Comparison of the biomechanical effect of pedicle-based dynamic stabilization: a study using finite element analysis

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Abstract

BACKGROUND CONTEXT: Recently, nonfusion pedicle-based dynamic stabilization systems (PBDSs) have been developed and used in the management of degenerative lumbar spinal diseases. Still effects on spinal kinematics and clinical effects are controversial. Little biomechanical information exists for providing biomechanical characteristics of pedicle-based dynamic stabilization according to the PBDS design before clinical implementation.

PURPOSE: To investigate the effects of implanting PBDSs into the spinal functional unit and elucidate the differences in biomechanical characteristics according to different materials and design.

STUDY DESIGN: The biomechanical effects of implantation of PBDS were investigated using the nonlinear three-dimensional finite element model of L4–L5.

METHODS: An already validated three-dimensional, intact osteoligamentous L4–L5 finite element model was modified to incorporate the insertion of pedicle screws. The implanted models were constructed after modifying the intact model to simulate postoperative changes using four different fixation systems. Four models instrumented with PBDS (Dynesys, NFlex, and polyetheretherketone [PEEK]) and rigid fixation systems (conventional titanium rod) were developed for comparison. The instrumented models were compared with those of the intact and rigid fixation model. Range of motion (ROM) in three motion planes, center of rotation (COR), force on the facet joint, and von Mises stress distribution on the vertebral body and implants with flexion-extension were compared among the models.

RESULTS: Simulated results demonstrated that implanted segments with PBDSs have limited ROM when compared with the intact spine. Flexion motion was the most limited, and axial rotation was the least limited, after device implantation. Among the PBDS selected in this analysis, the NFlex system had the closest instantaneous COR compared with the intact model and a higher ROM compared with other PBDS. Contact force on the facet joint in extension increased with an increase of moment in Dynesys and NFlex; however, the rigid or PEEK rod fixation revealed no facet contact force.

CONCLUSIONS: Implanted segments with PBDSs have limited ROM when compared with the intact spine. Center of rotation and stress distribution differed according to the design and materials used. These biomechanical effects produced a nonphysiological stress on the functional spinal unit when they were implanted. The biomechanical effects of current PBDSs should be carefully considered before clinical implementation. © 2013 Elsevier Inc. All rights reserved.

Keywords: Stabilization; Finite elements; Lumbar spinal segment; Motion; Stress

FDA device/drug status: Approved (DYNESYS; NFlex).


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Introduction

Spