: annular defect > 4 mm (Figure 2),

(iii) Type III: annular defect < 4 mm (Figure 3),

(iv) Type IV: massive-large annular defect (Figure 4).

The mean age of the patients was 48.19 (between 16 and 80). We determined the type of surgical intervention in reference to CS based on intraoperative observation and MR study. Clinic results were evaluated with visual analog scale (VAS) and Oswestry Disability Index (ODI) in the 3rd, 12th, and 24th months after the surgery. All patients who developed severe low back pain and/or recurrence sciatica were evaluated with MR for recurrence of disc herniation.

2.1. Surgical Technique. The surgical interventions were applied by five surgeons using standard microsurgical techniques at the same hospital. Before the surgical intervention, a single prophylactic antibiotic was given. According to the classification of modified Carragee, only fragmentectomy was applied to the cases of Type I herniation and discectomy was not applied in the course of the operation since annular tear was not observed under the surgical microscope. Limited discectomy was applied to the patients in the other groups. While discectomy was performed through the interlaminar gap in most of the patients, discectomy was applied to some patients following laminotomy with use of high speed drill. In the course of the operation the types of disc herniation were defined with regard to MCC.

In the cases with MC Type II herniation, fragmentectomy (annular tear > 4 mm), limited discectomy with excision of degenerate nucleus pulposus, and annulus repair were performed. Annulus repair is carried out with bipolar cauterization of damaged outer layers of annulus fibrosus under the surgical microscope. PTDS was applied under C-arm scopy through paravertebral muscles as per Wiltse method, Cosmic (Ulrich GmbH & Co. KG, Ulm, Germany) and Safinaz (Medikon, Ankara, Turkey) screw and rods used for PTDS. In the cases with MC Type III herniations, limited discectomy (annular tear < 4 mm) with excision of degenerate nucleus pulposus and annulus repair were performed and PTDS was applied. In the cases with MC Type IV herniations, limited discectomy (massive annular tear) with excision of degenerate nucleus pulposus and annulus repair were performed. Then PTDS was applied.

In the course of operation, annular structure and the size of the annular defect were evaluated by at least two surgeons.

3. Results

Totally 13 out of 98 patients, operated with fragmentectomy, limited discectomy applied to 20 patients, and limited discectomy and PTDS were applied to 65 patients. The frequent type of herniation observed in our study was MCC Type II (47.8%) and the frequency of Type I, Type III, and Type IV was 18.3%, 26.5%, and 7.4%, respectively. Intraoperative complication was not observed. In the course of followup, for patients with Type II herniation, one patient developed a screw break and in one patient we observed screw loosening. It was noticed that these two patients were morbid obese. In the postoperative 8th and 12th month, the instrumentation systems were revised. In Type IV group, in one patient screw break was observed following a severe trauma. The instrumentation system of this patient was revised in 16th postoperative month. Finally a recurrence disc herniation was observed in a patient whose body structure was above the normal standards according to her age. In two patients with Type II and one patient with Type IV, adjacent segment degeneration was monitored. On the other hand, these patients did not complain clinically; therefore an extra surgical intervention was not considered. The follow-up period of cases with Type I group, reherniation, and recurrence herniation were not recorded. In two patients with Type II group reherniation, I in two cases with Type III group reherniation, and in one case with Type IV group, and reherniation as recorded.

4. Discussion

Even though it is thought that lumbar disc herniation is a separate disease; in fact, the degenerative change of the vertebrae is a part of the process. Following disc degeneration and before the loss of total disc integrity, the disc becomes clinically problematic due to improvement of painful black

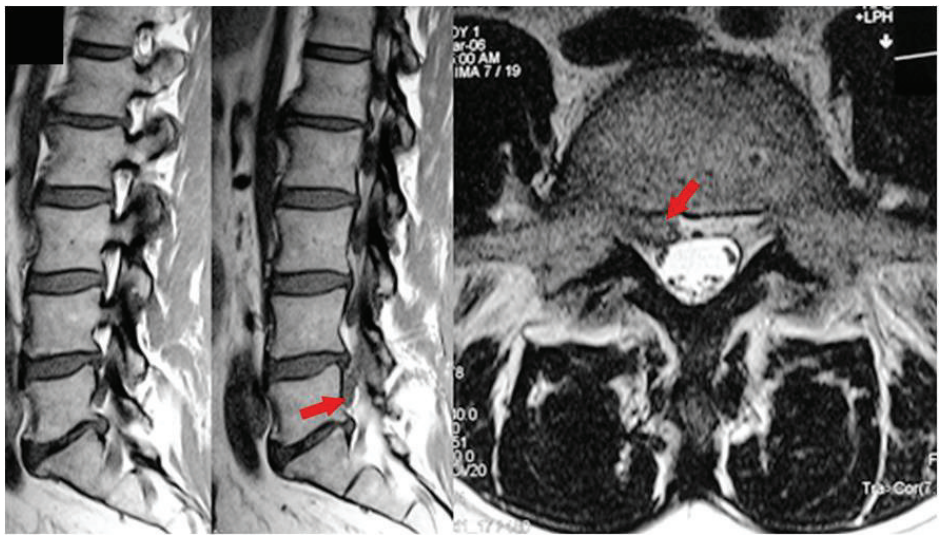


Figure 1: A small extruded fragment was observed under the nerve root. Notice that there is no apparent annulus defect (Carragee Type I).

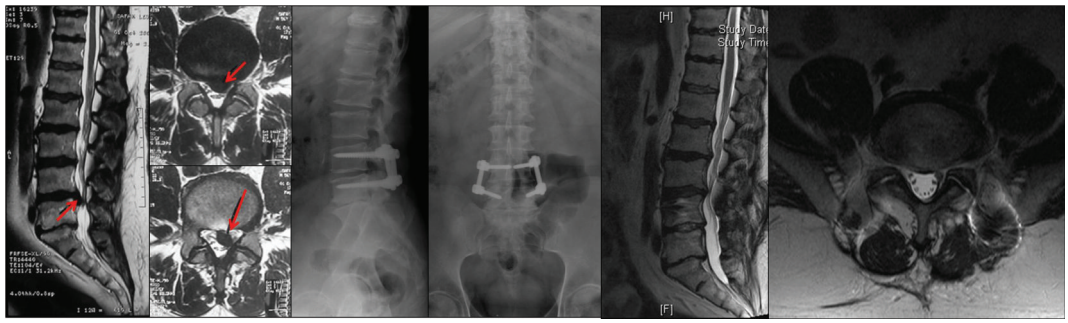


Figure 2: A large extruded fragment and noncontained disc herniation compress right S1 nerve root and cauda equina. Integrity of annulus fibrosus completely destroyed (Carragee Type II). The patient was operated on due to severe neurologic deficit and PTDS was applied to the patient after L5-S1 microdiscectomy and annular repair.

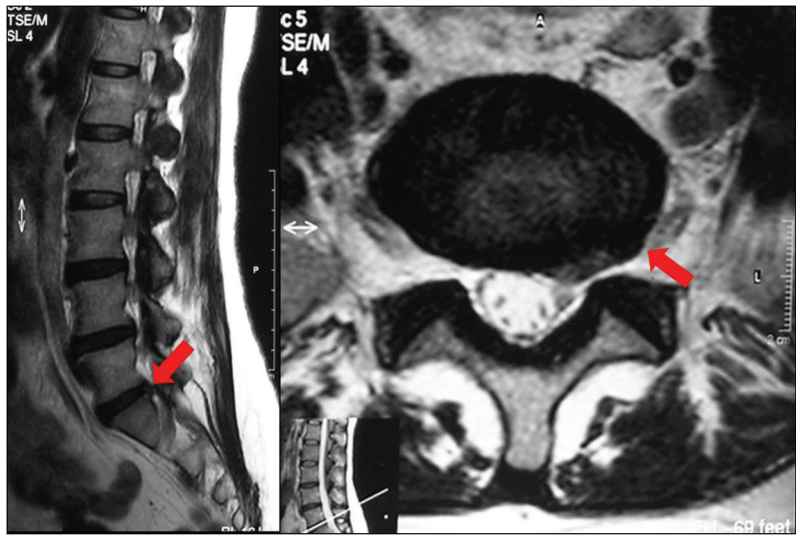


Figure 3: A small annulus defect (<4 mm) was observed at the left side just under the S1 nerve root. Integrity of the annulus fibrosus is preserved (Carragee Type III).

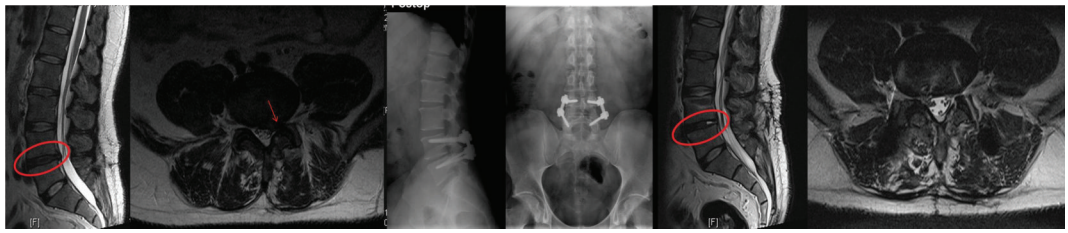


Figure 4: A large annulus defect (>4 mm) was observed at the midline of posterior annulus fibrosus. Integrity of annulus is preserved (Carragee Type IV). The patient is unresponsive to the conservative treatment and PTDS was applied to the patient after L5-S1 microdiscectomy and annular repair.

disc, degenerative spondylolisthesis, or lumbar disc herniation pathologies. That is why its treatment should be with the concepts by which we approach the degenerative process.

Since the beginning of the surgery for the treatment of lumbar disc herniation, the basic aim has been to increase the rate of success of the surgical treatment. Because while in some patients even there was no recurrence or residue herniation radiologically, there is still low back and/or radicular pain and in the other group who had very successful operation, they might have several recurrences on the same level and the same side. It has been thought that the results of the surgery implemented with little anatomic damage by using surgical microscope will affect in a positive way, and some reports supported this method [3, 4]. But the issues occurring after that period. However the later reports showed that the result did not change much in reference to the classic surgery [8, 9]. For a long time period, it is believed that fibrosis is sufical area which is somewhat more in some patients due to an unknown reason, and it is thought that the surgical success would increase if the improvement of fibrosis is prevented and made a big bid for this subject; yet, in the meantime the segmental instability was missed out [10–12]. Following the symptomatic lumbar disc herniation surgery at the height loss on disc space, the relaxation on the facet joint capsule, and ligamentous structures were well-known alternations. After the surgery, the load on the facet joints increases and it may lead to segmental instability [13–15]. For this reason, segmental instability and chronic lumbar pain which improve after the lumbar discectomy cause this type of treatment to which has been used for long years, become disputable [16]. Only the removal of nucleus pulposus is not suitable to stop the segmental degeneration related to the rotational and translational motions [17–19]. Therefore one of the important reasons of the failure of lumbar surgery is segmental instability. Yorimitsu has been following his patients for more than ten years after the disc surgery and concluded that the frequency of the chronic lumbar pain was more in proportion to reherniation based on the height loss on disc space [16].

Segmental instability has been shown with the radiological and clinical findings. These findings may not always support each other [20, 21]. The association of lumbar disc herniation and segmental instability is declared to be 20% in the literature [22]. Kotilainen determined that 22% of the patients developed segmental instability following one level microlumbar discectomy studies and concluded that 29% of them had chronic lumbar pain [23]. Frymoyer signified that on wide based L4-5 disc hernias, there was severe lumbar pain and it is related to degenerative instability [22].

In the surgical treatment of lumbar disc herniation, it is very obvious that disc tried to be taken out; that is to say, radical discectomy does not solve the problem. Although it was realized, disc should not be completely removed. The more the existing disc structure is kept, the better the patient will become after the operation. That is to say, the theory of being respectful of the integrity became the main topic of the conversation with Spengeler who defined limited discectomy in 1990. This concept was improved more, and it is suggested by Williams that the fragment only should be removed and the integrity of the disc should be protected [24, 25].

Williams reported successful clinic results with minimal disc tissue taken out from the disc while they documented 4–9% recurrence rate and 90% clinic success rate [25, 26].

Afterwards, in the literature the discussions began if fragmentectomy or discectomy would be better. Wera et al. compared subtotal discectomy and sequestrectomy in the cases of herniation in Type II. They found that while in the events made with subtotal discectomy, reoperation rate was 3.4%, in the events made only fragmentectomy reoperation rate was 21.2%. Consequently, they informed that in the herniation events in Type II, subtotal discectomy would be more suitable [6]. Rogers compared massive discectomy with fragmentectomy in the disc herniations which are ruptured and reported that in the events of fragmentectomy the recurrence rate was 21% which is in a high rate [27]. Mochida et al. compared the clinical and radiological results of the patients who were operated on by percutaneous nucleotomy and standard discectomy. They documented that in the younger people below 40, surgery performed by protected nucleus pulposus, there were better radiological and clinic results [28]. Thomé et al. stated that recurrence rate is higher by microdiscectomy compared to sequestrectomy [13]. Barth et al. compared the two year rates of reherniation with microdiscectomy and microscopic sequestrectomy. They observed 10.5% reherniation rate in the microdiscectomy group and 12.5% in the events of fragmentectomy and concluded that there was no significant difference between these two groups [29]. However even the results of the patients who had fragmentectomy are better;

due to high recurrence rates, some surgeons did not give up performing subtotal discectomy [6, 7].

It is Carragee who emphasized that in the treatment of the lumbar disc herniation, the success is related to the defect on the posterior annulus. Carragee et al. reported in their study that for the patients of Type I group (who had small annular defect with fragment), only fragmentectomy was applied. The rate of reherniation and reoperation was 1%. In the group of Type II (fragment defect), the rate of recurrence sciatica was 27.3%, reoperation rate was high like 21.2%. In the group of Type III (fragment-contained), the rate of recurrence was 11.9% and the reoperation rate was 4.8%. In the group of Type IV (non-fragment-contained), reherniation rate was 37.5% and the rate of reoperation was 6.3%. Only fragmentectomy was applied to Type I group; the other groups were operated on by limited discectomy. Although the clinic results in Type I group were satisfactory, for the other groups, it was observed that the rates of reherniation and reoperation were rather high [5].

Therefore, the persistent pain after the operation and the recurrence is related to segmental instability and directly proportional to the integrity of defect in the posterior annulus. In this study, we applied limited discectomy or fragmentectomy to support posterior tension band; appropriate cases are required in respect to the integrity of disc material. We supported the spine with PTDS. The system shares the load applied on to spine thus decreases the load on the anterior column and this might allow disc to repair itself. Despite the fact that for the patients in Type I and Type III, our approach is the same with Carragee, for patients in Type II and Type IV, we used PTDS in addition to decompression. As a result of this, we achieved better VAS and Oswestry results compared to Carragee and Wera. The rates of recurrence for Type II is 5% and in Type IV is 4%. When we review the patients with recurrence, it was determined that one of them had a trauma in earlier time after the operation and the rest of them were those whose height and weight standards were really high according to the standards of society.

Practically if we exclude the patients who are overweight and had trauma, the rate of recurrence will be lower. It is a necessity that for the overweight people in reference to standards, dynamic systems should be designed restoratively.

In conclusion, the concept of the stabilisation of the spine in motion has been developed lately.

There are still many dark spots such as how much it keeps the motion, long term clinic results are unknown; the effect of it on the adjacent segments are unknown. On the other hand, it has an undeniable reality in its clinical success. Dynamic system technology is open to improvement and it is very certain that we will see the breakthroughs. By time, the dynamic screws, dynamic rods, and even those screws will have the flexibility of their body in the course of adaptation to the bone, will be developed. The rigid systems will leave their places to the systems which will be close to the structure of ligaments. Thus, the use of dynamic systems in the treatment of the cases with Type II and Type IV disc herniations would not be an overtreated approach but it is a step directed to the protection of the disc space following discectomy in more physiological conditionsç.

References

[1] S. S. Hu, "Lumbar disc herniation section of disorders, diseases, and injuries of the spine," in *Current Diagnosis and Treatment in Orthopedics*, H. B. Skinner, Ed., pp. 246–249, McGraw-Hill, New York, NY, USA, 4th edition, 2006.

[2] W. J. Mixter and J. S. Barr, "Rupture of intervertebral disc with involvement of spinal canal," *New England Journal of Medicine*, vol. 211, pp. 210–215, 1934.

[3] W. Caspar, "A new surgical procedure for lumbar disc herniation causing less tissue damage through a microsurgical approach," *Lumbar Disc Adult Hydrocephalus*, vol. 4, pp. 74–80, 1977.

[4] M. G. Yasargil, "Microsurgical operation of herniated lumbar disc," *Advances in Neurosurgery*, vol. 4, p. 81, 1977.

[5] E. J. Carragee, M. Y. Han, P. W. Suen, and D. Kim, "Clinical outcomes after lumbar discectomy for sciatica: the effects of fragment type and anular competence," *Journal of Bone and Joint Surgery A*, vol. 85, no. 1, pp. 102–108, 2003.

[6] G. D. Wera, C. L. Dean, U. M. Ahn et al., "Reherniation and failure after lumbar discectomy: a comparison of fragment excision alone versus subtotal discectomy," *Journal of Spinal Disorders and Techniques*, vol. 21, no. 5, pp. 316–319, 2008.

[7] E. J. Carragee, A. O. Spinnickie, T. F. Alamin, and S. Paragioudakis, "A prospective controlled study of limited Versus subtotal posterior discectomy: short-term outcomes in patients with herniated lumbar intervertebral discs and large posterior anular defect," *Spine*, vol. 31, no. 6, pp. 653–657, 2006.

[8] Y. Katayama, Y. Matsuyama, H. Yoshihara et al., "Comparison of surgical outcomes between macro discectomy and micro discectomy for lumbar disc herniation: a prospective randomized study with surgery performed by the same spine surgeon," *Journal of Spinal Disorders and Techniques*, vol. 19, no. 5, pp. 344–347, 2006.

[9] K. Türeyen, "One-level one-sided lumbar disc surgery with and without microscopic assistance: 1-year outcome in 114 consecutive patients," *Journal of neurosurgery*, vol. 99, no. 3, pp. 247–250, 2003.

[10] A. F. Ozer, T. Oktenoglu, M. Sasani et al., "Preserving the ligamentum flavum in lumbar discectomy: a new technique that prevents scar tissue formation in the first 6 months postsurgery," *Neurosurgery*, vol. 59, supplement 1, pp. S126–S133, 2006.

[11] J. Brotchi, B. Pirotte, O. De Witte, and M. Levivier, "Prevention of epidural fibrosis in a prospective series of 100 primary lumbosacral discectomy patients: follow-up and assessment at reoperation," *Neurological Research*, vol. 21, supplement 1, pp. S47–S50, 1999.

[12] R. N. Alkalay, D. H. Kim, D. W. Urry, J. Xu, T. M. Parker, and P. A. Glazer, "Prevention of postlaminectomy epidural fibrosis using bioelastic materials," *Spine*, vol. 28, no. 15, pp. 1659–1665, 2003.

[13] C. Thomé, M. Barth, J. Scharf, and P. Schmiedek, "Outcome after lumbar sequestrectomy compared with microdiscectomy: a prospective randomized study," *Journal of Neurosurgery*, vol. 2, no. 3, pp. 271–278, 2005.

[14] C. Cinotti and F. Postacchini, "Biomechanics," in *Lumbar Disc Herniation*, F. Postacchini, Ed., pp. 81–93, Springer-Verlag, Wien, Austria, 1999.

[15] M. Wenger, L. Mariani, A. Kalbarczyk, and U. Gröger, "Long-term outcome of 104 patients after lumbar sequestrectomy according to Williams," *Neurosurgery*, vol. 49, no. 2, pp. 329–335, 2001.

[16] E. Yorimitsu, K. Chiba, Y. Toyama, and K. Hirabayashi, "Long-term outcomes of standard discectomy for lumbar disc herniation: a follow-up study of more than 10 years," *Spine*, vol. 26, no. 6, pp. 652–657, 2001.

[17] A. Fujiwara, K. Tamai, M. Yamato et al., "The relationship between facet joint osteoarthritis and disc degeneration of the lumbar spine: an MRI study," *European Spine Journal*, vol. 8, no. 5, pp. 396–401, 1999.

[18] C. A. Niosi, Q. A. Zhu, D. C. Wilson, O. Keynan, D. R. Wilson, and T. R. Oxland, "Biomechanical characterization of the three-dimensional kinematic behaviour of the Dynesys dynamic stabilization system: an in vitro study," *European Spine Journal*, vol. 15, no. 6, pp. 913–922, 2006.

[19] A. Rohlmann, T. Zander, H. Schmidt, H. J. Wilke, and G. Bergmann, "Analysis of the influence of disc degeneration on the mechanical behaviour of a lumbar motion segment using the finite element method," *Journal of Biomechanics*, vol. 39, no. 13, pp. 2484–2490, 2006.

[20] J. W. Frymoyer, E. N. Hanley, and J. Howe, "A comparison of radiographic findings in fusion and nonfusion patients ten or more years following lumbar disc surgery," *Spine*, vol. 4, no. 5, pp. 435–440, 1979.

[21] S. Sano, S. Yokokura, Y. Nagata, and Seong Zeon Young, "Unstable lumbar spine without hypermobility in postlaminectomy cases: mechanism of symptoms and effect of spinal fusion with and without spinal instrumentation," *Spine*, vol. 15, no. 11, pp. 1190–1197, 1990.

[22] J. W. Frymoyer and D. K. Selby, "Segmental instability: rationale for treatment," *Spine*, vol. 10, no. 3, pp. 280–286, 1985.

[23] E. Kotilainen and S. Valtonen, "Clinical instability of the lumbar spine after microdiscectomy," *Acta Neurochirurgica*, vol. 125, no. 1–4, pp. 120–126, 1993.

[24] D. M. Spengler, E. A. Ouellette, M. Battie, and J. Zeh, "Elective discectomy for herniation of a lumbar disc. Additional experience with an objective method," *Journal of Bone and Joint Surgery A*, vol. 72, no. 2, pp. 230–237, 1990.

[25] R. W. Williams, "Microlumbar discectomy. A conservative surgical approach to the virgin herniated lumbar disc," *Spine*, vol. 3, no. 2, pp. 175–182, 1978.

[26] R. W. Williams, "Microlumbar discectomy. A 12-year statistical review," *Spine*, vol. 11, no. 8, pp. 851–852, 1986.

[27] L. A. Rogers, "Experience with limited versus extensive disc removal in patients undergoing microsurgical operations for ruptured lumbar discs," *Neurosurgery*, vol. 22, no. 1, pp. 82–85, 1988.

[28] J. Mochida, K. Nishimura, T. Nomura, E. Toh, and M. Chiba, "The importance of preserving disc structure in surgical approaches to lumbar disc herniation," *Spine*, vol. 21, no. 13, pp. 1556–1564, 1996.

[29] M. Barth, C. Weiss, and C. Thomé, "Two-year outcome after lumbar microdiscectomy versus microscopic sequestrectomy-part 1: evaluation of clinical outcome," *Spine*, vol. 33, no. 3, pp. 265–272, 2008.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 451956, 6 pages
http://dx.doi.org/10.1155/2013/451956

Review Article

Biomechanics of Posterior Dynamic Stabilization Systems

D. U. Erbulut,[1,2] I. Zafarparandeh,[2] A. F. Ozer,[1] and V. K. Goel[3]

[1] *Department of Neurosurgery, School of Medicine, Koc University, Rumelifeneri Yolu, 34450 Istanbul, Turkey*
[2] *Department of Mechanical Engineering, Colleges of Engineering, Koc University, Rumelifeneri Yolu, 34450 Istanbul, Turkey*
[3] *Departments of Bioengineering and Orthopaedic Surgery, Engineering Center for Orthopaedic Research Excellence (E-CORE), Colleges of Engineering and Medicine, University of Toledo, Toledo, OH 43606, USA*

Correspondence should be addressed to A. F. Ozer; alifahirozer@gmail.com

Received 30 November 2012; Accepted 21 February 2013

Academic Editor: Tunc Oktenoglu

Spinal rigid instrumentations have been used to fuse and stabilize spinal segments as a surgical treatment for various spinal disorders to date. This technology provides immediate stability after surgery until the natural fusion mass develops. At present, rigid fixation is the current gold standard in surgical treatment of chronic back pain spinal disorders. However, such systems have several drawbacks such as higher mechanical stress on the adjacent segment, leading to long-term degenerative changes and hypermobility that often necessitate additional fusion surgery. Dynamic stabilization systems have been suggested to address adjacent segment degeneration, which is considered to be a fusion-associated phenomenon. Dynamic stabilization systems are designed to preserve segmental stability, to keep the treated segment mobile, and to reduce or eliminate degenerative effects on adjacent segments. This paper aimed to describe the biomechanical aspect of dynamic stabilization systems as an alternative treatment to fusion for certain patients.

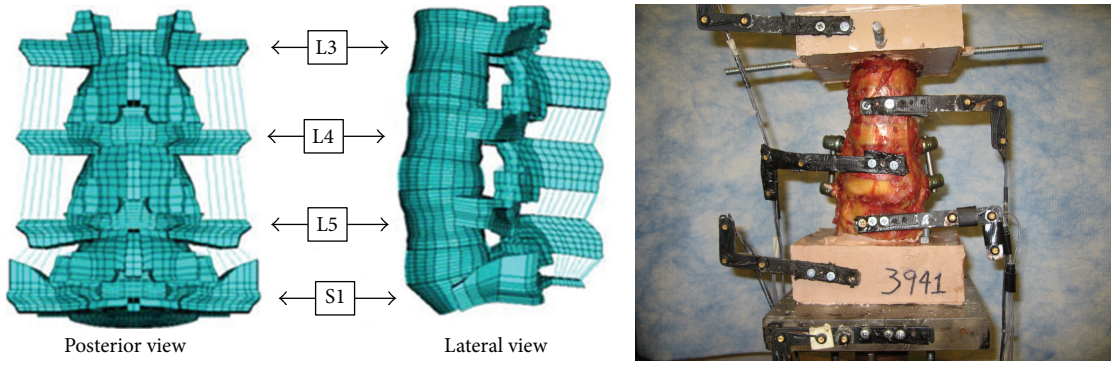
1. Introduction

Lower back pain is one of the major health problems around the world. One of the leading causes of lower back pain is considered to be degeneration of intervertebral disc. Disc herniation, spondylolisthesis, spondylosis, and spinal stenosis may follow intervertebral disc degeneration. Back pain occurs when posterior disc bulges out and impinges the nerve roots due to herniated disc. Another nerve root impingement may be seen in the condition of spinal stenosis, which is a reduction of the diameter of the spinal canal.

The treatment options of lower back pain may vary depending on the severity of the case. They include conservative treatment or surgical techniques. Conservative treatments include exercise, medications, physiotherapy, and rehabilitation. Surgical treatment is considered for the patients when the back pain limits their daily activities and when the condition does not respond to other therapies. Surgical methods include decompression with spinal fusion or nonfusion devices.

Spinal fusion supported by rigid instrumentation is widely used in the treatment of various spinal disorders. Since the procedure was first introduced by Albee and Hibbs in 1911, fusion has played an important role in the lumbar spine employed operations. The ideal result in performing fusion is to gain the necessary therapeutic goals with the minimal disruption of normal structure and function of the spinal column [1, 2]. However, usage of the rigid instrumentation results in a considerable amount of morbidity and of complications. Adjacent disc degeneration is reported by many investigators, known as one of the problems in fusion technique. Omitting the mobility causes the adjacent segments to be overloaded and as a result the number of interventions increases. Considering all these reasons, the search for alternative procedures with different concept was reinforced [3].

In recent years, posterior dynamic stabilization devices have been introduced as a trustworthy alternative to fusion and gained increasing popularity. The comparable advantages of these devices to fusion include retention and protection of the intervertebral disc, earlier surgical intervention, and minimally invasive techniques. Dynamic stabilization technique is aimed at preserving motion at the treated segment. It reduces the risk of accelerated degeneration at adjacent



(a) (b)

Figure 1: (a) FE model of the lumbar spine (E-CORE, University of Toledo), (b) the lumbar spine specimen with posterior dynamic stabilization system.

levels, which is a major concern in fusion because of the protective effects of continuing segmental motion [4, 5]. Although dynamic stabilization has gained a lot of attention by the investigators, designing a new spinal-implant system needs a cautious approach. The fusion implant needs to provide the stabilization until the fusion takes place; but for the dynamic stabilization systems, this role should be taken throughout lifetime [6]. So far, various posterior dynamic stabilization systems have been reported in the literature that can be mainly categorized as (1) pedicle screw-based systems and (2) posterior interspinous spacers. In this paper, biomechanical evaluation of posterior spinal implants was described, and biomechanical properties of several such devices were reviewed.

2. Biomechanical Evaluation of Dynamic Spinal Implants

Segmental biomechanics will be altered by the implantation. Therefore, it is crucial to evaluate biomechanical effects of implants on the treated and nontreated spinal segments before clinical trials. Biomechanical evaluation of posterior dynamic stabilization systems can be accomplished by *in vivo*, *in vitro*, and finite element analysis (FEA) studies. The change in decompression and stabilization parameters due to instrumentation with respect to intact case can be assessed using spine specimen. It is the so-called *in vitro* studies that include spine specimen from human or other species. *In vitro* studies should follow standard protocols [7] during the preparation of spine specimens and testing. Goel et al. [7] suggested that multispinal segment should be used in order to include one free functional spinal unit (FSU) on each side of the implanted segment. Desired loads are applied to the free end of the specimen, and motion data is recorded accordingly. There are two loading protocols known as displacement control and flexibility control loading. Load control protocol includes force loadings such as shear, pure moment, and complex loads.

FEA plays an important role in biomechanical evaluation of implants. It is helpful to determine the structural analysis of an implant, bone, and interaction in between the two. FE analysis gives full inside of load shearing, stresses, and strain of the interested construct under loading scenarios. It provides prospective outline of needed parameters for a desired spinal implant development. These parameters cannot be determined by *in vitro* experimental studies. However, finite element model needs to be validated by *in vitro* experimental study. Figure 1 depicts *in vitro* cadaver study and lumbar FE model.

3. Posterior Dynamic Stabilization Systems

3.1. Pedicle Screw-Based Stabilization Systems. The Dynesys (Dynamic Neutralization System for the Spine), known as a dynamic stabilization device, is one of the alternative solutions for the degenerative lumbar disc problems, Figure 2(a). It was implanted for the first time in 1994 by Dubois et al. [8] as a pedicle screw-based system. The intention for using the Dynesys as a flexible posterior spinal fixation system is to maintain intersegmental motions or reduce them to magnitudes found in the intact spine, reducing the negative effects on the adjacent segments. The Dynesys is a bilateral device and consists of titanium alloy pedicle screws and polycarbonate urethane (PCU) spacers that surround tensioned polyethylene terephthalate (PET) cords [9].

Schmoelz et al. [10] performed an *in vitro* study to evaluatethe the biomechanical effect of Dynesys on the magnitudes of stabilization at the treated segment. All the six spines were tested in four stages: the intact, with the defect of the middle segment, fixation with the Dynesys, and fixation with internal fixator. The cadavers were loaded with pure moments in three motion planes, that is, flexion-extension, lateral bending, and axial rotation. The results showed that for the bridged segment, the Dynesys was able to stabilize the spine. The study showed that Dynesys allowed more flexibility to the segment than the internal fixator. In another study with the same loading conditions, Schmoelz et al. [11] investigated the influence of the dynamic stabilization system (Dynesys) on the intervertebral disc which is bridged. It was observed that load bearing of the disc was slightly altered in the case of axial rotation. In flexion, both devices showed a good support of the anterior column by decreasing the intradiscal pressure but

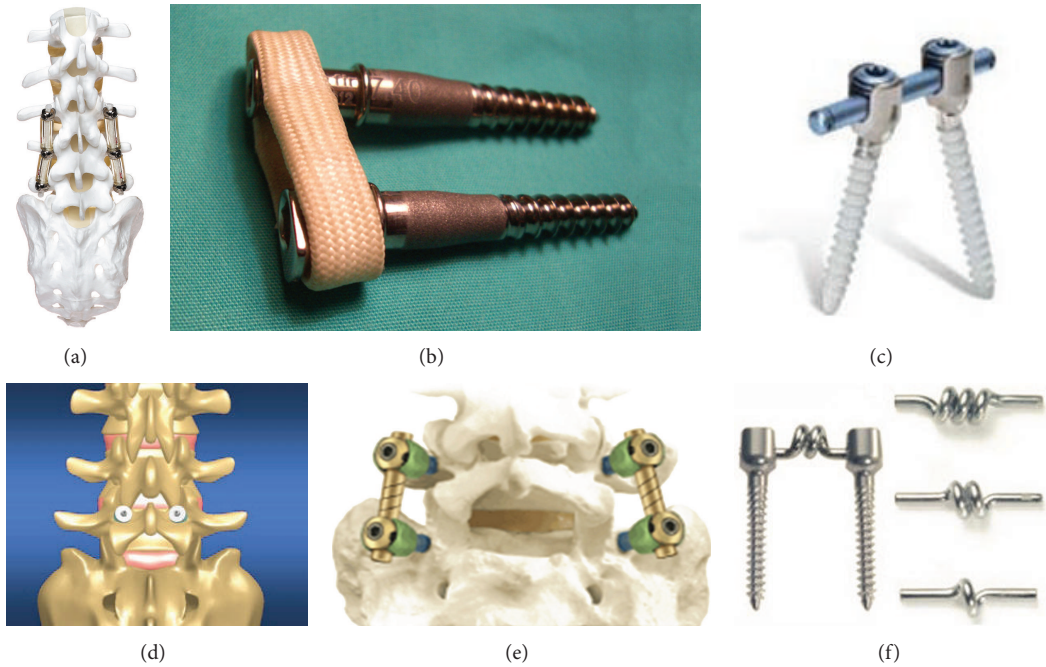


Figure 2: Posterior dynamic stabilization systems. (a) Dynesys; (b) Graf system; (c) PercuDyn; (d) Cosmic; (e) AccuFlex; (f) BioFlex.

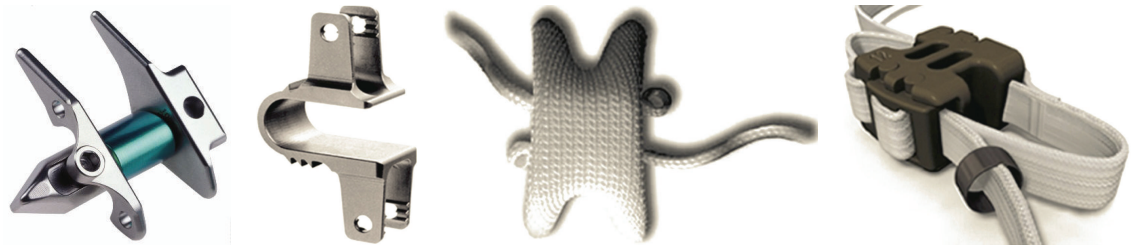
slightly below the intact level. Their results showed that the Dynesys did not show substantial differences in intradiscal pressure of the bridged disc compared to the internal fixator. Beastall et al. [12] investigated the biomechanical influence of the Dynesys on the lumbar spine. It was found that Dynesys significantly reduced motion at the bridged segment. However, implantation did not affect the range of motion at the adjacent segment.

Biomechanical investigations reported that some of the posterior dynamic stabilizations show similar effect on flexion, extension, and lateral bending, compared with rigid instrumentation due to dynamic implants with high stiffness [4, 9, 10, 13, 14]. Recent studies suggest that a dynamic implant with lower stiffness may be sufficient to stabilize the spinal segment [13, 15]. Dynamic implants with minimal stiffness of 45 N/mm axially and 30 N/mm bending are enough to reduce spinal flexibility by 30% of the intact range of motion, which is considered to be optimal motion reduction [13]. Another study demonstrated that the optimal axial stiffness value of the longitudinal rods should be approximately 50 N/mm for an effective pedicle screw-based dynamic implant [9]. For example, studies showed that Dynesys (Dynesys-Zimmer, Minneapolis, MN, USA) presents higher stiffness than initially expected [10, 14]. Posterior dynamic fixator with high stiffness does not allow enough mobility to the treated segment in order to have potential benefits as described previously. A dynamic rod with very low axial stiffness (<200 N/mm) did influence the segmental kinematics and allows more mobility [9].

Another alternative for the rigid spinal fusion is a soft or flexion stabilization technique introduced by Graf [16]. Graf Ligament (SEM Co., Mountrouge, France) is composed of titanium pedicle screws that are connected by polyester-threaded bands, Figure 2(b). In fact, the polyester bands prevent the abnormal rotary motion and preserve the segment physiological lordosis. Biomechanical investigations have shown that the Graf system reduces the angular motion in flexion extension without limiting the vertebral body translation in other directions. As a result, the Graf system design has drawbacks in preventing the spondylolisthesis. Kanayama et al. [17] studied the efficacy of the Graf system in the treatment of the degenerative spondylolitshesis. Their study included 64 patients that underwent Graf system. Based on the clinical and radiographic results, the vertebral slip could not be prevented, but in 80% of the patients the lordosis was maintained.

Cosmic (Ulrich GmbH & Co. KG, Ulm, Germany) is a posterior dynamic stabilization system using pedicle screws to provide nonrigid stability for the degenerative lumbar spine. The head of the pedicle screws is hinged shaped and it connects the threaded part to the screw. This composition enables the load sharing between the Cosmic and the anterior vertebral column, Figure 2(c). In a study [18], 103 consecutive patients were treated with Cosmic. The results showed a considerable improvement of pain, related stability, and mobility, but 10% reoperation during the followup was observed.

Wilke et al. [15] suggested that if one dynamic system provides 70% less range of motion compared to nondegenerated segment, it may prevent screw loosening. In addition, other studies showed a good agreement that a reduced load in the pedicle screw-based dynamic stabilization system minimizes the risk of screw loosening [19]. However, studies also showed that screw loosening problem can be minimized by using hinged dynamic screws regardless of posterior stabilization systems [20, 21].



(a) (b) (c) (d)

Figure 3: Interspinous spacer: (a) X-STOP, (b) Coflex, (c) DIAM system, and (d) Wallis system.

The PercuDyn (Interventional Spine Inc., Irvine, CA, USA) is known as an extension-limiting posterior dynamic stabilization implant, which is mainly a bilateral facet augmentation system, Figure 2(d). Two titanium screws anchor the device to the pedicles, and a polycarbonate urethane cushion bumper resting against the inferior auricular process provides the flexibility for the dynamic posterior stabilization system [5, 22]. Masala et al. [23] conducted a study on the PercuDyn implant to evaluate the efficiency of this system as a treatment for patients with lumbar stenosis. The implantation was performed on 24 consecutive patients with lumbar stenosis. The results demonstrated that in 20 patients (83%), 1-year follow-up improvement was observed. For the all patients, including responder and nonresponder, no complications were reported regarding the device.

The Accuflex (Globus Medical, Inc.) is a posterior dynamic stabilization system that achieves the flexibility from helical cuts on rod. It is categorized as a pedicle screw-based system including a dynamic rod and 6.5 mm pedicle screws made of titanium alloy, Figure 2(e). The helical cut transforms the rod into semirigid one that allows motion primarily in the flexion-extension mode. One of the advantages of the Accuflex is that it requires a technique similar to the standard pedicle screw/rod construct and due to that, the insertion can be performed by most spine surgeons [24]. Reyes-Sánchez et al. [25] reported the clinical outcome of a series of patients with lumbar spinal stenosis that underwent lumbar spine instrumentation with the Accuflex implant. Although clinical benefits were observed in 83% of the patients, the failure due to fatigue in 22.22% of the patients led to hardware removal.

BioFlex, similar to Dynesys, is a posterior dynamic stabilization system using titanium pedicle screws connected by Nitinol rods with coiling consisted of 1-2 turns, Figure 2(f). Nitinol is classified as a shape memory alloy and shows superelasticity behavior. In addition to this property, it is somewhat rigid and it can act as a tension band at the posterior spinal column. The BioFlex system resists excessive deformation during extension; thus, it maintains the physiological range of motion [26].

3.2. Interspinous Spacers. The lumbar interspinous process decompression (IPD) devices are known as trustable alternatives for the treatment of various spinal disorders. The first IPD device, X-STOP (St Francis Medical Technologies, Alameda, CA, USA), was introduced in the US for the treatment of patients with neurogenic intermittent claudication due to spinal stenosis, Figure 3(a). The major concept in the design of X-STOP is to limit the extension movement at the individual stenotic level while allowing the normal movement in all other directions of the treated and untreated level(s) [27]. Compared to other IPD devices, X-STOP has been documented extensively in the literature. Its features include two lateral wings to prevent migration, intended to distract the discs, increase the foraminal areas, and stabilize the posterior column [5]. Lindsey et al. [28] studied the effect of X-STOP device on the kinematics of the instrumented and adjacent levels. They tested seven lumbar spines (L2–L5) in three motion planes: flexion-extension, lateral bending, and axial rotation. The study showed that X-STOP did not affect the kinematics of the adjacent segment. Siddiqui et al. [29] studied kinematics of the lumbar spine with X-STOP device in sagittal plane at the instrumented and adjacent levels *in vivo*. They measured the disc heights, endplate angles, and segmental and lumbar range of movement after implanting the X-STOP. The results showed that no significant changes were seen in disc heights and segmental and total lumbar spine movements postoperatively. They concluded that the sagittal kinematics of the lumbar spine is affected using X-STOP. Kondrashov et al. [27] performed a 4-year followup on 18 X-STOP subjects. Twelve patients had the X-STOP implanted at either L3-4 or L4-5 levels while the other 6 patients had the X-STOP implanted at both L3-4 and L4-5 levels. Grade I spondylolisthesis was noticed in six patients.

Coflex device (Paradigm Spine, LCC, New York City, NY, USA), formerly Interspinous "U," is one of the dynamic interspinous implants that was first introduced by the French orthopaedic surgeon Jacques Samani as an alternative to arthrodesis, Figure 3(b). The aim of this U-shaped compressible device, which is manufactured from titanium, is to unload the facet joints, restore the foraminal height, and provide stability in order to improve the clinical outcome of surgery [30].

Diam implant (Medtronic, Memphis, TN, USA) system is an interspinous spacer and it has a silicon core with a polyethylene cover [31]. Three mesh bands are designed to secure the implant: two of them are around each spinous process and the other around the supraspinous ligament, Figure 3(c).

In mid-1980s, Sénégas introduced an interspinous implant, which was a "floating system" with the purpose of avoiding the risk of loosening. The implant system consisted of a titanium spacer placed between the spinous processes of

the lumbar spine. Two Dacron ligaments wrapping around the spinous processes were considered to secure the implant. Despite the favorable results, a second-generation device called Wallis (Spine Next, Bordeaux, France) was developed to improve the device functionality (Figure 3(d)). In the newer implant, the polyetheretherketone (PEEK) is replaced with the titanium. Sénégas recommends that the current design of implant can be used for lumbar disc disease in the following indications: (1) discectomy for a herniated disc with a large material loss, (2) a second discectomy for recurrence of herniated disc, (3) discectomy for herniation of a transitional disc with sacralization of L5, (4) degenerative disc disease at a level adjacent to a previous, and (5) isolated Modic I lesion leading to chronic lower back pain [32].

4. Conclusions

Fusion is a gold standard for lower back pain treatment to date. However, there have been several complications reported clinically. These complications are related mainly to adjacent segment degeneration due to high stiffness at the stabilized segment. Alternative treatment, nonfusion stabilization systems, became more and more popular in order to preserve mobility of a motion segment and eliminate adjacent segment phenomena. Current research studies emphasize long-term clinical evaluation of dynamic stabilization system.

On the other hand, the stiffness of the dynamic implants is a big concern due to not providing appropriate motion range. Therefore, it is important to optimize the dynamic implant stiffness for desired spinal range of motion achievement.

References

[1] A. A. White III and M. M. Panjabi, *Clinical Biomechanics of the Spine*, Lippincott-Raven, 1990.

[2] Q. H. Zhang and E. C. Teo, "Finite element application in implant research for treatment of lumbar degenerative disc disease," *Medical Engineering and Physics*, vol. 30, no. 10, pp. 1246–1256, 2008.

[3] O. Schwarzenbach, U. Berlemann, T. M. Stoll, and G. Dubois, "Posterior dynamic stabilization systems: DYNESYS," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 363–372, 2005.

[4] C. A. Niosi, Q. A. Zhu, D. C. Wilson, O. Keynan, D. R. Wilson, and T. R. Oxland, "Biomechanical characterization of the three-dimensional kinematic behaviour of the Dynesys dynamic stabilization system: an in vitro study," *European Spine Journal*, vol. 15, no. 6, pp. 913–922, 2006.

[5] S. N. Sangiorgio, H. Sheikh, S. L. Borkowski, L. Khoo, C. R. Warren, and E. Ebramzadeh, "Comparison of three posterior dynamic stabilization devices," *Spine*, vol. 36, no. 19, pp. E1251–E1258, 2011.

[6] R. W. Molinari, "Dynamic stabilization of the lumbar spine," *Current Opinion in Orthopaedics*, vol. 18, no. 3, pp. 215–220, 2007.

[7] V. K. Goel, M. M. Panjabi, A. G. Patwardhan, A. P. Dooris, and H. Serhan, "Test protocols for evaluation of spinal implants," *Journal of Bone and Joint Surgery A*, vol. 88, no. 2, pp. 103–109, 2006.

[8] G. Dubois, B. De Germay, N. S. Schaerer, and P. Fennema, "Dynamic neutralization: a new concept for restabilization of the spine," in *Lumbar Segmental Instability*, M. Szpalski, R. Gunzburg, and M. H. Pope, Eds., pp. 233–240, Lippincott Williams & Wilkins, Philadelphia, Pa, USA, 1999.

[9] A. Rohlmann, N. K. Burra, T. Zander, and G. Bergmann, "Comparison of the effects of bilateral posterior dynamic and rigid fixation devices on the loads in the lumbar spine: a finite element analysis," *European Spine Journal*, vol. 16, no. 8, pp. 1223–1231, 2007.

[10] W. Schmoelz, J. F. Huber, T. Nydegger, Dipl-Ing, L. Claes, and H. J. Wilke, "Dynamic stabilization of the lumbar spine and its effects on adjacent segments: an in vitro experiment," *Journal of Spinal Disorders and Techniques*, vol. 16, no. 4, pp. 418–423, 2003.

[11] W. Schmoelz, J. F. Huber, T. Nydegger, L. Claes, and H. J. Wilke, "Influence of a dynamic stabilisation system on load bearing of a bridged disc: an in vitro study of intradiscal pressure," *European Spine Journal*, vol. 15, no. 8, pp. 1276–1285, 2006.

[12] J. Beastall, E. Karadimas, M. Siddiqui et al., "The dynesys lumbar spinal stabilization system: a preliminary report on positional magnetic resonance imaging findings," *Spine*, vol. 32, no. 6, pp. 685–690, 2007.

[13] H. Schmidt, F. Heuer, and H. J. Wilke, "Which axial and bending stiffnesses of posterior implants are required to design a flexible lumbar stabilization system?" *Journal of Biomechanics*, vol. 42, no. 1, pp. 48–54, 2009.

[14] T. L. Schulte, C. Hurschler, M. Haversath et al., "The effect of dynamic, semi-rigid implants on the range of motion of lumbar motion segments after decompression," *European Spine Journal*, vol. 17, no. 8, pp. 1057–1065, 2008.

[15] H. J. Wilke, F. Heuer, and H. Schmidt, "Prospective design delineation and subsequent in vitro evaluation of a new posterior dynamic stabilization system," *Spine*, vol. 34, no. 3, pp. 255–261, 2009.

[16] T. Hashimoto, F. Oha, K. Shigenobu et al., "Mid-term clinical results of Graf stabilization for lumbar degenerative pathologies: a minimum 2-year follow-up," *Spine Journal*, vol. 1, no. 4, pp. 283–289, 2001.

[17] M. Kanayama, T. Hashimoto, and K. Shigenobu, "Rationale, biomechanics, and surgical indications for graf ligamentoplasty," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 373–377, 2005.

[18] M. Stoffel, M. Behr, A. Reinke, C. Stüer, F. Ringel, and B. Meyer, "Pedicle screw-based dynamic stabilization of the thoracolumbar spine with the Cosmic-system: a prospective observation," *Acta Neurochirurgica*, vol. 152, no. 5, pp. 835–843, 2010.

[19] K. Meyers, M. Tauber, Y. Sudin et al., "Use of instrumented pedicle screws to evaluate load sharing in posterior dynamic stabilization systems," *Spine Journal*, vol. 8, no. 6, pp. 926–932, 2008.

[20] A. Ozer, N. Crawford, M. Sasani et al., "Dynamic lumbar pedicle screw-rod stabilization: two-year follow-up and comparison with fusion," *The Open Orthopeadics Journal*, vol. 4, pp. 137–141, 2010.

[21] A. von Strempel, "Dynamic stabilisation: cosmic system," *Interactive Surgery*, vol. 3, no. 4, pp. 229–236, 2008.

[22] Z. A. Smith, S. Armin, D. Raphael, and L. T. Khoo, "A minimally invasive technique for percutaneous lumbar facet augmentation: technical description of a novel device," *Surgical Neurology International*, vol. 2, no. 165, 2011.

[23] S. Masala, U. Tarantino, G. Nano et al., "Lumbar spinal stenosis minimally invasive treatment with bilateral transpedicular

facet augmentation system," *Cardiovascular and Interventional Radiology*, 2012.

[24] C. E. Mandigo, P. Sampath, and M. G. Kaiser, "Posterior dynamic stabilization of the lumbar spine: pedicle based stabilization with the AccuFlex rod system," *Neurosurgical Focus*, vol. 22, no. 1, article E9, 2007.

[25] A. Reyes-Sánchez, B. Zárate-Kalfópulos, I. Ramírez-Mora, L. M. Rosales-Olivarez, A. Alpizar-Aguirre, and G. Sánchez-Bringas, "Posterior dynamic stabilization of the lumbar spine with the Accuflex rod system as a stand-alone device: experience in 20 patients with 2-year follow-up," *European Spine Journal*, vol. 19, no. 12, pp. 2164–2170, 2010.

[26] B. Y. Cho, J. Murovic, K. W. Park, and J. Park, "Lumbar disc rehydration postimplantation of a posterior dynamic stabilization system: case report," *Journal of Neurosurgery*, vol. 13, no. 5, pp. 576–580, 2010.

[27] D. G. Kondrashov, M. Hannibal, K. Y. Hsu, and J. F. Zucherman, "Interspinous process decompression with the X-STOP device for lumbar spinal stenosis: a 4-year follow-up study," *Journal of Spinal Disorders and Techniques*, vol. 19, no. 5, pp. 323–327, 2006.

[28] D. P. Lindsey, K. E. Swanson, P. Fuchs, K. Y. Hsu, J. F. Zucherman, and S. A. Yerby, "The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine," *Spine*, vol. 28, no. 19, pp. 2192–2197, 2003.

[29] M. Siddiqui, E. Karadimas, M. Nicol, F. W. Smith, and D. Wardlaw, "Effects of X-Stop device on sagittal lumbar spine kinematics in spinal stenosis," *Journal of Spinal Disorders and Techniques*, vol. 19, no. 5, pp. 328–333, 2006.

[30] A. Richter, C. Schütz, M. Hauck, and H. Halm, "Does an interspinous device (CoflexŮ) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients," *European Spine Journal*, vol. 19, no. 2, pp. 283–289, 2010.

[31] S. D. Christie, J. K. Song, and R. G. Fessler, "Dynamic interspinous process technology," *Spine*, vol. 30, no. 16, pp. S73–S78, 2005.

[32] J. Sénégas, "Mechanical supplementation by non-rigid fixation in degenerative intervertebral lumbar segments: the wallis system," *European Spine Journal*, vol. 11, no. 2, pp. S164–S169, 2002.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 874090, 9 pages
http://dx.doi.org/10.1155/2013/874090

Clinical Study

Posterior Transpedicular Dynamic Stabilization versus Total Disc Replacement in the Treatment of Lumbar Painful Degenerative Disc Disease: A Comparison of Clinical Results

Tunc Oktenoglu,[1] Ali Fahir Ozer,[2] Mehdi Sasani,[1] Yaprak Ataker,[3] Cengiz Gomleksiz,[4] and Irfan Celebi[5]

[1] *Neurosurgery Department, American Hospital, 34365 Istanbul, Turkey*
[2] *Neurosurgery Department, Koc University School of Medicine, 34450 Istanbul, Turkey*
[3] *Physical Therapy and Rehabilitation Department, American Hospital, 34365 Istanbul, Turkey*
[4] *Neurosurgery Department, Mengücek Gazi Training and Research Hospital,School of Medicine, Erzincan University, 2400 Erzincan, Turkey*
[5] *Radiology Department, Sisli Etfal Hospital, 34360 Istanbul, Turkey*

Correspondence should be addressed to Ali Fahir Ozer; alifahirozer@gmail.com

Received 19 October 2012; Accepted 28 November 2012

Academic Editor: Deniz Erbulut

Study Design. Prospective clinical study. *Objective*. This study compares the clinical results of anterior lumbar total disc replacement and posterior transpedicular dynamic stabilization in the treatment of degenerative disc disease. *Summary and Background Data*. Over the last two decades, both techniques have emerged as alternative treatment options to fusion surgery. *Methods*. This study was conducted between 2004 and 2010 with a total of 50 patients (25 in each group). The mean age of the patients in total disc prosthesis group was 37,32 years. The mean age of the patients in posterior dynamic transpedicular stabilization was 43,08. Clinical (VAS and Oswestry) and radiological evaluations (lumbar lordosis and segmental lordosis angles) of the patients were carried out prior to the operation and 3, 12, and 24 months after the operation. We compared the average duration of surgery, blood loss during the surgery and the length of hospital stay of both groups. *Results*. Both techniques offered significant improvements in clinical parameters. There was no significant change in radiologic evaluations after the surgery for both techniques. *Conclusion*. Both dynamic systems provided spine stability. However, the posterior dynamic system had a slight advantage over anterior disc prosthesis because of its convenient application and fewer possible complications.

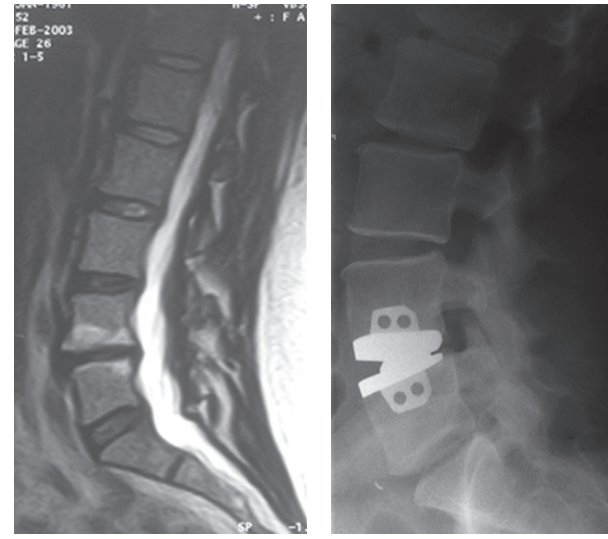
1. Introduction

Currently, one of the most important causes of chronic low back pain is thought to be a painful disc [1–3]. Some biomechanical and biochemical changes play a role in intervertebral disc degeneration; on the other hand intrinsic, extrinsic, and genetic factors are also important. Compression of the spine, torsional injuries, overload, and congenital anomalies have been shown to contribute to disc degeneration with applying excessive pressure onto intervertebral discs [4–10]. Despite numerous research studies, the etiology and physiopathology of disc degeneration remain unknown [2]. Annular tears resulting from degeneration of the annulus fibrosis, that contains pain receptors and internal disc ruptures, are the most common cause of pain [11–13]. Today, it is believed that degenerative disc disease (DDD) might cause instability in spine segments, and it is widely accepted that progressive back pain results due to this instability [14–16]. In fact, segmental instability begins when disc height deterioration is initiated by the progression of intervertebral disc degeneration. Instability as a consequence of disc degeneration has been described by Frymoyer [14, 15] as primary segmental instability and by Kirkaldy-Willis and Farfan [2] as the discogenic pain and instability stage in the overall process

of degeneration. Benzel [16] included degenerative disc disease among the chronic instabilities and described the disease as "dysfunctional segmental motion" and "torsional instability." Fusion is the standard surgical treatment option for painful lumbar degenerative disc disease that is unresponsive to conservative treatment modalities. Nonetheless, the side effects of fusion (pseudarthrosis, adjacent segment disease, and the donor site morbidity) and suboptimal clinical satisfaction rates, which have been reported even in patients with radiologically observed fusion, have led to a search for alternative treatments [17–22].

Numerous dynamic techniques were developed over the last two decades. Recently, these devices were classified as total disc replacement (TDR) and posterior transpedicular dynamic systems (PTDS) [23]. Both PTDS and TDR have been widely used in surgical treatment of degenerative disc diseases of the lumbar spine. Numerous studies showed promising clinical results [24–35]. However, there is no study that compares the TDR and PTDS techniques in the treatment of DDD.

In this prospective study, we evaluated and compared the clinic and radiologic outcome of TDR and PTDS in patients with painful lumbar degenerative disc disease through an extensive literature review.



(a) (b)

Figure 1: A 30-year-old woman complained of severe back pain attacks. She had no neurological deficits. (a) T2-weighted MRI scans showed advanced degeneration with Modic changes in the L4-L5 disc. (b) Maverick disc prosthesis was applied.

2. Material and Methods

2.1. Total Disc Replacement Group. We performed TDR on 25 patients (14 females and 11 males). The mean age of the patients was 37.32 (with a range from 25 to 50), and the mean follow-up period was 29.16 months (with a range from 24 to 42 months).

A lumbar total disc replacement (Maverick, Medtronic Sofamor Danek, Memphis, TN, USA) was placed into the intervertebral disc space with open window laparotomy technique [36].

All patients in the TDR group had a lumbar single-level painful disc. 15 patients showed L4-L5 DDD, and 10 patients showed L5-S1 DDD (Figure 1). All of the patients were informed about the surgery, and they signed a written, informed consent form. The inclusion criteria for TDR surgery included a complaint of lower back pain that had duration of at least 12 months and at least six months of conservative treatment without satisfactory results. Other inclusion criteria were that the patients must be less than 50 years old and have no signs of lumbar degenerative spondylolisthesis or osteoarthritis in their facet joints, which was confirmed with computerized tomography (CT) and dynamic plain radiographs. The patients also had to have symptomatic lumbar degenerative disc disease that was visible in magnetic resonance imaging (MRI) as a blackened disc as well as a confirmation of the diagnosis by displaying pain behaviors during discography.

2.2. Posterior Dynamic Transpedicular Stabilization Group . We performed posterior dynamic transpedicular stabilization on 25 patients (13 females and 12 males). The mean age of the patients was 43.08 years (with a range from 24 to 55 years), and the mean follow-up period was 36.48 months (with a range from 24 to 48 months).

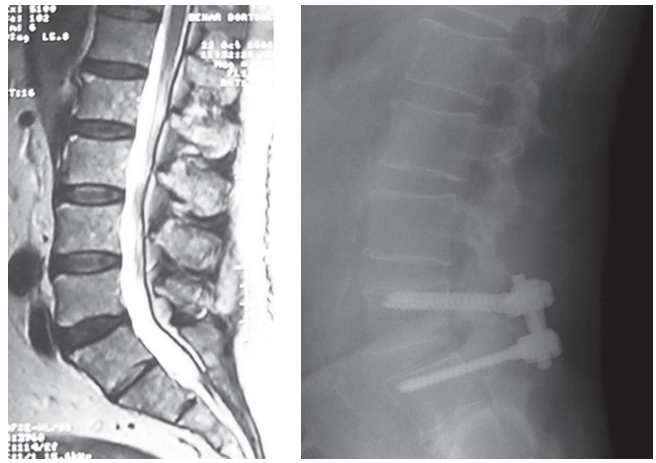
Patients in the dynamic posterior stabilization group were operated with the Cosmic (Ulrich GmbH & Co. KG, Ulm, Germany) posterior dynamic transpedicular stabilization system (hinged screw-rigid rod) through transmuscular approach [35].

All cases in the PTDS group had one-level painful disc disease. The operated discs were L4-L5 region (16 cases) and L5-S1 region (9 cases) (Figure 2).

Similar to the patients in the TDR group, the inclusion criteria included a confirmed diagnosis of symptomatic lumbar degenerative disc disease through MRI and positive discography, a complaint of lower back pain that had a duration of at least 12 months, at least 6 months of conservative treatment without satisfactory results, and the absence of apparent instability confirmed with lumbosacral dynamic X-rays.

2.3. Clinical Evaluation. We evaluated and compared the average surgical time, blood loss during the surgery, and the length of the stay in hospital for both groups of patients (Table 1). The visual analog scale (VAS) and the Oswestry Disability Index (ODI) were used for the clinical evaluations and follow-up examinations. Clinical evaluations of the patients were carried out in the data at preoperative period and 3, 12, and 24 months after the surgery (Tables 2 and 3).

2.4. Radiological Evaluation. To diagnose lumbar disc disease, an MRI examination of each patient was performed and a black disc was observed. Pain symptoms were confirmed with the detection of provocative pain through a discography



(a) (b)

Figure 2: (a) A 50-year-old male complained of severe back pain attacks. (a) T2-weighted MRI scans showed degeneration of the disc at L4-L5 lumbar disc (L5- S1 considered as sacralization). (b) Following posterior transpedicular dynamic stabilization with the Cosmic system.

Table 1: Comparison of TDR and PTDS groups.

		TDR ($n = 25$)	PTDS ($n = 25$)	P
Age	Min–Max	25–50	24–55	0.018*
	Mean ± SD	37.32 ± 6.62	43.08 ± 9.65	
Followup (month)	Min–Max	24–42	24–48	0.001**
	Mean ± SD	29.16 ± 4.77	36.48 ± 6.72	
Length of hospital stay (day)	Min–Max	3–5	2–5	0.022*
	Mean ± SD	3.56 ± 0.58	3.04 ± 0.93	
Operation time (minute)	Min–Max	120–260	40–70	0.001**
	Mean ± SD	181.20 ± 39.40	52.40 ± 7.79	
Blood loss (mL.)	Min–Max	300–600	75–175	0.001**
	Mean ± SD	402.00 ± 91.83	103.00 ± 22.03	

Student's t-test, $^{*}P < 0.05$, $^{**}P < 0.01$.

which was applied to the black disc. Lumbosacral plain and dynamic (hyperflexion and hyperextension) X-rays and CT examinations of the patients were carried out by independent radiology experts in preoperative. Follow-up plain X-Ray studies were obtained 3, 12, and 24 months after the surgery. Control CT study was performed in postoperative 24 months. Loose screws as well as broken screws, instrument migration, subsidence, and spontaneous fusion were evaluated. Additionally lumbar lordosis angle (LL) and segmental lordosis angle (α) data was obtained (Tables 4 and 5) (Figure 3).

2.5. Statistical Analysis. The Number Cruncher Statistical System (NCSS) 2007 and 2008 PASS Statistical Software (Utah, USA) were used for statistical analysis of the data. In addition to descriptive statistical methods (e.g., mean, standard deviation), Student's t-test was used to compare the normally distributed parameters between the two groups. The Mann-Whitney U test was used for the comparison of parameters with nonnormal distribution. Bonferroni test was used to compare the follow-up data with normal distribution, and paired sample t-test was used for dual comparison. In nonnormal distribution group, the follow-up data compared with Friedman test and Wilcoxon test was used for dual comparison. The significance level was $P < 0.05$.

3. Results

There was statistically significant difference observed between the mean ages and follow-up periods of the groups ($P < 0.05$) (Table 1). The PTDS applied to significantly older patients was compared to TDR group.

There was a statistically significant difference ($P < 0.01$) between the level of blood loss in the two groups. The level of blood loss was significantly higher in the TDR group compared to the PTDS group (Table 1, Figure 4).

The operation time was significantly longer ($P < 0.01$) in the TDR group compared to the posterior dynamic stabilization group (Table 1, Figure 5).

There was significant difference in the length of the hospital stay between the two groups ($P < 0.05$) (Table 1).

Table 2: (a) The comparison of VAS scores. (b) The comparison of decrease % in follow-up VAS data.

(a)

VAS		TDR ($n = 25$)	PTDS ($n = 25$)	[a]P
Preop VAS	Min–Max	6–10	6–9	0.219
	Mean ± SD	8.24 ± 1.09[8]	7.96 ± 0.79 [8]	
VAS (3 months)	Min–Max	0–5	1–5	0.588
	Mean ± SD	2.44 ± 1.16 [2]‡	2.64 ± 0.91 [2]‡	
VAS (12 months)	Min–Max	0–3	0–4	0.087
	Mean ± SD	1.68 ± 0.85 [2]‡	1.28 ± 0.94 [1]‡	
VAS (24 months)	Min–Max	0–2	0–3	0.240
	Mean ± SD	0.84 ± 0.69 [1]‡	0.68 ± 0.85 [1]‡	
	[b]P	0.001**	0.001**	

[a]Mann-Whitney U test, [b]Friedman test.
‡Wilcoxon signed-rank test $P < 0.001$.
$^{**}P < 0.01$.

(b)

VAS (decrease %)	TDR ($n = 25$) Mean ± SD	PTDS ($n = 25$) Mean ± SD	P
Preop ∗ VAS (3 months)	70.18 ± 14.14	66.18 ± 13.57	0.374
Preop ∗ VAS (12 months)	79.91 ± 10.00	83.71 ± 12.08	0.214
Preop ∗ VAS (24 months)	89.86 ± 8.41	91.30 ± 10.78	0.519

Mann-Whitney U test.

Table 3: (a) The comparison of ODI scores. (b) The comparison of decrease % in follow-up OSW data.

(a)

ODI		TDR ($n = 25$)	PTDS ($n = 25$)	[a]P
Preop ODI	Min–Max	40–100	46–98	0.847
	Mean ± SD	67.20 ± 20.79	66.16 ± 16.82	
ODI (3 months)	Min–Max	12–56	12–38	0.069
	Mean ± SD	32.32 ± 10.87‡	27.16 ± 8.63‡	
ODI (12 months)	Min–Max	4–34	2–26	0.010*
	Mean ± SD	18.00 ± 7.64‡	12.88 ± 5.75‡	
ODI (24 months)	Min–Max	2–20	2–18	0.408
	Mean ± SD	9.12 ± 4.28‡	8.04 ± 4.53‡	
	[b]P	0.001**	0.001**	

[a]Student's t-test, [b]repeated measures test.
‡Adjustment for multiple comparisons: Bonferroni $P < 0.01$.
$^{*}P < 0.05$, $^{**}P < 0.01$.

(b)

ODI (decrease %)	TDR ($n = 25$) Mean ± SD	PTDS ($n = 25$) Mean ± SD	P
Preop ∗ ODI (3 months)	49.96 ± 16.46	54.91 ± 20.00	0.669
Preop ∗ ODI (12 months)	72.80 ± 9.33	78.22 ± 11.68	0.093
Preop ∗ ODI (24 months)	86.15 ± 6.15	86.33 ± 8.92	0.808

Mann-Whitney U test.

Preoperative VAS and ODI levels were not significantly ($P > 0.05$ and $P > 0.05$) different between the groups (Tables 2 and 3).

In both groups the clinical parameters (VAS and ODI) showed significant improvement in all postoperative time periods when compared to preoperative data (Tables 2 and 3, $P < 0.01$). There were no statistically significant differences observed between the groups for the each follow-up VAS ($P < 0.05$, Table 2). The ODI data showed significant difference only in postop 12 months. The PTDS group had significantly

Table 4: The comparison of LL angles.

LL		TDR ($n = 25$)	PTDS ($n = 25$)	[a]P
Preop LL	Min–Max	25–65	34–72	0.948
	Mean ± SD	49.60 ± 10.46	49.80 ± 11.26	
LL (3 months)	Min–Max	26–65	34–69	0.747
	Mean ± SD	49.52 ± 9.51	48.60 ± 10.52	
LL (12 months)	Min–Max	24–64	30–67	0.764
	Mean ± SD	49.60 ± 10.15	48.72 ± 10.50	
LL (24 months)	Min–Max	22–65	35–65	0.786
	Mean ± SD	49.56 ± 10.38	48.80 ± 9.30	
	[b]P	0.998	0.890	

[a]Student's t-test, [b]repeated measures test.
LL: lumbar lordosis.

Table 5: The comparison of SL (α) angles.

ALPHA		TDR ($n = 25$)	PTDS ($n = 25$)	[a]P
Preop ALPHA	Min–Max	4–17	4–30	0.274
	Mean ± SD	10.32 ± 3.06	11.68 ± 5.33	
ALPHA (3 months)	Min–Max	3–19	3–33	0.566
	Mean ± SD	10.40 ± 3.70	11.20 ± 5.84	
ALPHA (12 months)	Min–Max	4–16	2–31	0.392
	Mean ± SD	10.36 ± 2.90	11.52 ± 6.05	
ALPHA (24 months)	Min–Max	5–14	3–30	0.248
	Mean ± SD	10.32 ± 2.28	11.56 ± 4.79	
	[b]P	0.989	0.858	

[a]Student's t-test, [b]repeated measures test.
SL: segmental lordosis.

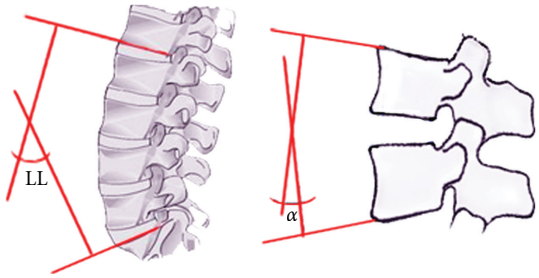


Figure 3: Lordosis of the lumbar spine (L1-S1) was measured via the angle between the lines drawn from the lower endplate of L1 and the upper endplate of S1 (LL). Additionally segmental lordosis (α) at the operation level was measured via the angle between the lines drawn from the upper and lower endplates of the vertebrae that form the operation segments.

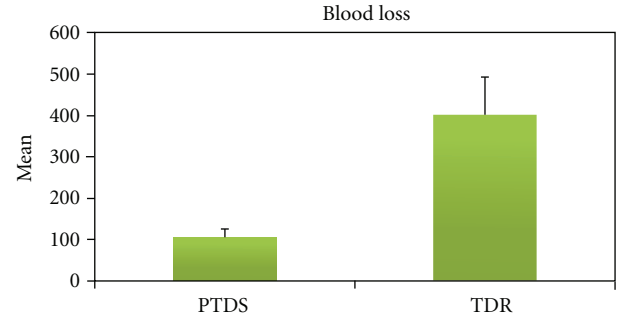


Figure 4: The data of blood loss in surgery for both groups.

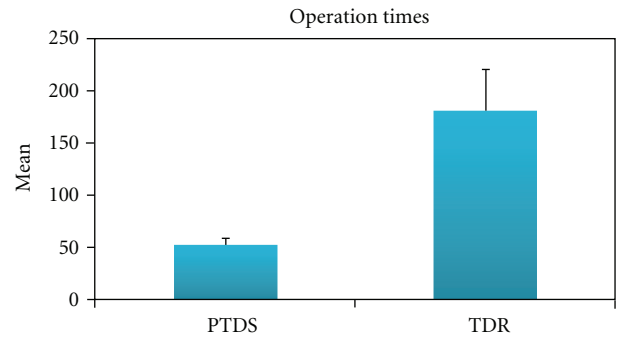


Figure 5: The data of operation times for both groups.

better outcome in this time period. However this advantage did not persist. There was no significant difference in 24-month scores ($P > 0.05$, Table 3) (Figures 6 and 7).

There were no significant differences observed between the preoperative and postoperative lumbar (LL) and segmental lordosis (alpha) evaluations for both techniques ($P > 0.05$) (Tables 4 and 5).

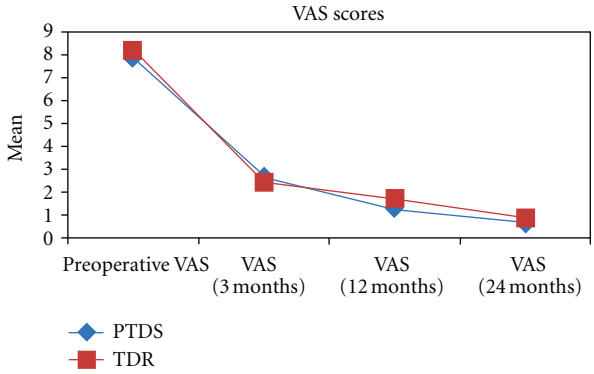


Figure 6: The distribution of VAS scores for both groups.

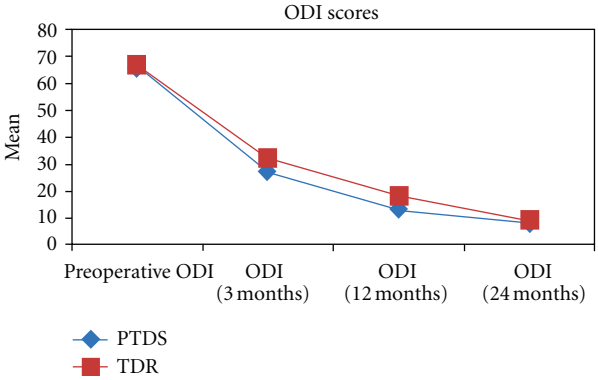


Figure 7: The distribution of ODI scores for both groups.

No surgical morbidity and/or complications observed in the group treated with PTDS. There were two iliac vein injuries that occurred in two patients in the TDR group. These injuries were sutured in the operation with no mortality and residual morbidity.

4. Discussion

Fusion has been widely used as a surgical treatment for painful disc disease. Fusion eliminates the abnormal movements and offers satisfactory outcome. On the other hand, even in patients with 100% fusion achieved with applying 360° fusion method, the satisfaction rate is not necessary optimal and might be low as 30% [19–21, 23, 24]. Donor site problems have also been a significant complication in fusion surgery [20]. Therefore, alternative treatment techniques were developed in an attempt to prevent side effects that are commonly observed after fusion surgery and to improve the patient satisfaction rate. In recent years, dynamic systems that provide spine mobility have been developed to avoid the well-known side effects of fusion technique. Today indications and contraindications of TDR and PTDS are well known [23]. Both techniques can be used for the same indications. A painful black disc can be treated with application of either technique.

TDR was developed over the past ten years as a promising surgery that was preferable over fusion surgery because the proponents of TDR claimed that the procedure preserves mobility and reduces the risk of adjacent segment disease. After a ten-year effort by Büttner-Janz et al., TDR was announced as a new solution method for painful disc disease [37]. Numerous TDR systems were developed and offered for clinical application [29, 32, 38]. Biomechanical studies showed that the TDR prosthesis stabilizes the spine while providing nearly intact segmental motion [29, 32, 39]. Early clinical results of TDR in the treatment of DDD showed promising outcomes [37, 40–46].

The patients treated with TDR usually have short recuperation times and less postoperative pain compared to fusion procedure. On the other hand, TDR application has several significant limitations including; (a) the patient should be between 30 and 50 years old, (b) there should not be any posterior column disruption, (c) intervertebral disc height should be ≥4 mm, and (d) single-level DDD is more appropriate to apply TDR. Beside these limitations TDR is an anterior approach which has its inherent risks such as injury to intra-abdominal organs and vascular structures. Additionally, the lesions in the peritoneal cavity caused by abrasion, ischemia, desiccation, infection, thermal injury, and foreign bodies can result in adhesion formation [47].

TDR is used extensively around the world; however severe complications have been associated with the technique [48, 49]. In this study we observed mild iliac vein injuries during the placement of the lumbar disc prosthesis in the two patients within the TDR group. Other possible disadvantages of TDR technique are as follows: revision surgery is quite difficult, biomechanically the L5-S1 level had no normal segmental motion, and results of two-level TDR use were not considered to be satisfactory according to patients [50]. Putzier et al. [51] concluded that the long-term results of a study by Charité were not satisfactory and they concluded their article yearning to fusion technique.

Guyer et al. [52] published the results of a 5-year study showing that TDR was not superior to fusion. The authors concluded that there was no strong evidence that TDR was superior to fusion, and they suggested that high-quality, randomized controlled trials with relevant control groups and a long-term followup were needed to evaluate the effectiveness and safety of TDR [53].

Posterior dynamic stabilization systems are designed to increase the success of spinal surgery and to eliminate the complications of fusion with rigid instrumentation such as adjacent segment disease (12.2–18.5%) [54] due to the stress-shielding properties (2–3% per year after stabilization) [55], pseudarthrosis (3–55%) [18, 56, 57], device-related osteopenia [58], and loss of motion in fused spinal segments. Besides these side effects of fusion, clinical healing might be suboptimal in cases even with satisfactory radiological results [22, 59]. Therefore, the use of posterior dynamic stabilization in the surgical treatment of DDD may provide greater patient satisfaction, resulting from shorter hospital stays, less recuperation time, and none of the disadvantages related to fusion, which requires more invasive procedures.

Numerous biomechanical studies proved that hinged screw stabilization can stabilize the spine almost as well as the rigid screw stabilization used in fusion surgery in

the treatment of chronic lumbar instability [60, 61]. There are no randomized controlled studies in the literature because PTDS is a new technique. However, there are many retrospective studies that are precursors for future randomized studies. Recently, studies on PTDS have shown very encouraging clinical results and demonstrated that these systems provide stabilization that is similar to the posterior rigid stabilization obtained with fusion surgery [23–28, 30, 31, 34, 35, 60, 62, 63].There are few studies which concluded that dynamic stabilization is not superior to rigid stabilization [63–66]. Although these results showed that there was no advantage of PTDS over fusion surgery in clinical outcome, on the other hand these studies also showed that PTDS is superior to fusion due to the simplicity of the procedure, low morbidity, and reduced hospitalization time to achieve similar satisfactory outcome as fusion. Similarly numerous studies have shown that posterior dynamic transpedicular stabilization caused less intraoperative blood loss and had a shorter operating time [25, 28, 31, 35]. Furthermore, several studies reported that PTDS slows down intervertebral disc degeneration by removing the load from the degenerative disc tissue and providing better load distribution which is an important advantage of this technique [25, 27, 30].

Based on previous studies, if a disc is in the beginning stage of degeneration and if there is only posterior annulus defect, the disc might repair itself after PTDS. On the other hand, if the disc has advanced degeneration including decreased disc height, significant dehydration, and/or slight bulging, fusion might occur slowly after PTDS. However, in both of these scenarios, the patient would be pain-free. In cases of advanced disc degeneration, the fusion results are satisfactory because fusion occurs easily. If PTDS is applied to advanced disc degeneration cases, the segments might fuse and the results will be the same. Therefore in regard of motion preservation, TDR may be a superior treatment in this group of patients if they have intact facet joints.

Huang et al. [67] reported the advantages and disadvantages of nonfusion technology in spinal surgery. Some of the potential benefits of nonfusion implants were the elimination of possible complications due to bone grafts and pseudarthrosis as well as a reduction in the surgical morbidity and the incidence of adjacent level degeneration. The potential risks of nonfusion implants included mechanical failure, dissolution and migration, subsidence, and same-level degeneration.

Previous studies suggested that lumbar total disc prosthesis would reduce the stress on the adjacent disc, after sagittal balance is restored. Harrop et al. [68] reviewed the literature on lumbar adjacent segment degeneration after fusion and TDR. They concluded that adjacent segment disease had a stronger relationship with fusion than arthroplasty. Stoll et al. [34] reported symptomatic adjacent segment disease in 9% of their posterior dynamic transpedicular stabilization patients after a 38-month follow-up period. Cakir et al. [63] reported their results after performing PTDS with Dynesys and TDR with ProDisc (Synthes-Spine Solutions, New York, NY). They suggested that both dynamic systems were promising alternative options compared to fusion for patients with different pathologies because of reduced morbidity. Cakir et al. [63] obtained good clinical results with both systems. Both TDR and PTDS result in less adjacent segment disease. Although a reduced incidence of adjacent segment degeneration appears to be the most important advantage of nonfusion systems, this advantage has not been proven.

Considering all of the features of both techniques, PTDS is a less invasive surgery compared to fusion and TDR techniques. Additionally, PTDS has no age limitation and does not require intact posterior spinal column as TDR technique. Finally, anterior lumbar disc prosthesis requires transperitoneal or retroperitoneal intervention and usually requires a multidisciplinary approach (general surgeon, cardiovascular surgeon, and spinal surgeon). Naturally, the complication rate decreases with a conventional surgical approach and increases when complex anatomical structures are involved in the surgery.

5. Conclusion

In this study, we observed that both dynamic techniques TDR and PTDS offered satisfactory outcome in the surgical treatment of lumbar DDD. However, in this limited study, PTDS had several advantages over TDR such as (a) less invasive technique, (b) shorter operation time, (c) less intraoperative bleeding, and (d) lower complication rates. Further prospective, randomized clinical studies with a larger number of patients and with a longer follow-up period are needed to support our findings.

References

[1] N. Bogduk, "The innervation of the lumbar spine," *Spine*, vol. 8, no. 3, pp. 286–293, 1983.

[2] W. H. Kirkaldy-Willis and H. F. Farfan, "Instability of the lumbar spine," *Clinical Orthopaedics and Related Research*, vol. 165, pp. 110–123, 1982.

[3] F. P. Morgan and T. King, "Primary instability of lumbar vertebrae as a common cause of low back pain," *Journal of Bone and Joint Surgery (British Volume)*, vol. 39, no. 1, pp. 6–22, 1957.

[4] J. MALINSKY, "The ontogenetic development of nerve terminations in the intervertebral discs of man," *Acta Anatomica*, vol. 38, pp. 96–113, 1959.

[5] M. C. Battié, T. Videman, and E. Parent, "Lumbar disc degeneration: epidemiology and genetic influences," *Spine*, vol. 29, no. 23, pp. 2679–2690, 2004.

[6] A. Ong, J. Anderson, and J. Roche, "A pilot study of the prevalence of lumbar disc degeneration in elite athletes with lower back pain at the Sydney 2000 Olympic Games," *British Journal of Sports Medicine*, vol. 37, no. 3, pp. 263–266, 2003.

[7] T. Videman, S. Sarna, M. C. Battie et al., "The long-term effects of physical loading and exercise lifestyles on back- related symptoms, disability, and spinal pathology among men," *Spine*, vol. 20, no. 6, pp. 699–709, 1995.

[8] C. J. Wallach, L. G. Gilbertson, and J. D. Kang, "Gene therapy applications for intervertebral disc degeneration," *Spine*, vol. 28, no. 15, supplement, pp. S93–S98, 2003.

[9] H. A. Horner and J. P. G. Urban, "2001 Volvo award winner in basic science studies: effect of nutrient supply on the viability of cells from the nucleus pulposus of the intervertebral disc," *Spine*, vol. 26, no. 23, pp. 2543–2549, 2001.

[10] L. Ala-Kokko, "Genetic risk factors for lumbar disc disease," *Annals of Medicine*, vol. 34, no. 1, pp. 42–47, 2002.

[11] M. A. Edgar and J. A. Ghadially, "Innervation of the lumbar spine," *Clinical Orthopaedics and Related Research*, vol. 115, pp. 35–41, 1976.

[12] M. Grönblad, J. Virri, S. Rönkkö et al., "A controlled biochemical and immunohistochemical study of human synovial-type (group II) phospholipase A2 and inflammatory cells in macroscopically normal, degenerated, and herniated human lumbar disc tissues," *Spine*, vol. 21, no. 22, pp. 2531–2538, 1996.

[13] H. V. Crock, "Internal disc disruption. A challenge to disc prolapse fifty years on," *Spine*, vol. 11, no. 6, pp. 650–653, 1986.

[14] J. W. Frymoyer, "Segmental instability," in *The Adult Spine*, J. W. Frymoyer, Ed., pp. 1873–1891, Raven Press, New York, NY, USA, 1991.

[15] J. W. Frymoyer and D. K. Selby, "Segmental instability: rationale for treatment," *Spine*, vol. 10, no. 3, pp. 280–286, 1985.

[16] E. C. Benzel, "Stability and instability of the spine," in *Biomechanics of Spine Stabilization*, E. C. Benzel, Ed., pp. 29–43, Thime, New York, NY, USA, 2001.

[17] S. J. Suratwala, M. R. Pinto, T. J. Gilbert, R. B. Winter, and J. M. Wroblewski, "Functional and radiological outcomes of 360° fusion of three or more motion levels in the lumbar spine for degenerative disc disease," *Spine*, vol. 34, no. 10, pp. E351–E358, 2009.

[18] A. A. Faundez, J. D. Schwender, Y. Safriel et al., "Clinical and radiological outcome of anterior-posterior fusion versus transforaminal lumbar interbody fusion for symptomatic disc degeneration: a retrospective comparative study of 133 patients," *European Spine Journal*, vol. 18, no. 2, pp. 203–211, 2009.

[19] B. I. Martin, S. K. Mirza, B. A. Comstock, D. T. Gray, W. Kreuter, and R. A. Deyo, "Reoperation rates following lumbar spine surgery and the influence of spinal fusion procedures," *Spine*, vol. 32, no. 3, pp. 382–387, 2007.

[20] J. C. Banwart, M. A. Asher, and R. S. Hassanein, "Iliac crest bone graft harvest donor site morbidity: a statistical evaluation," *Spine*, vol. 20, no. 9, pp. 1055–1060, 1995.

[21] T. R. Lehmann, K. F. Spratt, and J. E. Tozzi, "Long-term follow-up of lower lumbar fusion patients," *Spine*, vol. 12, no. 2, pp. 97–104, 1987.

[22] P. Fritzell, O. Hägg, and A. Nordwall, "Complications in lumbar fusion surgery for chronic low back pain: comparison of three surgical techniques used in a prospective randomized study. A report from the Swedish lumbar spine study group," *European Spine Journal*, vol. 12, no. 2, pp. 178–189, 2003.

[23] T. Kaner, M. Sasani, T. Oktenoglu, and A. F. Ozer, "Dynamic stabilization of the spine: a new classification system," *Turkish Neurosurgery*, vol. 20, no. 2, pp. 205–215, 2010.

[24] T. Kaner, M. Sasani, T. Oktenoglu, M. Cosar, and A. F. Ozer, "Utilizing dynamic rods with dynamic screws in the surgical treatment of chronic instability: a prospective clinical study," *Turkish Neurosurgery*, vol. 19, no. 4, pp. 319–326, 2009.

[25] T. Kaner, S. Dalbayrak, T. Oktenoglu, M. Sasani, A. L. Aydin, and F. O. Ozer, "Comparison of posterior dynamic and posterior rigid transpedicular stabilization with fusion to treat degenerative spondylolisthesis," *Orthopedics*, vol. 33, no. 5, 2010.

[26] T. Kaner, M. Sasani, T. Oktenoglu et al., "Minimum two-year follow-up of cases with recurrent disc herniation treated with microdiscectomy and posterior dynamic transpedicular stabilisation," *Open Orthopaedics*, vol. 4, pp. 120–125, 2010.

[27] T. Kaner, M. Sasani, T. Oktenoglu, M. Cosar, and A. F. Ozer, "Clinical outcomes after posterior dynamic transpedicular stabilization with limited lumbar discectomy: carragee classification system for lumbar disc herniations," *SAS Journal*, vol. 4, no. 3, pp. 92–97, 2010.

[28] A. F. Ozer, N. R. Crawford, M. Sasani et al., "Dynamic lumbar pedicle screw-rod stabilization: two year follow-up and comparison with fusion," *Open Orthopaedics*, vol. 4, pp. 137–141, 2010.

[29] M. Sasani, T. Öktenoğlu, K. Tuncay, N. Canbulat, S. Carilli, and F. A. Özer, "Total disc replacement in the treatment of lumbar discogenic pain with disc herniation: a prospective clinical study," *Turkish Neurosurgery*, vol. 19, no. 2, pp. 127–134, 2009.

[30] M. Putzier, S. V. Schneider, J. F. Funk, S. W. Tohtz, and C. Perka, "The surgical treatment of the lumbar disc prolapse: nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone," *Spine*, vol. 30, no. 5, pp. E109–E114, 2005.

[31] A. Von Strempel, D. Moosmann, C. Stoss et al., "Stabilization of the degenerated lumbar spine in the nonfusion technique with cosmic posterior dynamic system," *The Wall Street Journal*, vol. 1, pp. 40–47, 2006.

[32] J. C. Le Huec, H. Mathews, Y. Basso et al., "Clinical results of Maverick lumbar total disc replacement: two-year prospective follow-up," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 315–322, 2005.

[33] M. Kanayama, T. Hashimoto, K. Shigenobu et al., "Adjacent-segment morbidity after Graf ligamentoplasty compared with posterolateral lumbar fusion," *Journal of Neurosurgery*, vol. 95, no. 1, pp. 5–10, 2001.

[34] T. M. Stoll, G. Dubois, and O. Schwarzenbach, "The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system," *European Spine Journal*, vol. 11, no. 2, supplement, pp. S170–S178, 2002.

[35] T. Oktenoglu, A. F. Ozer, M. Sasani et al., "Posterior dynamic stabilization in the treatment of lumbar degenerative disc disease: 2-year follow-up," *Minimally Invasive Neurosurgery*, vol. 53, no. 3, pp. 112–116, 2010.

[36] S. Carilli, T. Oktenoglu, and A. F. Ozer, "Open-window laparotomy during a transperitoneal approach to the lower lumbar vertebrae: new method for reducing complications," *Minimally Invasive Neurosurgery*, vol. 49, no. 4, pp. 227–229, 2006.

[37] K. Büttner-Janz, K. Schelnack, and Zippel H, "An alternative teratment strategy for lumbar disc damage using the SB Charité modular disc prosthesis," *Zeitschrift fur Orthopadie und Ihre Grenzgebiete*, vol. 125, no. 1, pp. 1–6, 1987.

[38] T. Marnay, *ProDisc Retrospective Clinical Study: 7–11 Year Follow Up*, Spine Solutions, New York, NY, USA, 2002.

[39] T. J. Errico, "Lumbar disc arthroplasty," *Clinical Orthopaedics and Related Research*, no. 435, pp. 106–117, 2005.

[40] S. Blumenthal, P. C. McAfee, R. D. Guyer et al., "A prospective, randomized, multicenter food and drug administration investigational device exemptions study of lumbar total disc replacement with the CHARITÉ artificial disc versus lumbar fusion—part I: evaluation of clinical outcomes," *Spine*, vol. 30, no. 14, pp. 1565–1575, 2005.

[41] J. Zigler, R. Delamarter, J. M. Spivak et al., "Results of the prospective, randomized, multicenter food and drug administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease," *Spine*, vol. 32, no. 11, pp. 1155–1162, 2007.

[42] S. H. Hochschuler, D. D. Ohnmeiss, R. D. Guyer, and S. L. Blumenthal, "Artificial disc: preliminary results of a prospective study in the United States," *European Spine Journal*, vol. 11, no. 2, supplement, pp. S106–S110, 2002.

[43] H. Mayer, K. Wiechert, A. Korge, and I. Qose, "Minimally invasive total disc replacement: surgical technique and preliminary clinical results," *European Spine Journal*, vol. 11, no. 2, supplement, pp. S124–S130, 2002.

[44] R. Bertagnoli and S. Kumar, "Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indications," *European Spine Journal*, vol. 11, no. 2, supplement, pp. S131–S136, 2002.

[45] P. C. McAfee, B. Cunningham, G. Holsapple et al., "A prospective, randomized, multicenter food and drug administration investigational device exemption study of lumbar total disc replacement with the CHARITÉtrade; artificial disc versus lumbar fusion—part II: evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes," *Spine*, vol. 30, no. 14, pp. 1576–1583, 2005.

[46] T. David, "Charité artifi cial disc long term results of one level (10 year)," *Spine*, vol. 32, no. 6, pp. 661–666, 2007.

[47] F. H. Geisler, S. L. Blumenthal, R. D. Guyer et al., "Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: results of a multicenter, prospective, randomized investigational device exemption study of Charité intervertebral disc. Invited submission from the Joint section meeting on disorders of the spine and peripheral nerves, March 2004," *Journal of Neurosurgery: Spine*, vol. 1, no. 2, pp. 143–154, 2004.

[48] C. Rosen, P. D. Kiester, and T. Q. Lee, "Lumbar disk replacement failures: review of 29 patients and rationale for revision," *Orthopedics*, vol. 32, no. 8, article 562, 2009.

[49] A. van Ooij, F. Cumhur Oner, and A. J. Verbout, "Complications of artificial disc replacement: a report of 27 patients with the SB Charité disc," *Journal of Spinal Disorders and Techniques*, vol. 16, no. 4, pp. 369–383, 2003.

[50] C. J. Siepe, H. M. Mayer, K. Wiechert, and A. Korge, "Clinical results of total lumbar disc replacement with ProDisc II: three-year results for different indications," *Spine*, vol. 31, no. 17, pp. 1923–1932, 2006.

[51] M. Putzier, J. F. Funk, S. V. Schneider et al., "Charité total disc replacement—clinical and radiographical results after an average follow-up of 17 years," *European Spine Journal*, vol. 15, no. 2, pp. 183–195, 2006.

[52] R. D. Guyer, P. C. McAfee, R. J. Banco et al., "Prospective, randomized, multicenter food and drug administration investigational device exemption study of lumbar total disc replacement with the CHARITÉ artificial disc versus lumbar fusion: five-year follow-up," *Spine Journal*, vol. 9, no. 5, pp. 374–386, 2009.

[53] K. D. van den Eerenbeemt, R. W. Ostelo, B. J. van Royen, W. C. Peul, and M. W. van Tulder, "Total disc replacement surgery for symptomatic degenerative lumbar disc disease: a systematic review of the literature," *European Spine Journal*, vol. 19, no. 8, pp. 1262–1280, 2010.

[54] P. Park, H. J. Garton, V. C. Gala, J. T. Hoff, and J. E. McGillicuddy, "Adjacent segment disease after lumbar or lumbosacral fusion: review of the literature," *Spine*, vol. 29, no. 17, pp. 1938–1944, 2004.

[55] V. K. Goel, T. H. Lim, J. Gwon et al., "Effects of rigidity of an internal fixation device: a comprehensive biomechanical investigation," *Spine*, vol. 16, no. 3, pp. S155–S161, 1991.

[56] S. M. Juratli, G. M. Franklin, S. K. Mirza, T. M. Wickizer, and D. Fulton-Kehoe, "Lumbar fusion outcomes in Washington State workers' compensation," *Spine*, vol. 31, no. 23, pp. 2715–2723, 2006.

[57] A. Waguespack, J. Schofferman, P. Slosar, and J. Reynolds, "Etiology of long-term failures of lumbar spine surgery," *Pain Medicine*, vol. 3, no. 1, pp. 18–22, 2002.

[58] P. C. McAfee, I. D. Farey, C. E. Sutterlin, K. R. Gurr, K. E. Warden, and B. W. Cunningham, "The effect of spinal implant rigidity on vertebral bone density: a canine model," *Spine*, vol. 16, no. 6, supplement, pp. S190–S197, 1991.

[59] N. Boos and J. K. Webb, "Pedicle screw fixation in spinal disorders: a European view," *European Spine Journal*, vol. 6, no. 1, pp. 2–18, 1997.

[60] H. Bozkuş, M. Şenoğlu, S. Baek et al., "Dynamic lumbar pedicle screw-rod stabilization: in vitro biomechanical comparison with standard rigid pedicle screw-rod stabilization—laboratory investigation," *Journal of Neurosurgery: Spine*, vol. 12, no. 2, pp. 183–189, 2010.

[61] W. Schmoelz, U. Onder, A. Martin, and A. Von Strempel, "Non-fusion instrumentation of the lumbar spine with a hinged pedicle screw rod system: an in vitro experiment," *European Spine Journal*, vol. 18, no. 10, pp. 1478–1485, 2009.

[62] V. K. Goel, R. J. Konz, H. T. Chang et al., "Hinged-dynamic posterior device permits greater loads on the graft and similar stability as compared with its equivalent rigid device: a three-dimensional finite element assessment," *Journal of Prosthetics and Orthotics*, vol. 13, no. 1, pp. 17–20, 2001.

[63] B. Cakir, M. Richter, K. Huch, W. Puhl, and R. Schmidt, "Dynamic stabilization of the lumbar spine," *Orthopedics*, vol. 29, no. 8, pp. 716–722, 2006.

[64] D. Grob, A. Benini, A. Junge, and A. F. Mannion, "Clinical experience with the dynesys semirigid fixation system for the lumbar spine: surgical and patient-oriented outcome in 50 cases after an average of 2 years," *Spine*, vol. 30, no. 3, pp. 324–331, 2005.

[65] P. Korovessis, Z. Papazisis, G. Koureas, and E. Lambiris, "Rigid, semirigid versus dynamic instrumentation for degenerative lumbar spinal stenosis: a correlative radiological and clinical analysis of short-term results," *Spine*, vol. 29, no. 7, pp. 735–742, 2004.

[66] C. C. Würgler-Hauri, A. Kalbarczyk, M. Wiesli, H. Landolt, and J. Fandino, "Dynamic neutralization of the lumbar spine after microsurgical decompression in acquired lumbar spinal stenosis and segmental instability," *Spine*, vol. 33, no. 3, pp. E66–E72, 2008.

[67] R. C. Huang, F. P. Girardi, M. R. Lim, and F. P. Cammisa, "Advantages and disadvantages of nonfusion technology in spine surgery," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 263–269, 2005.

[68] J. S. Harrop, J. A. Youssef, M. Maltenfort et al., "Lumbar adjacent segment degeneration and disease after arthrodesis and total disc arthroplasty," *Spine*, vol. 33, no. 15, pp. 1701–1707, 2008.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2012, Article ID 218385, 9 pages
doi:10.1155/2012/218385

Review Article

Role of Dynesys as Pedicle-Based Nonfusion Stabilization for Degenerative Disc Disorders

Neel Anand[1] and Eli M. Baron[2]

[1] *Minimally Invasive Spine Surgery, Department of Surgery, Cedars Sinai Spine Center, 444 S. San Vicente Boulevard, Suite 800, Los Angeles, CA 90048, USA*
[2] *Department of Neurosurgery, Cedars Sinai Spine Center, 444 S. San Vicente Boulevard, Suite 800, Los Angeles, CA 90048, USA*

Correspondence should be addressed to Neel Anand, neel.anand@cshs.org

Received 15 July 2012; Revised 13 December 2012; Accepted 18 December 2012

Academic Editor: Vijay K. Goel

Posterior nonfusion pedicle-screw-based stabilization remains a controversial area of spine surgery. To date, the Dynesys system remains the most widely implanted posterior nonfusion pedicle screw system. We review the history of Dynesys and discuss clinical outcome studies and biomechanical evaluations regarding the Dynesys system. Indications for surgery and controversies are discussed. Recommendations are made regarding technical implantation.

1. Introduction

Posterior nonfusion pedicle-screw-based stabilization is a controversial area of spine surgery. In the last 15–20 years, numerous devices have appeared on the market only to fall out of favor with clinical trials. Various proposed indications exist ranging from discogenic pain to fusion alternatives in the case of possible instability. Additionally, these devices have been used in the setting of artificial discs, in a hybrid construct adjacent to a fusion, and even in the setting of degenerative scoliosis. Out of all of the devices available, the largest experience is with Dynesys. We review the history and literature regarding Dynesys. We also detail our experience with Dynesys in detail and discuss lessons learned in terms of the treatment of degenerative disc disease with these technologies.

2. Brief History

The first commonly used posterior pedicle-screw-based nonfusion system was the Graf ligament. This was followed by the use of the Dynesys System. It has been postulated that pedicle-screw-based systems function as a tension band resulting in offloading of the disc possibly resulting in functional improvement [1–3].

Graf ligamentoplasty, introduced in the 1990s, was the first widely used pedicle-screw-based nonfusion stabilization procedure. In this procedure, braided polyester ligaments in the form of a loop were applied around pedicle screws under tension to lock an individual segment in extension [4]. In theory, this device shifted the load from the anterior part of the disc to the posterior annulus [5]. By offloading the painful anterior portion of the disc, this device theoretically may be useful in the treatment of back pain [4, 6].

Grevitt et al. [5] reviewed the outcome of 50 patients undergoing Graf ligamentoplasty. This was done primarily for degenerative disc disease. At an average followup of 24 months, they reported Oswestry Disability Indices (ODIs) scores improving from an average of 59% to 31%. Similar results were found by Gardner and Pande where they reported excellent results in 62% of patients with an average followup of 7.84 years [7]. Mean ODIs improved from 59% ± 10% preoperatively to 37.7% ± 14% after seven years. Brechbühler et al. concluded that good results were seen in patients with a combination of minor disc degeneration and mild loss of intervertebral height, fixed back musculature and facet arthritis [1].

Hadlow et al. compared the results of posterolateral fusion to Graf ligamentoplasty in a retrospective series of

83% of patients [8]. They noted a higher rate of revision with Graf ligamentoplasty of two years with better outcomes in patients managed by posterolateral fusion. While this was significant at one year, at two years the differences were no longer statistically significant. Nevertheless, the authors questioned the use of Graf ligamentoplasty.

Similarly, Rigby et al. noted poor long-term results of Graf ligamentoplasty [9]. They noted in the retrospective series of 51 patients, a 21.5% complication rate with seven patients needing to go into spinal fusion procedures. As a result, this procedure was not recommended.

The Graf ligamentoplasty had several theoretical drawbacks [6]. The device may result in increased lateral recess narrowing with hypothetical nerve root compression, and foraminal narrowing especially in the presence of preexisting stenosis [6]. Additionally, the device is applied with compression across the pedicle screws, and as a result of the compression flexion is restricted and in theory loads are increased across the posterior annulus. Increased loading of the posterior annulus may be associated with increased discogenic back pain [4, 6].

As a result of the issues with the Graf ligamentoplasty, especially with regards to compression of the posterior annulus, the Dynesys was developed. Dynesys (dynamic neutralization system of the spine) consists of pedicle screws, which are made of a titanium alloy (Protasul-100) and polyethylene terephthalate (Sulene-PET) cord and polycarbonate urethane spacers [3]. This was designed to reduce the high revision rate seen with the Graf ligamentoplasty. The polyester bands used with the Graf system were eliminated and replaced with a cord spacer between screw heads. As the spacers are not elastic, flexion results in compression of the disc in the axis of flexion of the posterior ligament. When a patient extends with Dynesys, however, the anterior annulus opens, without compression of the posterior annulus, and the system theoretically unloads the disc space. This is especially true when the patient is maintaining a lordosis and when the spacers become weight bearing [6]. This is specifically because the device limits extension as opposed to the Graf ligamentoplasty.

Schmoelz et al. demonstrated that the Dynesys system offloads the disc in extension as conveyed in biomechanical testing [10]. Thus, the problem seen with the Graf ligamentoplasty resulting in posterior annulus related compression is avoided. MRI has also shown a reduction in overall motion of the instrumented segment with Dynesys [11]. Beastall et al. confirmed no reduction in posterior disc height, while a small decrease was noted in anterior disc height [11]; they also noted no significant differences in the patient's segment motion when comparing adjacent levels to preop.

3. Series with Positive Results with Dynesys Implantation

Stoll et al. reported very good results in 83 patients undergoing Dynesys in a multicenter trial [12]. The implants were placed for a variety of degenerative disorders including disc herniation revision surgery and spinal stenosis. The authors noted no screw breakage, but they reported 9 failures out of 83 cases, 4 required early revision, 7 screw loosening, and 7 cases with adjacent segment degeneration. They postulated that the lack of breakage might be due to the elasticity of the spacers-cord combination, which may cause a cyclic peak load on the implant to be lower than in rigid constructs. They also theorized that offloading of the discs might result in reduced disc degeneration. Putzier et al. corroborated this comparing the results of 49 patients undergoing microdiscectomy alone versus 35 undergoing microdiscectomy with addition of Dynesys stabilization [2]. They noted that patients with Dynesys had no further degenerative disc changes in height configuration or morphology. They hypothesized that this was due to neutralization of disc pressures and offloading of the facet joints. Nevertheless, followup for these theories was quite short, and it has been suggested that longer followup is necessary before concluding that Dynesys is actually effective in reducing disc degeneration. Also, the authors noted that patients with marked degeneration or spinal deformity are inappropriate candidates for Dynesys implantation [2].

Bordes-Monmeneu et al. reported good outcomes with Dynesys [13]. They reported two-year outcome in 94 patients undergoing Dynesys implantation for disc herniation, degenerative disc disease, and lumbar stenosis. Overall, they reported a good outcome with ODI decreasing from 56.8% to 21.4%. They concluded that Dynesys may be useful incorporating the functionality concept as opposed to restricting movement.

Lee et al. also noted good outcomes with Dynesys [14]. They reported on 20 consecutive patients who underwent decompression and dynamic stabilization with the Dynesys system. This was done for various degenerative disorders including spinal stenosis with degenerative spondylolisthesis, degenerative spinal stenosis, adjacent segment disease after fusion, and spinal stenosis with degenerative scoliosis. They noted in a mean followup period of 27.25 months that the mean VAS decreased from 8.5 to 2.2. The ODIs improved from 79.58% to 22.17%. They also noted no cases of implant failure. They concluded that Dynesys could preserve the motion of stabilized segments and provide clinical improvement in patients with degenerative spinal stenosis with instability. They concluded that Dynesys might be a viable alternative to spinal fusion.

Long-term good outcomes with Dynesys were reported by Schaeren et al. [15]. They reported a minimum four-year followup of spinal stenosis with degenerative spondylolisthesis treated with Dynesys and decompression. Twenty-six patients were followed with a mean age of 71, who underwent surgical treatment. They noted at a minimum followup of four years that VAS scores improved significantly and that radiologically their spondylolisthesis did not progress and motion segments remained stable. They did note 1 patient to have screw breakage with low back pain. At a 4-year followup, 47% of patients also showed some degeneration of adjacent segments. Overall, patient satisfaction remained high; 95% of patients would undergo the procedure again. They concluded that this procedure would be useful for spinal stenosis and degenerative spondylolisthesis. They highlighted the lack of bone grafting need with Dynesys and thus

lack of graft harvest morbidity. They did note, however, that degenerative disc disease is progressive and degeneration of adjacent segments continues to be a problem.

Good results were also reported by Hu et al. on 32 patients who underwent posterior laminectomy and Dynesys implantation for spinal stenosis with spondylolisthesis or lumbar disc protrusion [16]. All patients were followed for six to 23 months with a mean followup of 16.4 months. They noted ODIs to improve from preoperative 69% to postoperative 28%. They noted VAS scores to also be significantly improved. They noted no loosening of screws, cords, or polyester spacers. They concluded that Dynesys, combined with decompression, could achieve satisfactory and short-term clinical results in lumbar degenerative disease.

Yu et al. compared 35 patients who received Dynesys implantation at three segments ranging from L1 to S1 with 25 patients with the same indications who underwent three-level posterior lumbar interbody fusion (PLIF) [17]. All patients had a three-year followup. They noted the Dynesys patients to have a higher preservation of motion at operative levels as well as total range of motion. They also noted that a decrease of anterior disc height was seen in the Dynesys group, while an increase was seen in the posterior lumbar interbody fusion group. Overall, however, they noted the Dynesys group showing a greater improvement in Oswestry Disability Index and Visual Analog Scale back pain at three years postoperatively. They concluded that Dynesys was an acceptable alternative to PLIF for the treatment of multi-segment lumbar disease [17].

Kim et al. compared outcomes of single-versus multilevel dynamic stabilization using Dynesys [18]. They noted 21 patients were evaluated, on average at 31 months postop. Single-level Dynesys versus multilevel Dynesys were groups were compared. They noted that the disc height was preserved in both groups. However, they reported retrolisthesis in adjacent segments above in six patients within the group that had a multi-level Dynesys implantation. The authors concluded that dynamic stabilization is a good alternative treatment option for degenerative spinal disease. However, dynamic stabilization preserves only limited motion and may cause stress on the adjacent level above. They caution to observe adjacent segment disease closely, especially in the cases of multi-level instrumentation.

4. Series with Negative Results with Dynesys Implantation

Würgler-Hauri reported on 37 consecutive patients with acquired lumbar stenosis and instability that underwent lumbar microsurgical decompression and implantation of Dynesys [19]. They followed the patients at three months and at 12 months. They noted a decrease in pain from 59.2% to 27.3% after microsurgical decompression. They also noted, however, a high complication rate including four broken and two misplaced pedicle screws within a total of 224 screws implanted. They also noted two loosened systems and one cerebrospinal fistula. At one year, a total of 7 patients (19%) required surgical revision. They concluded that "the reported biomechanical principles of Dynesys do not reflect the advantages and outcomes compared with none or other stabilization systems after microsurgical and radicular decompression reported in the literature."

Grob et al. reported the results of 31 patients who underwent Dynesys implantation [20]. While they reported a 67% improvement rate, they noted a late reoperation rate as high as 19%. Grob's series assessed Dynesys implanted for a variety of indications including lumbar stenosis, spondylosis, disc degeneration, failed back surgery, degenerative listhesis, and extradural tumor. Given the small series and the very heterogeneous group if indicated, it was difficult to draw any firm conclusions. Nevertheless, Grob's feeling was that the device was not superior in any way to posterolateral fusion.

5. United States Food and Drug Administration (FDA) Study

Welch et al. optimistically reported preliminary results from the Food and Drug Administration investigational device exemption clinical trial of Dynesys [21]. They noted significant improvement at one year both in leg and back pain (ODI scores improved from 80.3% to 25.5% and from 55.6% to 26.3%, resp.). The authors noted that Dynesys might be preferable to fusion for surgical treatment of degenerative spondylolisthesis and stenosis because it decreases back and leg pain, while avoiding the greater tissue destruction and morbidity of donor site problems encountered in fusion. They also noted that this might be related to Dynesys preserving the disc, unloading the facet joints, and permitting more normal motion.

Nevertheless, when the FDA reported their Executive Summary on the Dynesys system in November 2009, their conclusions were not favorable [22]. Three hundred sixty-seven patients were randomized to Dynesys or fusion using posterior pedicle screws and autogenous bone grafting. Inclusion criteria included degenerative spondylolisthesis or retrolisthesis and/or spinal stenosis, lumbar radiculopathy, leg pain greater than back pain, among others. Patients were prospectively evaluation preoperative, intraoperatively and postoperatively at 3 weeks, 3, 6, 12, and 24 months. Complications and adverse events were noted. Dynesys outcomes were noted to be superior to fusion success rate for VAS leg pain (87% versus 73%), ODI success (76% versus 70%), and neurologic success (92% versus 84%) at 24 months postop. The FDA noted that the overall clinical success results of Dynesys were noninferior to the fusion (52% versus 40%). The FDA advisory committee concluded, however, that the data here was unclear and that changes should have been made to the clinical trial. They recommended against the wider use of the system.

6. Biomechanics and Adjacent Segment Degeneration with Dynesys Implantation

In a nonhuman primate model, Cunningham et al. studied 14 baboons where Dynesys was implanted [23]. Eight animals underwent spinal surgery to implant Dynesys spanning two levels. Six animals were sacrificed acutely and their spines were biomechanically tested in the intact condition

with instrumentation implanted. They noted that a flexion/extension motion for the acute group of instrumented spines was 27% of intact condition. After six months with instrumentation in situ, flexion/extension was 56% of the intact condition. After 12 months with instrumentation in situ, flexion/extension was 70% of the intact condition. With the instrumentation explanted, flexion/extension at six and 12 months was not different from the intact condition ($P > 0.05$). They noted similar results for lateral bending. They noted no significant differences in axial rotation between any of the groups at any point. The facet joints at the operative and adjacent levels exhibited normal articular cartilage at both six and 12 months postoperative time points. They did report, however, that after 12 months 25% rate of screw loosening was noted.

Delank et al. compared in a biomechanical study rigid pedicle screw fixation versus Dynesys [24]. They noted an almost equal reduction in flexion and extension and right and left bending for both the rigid and dynamic systems. At the adjacent segments, they noted a slightly higher mobility for rigid stabilization than for dynamic stabilization. They noted that in rigid stabilization that the first cranial segment has compensatory flexion/extension movement, while in the cases of dynamic stabilization the compensation is distributed among the first and second crania and by 20% in the caudal adjacent segment. They concluded that rigid and dynamic stabilization do not result in the significant changes in range of motion of the instrumented segment. However, the distribution of compensatory adjacent segment movement is different.

A radiographic study of motion and alignment of patients after Dynesys implantation was conducted by Cakir et al. [25]. Twenty-six patients undergoing either decompression and fusion or decompression and Dynesys. They were followed radiographically with flexion/extension radiographs. Based on image analysis, they concluded that there was significant reduction in the global range of motion of the lumbar spine and the segmental range of motion at the index level in the fusion groups, where adjacent level range of motion did not change significantly. In the Dynesys group, they noted no significant changes in global lumbar spinal movement and segmental range of motion. They concluded that neither monosegmental instrumented fusion nor Dynesys altered the range of motion of the cranial or caudal adjacent segments. Consequently, Dynesys may have no effect with regard to adjacent segment mobility when compared to monosegmental fusion.

Strube et al. reported on biomechanical results in a cadaveric model of Dynesys implantation versus rigid instrumentation implantation [26]. The authors noted that both dynamic and rigid fixation of L4-L5 adjacent to rigid fixation of L5-S1 led to an increase of the mean range of motion of L3-L4 in extension, flexion, lateral bending, and left axillary rotation and at L2-L3 in all major planes of motion. Compared to single-level fixation with segmental instrumentation, both dynamic and rigid ones led to a further increase in the mean range of motion for flexion and right lateral bending, whereas axial rotation and extension seemed not to be significantly affected by the additional fixation at L4-L5 superior to rigid fixation. They concluded that hypermobility of the adjacent levels increased with the number of fixated levels. They also noted effects of Dynesys implant to be very close to those of rigid fixation since there were no differences at L3-L4 between any of the dynamic or rigid fixation when done above a fusion. They noted a slight difference in lateral bending when dynamic fixation was used versus rigid fixation. They concluded, however, that dynamic instrumentation cannot be recommended if prevention of hypermobility in the adjacent level is a main target.

Beastall et al. reported on 24 patients with predominantly low back pain with or without leg pain that were treated with Dynesys [11]. All patients underwent positional MRI before surgery and nine months after surgery. Measures were made to assess the differences at the operated level, the adjacent, and whole lumbar spine. They noted that statistically significant reduction in flexion and extension range of movement both of the whole lumbar spine by 13.37° and at the instrumented segment by 4.8° following the surgery. There was an insignificant reduction in the range of movement of the level of above the instrumentation. Mean anterior disc height at the instrumented level reduced by 0.7 mm following insertion of the Dynesys. Mean posterior disc height reduced by 0.3 mm. In neutral posture, they noted the Dynesys to have no significant impact on lordosis or inclination of the operated or adjacent levels. They noted the Dynesys to appear to restrict extension more than flexion with respect to neutral posture. They concluded that Dynesys allowed movement at the instrumented level, albeit reduced, with no significant increase in mobility at the adjacent segments, but with reduction of the anterior disc height without significant increase in posterior disc height.

Interestingly, Beastall et al.'s in vivo findings were opposite to the earlier cadaver model findings of Schmoelz et al., where Dynesys was found to stabilize the spine least in extension, where motion resembled the intact spine [27]. In their cadaveric study, Schmoelz et al. noted Dynesys to stabilize the spine, but they noted it to be more flexible than a rigid external fixator. They noted the greatest difference between the two devices in extension. They also noted that adjacent segment motion was not affected by either form of fixation. In a later study, with a similar model, Schmoelz et al. studied the effect of Dynesys versus rigid fixation on disc loading [10]. They noted both Dynesys and the rigid fixator to significantly reduce intradiscal pressure in extension and in lateral bending compared to the intact state. There was no significant change in intradiscal pressure with flexion with either form of fixation. They also noted no changes in intradiscal pressure in the adjacent discs for either the Dynesys or the internal fixator. Liu et al. studied Dynesys implanted in a three-dimensional nonlinear finite-element model of the L1-L5 lumbar spine [28]. Range of motions and stress was studied. Under flexion, extension, and lateral bending, Dynesys provided significant stability at the surgical level but increased range of motion at the adjacent level. Under flexion and lateral bending, the Dynesys alleviated annular stress at the surgical level but was noted to increase annular stress at the adjacent level. Under extension, Dynesys decreased facet loading at the surgical level but increased facet loading at the

adjacent level. The authors concluded that Dynesys was able to restore stability and alleviate loading on disc and facet at the instrumented level, but they noted at adjacent levels greater range of motion, annular stress, and facet loading were found. In addition, they noted that profile of screw placement caused only a minor influence on the range of motion, annular stress, and facet loading, but screw stress was notably increased.

7. Hybrid Dynamic Stabilization and Fusion System

Maserati et al. described the use of a hybrid dynamic stabilization and fusion system where Dynesys was used in conjunction with Optima pedicle screws in the setting of Dynesys being used for dynamic stabilization above fusion, with transforaminal lumbar interbody fusion being performed at the caudal segment [29]. They reported on 24 consecutive patients. Indication for implantation of the hybrid system was unclearly reported. They stated that "patients with degenerative lumbar disc disease were chosen to undergo the procedure if they were candidates for fusion and had symptomatic adjacent level pathology in which dynamic stabilization was thought to be more appropriate than arthrodesis." They noted, at followup of eight months, VAS score to be improved. Additionally, they noted five perioperative complications including two dural tears and one case of medially placed pedicle screws. They also noted 3% of their patients to have failure requiring extension of their fusion. They noted that 1 patient developed symptomatic degeneration of the dynamic stabilized segment and 2 patients had symptomatic degeneration above the dynamically stabilized segment.

In another study on hybrid dynamic stabilization, Putzier et al. reported on the use of Dynesys adjacent to a single-level fusion [30]. In a study designed to compare dynamic fixation of a clinically asymptomatic adjacent segment disease with circumferential lumbar fusion alone, 60 patients with symptomatic degeneration of L5-S1, L4-L5, and asymptomatic adjacent segment degeneration were divided into two groups. Thirty patients were treated with circumferential single-level fusion and 30 were treated with a dynamic fixation and transition above the level of fusion. Patients were assessed postoperatively at 12 months and a mean followup of 76.4 months. Radiologic parameters in addition to clinical parameters were followed. At final followup, two nonfusions were observed in both groups. Six single-level fusion patients and one dynamically fixed transition patient presented with a progression of adjacent segment disease. In 2 of the dynamic fixation transition patients, however, symptomatic progressive adjacent segment degeneration occurred in the segment superior to the dynamic fixation. In 1 of the patients with Dynesys, the fusion of the dynamically fixated segment was observed. Four of the dynamically fixated transition patients presented with radiologic implant failures. The authors recommended against dynamically fixating adjacent segments in patients with clinically asymptomatic adjacent segment degeneration. The reduced numbers of progression of adjacent segment degeneration seen with dynamic fixation were accompanied by a higher number of implant failures and a shift of adjacent segment degeneration to a shift above the superior segment.

8. Controversies and Controversial Indications

Vaga et al. reported molecular MRI imaging for an evaluation of the effect of Dynesys on lumbar intravertebral discs [31]. Ten patients with low back pain unresponsive to conservative treatment underwent implantation of Dynesys at one to three spinal levels. Subsequently, authors assessed the quantification of glycosaminoglycan (GAG) concentration within instrumented and adjacent levels by mean of delayed gadolinium enhanced MRI imaging of cartilage protocol. At six months after implantation, they noted VAS and Oswestry scores to improve. They noted GAG to increase in 61% of the instrumented levels, while 68% of the noninstrumented levels showed a decrease in GAG, mainly in the posterior disc portion. The authors concluded that dynamic stabilization of the lumbar spine is able to stop and partially reverse disc degeneration especially in seriously degenerated discs, while increasing the stress at the adjacent levels.

Their findings, however, were contradicted in a study by Kumar et al. where 32 patients who underwent Dynesys procedure had their discs assessed at 2 years postop. using MRI and the Woodend disc degeneration scoring system [32]. They noted disc degeneration to increase in both the bridged and adjacent levels when compared to preop.

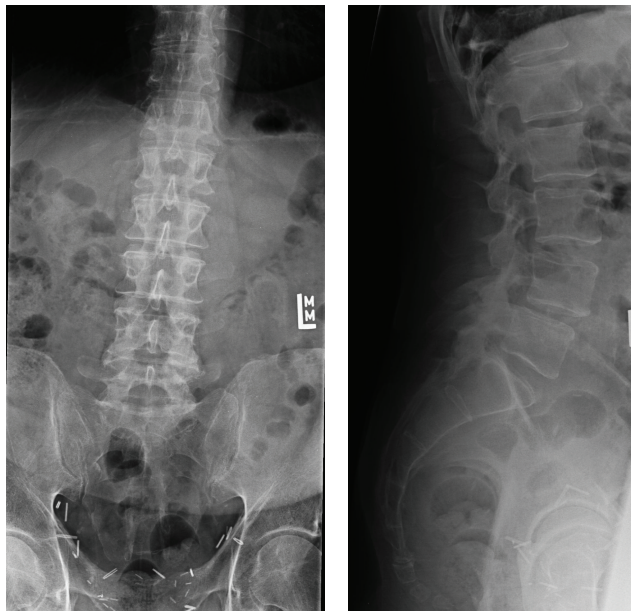
Di Silvestre et al. reported outcomes of 29 elderly patients with mild degenerative scoliosis (mean Cobb angle 16.9°) who underwent Dynesys with laminectomy [33]. Mean followup was 54 months. ODI, back pain, and leg pain improved considerably. Mean Cobb improved from 16.9 to 11.1 degrees. Additionally associated spondylolisthesis was stable. They noted 4 cases of asymptomatic radiolucencies around S1 screws. They concluded that Dynesys with laminectomy provided enough stability to prevent progression of scoliosis and instability.

Another unusual indication for Dynesys is correction of disc tilt after total disc replacement. Cheng et al. reported on 3 patients presenting with tilted total disc replacement [34]. All patients underwent corrective surgery with Dynesys, where the collapsed side was expanded and the contralateral side was compressed using manipulation of the universal spacer.

Ko et al. reported on screw loosening in a Dynesys stabilization system [35]. They reviewed the charts, radiographic films, and medical records of 71 patients who underwent decompression and Dynesys dynamic stabilization for one or two levels. Mean follow-up duration was 16.6 months and 71 patients were studied. They noted an overall radiographic evidence of loosening in 19.7% of patients and 4.6% of screws. Nevertheless, they noted no adverse effect on clinical improvement. The followup, however, was relatively short.

9. Indications for Dynesys

Though as indicated above, many proposed indications of dynamic stabilization have been used. In our experience,



(a) (b)

Figure 1: (a) and (b) Anteroposterior and lateral radiographs of a 63-year-old gentleman with severe left lower extremity pain unresponsive to conservative measures. Workup revealed him to have an L4-5 degenerative spondylolisthesis in addition to having a left-sided juxtafacet cyst compressing the descending root of L5. The patient underwent L4-5 Dynesys placement in addition to laminoforaminotomy, mesial facetectomy, and excision of the facet cyst.

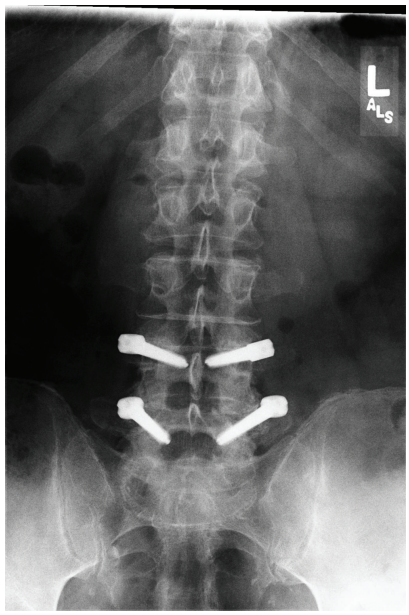
we have had best results in patients who have mild-to-moderate degeneration with mechanical loading back pain with no secondary gain factors. Our ideal patient would have mechanical loading back pain limited to one or two segment disease. The following radiologic factors would be acceptable: disc collapse less than 50% of normal, up to grade 1 degenerative spondylolisthesis, translational motion less than 3 mm on flexion/extension, not more than grade 1 or 2 facet degenerative changes, no lateral listhesis, no scoliotic tilt or segmental collapse, and bone density T score greater than -1.5 (Figures 1, 2, 3, and 4). Stenosis of any degree at the involved levels is not a contraindication. We have performed a microscopic laminoforaminotomy to achieve decompression, avoiding a laminectomy.

We reported outcomes on 88 patients who underwent Dynesys both using the muscle sparing paraspinal approach versus midline approach [36]. At mean followup of 18 months, both groups showed significant improvements in terms of VAS, ODI, SF-36 outcomes, and treatment intensity score (TIS, which reflects narcotic use). For the first 6 weeks postop., however, the paraspinal approach group had significantly better TIS scores. This trend continued, but was not statistically significantly at 6 months. Thus, we prefer the paraspinal approach. Additionally we reported on 35 patients undergoing Dynesys stabilization for back pain from lumbar degenerative disc disease [37]. The average age was 44 years with 22 females and 14 males. All patients had a clear history of discogenic back pain with no leg pain, further corroborated by MRI and a discogram. Average followup was 18 months. Patients did well with Dynesys where their VAS scores were reduced from 9 to 2.5. Additionally, there was significant reduction in SF-36 and ODI scores.

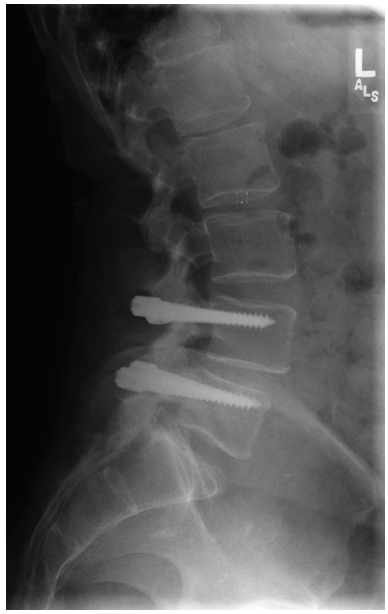
10. Technical Notes for Implantation of Dynesys

All patients are positioned prone on a Jackson table with care taken to maximize lordosis. All patients are operated through a bilateral paraspinal muscle sparing approach. Patients who need a decompression are operated on through a midline fascial approach with the skin on the symptomatic side retracted to the midline. Microscopic laminotomy or laminoforaminotomy, including decompression of the opposite side when indicated is done, with or without discectomy followed by posterior nonfusion stabilization with the facet capsule and facet joints carefully preserved. The midline structures are preserved in all cases with great care being taken to suture the lumbodorsal fascia back to the midline at the end of the procedure. No patients undergo laminectomy. Patients not needing decompression are purely instrumented with bilateral paraspinal muscles sparing approaches. In this manner, tissue damage, especially of the multifidus, is minimized. Additionally, care is taken not to violate the facet capsules or any of the muscle attachments. We feel it critical to preserve the soft tissues when nonfusion stabilization is performed.

As regards the approach, we prefer the term modified muscle sparing approach, where plane is teased apart by using a Langenbeck elevator where the fibers of the multifidus are teased medially and the longissimus laterally, demonstrating a clear cleavage plane. The transverse process for the instrumented pedicle is palpated and confirmed radiologically. We then use a narrow McCulloch blade retractor laterally and a shorter blade medially for retraction directly over the transverse process. This can be done very cleanly with minimal-to-no muscle bleeding encountered if



(a)



(b)

Figure 2: (a) and (b) Postop. anteroposterior and lateral radiographs at 1 year showing instrumentation intact and disc height comparable to preop.

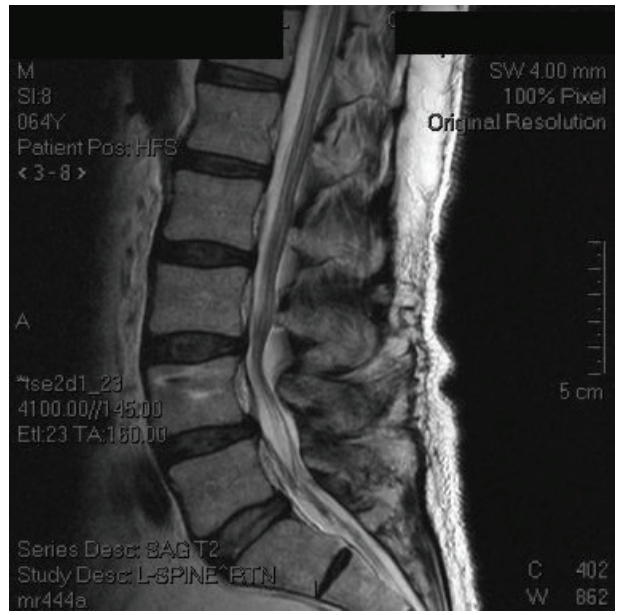


Figure 3: Midsagittal MRI at 2 years outdemonstrating maintenance of disc configuration at L4-5 and a well-hydrated supraadjacent segment.

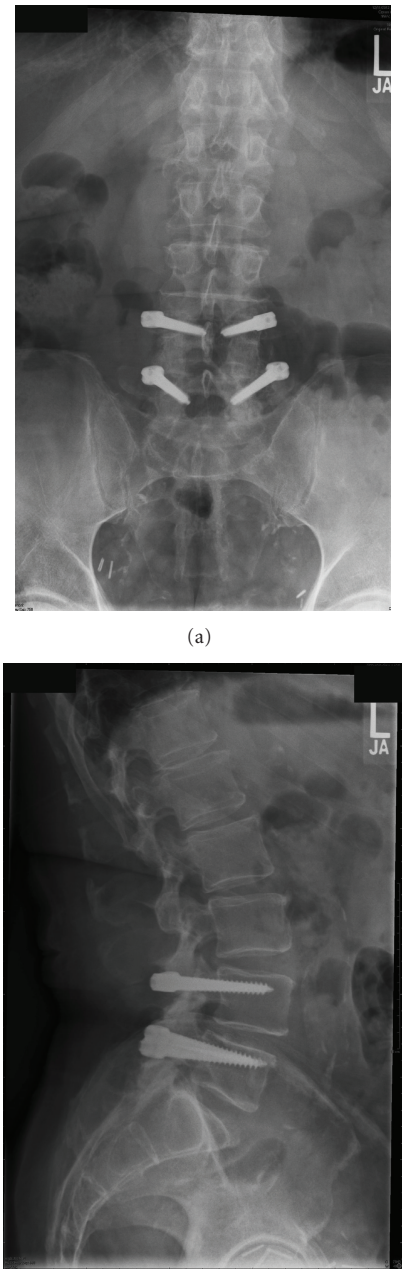
the proper plane is identified. We have described this technique elsewhere [38]. In terms of pedicle screw insertion, care must be taken not to violate the facet joints. We typically expose the transverse process, mammillary process, and pars only without exposing the facet capsule. This, we feel, may be important in minimizing the chance of further facet degeneration in supra-adjacent segment disease. Screws are placed in a converging fashion from a far out-to-in direction with care taken not to violate the facet. Screws as long as safely possible without being bicortical are used with the screw head placed as low as possible at the junction of the superior facet and transverse process.

Tensioning of the spacer and choosing the correct size of the spacer has been the most difficult to accurately reproduce and quantify. The proprietary tensioner available on the set gives some indication as to the amount of tension between the screws and in determining the size of the spacer, but yet this step in the procedure remains an art and difficult to quantify with any scientific accuracy. This in itself maybe partially responsible for the wide disparity in results reported amongst different series. The issue of tensioning each segment becomes even more relevant when multiple levels are instrumented and in our experience when three or more levels were instrumented the results were less than optimal as compared to one- or two-level instrumentation.

Given the benefits we have seen for the paraspinal approach, we prefer to use this approach for all patients having pedicle screw posterior nonfusion stabilization and feel once again that the approach for this technology may be an important factor determining clinical outcomes.

11. Conclusions

There has been considerable experience both clinically and with biomechanics with regard to the Dynesys posterior nonfusion pedicle-screw-based systems. Nevertheless, it is our belief that heterogeneous indications and heterogeneous techniques during implantation may result in less than desired outcomes. In carefully selected patients, we believe the technology to be quite useful. As evidenced by certain biomechanical and radiologic studies above, there may be a use in the future where the disc needs to be stabilized, for example, with stem cells or other restorative technologies.



(a)

(b)

Figure 4: (a) and (b) Postop. anteroposterior and lateral radiographs at 7.5 years postop. showing instrumentation intact and disc height comparable to preop.

In the meantime, especially where early disc degeneration is present and low-grade spondylolisthesis is present, it may be useful for selected patients.

References

[1] D. Brechbühler, T. M. Markwalder, and M. Braun, "Surgical results after soft system stabilization of the lumbar spine in degenerative disc disease—long term results," *Acta Neurochirurgica*, vol. 140, no. 6, pp. 521–525, 1998.

[2] M. Putzier, S. V. Schneider, J. F. Funk, S. W. Tohtz, and C. Perka, "The surgical treatment of the lumbar disc prolapse: nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone," *Spine*, vol. 30, no. 5, pp. E109–E114, 2005.

[3] O. Schwarzenbach, U. Berlemann, T. M. Stoll, and G. Dubois, "Posterior dynamic stabilization systems: DYNESYS," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 363–372, 2005.

[4] D. K. Sengupta, "Dynamic stabilization devices in the treatment of low back pain," *Neurology India*, vol. 53, no. 4, pp. 466–474, 2005.

[5] M. P. Grevitt, A. D. H. Gardner, J. Spilsbury et al., "The Graf stabilisation system: early results in 50 patients," *European Spine Journal*, vol. 4, no. 3, pp. 169–175, 1995.

[6] R. C. Mulholland and D. K. Sengupta, "Rationale, principles and experimental evaluation of the concept of soft stabilization," *European Spine Journal*, vol. 11, supplement 2, pp. S198–S205, 2002.

[7] A. Gardner and K. C. Pande, "Graf ligamentoplasty: a 7-year follow-up," *European Spine Journal*, vol. 11, supplement 2, pp. S157–S163, 2002.

[8] S. V. Hadlow, A. B. Fagan, T. M. Hillier, and R. D. Fraser, "The graft ligamentoplasty procedure: comparison with posterolateral fusion in the management of low back pain," *Spine*, vol. 23, no. 10, pp. 1172–1179, 1998.

[9] M. C. Rigby, G. P. Selmon, M. A. Foy, and A. Fogg, "Graf ligament stabilisation: mid- to long-term follow-up," *European Spine Journal*, vol. 10, no. 3, pp. 234–236, 2001.

[10] W. Schmoelz, J. F. Huber, T. Nydegger, L. Claes, and H. J. Wilke, "Influence of a dynamic stabilisation system on load bearing of a bridged disc: an in vitro study of intradiscal pressure," *European Spine Journal*, vol. 15, no. 8, pp. 1276–1285, 2006.

[11] J. Beastall, E. Karadimas, M. Siddiqui et al., "The dynesys lumbar spinal stabilization system: a preliminary report on positional magnetic resonance imaging findings," *Spine*, vol. 32, no. 6, pp. 685–690, 2007.

[12] T. M. Stoll, G. Dubois, and O. Schwarzenbach, "The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system," *European Spine Journal*, vol. 11, supplement 2, pp. S170–S178, 2002.

[13] M. Bordes-Monmeneu, V. Bordes-García, F. Rodrigo-Baeza, and D. Sáez, "System of dynamic neutralization in the lumbar spine. Experience on 94 cases," *Neurocirugia*, vol. 16, no. 6, pp. 499–506, 2005.

[14] S. E. Lee, S. B. Park, T. A. Jahng, C. K. Chung, and H. J. Kim, "Clinical experience of the dynamic stabilization system for the degenerative spine disease," *Journal of Korean Neurosurgical Society*, vol. 43, no. 5, pp. 221–226, 2008.

[15] S. Schaeren, I. Broger, and B. Jeanneret, "Minimum four-year follow-up of spinal stenosis with degenerative spondylolisthesis treated with decompression and dynamic stabilization," *Spine*, vol. 33, no. 18, pp. E636–E642, 2008.

[16] Y. Hu, Y. J. Gu, R. M. Xu et al., "Short-term clinical observation of the Dynesys neutralization system for the treatment of degenerative disease of the lumbar vertebrae," *Orthopaedic Surgery*, vol. 3, pp. 167–175, 2011.

[17] S. W. Yu, C. Y. Yen, C. H. Wu et al., "Radiographic and clinical results of posterior dynamic stabilization for the treatment of multisegment degenerative disc disease with a minimum follow-up of 3 years," *Orthopaedic and Trauma Surgery*, vol. 132, pp. 583–589, 2012.

[18] C. H. Kim, C. K. Chung, and T. A. Jahng, "Comparisons of outcomes after single or multilevel dynamic stabilization:

effects on adjacent segment," *Journal of Spinal Disorders and Techniques*, vol. 24, no. 1, pp. 60–67, 2011.

[19] C. C. Würgler-Hauri, A. Kalbarczyk, M. Wiesli, H. Landolt, and J. Fandino, "Dynamic neutralization of the lumbar spine after microsurgical decompression in acquired lumbar spinal stenosis and segmental instability," *Spine*, vol. 33, no. 3, pp. E66–E72, 2008.

[20] D. Grob, A. Benini, A. Junge, and A. F. Mannion, "Clinical experience with the dynesys semirigid fixation system for the lumbar spine: surgical and patient-oriented outcome in 50 cases after an average of 2 years," *Spine*, vol. 30, no. 3, pp. 324–331, 2005.

[21] W. C. Welch, B. C. Cheng, T. E. Awad et al., "Clinical outcomes of the Dynesys dynamic neutralization system: 1-year preliminary results," *Neurosurgical Focus*, vol. 22, no. 1, p. E8, 2007.

[22] Panel FOaRD, "FDA Executive Summary for Zimmer Spine's Dynesys Spinal System," July 2012, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel /UCM188734.pdf.

[23] B. W. Cunningham, J. M. Dawson, N. Hu, S. W. Kim, P. C. McAfee, and S. L. Griffith, "Preclinical evaluation of the Dynesys posterior spinal stabilization system: a nonhuman primate model," *The Spine Journal*, vol. 10, no. 9, pp. 775–783, 2010.

[24] K. S. Delank, E. Gercek, S. Kuhn et al., "How does spinal canal decompression and dorsal stabilization aVect segmental mobility? A biomechanical study," *Archives of Orthopaedic and Trauma Surgery*, vol. 130, no. 2, pp. 285–292, 2010.

[25] B. Cakir, C. Carazzo, R. Schmidt, T. Mattes, H. Reichel, and W. Käfer, "Adjacent segment mobility after rigid and semirigid instrumentation of the lumbar spine," *Spine*, vol. 34, no. 12, pp. 1287–1291, 2009.

[26] P. Strube, S. Tohtz, E. Hoff, C. Gross, C. Perka, and M. Putzier, "Dynamic stabilization adjacent to single-level fusion: Part I. Biomechanical effects on lumbar spinal motion," *European Spine Journal*, vol. 19, pp. 2171–2180, 2010.

[27] W. Schmoelz, J. F. Huber, T. Nydegger, Dipl-Ing, L. Claes, and H. J. Wilke, "Dynamic stabilization of the lumbar spine and its effects on adjacent segments: an in vitro experiment," *Journal of Spinal Disorders and Techniques*, vol. 16, no. 4, pp. 418–423, 2003.

[28] C. L. Liu, Z. C. Zhong, S. L. Shih, C. Hung, Y. E. Lee, and C. S. Chen, "Influence of dynesys system screw profile on adjacent segment and screw," *Journal of Spinal Disorders and Techniques*, vol. 23, no. 6, pp. 410–417, 2010.

[29] M. B. Maserati, M. J. Tormenti, D. M. Panczykowski, C. M. Bonfield, and P. C. Gerszten, "The use of a hybrid dynamic stabilization and fusion system in the lumbar spine: preliminary experience," *Neurosurgical Focus*, vol. 28, no. 6, p. E2, 2010.

[30] M. Putzier, E. Hoff, S. Tohtz, C. Gross, C. Perka, and P. Strube, "Dynamic stabilization adjacent to single-level fusion: part II. No clinical benefit for asymptomatic, initially degenerated adjacent segments after 6 years follow-up," *European Spine Journal*, vol. 19, pp. 2181–2189, 2010.

[31] S. Vaga, M. Brayda-Bruno, F. Perona et al., "Molecular MR imaging for the evaluation of the effect of dynamic stabilization on lumbar intervertebral discs," *European Spine Journal*, vol. 18, supplement 1, pp. S40–S48, 2009.

[32] A. Kumar, J. Beastall, J. Hughes et al., "Disc changes in the bridged and adjacent segments after Dynesys dynamic stabilization system after two years," *Spine*, vol. 33, no. 26, pp. 2909–2914, 2008.

[33] M. Di Silvestre, F. Lolli, G. Bakaloudis, and P. Parisini, "Dynamic stabilization for degenerative lumbar scoliosis in elderly patients," *Spine*, vol. 35, no. 2, pp. 227–234, 2010.

[34] W. K. Cheng, D. K. Palmer, and V. Jadhav, "Novel indication for posterior dynamic stabilization: correction of disc tilt after lumbar total disc replacement," *SAS Journal*, vol. 5, no. 2, pp. 44–47, 2011.

[35] C. C. Ko, H. W. Tsai, W. C. Huang et al., "Screw loosening in the Dynesys stabilization system: radiographic evidence and effect on outcomes," *Neurosurgical Focus*, vol. 28, no. 6, p. E10, 2010.

[36] N. Anand, E. M. Baron, and R. S. Bray, "Benefits of the paraspinal muscle-sparing approach versus the conventional midline approach for posterior nonfusion stabilization: comparative analysis of clinical and functional outcomes," *SAS Journal*, vol. 1, no. 3, pp. 93–99, 2007.

[37] N. Anand, E. M. Baron, and R. S. J. Bray, *Posterior Non-Fusion Stabilization of the Lumbar Spine For Degenerative Disc Disease*, Spine Arthoplasty Summit 7, Berlin, Germany, 2007.

[38] N. Anand, E. M. Baron, and R. S. Bray, "Modified muscle-sparing paraspinal approach for stabilization and interlaminar decompression: a minimally invasive technique for pedicle screw-based posterior nonfusion stabilization," *SAS Journal*, vol. 2, no. 1, pp. 40–42, 2008.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2012, Article ID 629698, 12 pages
doi:10.1155/2012/629698

Review Article

A Short History of Posterior Dynamic Stabilization

Cengiz Gomleksiz,[1] Mehdi Sasani,[2] Tunc Oktenoglu,[2] and Ali Fahir Ozer[3]

[1] *Neurosurgery Department, School of Medicine, Mengücek Gazi Training and Research Hospital, Erzincan University, 24000 Erzincan, Turkey*
[2] *Neurosurgery Department, American Hospital, 34365 Istanbul, Turkey*
[3] *Neurosurgery Department, School of Medicine, Koc University, Rumelifeneri Yolu Sarıyer, 34450 Istanbul, Turkey*

Correspondence should be addressed to Ali Fahir Ozer, alifahirozer@gmail.com

Received 7 September 2012; Accepted 7 November 2012

Academic Editor: Deniz Erbulut

Interspinous spacers were developed to treat local deformities such as degenerative spondylolisthesis. To treat patients with chronic instability, posterior pedicle fixation and rod-based dynamic stabilization systems were developed as alternatives to fusion surgeries. Dynamic stabilization is the future of spinal surgery, and in the near future, we will be able to see the development of new devices and surgical techniques to stabilize the spine. It is important to follow the development of these technologies and to gain experience using them. In this paper, we review the literature and discuss the dynamic systems, both past and present, used in the market to treat lumbar degeneration.

1. Introduction

Lumbar spine degeneration was first described by Kirkaldy-Willis and Farfan in 1982, using a 3 stage concept: (1) temporal dysfunction, (2) unstable stage, and (3) stabilization [1]. Stage 1 patients may respond to conservative treatments, but stage 2 and stage 3 patients require surgery for stabilization, decompression, and to correct deformities. Although disc degeneration is one reason for chronic lower back pain, the primary reason for back pain is the instability of the lumbar spine [2]. However, lumbar instability is not clearly defined. Kirkaldy-Willis and Farfan defined instability as the clinical status of patients with back problems who, with the least provocation, transition from being mildly symptomatic to experiencing a severe episode [1]. According to Panjabi [3] instability results from the inability to maintain control of the lumbar neutral zone, where spine motion occurs with minimal internal resistance and within normal physiological limits. In this study, instability is defined as the source of pain and abnormal motion. Stokes at al. [4] and Weiler et al. [5] also related abnormal motion to chronic back pain. However, as a definition of instability, abnormal motion does not cause back pain in all cases, such as when abnormal movement is observed radiologically in degenerated discs associated with spondylolisthesis, and pain is not continuous [6]. Therefore, the definition of instability has been updated to include abnormal movements at the joint surface and altered load transmission [2]. Lumbar spinal fusion is a common surgical treatment used in disc degeneration, which is related to chronic lower back pain and other spinal disorders, such as disc herniation, spondylolisthesis, facet arthropathy, and spinal stenosis [7]. Spinal fusion was first described by Albee for the treatment of Pott disease [8] and by Hibbs who performed spinal fusion for the treatment of spinal deformity [9]. Over the last 50 years, spinal fusion has become the gold standard for the treatment of several degenerative spinal disorders. Despite the many benefits of fusion surgery, there are several complications associated with this technique, including adjacent segment degeneration and pseudoarthrosis [10, 11]. Biomechanical studies have shown that fusion surgeries cause increased motion loading, which increases the stress placed on adjacent vertebral segments, and long-term clinical studies have shown radiographic degenerations of the adjacent vertebral segments [12–14]. The incidence of adjacent segment degeneration after fusion surgeries is in the range of 5.2% to 100% [15]. Among the

lumbar fusion surgery procedures, those performed between the thoracolumbar junction and the lumbosacral junction (the so-called "floating fusions") appear to be associated with the greatest risk [14]. As a result, additional surgeries are often required to treat adjacent segment degenerations after lumbar fusion surgeries [16].

As mentioned above, motion preservation surgeries have been developed for the treatment of lumbar degenerative diseases in order to prevent adjacent segment degenerations [17, 18]. Sengupta described the hypothesis behind dynamic stabilizations, control abnormal motions, so that greater physiological load transmissions can relieve pain and prevent adjacent segment degenerations. A remote expectation is that once normal motion and load transmission is achieved, the damaged disc may repair itself, unless the degeneration is too advanced [19]. Posterior motion-sparing systems have been designed to off-load the posterior facets and annulus and to control motion in defined planes. By stabilizing vertebral motion, pain may be minimized, and the controlled motion may also decrease the secondary effects of fusion [20].

Posterior dynamic stabilization system devices can be classified into three types: (1) posterior interspinous spacers, (2) posterior pedicle fixation-based dynamic stabilization devices, and (3) total facet replacement devices [21]. Kaner et al. recently classified these dynamic systems [22], and the most important differences were seen in the groups where dynamic rods and screws were used together. This group was accepted as an independent group in their classification. In this paper, we will summarize and discuss the devices in which dynamic rods and screws are used together.

2. Posterior Pedicle Fixation-Based Dynamic Stabilization Devices

2.1. Dynamic Rods

2.1.1. Graf Ligament. In 1992, Graf described the use of the Graf ligamentoplasty system to treat low back pain without fusion [23]. According to his theory, abnormal rotary motion was the primary source of mechanical low back pain. He later improved the Graf ligamentoplasty system by inserting titanium pedicle screw anchors into the vertebra, both superior and inferior to the symptomatic level, and using a braided polypropylene tension band to link the titanium pedicle screws (Figure 1).

Due to compressions on the posterior annulus, it was claimed that Graf's system allowed annular tears to heal. Initial outcomes from Graf ligamentoplasty surgeries showed only modest improvements in functional ability and required high rates of reoperation. Grevitt et al. reported on a study of 50 patients who underwent Graf ligamentoplasty for intractable, symptomatic degenerative disc disease and chronic low back pain [24]. The Oswestry disability index (ODI) improved postoperatively from 59% to 31%, but postoperative radiculopathies were reported in 12 of the 50 patients. Therefore, prophylactic foraminal decompressions prior to device placement were recommended. Markwalder and Wenger reported long-term results in 41 patients treated with Graf ligamentoplasty. Sixty-six percent of patients reported no pain, 25.7% of patients reported significantly less pain, and 7.7% of patients reported somewhat less pain. The authors concluded that in younger patients with painful mechanical spine disease refractive to conservative treatment, Graf ligamentoplasty is an acceptable alternative to fusion surgery and provides long-term symptomatic relief [25].

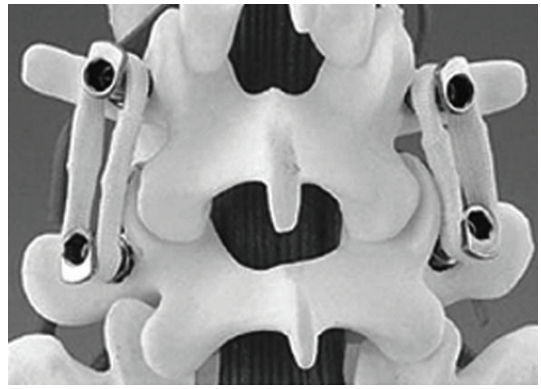


Figure 1: Graf ligamentoplasty system (left) and application on the lumbar spine model.

On the other hand, Hadlow et al. reported on a retrospective case-control comparison between Graf ligamentoplasty and posterolateral fusion in a series of 83 patients suffering from low back pain [26]. There was a significantly high rate of reoperation in Graf ligamentoplasty groups 2 years after surgery (72%). Therefore, for the treatment of low back pain, the authors concluded that Graf ligamentoplasty did not show superiority to posterolateral fusion.

Graf ligamentoplasties also produce a significant increase in lateral canal stenosis, especially when patients exhibited preexisting degenerative changes in the facet joints or in the infolding of the ligamentum flavum, owing to the marked lordosis of the segment instrumented. Early clinical failures were associated with this surgical complication [24]. Graf ligaments transfer the load from the anterior aspect of the disc to the posterior annulus, thereby increasing the disc pressure in this region. This may explain the late failure of the Graf ligament, which accelerates disc degeneration by overloading the posterior part of the disc [19].

Recent randomized evaluations reported better clinical outcomes in patients that underwent Graf ligament placements versus fusions. If the patient is experiencing spondylolisthesis or flexion instability, then a Graf ligamentoplasty is a good choice. However, if the patient complains of scoliosis or lateral listhesis, then the Graf ligamentoplasty is not a good choice and could lead to a higher likelihood of reoperation.

2.1.2. Dynamic Neutralization System (Dynesys). The dynamic neutralization system (Dynesys) was developed by Stoll et al. 2002 [27]. This system consists of titanium alloy (protasul 100) pedicle screws, polyester (sulene-PET) cords, and polycarbonate urethane (sulene-PCU) spacers (Figure 2). The PET cord resists tensile forces and provides

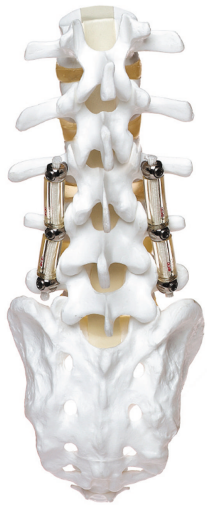


Figure 2: Dynesys device applied on a spinal model.

resistance to spine flexion, similar to the concept used in Graf ligamentoplasties. However, the Dynesys PCU spacers resist compression during extension and thereby prevent foraminal narrowing by maintaining foraminal height and decreasing load to the posterior annulus [28, 29] (Figure 3).

The results from the clinical studies on the Dynesys system are twofold. Cheng et al. reported that there was no significant difference between using the Dynesys or using traditional rigid fusion to treat adjacent segment disease [10]. However, several studies have suggested that using the Dynesys as a nonfusion device results in superior clinical outcomes compared with traditional rigid fusions [27, 30, 31]. Grob et al. reported on a retrospective study of 50 patients treated with the Dynesys for either degenerative disc disease or stenosis-associated instability. Thirty-one of these patients had at least a 2-year followup period [32]. Back pain improved in 67% of the patients, 30% of the patients reported that their condition was unchanged, and 3% of the patients reported a worsening of symptoms. Leg pain improved in 64% of the patients, 21% of the patients reported that their condition was unchanged, and 14% of the patients reported an increase in pain after treatment. However, functional capacity only improved in 40% of the patients, and within the 2-year followup period, 6 of the 31 patients (19%) underwent an additional operation.

Bothmann et al. evaluated clinical, radiographic, and computed tomography (CT) scans in 54 consecutive cases that underwent nonfusion surgery using the Dynesys [33]. Postoperative pain scores improved in 29 of the cases (79%), and scores were optimal when dynamic fusion was used in conjunction with nerve root decompression. The outcomes were not superior to the conventional rigid fusion system, and complications required revision surgery in 27.5% of the cases.

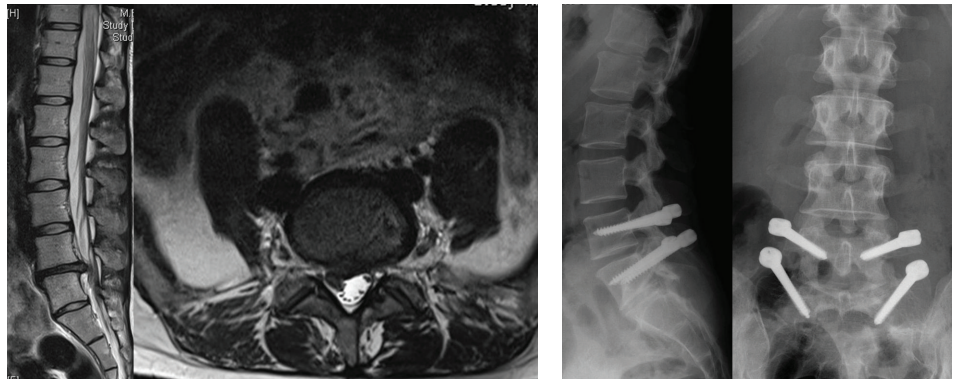
Cienciala et al. studied dynamic stabilizations with the Dynesys in 102 patients with degenerative disc diseases [34]. The improvement in the patients' health status was statistically significant during all 3-year postoperative periods. The Dynesys resulted in the postoperative disappearance of disc bulging and the restoration of both the posterior longitudinal ligament and the space in the lumbar spinal canal; repeated MRI examinations confirmed the disappearance of the bulge in these 26 patients. In their three-year followup period, patients had improved subjective feelings, morphological findings, pain, and functional status.

Dynesys treatment is indicated for patients with degenerative diseases in the lumbar motion segment, instability, and in combination with functional or structural spinal canal stenosis. Contraindications for this system are spinal fractures, infections, lytic/isthmic spondylolisthesis, degenerative spondylolisthesis >I°-II°, facetectomy, and stabilization of the thoracic and cervical spine.

2.1.3. Accuflex Rod System. The Accuflex rod system (Globus Medical Inc.) includes a dynamic rod and 6.5 mm pedicle screws made of titanium. The rod has double helical cuts that perform flexion-extension movements while providing a posterior tension band that can unload the disk (Figure 4). This system received FDA clearance for single level dynamic fusion. In a study conducted by Reyes-Sánchez et al., 20 consecutive patients underwent dynamic stabilization surgery with the Accuflex rod system to treat lumbar spinal stenosis and dysfunctional segment motion [35]; the clinical, radiographic, and magnetic resonance imaging (MRI) findings were fully described. During a 2-year followup period, 22.22% of the patients required device removal due to fatigue, while there was no progression of disk degeneration observed after implantation of the Accuflex system in 83% of the patients. Three patients (16%) also showed disc rehydration in followup MRI imaging. Even with a relatively high rate of device removal (22.22%), the use of the Accuflex rod system provided enhanced clinical benefits and stopped the degenerative process in 83% of the patients.

2.1.4. Isobar TTL. The Isobar TTL system (Scient'x USA) is one of the first described semirigid rods. This implant received FDA clearance for use as an adjunct to spinal fusion in 1999. This system is composed of a titanium alloy rod with a dampener made of stacked titanium alloy o-rings. The Isobar TTL system allows a small amount of both axial and angular motion via this dampener (Figure 5). Perrin and Cristini reported on a retrospective study of 22 patients that underwent dynamic stabilization using the Isobar TTL system to treat lumbar spondylolisthesis [36]. The slipped levels were treated with polyetheretherketone (PEEK) cage, followed by a two level posterior fixation using the Isobar TTL system. During the 8.27-year followup period, 68.2% of the patients reported mild leg pain, 72% of the patients reported no or mild back pain, and 91% of the patients were complaint free. The adjacent level was also protected by the Isobar TTL system.

2.1.5. CD-Horizon Legacy PEEK Rod. The CD-Horizon Legacy PEEK rod (Medtronic Sofamor Danek, Memphis, TN) is composed of polyetheretherketone and is more flexible than the titanium rods (Figure 6). This system received



(a) (b)

Figure 3: 34-year-old female patient with right leg pain and back pain. (a) T2 weighted MRI scans show L4-5 disc herniation; (b) the Dynesys system was applied.

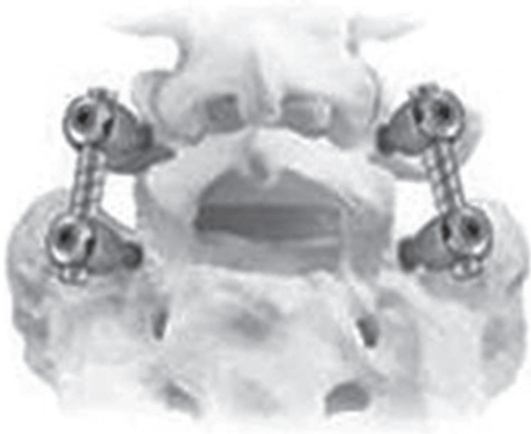


Figure 4: The Accuflex rod system.

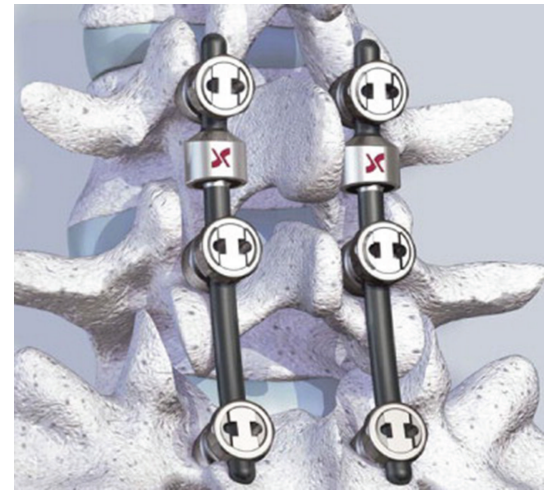


Figure 5: The Isobar TTL device.

FDA clearance in 2005. The PEEK rod is currently FDA approved to treat adjunct fixation for a one-level interbody fusion. Abode-Iyamah et al. reported a cadaveric study that measured intradiscal pressure differences between the PEEK rod and the titanium rod [37]. Pressure differences were greater for the titanium rods compared with the PEEK rods. However, it has not been determined whether dynamic rods, such as DYNESYS and Accuflex or PEEK rods could be used with dynamic screws instead of using rigid titanium rods because PEEK rods are more flexible compared with titanium rods (Figure 7). As a result, the authors concluded that the PEEK rods decreased adjacent disc disease by maintaining a lower intradiscal pressure.

2.1.6. Bioflex Spring Rod Pedicle Screw System. The Bioflex system (Bio-Spine Inc.) is a pedicle screw-based system that is composed of rod-shaped Nitinol with one or two loops to confer stability in flexion, extension, and lateral bending (Figure 8). Nitinol is an alloy of titanium and nickel, also called the "memory metal" due to its ability to return to its original shape after deformation. In a study conducted by Kim et al., 103 patients treated with the Bioflex system were observed preoperatively and postoperatively for range of motion (ROM) changes. The patients were divided into two groups: dynamic stabilization with or without posterior lumbar interbody fusion (PLIF) (Group 1) and rigid fixation (PLIF+ Bioflex system only) (Group 2). The changes in the ROM in looped segments that were treated with PLIF were significantly reduced, but the changes in the ROM in looped segments without PLIF were not significant. The authors concluded that the Nitinol Bioflex dynamic stabilization system achieved stabilization while simultaneously permitting physiological movement which in turn decreases the degeneration of adjacent segments [38].

In a study conducted by Zhang et al., 12 patients were treated with the Bioflex system to examine functional motion one or more years after Bioflex system placement. Six patients were treated with a L3-4-5 construct, and another six patients were treated with a L4-5-S1 construct. The followup period varied from 12 to 33 months; standing neutral lateral flexion, extension, and posteroanterior radiographs

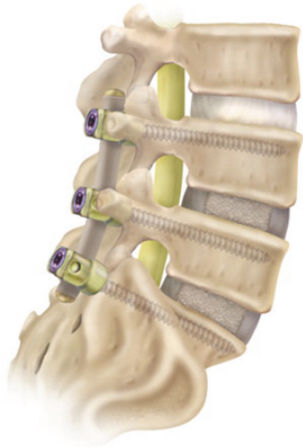


Figure 6: The CD-Horizon Legacy PEEK rod.

were obtained at 3, 6, 9, 12, and more than 12 months postoperatively. The ROM for whole lumbar lordosis and segments from L2 to S1 were determined. The authors concluded that the Bioflex system was able to preserve functional motion to some degree at instrumented levels. However, although total lumbar lordosis was preserved, the ROM at the implanted segments was lower than their preoperative values [18].

2.1.7. Fulcrum-Assisted Soft Stabilization System (FASS). The FASS (Fulcrum-Assisted Soft Stabilization) system was developed by Sengupta and Mulholland [39] to address the most common disadvantages of the Graf system (Figure 9).

(1) Increased lordosis, which produces a narrowing of the lateral recess, leading to root entrapment, especially with preexisting facet arthropathy.

(2) Increased loading of the posterior annulus, which is typically observed in patients with painful degenerated discs.

The presence of a fulcrum may prevent both of these problems. The fulcrum is placed between the pedicle screws, in front of the ligament, and acts by distracting the posterior annulus. The elastic ligament is placed at the heads of the pedicle screws, posterior to the fulcrum and maintains lordosis. The fulcrum transforms the compressive effect of the elastic ligament into an anterior distraction force that unloads the disc.

2.2. Dynamic Screw

2.2.1. Cosmic Posterior Dynamic System. The Cosmic posterior dynamic system (Ulrich medical) is a pedicle screw-based dynamic stabilization system (Figure 10). Indications for this device include spinal stenosis, degenerative spondylolisthesis. The main characteristic of this system is a hinged pedicle screw head that allows segmental motion, thereby reducing stress at the bone-screw interface. The screw threads are coated with calcium phosphate to promote ingrowths and assist in long-term fixation.

A hinged screw stabilizes the spine in a nearly rigid system [40, 41]. The results are similar to fusion after two years of followup [42–44]. Kaner et al. found that treatment with hinged screws was effective for addressing degenerative spondylolisthesis, spinal canal stenosis [43, 45], and recurrent disc herniations [46]. Similar results were found after a multilevel study of dynamic screws [47] (Figure 11).

Von Strempel et al. reported on a two year followup study for patients surgically treated with the Cosmic system to relieve degenerative lumbar disease [48]. The results of this study showed that the Cosmic system is an alternative to traditional fusion surgery to treat degenerative lumbar disease, but long-term followup studies are still necessary to fully evaluate this system on adjacent-level diseases.

Stoffel et al. published results from a study of 103 patients that were consecutively treated using the Cosmic system for painful degenerative segmental instability ± spinal stenosis between April 2006 and December 2007 [49]. This study showed that dynamic stabilization with Cosmic achieved significant improvements in pain, related disability, mental/physical health, and mobility, respectively, and a high rate of satisfied patients.

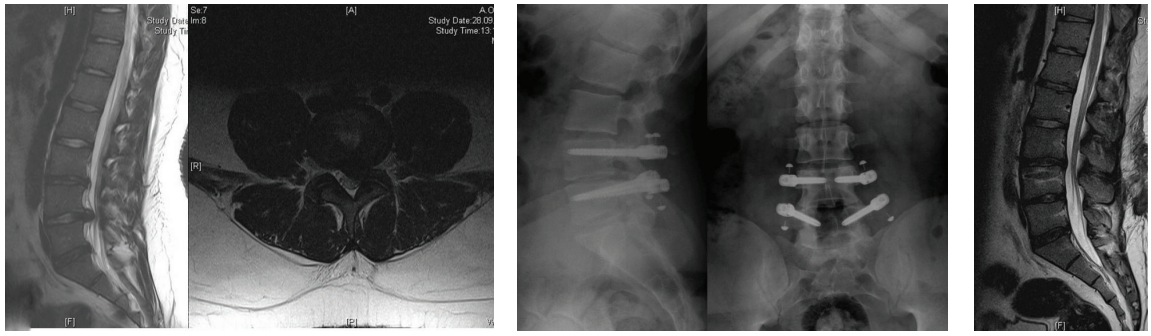
2.2.2. Saphinas System. The Saphinas system (Medikon Company) is another treatment which localizes between the head and the body of the screw (Figure 12). This treatment provides flexion extension movements and 1° of rotational movement past the designed screw. Biomechanical studies have shown that this system demonstrates sufficient stabilization over degenerative motion segments [40]. Clinical studies have also shown that the Saphinas system established a stable, rigid system [44] (Figure 13).

2.3. Dynamic Rods with Dynamic Screws. The main function of dynamic rods is to provide enough posterior tension over the posterior column of the spine. In biomechanical studies, the dynamic rods acted as a rigid system, and their stiffness was too close to the rigid system [50]. Dynamic rods are more flexible than the well-known rods currently available. Biomechanical studies show that more flexible rods with dynamic screws can stabilize the spine more effectively [50].

An agile rod is the first rod that we used with dynamic screws (Figure 14) [51]. However, agile rods were withdrawn from the market after a more flexible rod, BalanC, was developed and used with dynamic screws. Our preliminary results are very promising, and upon the study's completion, our results will be published (Figure 15).

2.4. The Systems Represent Facet Functions

2.4.1. Stabilimax NZ. Stabilimax NZ (Applied Spine Technologies, New Haven, CT) is a pedicle screw-based posterior stabilization system that was designed as an alternative to fusion treatment to treat low back pain (Figure 16). Panjabi reported on the importance and the role of the "neutral



(a) (b) (c)

Figure 7: 20-year-old male patient with left leg pain and back pain. (a) T2 weighted MRI scans show L4-5 disc herniation; (b) PEEK rod was applied; (c) the patient was in very good condition, and T2 weighted MRI scan showed a nearly normal appearance after one year.

Figure 8: The Bioflex dynamic stabilization system.

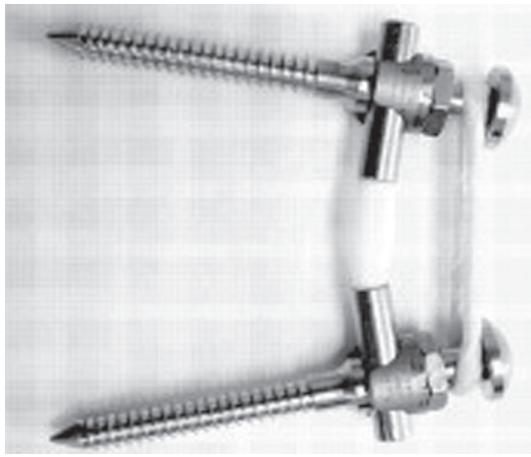


Figure 9: The Fulcrum-Assisted Soft Stabilization system (FASS).

zone" (NZ) in the development of spinal instability [3]. The NZ is a region of intervertebral motion around the neutral posture where little resistance is offered by the passive spinal column. It is believed that the NZ increases during disc degeneration and injury, resulting in greater instability and pain. The Stabilimax NZ system was developed to reduce the

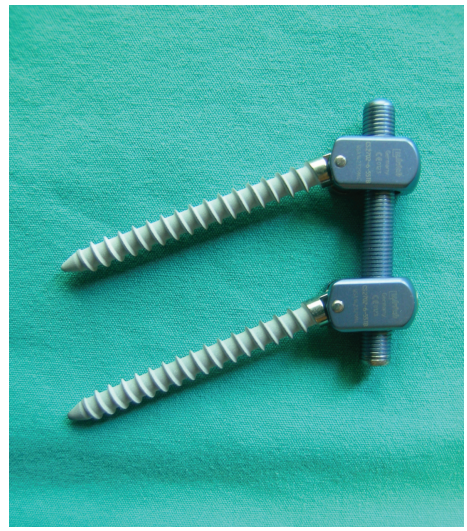
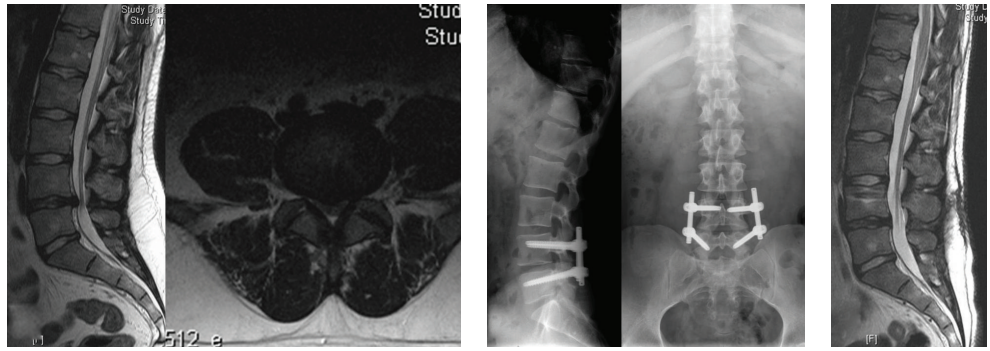


Figure 10: The Cosmic posterior dynamic system.

impact of the NZ on mechanical back pain. The Stabilimax NZ system is composed of a rod with dual concentric springs that maintain the spinal segment in a neutral position during spinal motion.

This system received FDA/IDE approval to begin randomized controlled clinical trials comparing instrumented fusion to Stabilimax for the treatment of spinal stenosis with or without grade I spondylolisthesis. The data from these studies have yet to be published.

2.4.2. Dynamic Stabilization System (DSS). The DSS system was developed by Sengupta et al. [52] as an improvement of the FASS system. Biomechanical studies show that the FASS system produces too much loading during flexion which leads to early device failures. The DSS system has two designs that have been tested in the laboratory. The DSS-I consists of a titanium spring, made of a 3 mm cross-section diameter of spring-grade titanium wire (Figure 17). The DSS-II system consists of an elliptical coil spring, made from 4 mm spring-grade titanium rods.



(a) (b) (c)

Figure 11: 24-year-old male university student, with acute attacks of low back pain (2–4 times per year). He experienced right leg pain in a sciatalgia form, accompanied by severe low back pain in the last attack. In his neurological examination, he had L5 hypoesthesia but no motor deficit. (a) T2 weighted MRI scans show l4-5 disc herniation; (b) cosmic was applied; (c) the patient was in very good condition, and T2 weighted MRI scan shows a nearly normal appearance after one year.

Figure 12: Saphinas screw.

In 2006, Sengupta et al. reported the results of a 16 patient study where participants were treated with the DSS for single level mechanical back pain associated with disc degenerations with a two-year followup period [53]. The mean ODI scores decreased from 65% to 27%, and VAS scores decreased from 7.3 to 3.7. There were no reports of instrumentation failure or screw loosening.

2.5. Total Facet Replacement Devices

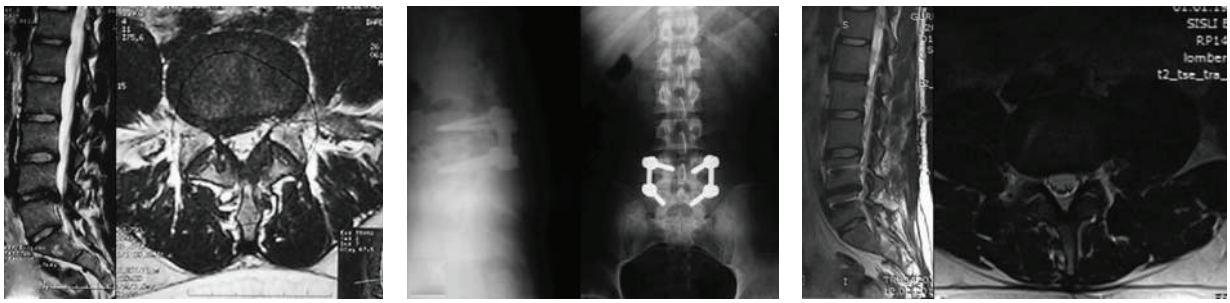
2.5.1. Total Posterior Arthroplasty System. The Total Posterior Arthroplasty System (TOPS) uses a pedicle screw-based posterior arthroplasty prosthesis that was developed to provide dynamic, multiaxial, and 3-column stabilization while preserving normal motion (Figure 18).

Wilke et al. published the results of an in vitro study using the TOPS in six human cadavers [54]. The cadavers were loaded with pure moments of ±7.5 Nm in flexion/extension, lateral bending, and axial rotation. The following states were investigated: (1) intact; (2) after bilateral laminectomy, including facetectomy of the lower facet joints, of the upper vertebra L4; and (3) after device implantation. The ROM, neutral zone, and intradiscal pressure were determined from a third round of treatment. In a second step, the ROM during axial rotations was determined as a function of the different flexion/extension postures. The authors concluded that the TOPS implant almost ideally restored the ROM in lateral bending and axial rotation compared to that of the intact specimen.

McAfee et al. reported the results of a study in which 29 patients were treated with the TOPS for spinal stenosis and/or spondylolisthesis at L4-5 due to facet arthropathy [55]. The average surgery lasted 3.1 hours, and the patients' clinical status improved significantly following treatment with the TOPS device. One year after surgery the mean ODI score decreased by 41%, and the 100-mm VAS score decreased by 76 mm. Radiographic analysis showed that lumbar motion was maintained, disc height was preserved, and there was no evidence of screw loosening; there were no device malfunctions, no migrations, and no device-related adverse events reported during the study.

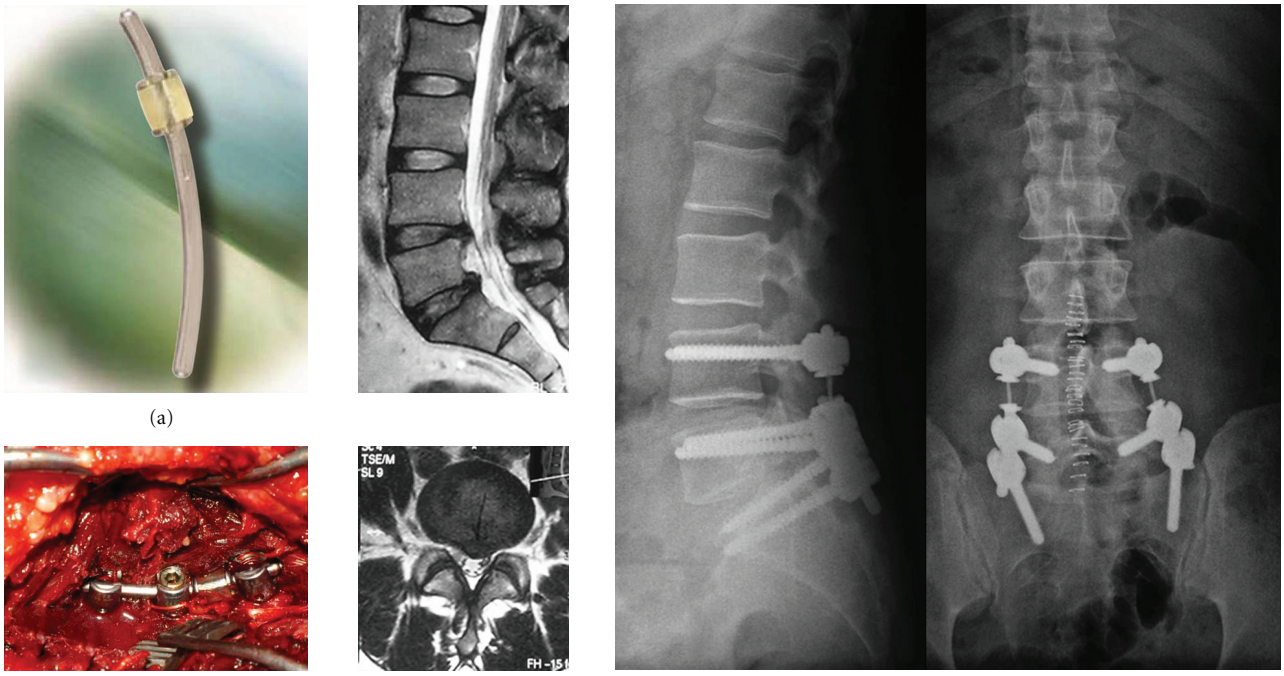
2.5.2. Total Facet Arthroplasty System. The Total Facet Arthroplasty System (TFAS) is a posterior nonfusion stabilization device designed to stabilize the spine after a laminectomy to treat moderate-to-severe spinal stenosis (Figure 19). The TFAS is designed to replace the degenerated facet joints with prosthetic metal joints, as used in knee and hip arthroplasty.

Phillips et al. reported an in vitro study using TFAS in nine human cadaveric spine specimens [56]. Nine human lumbar spines (L1 to sacrum) were tested inflexion-extension (+8 to −6 Nm), later albending (±6 Nm), and axial rotation (±5 Nm). Flexion-extension was tested under 400 N following preload. Specimens were tested intact, after complete L3 laminectomy with L3-L4 facetectomy, after L3-L4 pedicle screw fixation, and after L3-L4 TFAS implantation. The ROM was assessed in all of the tested directions. The neutral zone and stiffness during flexion-extension were calculated



(a) (b) (c)

Figure 13: 18-year-old, male patient with severe acute back pain attacks. In the last attack, he became aware of sciatalgia on the right side. He had no response to medical treatment and physical therapy; he had difficulties in daily life. (a) Preoperative MRI showed posterior annular defects, and a bulging disc to the right L5 nerve root is compressed; (b) saphinas system was applied; (c) one year after surgery the patient is very satisfied with this surgery, and MRI showed no bulging or defects of posterior annulus.



(a)

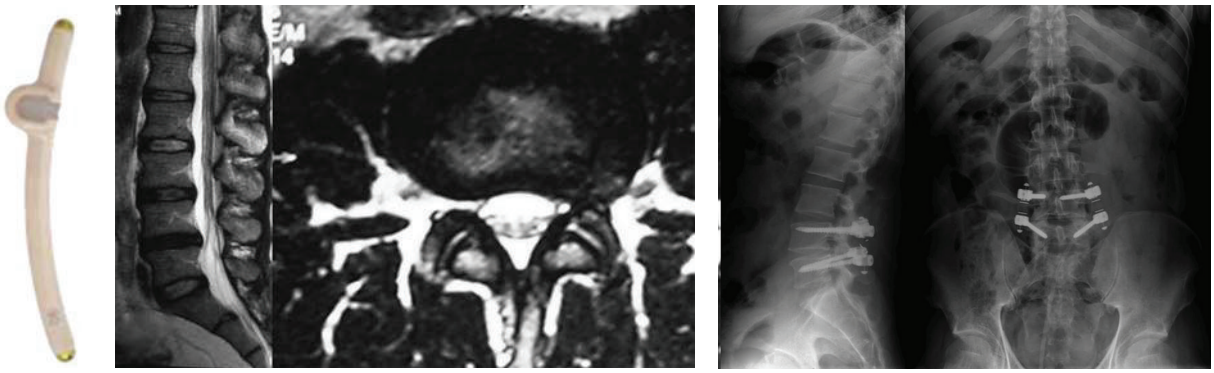
(b) (c) (d)

Figure 14: ((a) and (b)) Agile rod; (c) 40-year-old male patient with severe right leg pain; (d) agile rod was applied, and the patient was in very good condition in postoperative year one.

to assess the quality of motion. The authors concluded that after a wide range of decompressions on the neural elements, TFAS overcame the need for fusion by stabilizing the surgically modified spine in a manner similar to intact vertebrae, while restoring the physiologic kinematics (range and pattern of motion) at an operative level. Furthermore, TFAS resulted in more natural kinematics in the adjacent levels when compared with fusion.

2.6. Posterior Interspinous Spacers

2.6.1. Wallis Implant. Senegas et al. described an interspinous spacer in 1988 [57]. This device was made of titanium and held between the spinous processes via a dacron tape. After the successes of the first implant over three hundred patients, the authors redesigned the system known as "Wallis implant" which uses PEEK (polyetheretherketone) material as the spacer instead of titanium (Figure 20). The interspinous implant, located the interspinous space, blocks the extension of segment, and via distraction of the spinous processes, provides a relative flexion posture that known as a posture relieving neurogenic claudication pain by enhancing foraminal width. Additionally, the Dacron tape acts as a flexion limitation factor at the implant's located segment. Because of these features, this device can be described as a hybrid of interspinous distraction device and interspinous ligament. The authors recommend the usage of the Wallis system in the following indications: (1) discectomy of



(a) (b) (c)

Figure 15: (a) BalanC rod. (b) 25-year-old male patient with severe back pain attacks every two months in last year. T2 weighted MRI scans show posterolateral annular rupture on the left side. (c) After repairing the posterior annulus under a microscope, dynamic screws (Cosmic screw) were used with dynamic rods (BalanC). The patient was very well 6 months after the of operation.

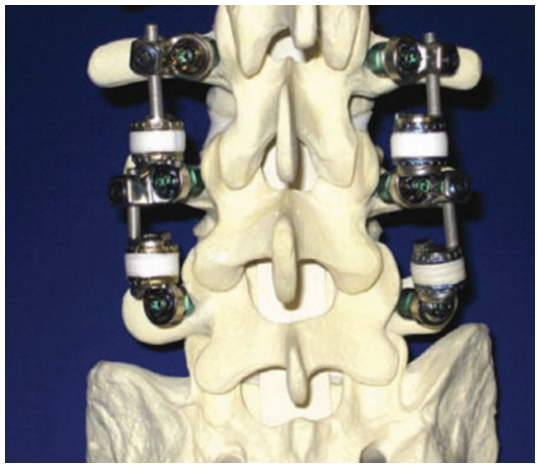


Figure 16: Stabilimax NZ device.

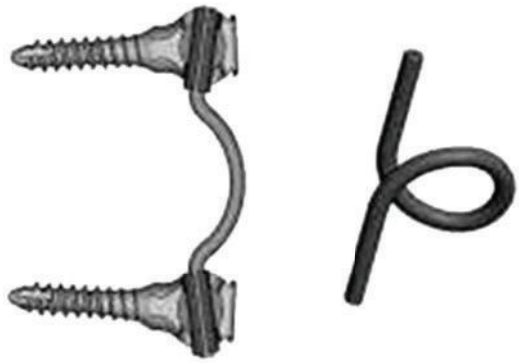


Figure 17: The DSS-I system.

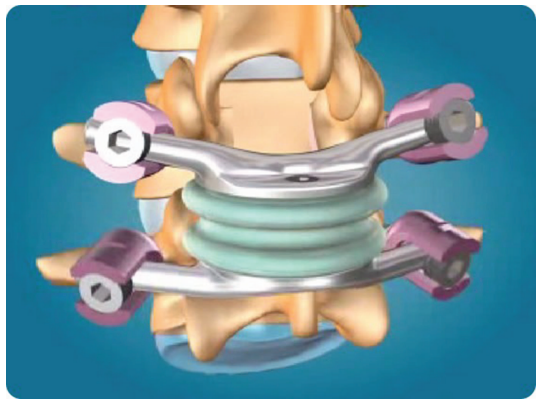


Figure 18: Total Posterior Arthroplasty System.

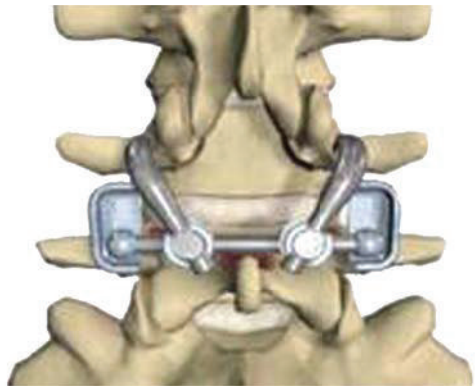


Figure 19: Total Facet Arthroplasty System.

massive herniated disc leading to substantial loss of disc material, (2) a second discectomy for recurrence of herniated disc, (3) discectomy for herniation of a transitional disc with sacralization of L5, (4) degenerative disc disease at a level adjacent to a previous fusion, and (5) isolated Modic 1 lesion leading to chronic low-back pain.

2.6.2. X-Stop. This titanium interspinous distraction device (Figure 21) (X-Stop, St. Francis Medical Technologies, Inc.,

(a) (b)

Figure 20: The Wallis implant.

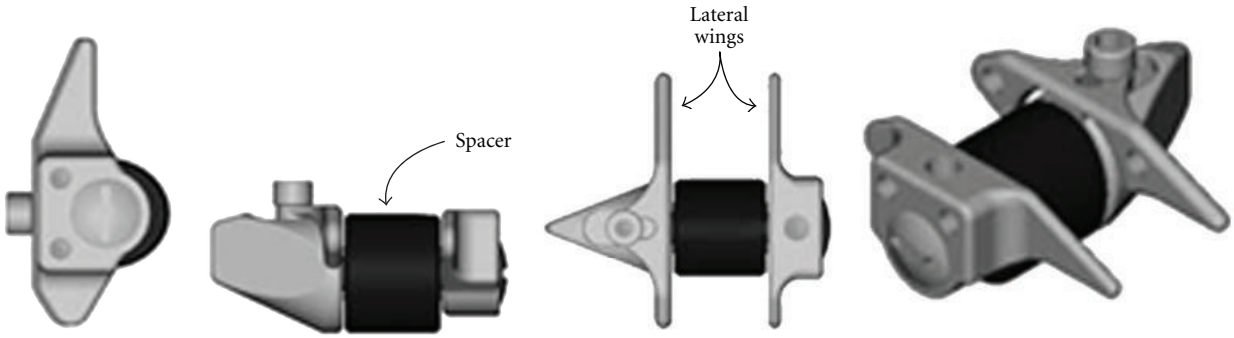


Figure 21: A sagittal, transverse, posterior, and orthogonal view of X-Stop implant.

Alameda, CA) has been introduced as a minimal invasive surgical procedure to treat symptomatic degenerative lumbar spinal stenosis. This device can be introduced by a minimally invasive approach under local anesthesia and may be useful for treatment of degenerative lumbar spinal stenosis in elderly patients who cannot take general anesthesia because of comorbid conditions. There are many controversial researches in the literature about clinical results of X-Stop device. While Verhoof et al. reported that X-Stop interspinous distraction device showed an extremely high failure rate defined as surgical reintervention after short-term followup in patients with spinal stenosis caused by degenerative spondylolisthesis [58]. Zucherman et al. reported that X-Stop offers a safe and effective treatment for lumbar spinal stenosis [59].

3. Conclusion

Traditional fusion surgeries have been performed for several years, as the predominant technique used to treat degenerative spinal disorders. Although there are several benefits to use this surgical technique, adjacent segment diseases occur due to a transfer of stress from a stabilized motion segment to the adjacent level. Dynamic stabilization of the spine was developed to solve this problem by mimicking natural spine movements. Transferring the load from a degenerated disc or facet to a dynamic stabilization construct, while preserving segmental motion, is a critical feature required to develop novel dynamic stabilization devices.

Short-term results from studies using these devices are promising, and the most common problem results from loosening failures because there is not enough active fusion mass to resist the physiological loads. Therefore, dynamic stabilization devices are not viable options to treat osteoporotic patients.

References

[1] W. H. Kirkaldy-Willis and H. F. Farfan, "Instability of the lumbar spine," *Clinical Orthopaedics and Related Research*, no. 165, pp. 110–123, 1982.

[2] S. Lau and K. S. Lam, "Lumbar stabilisation techniques," *Current Orthopaedics*, vol. 21, no. 1, pp. 25–39, 2007.

[3] M. M. Panjabi, "The stabilizing system of the spine. Part II. Neutral zone and instability hypothesis," *Journal of Spinal Disorders*, vol. 5, no. 4, pp. 390–397, 1992.

[4] I. A. Stokes and J. W. Frymoyer, "Segmental motion and instability," *Spine*, vol. 12, no. 7, pp. 688–691, 1987.

[5] P. J. Weiler, G. J. King, and S. D. Gertzbein, "Analysis of sagittal plane instability of the lumbar spine in vivo," *Spine*, vol. 15, no. 12, pp. 1300–1306, 1990.

[6] R. C. Mulholland and D. K. Sengupta, "Rationale, principles and experimental evaluation of the concept of soft stabilization," *European Spine Journal*, vol. 11, supplement 2, pp. S198–S205, 2002.

[7] Q. H. Zhang and E. C. Teo, "Finite element application in implant research for treatment of lumbar degenerative disc disease," *Medical Engineering and Physics*, vol. 30, no. 10, pp. 1246–1256, 2008.

[8] F. H. Albee, "Transplantation of a portion of the tibia into the spine for Pott's disease," *Journal of the American Medical Association*, vol. 57, p. 11, article 885, 1911.

[9] R. A. Hibbs, "An operation for progressive spinal deformities," *New York Medical Journal*, vol. 93, pp. 1013–1016, 1911.

[10] B. C. Cheng, J. Gordon, J. Cheng, and W. C. Welch, "Immediate biomechanical effects of lumbar posterior dynamic stabilization above a circumferential fusion," *Spine*, vol. 32, no. 23, pp. 2551–2557, 2007.

[11] A. Kumar, J. Beastall, J. Hughes et al., "Disc changes in the bridged and adjacent segments after Dynesys dynamic stabilization system after two years," *Spine*, vol. 33, no. 26, pp. 2909–2914, 2008.

[12] A. Gardner and K. C. Pande, "Graf ligamentoplasty: a 7-year follow-up," *European Spine Journal*, vol. 11, supplement 2, pp. S157–S163, 2002.

[13] C. K. Lee, "Accelerated degeneration of the segment adjacent to a lumbar fusion," *Spine*, vol. 13, no. 3, pp. 375–377, 1988.

[14] A. S. Hilibrand and M. Robbins, "Adjacent segment degeneration and adjacent segment disease: the consequences of spinal fusion?" *Spine Journal*, vol. 4, supplement 6, pp. S190–S194, 2004.

[15] J. S. Harrop, J. A. Youssef, M. Maltenfort et al., "Lumbar adjacent segment degeneration and disease after arthrodesis and total disc arthroplasty," *Spine*, vol. 33, no. 15, pp. 1701–1707, 2008.

[16] P. Park, H. J. Garton, V. C. Gala, J. T. Hoff, and J. E. McGillicuddy, "Adjacent segment disease after lumbar or lumbosacral fusion: review of the literature," *Spine*, vol. 29, no. 17, pp. 1938–1944, 2004.

[17] C. M. Bono, M. Kadaba, and A. R. Vaccaro, "Posterior pedicle fixation-based dynamic stabilization devices for the treatment of degenerative diseases of the lumbar spine," *Journal of Spinal Disorders and Techniques*, vol. 22, no. 5, pp. 376–383, 2009.

[18] H. Y. Zhang, J. Y. Park, and B. Y. Cho, "The BioFlex system as a dynamic stabilization device: does it preserve lumbar motion?" *Journal of Korean Neurosurgical Society*, vol. 46, no. 5, pp. 431–436, 2009.

[19] D. K. Sengupta, "Dynamic stabilization devices in the treatment of low back pain," *Neurology India*, vol. 53, no. 4, pp. 466–474, 2005.

[20] J. J. Song, C. Y. Barrey, R. K. Ponnappan, J. T. Bessey, A. L. Shimer, and A. R. Vaccaro, "Pedicle screw-based dynamic stabilization of the lumbar spine," *Pan Arab Journal of Neurosurgery*, vol. 14, no. 1, pp. 1–141, 2010.

[21] P. Khoueir, K. A. Kim, and M. Y. Wang, "Classification of posterior dynamic stabilization devices," *Neurosurgical Focus*, vol. 22, no. 1, article E3, 2007.

[22] T. Kaner, M. Sasani, T. Oktenoglu, and A. F. Ozer, "Dynamic stabilization of the spine: a new classification system," *Turkish Neurosurgery*, vol. 20, no. 2, pp. 205–215, 2010.

[23] H. Graf, "Evaluation of the therapeutic effect of the graf stabilisation system," in *Proceedings of the 2nd Annual Meeting of the European Spine Society*, Rome, Italy, 1991.

[24] M. P. Grevitt, A. D. H. Gardner, J. Spilsbury et al., "The Graf stabilisation system: early results in 50 patients," *European Spine Journal*, vol. 4, no. 3, pp. 169–175, 1995.

[25] T. M. Markwalder and M. Wenger, "Dynamic stabilization of lumbar motion segments by use of Graf's ligaments: results with an average follow-up of 7.4 years in 39 highly selected, consecutive patients," *Acta Neurochirurgica*, vol. 145, no. 3, pp. 209–214, 2003.

[26] S. V. Hadlow, A. B. Fagan, T. M. Hillier, and R. D. Fraser, "The graft ligamentoplasty procedure: comparison with posterolateral fusion in the management of low back pain," *Spine*, vol. 23, no. 10, pp. 1172–1179, 1998.

[27] T. M. Stoll, G. Dubois, and O. Schwarzenbach, "The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system," *European Spine Journal*, vol. 11, supplement 2, pp. S170–S178, 2002.

[28] R. B. Delamarter, J. Maxwell, R. Davis, J. Sherman, and W. Welch, "Nonfusion application of the Dynesys system in the lumbar spine: early results from IDE multicenter trial," *Spine Journal*, vol. 6, supplement 1, article S77, no. 5, 2006.

[29] K. J. Schnake, S. Schaeren, and B. Jeanneret, "Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis," *Spine*, vol. 31, no. 4, pp. 442–449, 2006.

[30] B. Cakir, B. Ulmar, H. Koepp, K. Huch, W. Puhl, and M. Richter, "Posterior dynamic stabiliziation as on alternative for instrumented fusion in the treatment of degenerative lumbar instability with spinal stenosis," *Zeitschrift fur Orthopadie und Ihre Grenzgebiete*, vol. 141, no. 4, pp. 418–424, 2003.

[31] C. Feloukatzis, G. Barlas, S. Pichas, and L. Drosos, "The dynamic neutralization system (Dynesys) in the treatment of degenerative lumbar spine disease," in *Proceedings of the 3rd Interdisciplinary Congress on Spine Care*, Rio De Janeiro, Brazil, July 2005.

[32] D. Grob, A. Benini, A. Junge, and A. F. Mannion, "Clinical experience with the dynesys semirigid fixation system for the lumbar spine: surgical and patient-oriented outcome in 50 cases after an average of 2 years," *Spine*, vol. 30, no. 3, pp. 324–331, 2005.

[33] M. Bothmann, E. Kast, G. J. Boldt, and J. Oberle, "Dynesys fixation for lumbar spine degeneration," *Neurosurgical Review*, vol. 31, no. 2, pp. 189–196, 2008.

[34] J. Cienciala, R. Chaloupka, M. Repko, and M. Krbec, "Dynamic neutralization using the dynesys system for treatment of degenerative disc disease of the lumbar spine," *Acta Chirurgiae Orthopaedicae et Traumatologiae Cechoslovaca*, vol. 77, no. 3, pp. 203–208, 2010.

[35] A. Reyes-Sánchez, B. Zárate-Kalfópulos, I. Ramírez-Mora, L. M. Rosales-Olivarez, A. Alpizar-Aguirre, and G. Sánchez-Bringas, "Posterior dynamic stabilization of the lumbar spine with the Accuflex rod system as a stand-alone device: experience in 20 patients with 2-year follow-up," *European Spine Journal*, vol. 19, no. 12, pp. 2164–2170, 2010.

[36] G. Perrin and A. Cristini, "Prevention of adjacent level degeneration above a fused vertebral segment: long term effect, a fter a mean follow up of 8, 27 years, of the semirigid intervertebral fixation as a protective technique for pathological adjacent disc," in *Proceedings of the International Meeting for Advanced Spine Technologies*, December 2003.

[37] K. O. Abode-Iyamah, E. M. Cox, R. Kumar, and P. W. Hitchon, "PEEK rods decrease intradiscal pressure in levels adjacent to spinal instrumentation," in *Proceedings of the Congress of Neurological Surgeons Annual Meeting (CNS '11)*, Washington, DC, USA, 2011.

[38] Y. S. Kim, H. Y. Zhang, B. J. Moon et al., "Nitinol spring rod dynamic stabilization system and Nitinol memory loops in surgical treatment for lumbar disc disorders: short-term follow up," *Neurosurgical Focus*, vol. 22, no. 1, article E10, 2007.

[39] D. K. Sengupta and R. C. Mulholland, "Fulcrum assisted soft stabilization system: a new concept in the surgical treatment of degenerative low back pain," *Spine*, vol. 30, no. 9, pp. 1019–1029, 2005.

[40] H. Bozkus, M. Senoğlu, S. Baek et al., "Dynamic lumbar pedicle screw-rod stabilization: in vitro biomechanical comparison with standard rigid pedicle screw-rod stabilization—laboratory investigation," *Journal of Neurosurgery Spine*, vol. 12, no. 2, pp. 183–189, 2010.

[41] W. Schmoelz, J. F. Huber, T. Nydegger, Dipl-Ing, L. Claes, and H. J. Wilke, "Dynamic stabilization of the lumbar spine and its effects on adjacent segments: an in vitro experiment," *Journal of Spinal Disorders and Techniques*, vol. 16, no. 4, pp. 418–423, 2003.

[42] T. Oktenoglu, A. F. Ozer, M. Sasani et al., "Posterior dynamic stabilization in the treatment of lumbar degenerative disc disease: 2-year follow-up," *Minimally Invasive Neurosurgery*, vol. 53, no. 3, pp. 112–116, 2010.

[43] T. Kaner, S. Dalbayrak, T. Oktenoglu, M. Sasani, A. L. Aydin, and F. O. Ozer, "Comparison of posterior dynamic and posterior rigid transpedicular stabilization with fusion to treat degenerative spondylolisthesis," *Orthopedics*, vol. 33, no. 5, article 309, 2010.

[44] A. F. Ozer, N. R. Crawford, M. Sasani et al., "Dynamic lumbar pedicle screw-rod stabilization: two-year follow-up and comparison with fusion," *The Open Orthopaedics Journal*, vol. 4, pp. 137–141, 2010.

[45] T. Kaner, M. Sasani, T. Oktenoglu, A. L. Aydin, and A. F. Ozer, "Clinical outcomes of degenerative lumbar spinal stenosis treated with lumbar decompression and the Cosmic "semi-rigid" posterior system," *SAS Journal*, vol. 4, no. 4, pp. 99–106, 2010.

[46] T. Kaner, M. Sasani, T. Oktenoglu, A. L. Aydin, and A. F. Ozer, "Minimum two-year follow-up of cases with recurrent disc herniation treated with microdiscectomy and posterior dynamic transpedicular stabilisation," *The Open Orthopaedics Journal*, vol. 4, pp. 120–125, 2010.

[47] A. Maleci, R. D. Sambale, M. Schiavone, F. Lamp, A. F. Ozer, and A. von Strempel, "Nonfusion stabilization of the degenerative lumbar spine," *Journal of Neurosurgery Spine*, vol. 15, no. 2, pp. 151–158, 2011.

[48] A. von Strempel, D. Moosman, C. Stoss, and A. Martin, "Stabilization of the degenerated lumbar spine in the non fusion technique with Cosmic posterior dynamic system," *World Spine Journal*, vol. 1, no. 1, pp. 40–47, 2006.

[49] M. Stoffel, M. Behr, A. Reinke, C. Stüer, F. Ringel, and B. Meyer, "Pedicle screw-based dynamic stabilization of the thoracolumbar spine with the Cosmic-system: a prospective observation," *Acta Neurochirurgica*, vol. 152, no. 5, pp. 835–843, 2010.

[50] D. Erbulut, "Kinematical and load sharing effect of a novel posterior dynamic stabilization system implanted in lumbar spine," in *Proceedings of the 36th Annual Meeting of the American Society of Biomechanics*, Gainesville, Fla, USA, August 2012.

[51] T. Kaner, M. Sasani, T. Oktenoglu, M. Cosar, and A. F. Ozer, "Utilizing dynamic rods with dynamic screws in the surgical treatment of chronic instability: a prospective clinical study," *Turkish Neurosurgery*, vol. 19, no. 4, pp. 319–326, 2009.

[52] D. K. Sengupta, H. N. Herkowitz, S. Hochschuler, and R. C. Mullholland, "Load sharing characteristics of two novel soft stabilization devices in the lumbar motion segments-a biomechanical study in cadaver spine," in *Proceedings of the Spine Arthroplasty Society Congress*, 2003.

[53] D. Sengupta, R. C. Mulholland, and L. Pimenta, "Prospective clinical study of dynamic stabilization with the DSS system in isolated activity related mechanical low back pain, with outcome at minimum 2-year follow-up," *Spine Journal*, vol. 6, no. 5, article 147, 2006.

[54] H. J. Wilke, H. Schmidt, K. Werner, W. Schmölz, and J. Drumm, "Biomechanical evaluation of a new total posterior-element replacement system," *Spine*, vol. 31, no. 24, pp. 2790–2796, 2006.

[55] P. McAfee, L. T. Khoo, L. Pimenta et al., "Treatment of lumbar spinal stenosis with a total posterior arthroplasty prosthesis: implant description, surgical technique, and a prospective report on 29 patients," *Neurosurgical Focus*, vol. 22, no. 1, article E13, 2007.

[56] F. M. Phillips, M. N. Tzermiadianos, L. I. Voronov et al., "Effect of the Total Facet Arthroplasty system after complete laminectomy-facetectomy on the biomechanics of implanted and adjacent segments," *Spine Journal*, vol. 9, no. 1, pp. 96–102, 2009.

[57] J. Senegas, J. P. Etchevers, J. M. Vital, D. Baulny, and F. Grenier, "Widening of the lumbar vertebral canal as an alternative to laminectomy in the treatment of lumbar stenosis," *Revue de Chirurgie Orthopedique et Reparatrice de l'Appareil Moteur*, vol. 74, no. 1, pp. 15–22, 1988.

[58] O. J. Verhoof, J. L. Bron, F. H. Wapstra, and B. J. Van Royen, "High failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis," *European Spine Journal*, vol. 17, no. 2, pp. 188–192, 2008.

[59] J. F. Zucherman, K. Y. Hsu, C. A. Hartjen et al., "A multi-center, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results," *Spine*, vol. 30, no. 12, pp. 1351–1358, 2005.

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2012, Article ID 496817, 7 pages
doi:10.1155/2012/496817

Clinical Study

Skipping Posterior Dynamic Transpedicular Stabilization for Distant Segment Degenerative Disease

Bilgehan Solmaz,[1] Ahmet Levent Aydin,[2] Cengiz Gomleksiz,[3] Yaprak Ataker,[4] Mehdi Sasani,[5] Tunc Oktenoglu,[5] and Ali Fahir Ozer[6]

[1] *Neurosurgery Department, Medistate Hospital, Istanbul, Turkey*
[2] *Neurosurgery Department, Istanbul Physical Therapy and Rehabilitation Training Hospital, Istanbul, Turkey*
[3] *Neurosurgery Department, School of Medicine, Mengücek Gazi Training and Research Hospital, Erzincan University, Erzincan, Turkey*
[4] *Physical Therapy and Rehabilitation Department, American Hospital, Istanbul, Turkey*
[5] *Neurosurgery Department, American Hospital, Istanbul, Turkey*
[6] *Neurosurgery Department, School of Medicine, Koc University, Istanbul, Turkey*

Correspondence should be addressed to Ali Fahir Ozer, alifahirozer@gmail.com

Received 6 June 2012; Accepted 24 August 2012

Academic Editor: Deniz Erbulut

Objective. To date, there is still no consensus on the treatment of spinal degenerative disease. Current surgical techniques to manage painful spinal disorders are imperfect. In this paper, we aimed to evaluate the prospective results of posterior transpedicular dynamic stabilization, a novel surgical approach that skips the segments that do not produce pain. This technique has been proven biomechanically and radiologically in spinal degenerative diseases. *Methods*. A prospective study of 18 patients averaging 54.94 years of age with distant spinal segment degenerative disease. Indications consisted of degenerative disc disease (57%), herniated nucleus pulposus (50%), spinal stenosis (14.28%), degenerative spondylolisthesis (14.28%), and foraminal stenosis (7.1%). The Oswestry Low-Back Pain Disability Questionnaire and visual analog scale (VAS) for pain were recorded preoperatively and at the third and twelfth postoperative months. *Results*. Both the Oswestry and VAS scores showed significant improvement postoperatively ($P < 0.05$). We observed complications in one patient who had spinal epidural hematoma. *Conclusion*. We recommend skipping posterior transpedicular dynamic stabilization for surgical treatment of distant segment spinal degenerative disease.

1. Introduction

The most frequent clinical problem of the adult spine is back pain. It is known that 60–80% of the population will have back pain at some point in their lives that may affect their general health, daily activities, and their working capacity. It is assumed that back pain only has a defined pathology in 15% of patients [1], and dysfunctional segmental motion and discogenic pain are problems that may need to be treated surgically. According to Bertagnoli, disc-related spinal problems could be treated because of the state of degenerative segmental alterations [2]. Those at an earlier stage of disc degeneration may respond to the conservative treatment. More advanced disc degeneration may require open-disc surgery, especially concomitant nerve root compression. Fusion surgery is usually indicated in more advanced segmental degeneration. Discectomy and fusion are performed with the aim of reducing pain and eliminating neural compression rather than restoring disc or segmental function. Researchers have demonstrated the benefits of fusion over nonsurgical treatment in the alleviation of chronic low-back pain [3, 4]. Although studies have shown improvements in the instrumentation techniques that have increased the radiological fusion rate to >94%, they have failed to provide evidence of actual improvements in clinical outcome [5].

Retrospective clinical studies have demonstrated that the lumbar fusion can lead to an acceleration in pathologic changes of the adjacent motion segment [6]. The quest

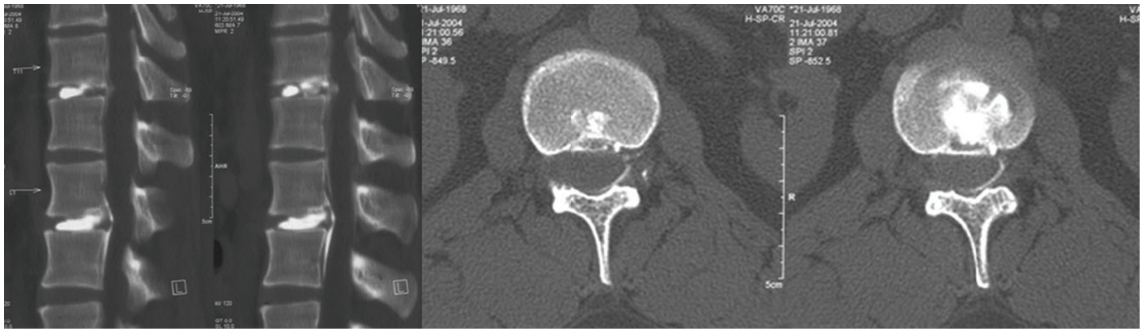


Figure 1: Provocative discography shows degeneration of the disc.

for a more physiological surgical solution than fusion has initiated the so-called nonfusion technologies. One of them, posterior dynamic stabilizing implants, is intended to realign and stabilize one or more linked vertebral segments without complete immobilization of the segments. Therefore, we planned a novel surgical approach using posterior dynamic transpedicular stabilization (PDTS) to relieve pain and reduce morbidity and mortality. This paper presents prospective results of skipping the segments that do not cause pain. This technique is proven biomechanically and radiologically as a surgical approach of PDTS in spinal degenerative diseases.

2. Materials and Methods

This study included 18 patients averaging 54.94 years of age; there were 10 females and 8 males. Our selection criteria for this procedure included any neurogenic, radicular pain and/or chronic low-back pain that was resistant to any conservative treatment and neurological deficit. The level of provocative pain was determined by discography in cases where the source of pain was not confirmed by clinical and radiological findings (Figure 1). Radiological evaluations prior to magnetic resonance (MR) (Figure 2) and after surgery consisted of anteroposterior (AP) and lateral X-ray studies (Figure 3). Primary indications, demographic data, and details of the operations performed are shown in Table 1.

Statistical Methods. The Oswestry Disability Index (ODI) and the visual analog scale (VAS) were used for preoperative and postoperative subjective patient evaluations.

Preoperative and postoperative values (VAS and ODI) were compared with the Wilcoxon ranked sum test.

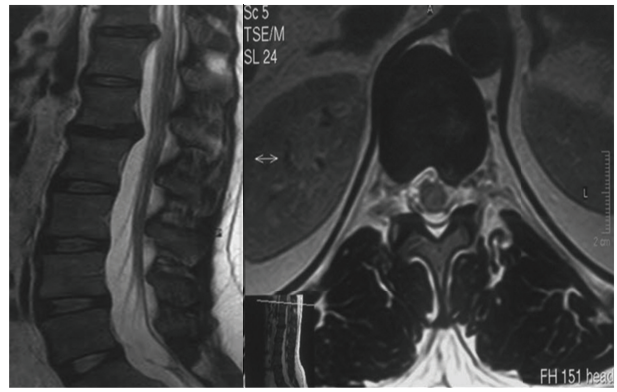


Figure 2: The patient has two distinct degenerative disc diseases in the spine. The rest of the vertebral column has no problem.

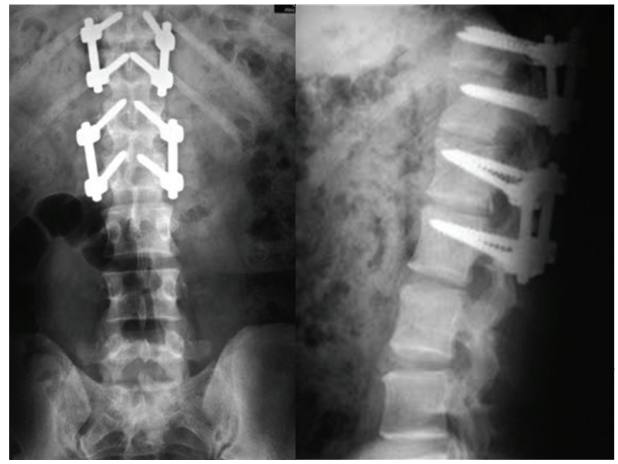


Figure 3: Two different levels of posterior dynamic stabilizations were performed in the same patient.

3. Results

Oswestry scale and VAS scale values were compared between the following groups: preoperative and 3-month postoperative, preoperative and 12-month postoperative, 3-month postoperative and 12-month postoperative. We observed significant changes between the groups. The preoperative mean Oswestry scale score was 68.00, the 3-month postoperative mean Oswestry scale score was 23.89, and the 12-month postoperative mean Oswestry scale score was 14.00. This decrease in the mean Oswestry scale score as the postoperative time increased was significant ($P < 0.05$, Wilcoxon test). The preoperative mean VAS score was 7.28, the 3-month postoperative mean VAS score was 2.50, and the 12-month postoperative mean VAS score was 1.33 (Table 2). This decrease in the mean VAS as the postoperative time increased was also significant ($P < 0.05$, Wilcoxon test).

Table 1: Patient demographic data.

Patient No.	Gender	Age	Preoperative neurological findings	Radiologic findings (X-Ray, MRI)	Operation	Complication
1	M	66	Bilateral SLR 30°+ Left FST+ Left gastrocnemius 2/5 MW	Left L3-4 HNP Right L5-S1 HNP L3-4 spinal stenosis	Left L3-4, right L5-S1 microlumbar discectomy L3-4, L5-S1 PDI	None
2	F	60	LBP	L3-4, L4-5 DDD	L3-4, L4-5 PDI	None
3	F	48	LBP Left FST+ Left SLR 60°+	Left L3-4 HNP Right L5-S1 HNP	Left L3-4, right L5-S1 microlomber discectomy L3-4, L5-S1 PDI	None
4	F	74	LBP Left L5 dermatomal hypoesthesia	L1-2, L4-5 spinal stenosis	L1, L4 hemilaminectomy L1-2, L4-5 PDI	None
5	F	60	LBP Left SLR 60°+	L1-2 midline HNP L5-S1 left HNP	Right L1-2, left L5-S1 microlumbar discectomy + L1-2 and L5-S1 PDI	None
6	M	40	LBP	T11-T12, L1-2 DDD	T11-T12, L1-2 PDI	None
7	F	54	LBP	L2-3, L4-5, DDD, spondylolisthesis	L2-3, L4-5 PDI	None
8	M	53	LBP	L5-S1 and L1-2, L2-3 DDD	L1-2, L2-3, L5-S1 PDI	None
9	M	47	LBP Right SLR 45°+ S1 dermatomal hypoesthesia	L3-4 DDD right L5-S1 HNP	Right L5-S1 microlomber discectomy L3-4, L5-S1 PDI	None
10	M	29	LBP	L3-4, L5-S1 DDD	L3-4, L5-S1 PDI	None
11	F	49	Left FST+ Left SLR 30°+ Left achilles reflex hypoactive Left gastrocnemius L5-S1 1/5 MW	Left T12-L1 HNP Left L5-S1 HNP L4-5 retrolisthesis	Left T12-L1, L5-S1 microlomber discectomy L4-5-S1 PDI	None
12	F	74	LBP	L3-4, L5-S1 DDD	L3-4, L5-S1 PDI	Spinal epidural hematoma
13	M	50	LBP Left SLR 45° Left L4 dermatomal paresthesia	Left L3-4, L5-S1 HNP Foraminal stenosis	Left L3-4, L5-S1 microlomber discectomy L3-4, L5-S1 PDI	None
14	F	48	LBP	L1-2 HNP, L1-2, L4-5, L5-S1 DDD	Left L1-2 microlomber discectomy Left L4-5 microlomber decompression, L1-2, L4-5-S1 PDI	None
15	M	73	LBP	L5-S1 DDD T12-L2 foraminal stenosis	L5-S1, microlomber discectomy L5-S1, T12-L2 PDI	None
16	F	68	LBP	L2-3, L5-S1 DDD	L2-3, L5-S1 PDI	None
17	F	54	LBP	L1–3 and L4-5 DDD	L1–3 and L4-5 PDI	None
18	M	42	LBP	L2-3 and L4-5 DDD	L2-3 and L4-5 PDI	None

PDI: posterior dynamic instrumentation, FST: femoral stretching test, SLR: straight leg rising, HNP: hernia nucleus pulposus, LBP: lower back pain, and DDD: degenerative disc disease.

Table 2: Patient preoperative and postoperative data.

Patient no.	Preoperative VAS	Postoperative 3-month VAS	Postoperative 12-month VAS	Preoperative Oswestry	Postoperative 3-month Oswestry	Postoperative 12-month Oswestry
1	5	3	1	56	48	10
2	8	2	2	58	32	24
3	6	3	2	68	32	24
4	7	3	1	52	24	6
5	7	3	2	72	28	16
6	6	4	2	56	32	26
7	7	2	1	74	24	16
8	8	3	2	68	48	26
9	7	1	1	64	8	12
10	8	2	2	78	6	12
11	8	3	2	64	18	16
12	8	2	2	72	12	8
13	7	3	3	68	24	18
14	6	3	2	64	18	12
15	8	2	1	78	18	12
16	9	3	0	74	24	6
17	8	1	1	82	18	8
18	8	2	0	76	16	4
Mean	7.28	2.50	1.33	68.00	23.89	14.00

4. Discussion

Back pain at a symptomatic motion segment may originate from vertebral endplates, disc annulus, vertebral periosteum, facet joints, and/or surrounding soft tissue structures [7]. These structures also contribute to the biomechanical stability of the spinal column. The pathology of discogenic pain and degenerative instability has been described by Kirkaldy-Willis and Farfan [8]. Pain is reported to be the simplest description as well as the major symptom of instability. If a patient's limited instability is the result of glacial instability and dysfunctional segmental motion, he or she will experience pain but will be able to lead a life without neurologic deficit [9]. Recent studies have suggested that the chronic instability related to the disc or vertebral body degenerative changes associated with abnormal motion results in the potential for pain.

The management of painful, unstable spinal segments due to degenerative disorders is much more difficult than spinal trauma or tumor surgery. During spinal surgery, instability must be taken into account when relieving pain with adequate neural tissue decompression. Whenever possible, bone, joint, ligament, and muscle tissues must be preserved, and suitable fixation methods must be chosen for the damaged ones; otherwise, decompressive procedures may induce or increase instability [10–13].

The concept of spinal segment arthrodesis as a treatment for unstable degenerate spinal segments evolved almost 100 years ago. Spinal fusion was first described by Albee [3], for the treatment of Pott disease, and Hibbs [14], who performed spinal fusion as a treatment for spinal deformity. Since that time, fusion has been the conventional surgical treatment for chronic low-back pain attributed to degenerative disorders. For a long time, fusion was thought to be a necessity for a successful outcome, but the results of many recent studies have challenged this concept by showing that patients had limited improvements in pain relief and increased mobility after surgery [15–18]. Posterior spinal instrumentation and fusion led to deteriorated biomechanical properties of the ligamentum flavum, posterior longitudinal ligament, and interspinous and supraspinous ligaments [19]. Adequate preservation of the partial lamina, spinous process, and supraspinous and interspinous ligaments during laminectomy was helpful for alleviating the stress on the adjacent segment. Furthermore, biomechanical studies showed that posterolateral fusion with hemilaminectomy had less stress concentrated on the adjacent disc than posterolateral fusion with total laminectomy had on flexion [20]. Moreover, fusion eliminates the motion of the functional spinal segment and may overload the adjacent segments. Indeed, adjacent segment degeneration is a known consequence of spinal fusion [3, 4, 21–25]. Lehmann et al. reported accelerated degenerative changes of the adjacent segment and segmental instability above the fusion in 45% of their patients [26]. Major drawbacks of spinal fusion are stiffness, pseudoarthrosis, mechanical failure, and/or adjacent degenerative disease [27–31]. Because of these problems, less rigid stabilization systems have recently become more popular in spine surgery. Mobile stabilization systems have been shown to neutralize injurious forces and

restore normal functions of the spine segments while also protecting the adjacent segments [32]. One of the motion preservation technologies is the dynamic pedicular screw-rod system. It is a nonfusion dynamic implant system that controls displacement in rotation and translation as well as providing stabilization. This system allows potential sagittal mobility at the hinge site between the screw head and the shank of the screw. Mobility occurs mechanically between the longitudinally oriented rod and the sagittally placed screw shank. This articulated connection between the rod and the screw caused a reduction in flexion strain and resulted in a lower rate of implant failure [33]. In these systems, the stress load was transferred from the implant to the spine, which decreased the tension on the bone [34]. Although it tends to restrict mobility in flexion, extension, lateral bending, and axial rotation, a sharing of the motion and stress load still permits movement, prevents deterioration of the neighboring superior disc level, and slows the process of degenerative progression at the adjacent levels [35]. Further, this controlled distribution of load between the implant and the spine may reduce postoperative damage to joint segments.

Microdiscectomy using Yasargil's microscope has been the standard surgical treatment for symptomatic disc herniation. However, treatment of disc herniations with degenerative changes is still a matter of debate. A simple discectomy cannot stop the continuing segmental degeneration and in some instances can even cause an acceleration of this process [6, 36–39]. In addition, the segmental fusion leads to an irreversible loss of function of the treated segment and a resulting risk of adjacent segmental degeneration and pseudoarthrosis [6, 36–39]. Disappointing surgical outcomes observed in the literature were generally due to increasing instability after surgery [40, 41]. Additional dynamic stabilization, applied by Putzier et al., showed significantly fewer signs of progressive degeneration and stabilized the motion segment after nucleotomy to prevent further disc degeneration [35]. Kaner et al. showed the importance of the annular defect. They concluded that to apply a posterior dynamic stabilization is reasonable to the patients with disc herniation and an annular defect larger than 6 mm [42].

In spinal stenosis with degenerative spondylolisthesis, decompression and fusion are widely recommended. Clinical improvements observed in patients with spinal stenosis and degenerative spondylolisthesis generally depend on the effectiveness of the neural decompression; however, the value of instrumentation is still a matter of debate. Some surgeons recommend fusion with instrumentation because it prevents further sliding and applies more decompression without the risk of destabilization. Studies show that the decompression combined with arthrodesis (posterolateral or interbody) significantly improved patient outcome compared to decompression alone [43–48]. However, some studies revealed that the additive instrumentation leads to higher fusion rates and less progression of spondylolisthesis; however, it is unlikely to improve clinical outcome [17, 46, 49–52].

Surgeons advocating fusion without instrumentation indicate that this process gives a little chance to adjacent segment degeneration, and this concept is supported by various studies. Fischgrund et al. reported a randomized study comparing decompressive laminectomy and arthrodesis with or without spinal instrumentation. After a 2-year followup period, the authors concluded that successful fusion did not influence the patients' outcomes [17]. Considering the older age of patients, major lengthy procedures like a fusion operation, especially posterolateral and interbody fusion with autogenous iliac crest graft, are associated with wound problems in the donor site, neurovascular damage, infections, pelvic fracture, and bleeding, all of which increase morbidity and mortality [53, 54]. Because the degenerative spondylolisthesis is a dynamic process, the purpose of fusion should be to prevent listhesis rather than cure the mechanical pain. Recent studies suggest that the dynamic stabilization system may maintain enough stability to prevent further translation of vertebra without fusion [55–57].

Lumbar arthrodesis for the management of an unstable spine has dramatically increased over the last few decades. The purpose of spinal instrumentation is to increase fusion, but it is obvious that fusion with very long segment instrumentation is being tried, especially for different segment degenerative disorders.

In our study, we adopted a surgical approach that only targeted unstable degenerated and pain-producing segments. Using this approach, we applied neural decompression by a minimally invasive approach that resulted in very little disruption of tissue integrity, discectomy by sparing ligamentum flavum, and decompression by hemilaminectomy in stenosis [58]. We provided stabilization of pain-producing degenerated unstable segments by posterior dynamic transpedicular instrumentation while skipping stable segments. Postoperative VAS and Oswestry scores of a limited series of patients treated with this preservative surgical approach were satisfactory.

References

[1] G. Waddell, "Diagnostic triage," in *The Back Pain Revolution*, G. Waddell, Ed., pp. 9–26, Churcill Livingstone, Edinburgh, UK, 2004.

[2] R. Bertagnoli, "Review of modern treatment options for degenerative disc disease," in *Spinal Restabilization Procedures*, D. L. Kaech and J. R. Jinkins, Eds., pp. 365–375, Elsevier Science, Amsterdam, The Netherlands, 2002.

[3] F. H. Albee, "Transportation of a portion of the tibia into the spine for Pott's disease," *Journal of the American Medical Association*, vol. 57, p. 885, 1911.

[4] P. Fritzell, O. Hägg, P. Wessberg, and A. Nordwall, "2001 Volvo award winner inclinical studies: lumbar fusion versus nonsurgical treatment for chronic low back pain. A multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group," *Spine*, vol. 26, no. 23, pp. 2521–2534, 2001.

[5] C. K. Lee, P. Vessa, June Kyu Lee, and S. Wiesel, "Chronic disabling low back pain syndrome caused by internal disc derangements: the results of disc excision and posterior lumbar interbody fusion," *Spine*, vol. 20, no. 3, pp. 356–361, 1995.

[6] J. C. Eck, S. C. Humphreys, and S. D. Hodges, "Adjacent-segment degeneration after lumbar fusion: a review of clinical,

biomechanical, and radiologic studies.," *American journal of orthopedics*, vol. 28, no. 6, pp. 336–340, 1999.

[7] N. Bogduk, "The innervation of the lumbar spine," *Spine*, vol. 8, no. 3, pp. 286–293, 1983.

[8] W. H. Kirkaldy-Willis and H. F. Farfan, "Instability of the lumbar spine," *Clinical Orthopaedics and Related Research*, vol. 165, pp. 110–123, 1982.

[9] K. Abumi, M. M. Panjabi, K.M. Kramer, J. Duranceau, T. Oxland, and J. J. Crisco, "Biomechanical evaluation of lumbar spinal stability after graded facetectomies," *Spine*, vol. 15, no. 11, pp. 1142–1147, 1990.

[10] K. Abumi, M. M. Panjabi, K. M. Kramer, J. Duranceau, T. Oxland, and J. J. Crisco, "Biomechanical evaluation of lumbar spinal stability after graded facetectomies," *Spine*, vol. 15, no. 11, pp. 1142–1147, 1990.

[11] S. D. Boden, C. Martin, R. Rudolph, J. S. Kirkpatrick, S. M. R. Moeini, and W. C. Hutton, "Increase of motion between lumbar vertebrae after excision of the capsule and cartilage of the facets. A cadaver study," *Journal of Bone and Joint Surgery A*, vol. 76, no. 12, pp. 1847–1853, 1994.

[12] J. W. Frymoyer and D. K. Selby, "Segmental instability: rationale for treatment," *Spine*, vol. 10, no. 3, pp. 280–286, 1985.

[13] B. Jönsson, M. Akesson, K. Jonsson, and B. Stromqvist, "Low risk for vertebral slipping after decompression with facet joint preserving technique for lumbar spinal stenosis," *European Spine Journal*, vol. 1, no. 2, pp. 100–104, 1992.

[14] R. H. Hibbs, "An operation for progressive spinal deformities," *New York Medical Journal*, vol. 93, pp. 10–13, 1911.

[15] S. Agazzi, A. Reverdin, and D. May, "Posterior lumbar interbody fusion with cages: an independent review of 71 cases," *Journal of Neurosurgery*, vol. 91, no. 2, pp. 186–192, 1999.

[16] F. B. Christensen, E. Stender Hansen, M. Laursen, K. Thomsen, and C. E. Bünger, "Long-term functional outcome of pedicle screw instrumentation as a support for posterolateral spinal fusion: randomized clinical study with a 5-year follow-up," *Spine*, vol. 27, no. 12, pp. 1269–1277, 2002.

[17] J. S. Fischgrund, M. Mackay, H. N. Herkowitz, R. Brower, D. M. Montgomery, and L. T. Kurz, "Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective, randomized study comparing decompressive laminectomy and arthrodesis with and without spinal instrumentation," *Spine*, vol. 22, no. 24, pp. 2807–2812, 1997.

[18] P. Fritzell, O. Hägg, P. Wessberg, and A. Nordwall, "Chronic low back pain and fusion: a comparison of three surgical techniques: a prospective multicenter randomized study from the Swedish Lumbar Spine Study Group," *Spine*, vol. 27, no. 11, pp. 1131–1141, 2002.

[19] Y. Kotani, B. W. Cunningham, A. Cappuccino, K. Kaneda, and P. C. McAfee, "The effects of spinal fixation and destabilization on the biomechanical and histologic properties of spinal ligaments: an in vivo study," *Spine*, vol. 23, no. 6, pp. 672–683, 1998.

[20] C. S. Chen, C. K. Feng, C. K. Cheng, M. J. Tzeng, C. L. Liu, and W. J. Chen, "Biomechanical analysis of the disc adjacent to posterolateral fusion with laminectomy in lumbar spine," *Journal of Spinal Disorders and Techniques*, vol. 18, no. 1, pp. 58–65, 2005.

[21] P. Fritzell, O. Hägg, P. Wessberg, and A. Nordwall, "2001 Volvo award winner in clinical studies: lumbar fusion versus nonsurgical treatment for chronic low back pain. A multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group," *Spine*, vol. 26, no. 23, pp. 2521–2534, 2001.

[22] J. N. A. Gibson, I. C. Grant, and G. Waddell, "The Cochrane review of surgery for lumbar disc prolapse and degenerative lumbar spondylosis," *Spine*, vol. 24, no. 17, pp. 1820–1832, 1999.

[23] J. Glaser, M. Stanley, H. Sayre, J. Woody, E. Found, and K. Spratt, "A 10-year follow-up evaluation of lumbar spine fusion with pedicle screw fixation," *Spine*, vol. 28, no. 13, pp. 1390–1395, 2003.

[24] P. V. Mummaneni, R. W. Haid, and G. E. Rodts, "Lumbar interbody fusion: state-of-the-art technical advances," *Journal of Neurosurgery*, vol. 101, no. 1, pp. 24–30, 2004.

[25] O. Schwarzenbach, U. Berlemann, T. M. Stoll, and G. Dubois, "Posterior dynamic stabilization systems: Dynesys," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 363–372, 2005.

[26] T. R. Lehmann, K. F. Spratt, and J. E. Tozzi, "Long-term follow-up of lower lumbar fusion patients," *Spine*, vol. 12, no. 2, pp. 97–104, 1987.

[27] G. Ghiselli, J. C. Wang, N. N. Bhatia, W. K. Hsu, and E. G. Dawson, "Adjacent segment degeneration in the lumbar spine," *Journal of Bone and Joint Surgery A*, vol. 86, no. 7, pp. 1497–1503, 2004.

[28] R. C. Huang, F. P. Girardi, M. R. Lim, and F. P. Cammisa Jr, "Advantages and disadvantages of nonfusion technology in spine surgery," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 263–269, 2005.

[29] R. C. Huang, T. M. Wright, M. M. Panjabi, and J. D. Lipman, "Biomechanics of nonfusion implants," *Orthopedic Clinics of North America*, vol. 36, no. 3, pp. 271–280, 2005.

[30] S. Inceoglu, "Posterior dynamic stabilization of the lumbar spine," *World Spine Journal*, vol. 1, pp. 62–67, 2006.

[31] H. Ishihara, R. Osada, M. Kanamori et al., "Minimum 10-year follow-up study of anterior lumbar interbody fusion for isthmic spondylolisthesis," *Journal of Spinal Disorders*, vol. 14, no. 2, pp. 91–99, 2001.

[32] T. M. Stoll, G. Dubois, and O. Schwarzenbach, "The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system," *European Spine Journal*, vol. 11, supplement 2, pp. S170–S178, 2002.

[33] M. Sasani, A. L. Aydin, T. Oktenoglu et al., "The combined use of a posterior dynamic transpedicular stabilization system and a prosthetic disc nucleus device in treating lumbar degenerative disc disease with disc herniations," *SAS Journal*, vol. 2, no. 3, pp. 130–136, 2008.

[34] A. Strempel, A. Neckritz, P. Mualenaere, and G. du Toit, "Dynamic versus rigid spinal implants," in *Lumbar Spinal Stenosis*, R. Gunzburg and M. Szpalski, Eds., pp. 275–285, Lippincott-Williams and Wilkins, Philadelphia, Pa, USA, 2000.

[35] M. Putzier, S. V. Schneider, J. F. Funk, S. W. Tohtz, and C. Perka, "The surgical treatment of the lumbar disc prolapse: nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone.," *Spine.*, vol. 30, no. 5, pp. E109–E114, 2005.

[36] H. Frei, T. R. Oxland, G. C. Rathonyi, and L. P. Nolte, "The effect of nucleotomy on lumbar spine mechanics in compression and shear loading," *Spine*, vol. 26, no. 19, pp. 2080–2089, 2001.

[37] O. L. Osti, B. Vernon-Roberts, and R. D. Fraser, "1990 Volvo award in experimental studies: anulus tears and intervertebral disc degeneration: an experimental study using an animal model," *Spine*, vol. 15, no. 8, pp. 762–767, 1990.

[38] M. D. Rahm and B. B. Hall, "Adjacent-segment degeneration after lumbar fusion with instrumentation: a retrospective

study," *Journal of Spinal Disorders*, vol. 9, no. 5, pp. 392–400, 1996.

[39] J. Zucherman, K. Hsu, G. Picetti, A. White, G. Wynne, and L. Taylor, "Clinical efficacy of spinal instrumentation in lumbar degenerative disc disease," *Spine*, vol. 17, no. 7, pp. 834–837, 1992.

[40] K. E. Johnsson, S. Willner, and K. Johnsson, "Postoperative instability after decompression for lumbar spinal stenosis," *Spine*, vol. 11, no. 2, pp. 107–110, 1986.

[41] E. Kotilainen, A. Alanen, M. Erkintalo, S. Valtonen, and M. Kormano, "Association between decreased disc signal intensity in T2-weighted MRI and a 5-year outcome after lumbar minimally invasive discectomy association between decreased disc signal intensity in preoperative," *Minimally Invasive Neurosurgery*, vol. 44, no. 1, pp. 31–36, 2001.

[42] T. Kaner, S. Dalbayrak, T. Oktenoglu, M. Sasani, A. L. Aydin, and F. O. Ozer, "Comparison of posterior dynamic and posterior rigid transpedicular stabilization with fusion to treat degenerative spondylolisthesis," *Orthopedics*, vol. 33, no. 5, p. 12, 2010.

[43] H. Bassewitz and H. Herkowitz, "Lumbar stenosis with spondylolisthesis: current concepts of surgical treatment," *Clinical Orthopaedics and Related Research*, no. 384, pp. 54–60, 2001.

[44] H. L. Feffer, S. W. Wiesel, J. M. Cuckler, and R. H. Rothman, "Degenerative spondylolisthesis: to fuse or not to fuse," *Spine*, vol. 10, no. 3, pp. 287–289, 1985.

[45] H. N. Herkowitz and L. T. Kurz, "Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective study comparing decompression with decompression and intertransverse process arthrodesis," *Journal of Bone and Joint Surgery A*, vol. 73, no. 6, pp. 802–808, 1991.

[46] J. S. Lombardi, L. L. Wiltse, and J. Reynolds, "Treatment of degenerative spondylolisthesis," *Spine*, vol. 10, no. 9, pp. 821–827, 1985.

[47] R. J. Nasca, "Rationale for spinal fusion in lumbar spinal stenosis," *Spine*, vol. 14, no. 4, pp. 451–454, 1989.

[48] S. E. Nork, S. S. Hu, K. L. Workman, P. A. Glazer, and D. S. Bradford, "Patient outcomes after decompression and instrumented posterior spinal fusion for degenerative spondylolisthesis," *Spine*, vol. 24, no. 6, pp. 561–569, 1999.

[49] K. C. Booth, K. H. Bridwell, B. A. Eisenberg, C. R. Baldus, and L. G. Lenke, "Minimum 5-year results of degenerative spondylolisthesis treated with decompression and instrumented posterior fusion," *Spine*, vol. 24, no. 16, pp. 1721–1727, 1999.

[50] K. H. Bridwell, T. A. Sedgewick, M. F. O'Brien, L. G. Lenke, and C. Baldus, "The role of fusion and instrumentation in the treatment of degenerative spondylolisthesis with spinal stenosis," *Journal of Spinal Disorders*, vol. 6, no. 6, pp. 461–472, 1993.

[51] J. N. Gibson, G. Waddell, and I. C. Grant, "Surgery for degenerative lumbar spondylosis.," *Cochrane Database of Systematic Reviews*, no. 3, p. CD001352, 2000.

[52] F. Postacchini, G. Cinotti, and D. Perugia, "Degenerative lumbar spondylolisthesis. II. Surgical treatment.," *Italian Journal of Orthopaedics and Traumatology*, vol. 17, no. 4, pp. 467–477, 1991.

[53] J. C. Banwart, M. A. Asher, and R. S. Hassanein, "Iliac crest bone graft harvest donor site morbidity: a statistical evaluation," *Spine*, vol. 20, no. 9, pp. 1055–1060, 1995.

[54] E. M. Younger and M. W. Chapman, "Morbidity at bone graft donor sites," *Journal of orthopaedic trauma*, vol. 3, no. 3, pp. 192–195, 1989.

[55] B. Cakir, B. Ulmar, H. Koepp, K. Huch, W. Puhl, and M. Richter, "Posterior dynamic stabiliziation as on alternative for instrumented fusion in the treatment of degenerative lumbar instability with spinal stenosis," *Zeitschrift fur Orthopadie und Ihre Grenzgebiete*, vol. 141, no. 4, pp. 418–424, 2003.

[56] W. Schmoelz, J. F. Huber, T. Nydegger, Dipl-Ing, L. Claes, and H. J. Wilke, "Dynamic stabilization of the lumbar spine and its effects on adjacent segments: an in vitro experiment," *Journal of Spinal Disorders and Techniques*, vol. 16, no. 4, pp. 418–423, 2003.

[57] K. J. Schnake, S. Schaeren, and B. Jeanneret, "Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis," *Spine*, vol. 31, no. 4, pp. 442–449, 2006.

[58] A. F. Ozer, T. Oktenoglu, M. Sasani et al., "Preserving the ligamentum flavum in lumbar discectomy: a new technique that prevents scar tissue formation in the first 6 months postsurgery," *Neurosurgery*, vol. 59, supplement 1, pp. S-126–S-133, 2006.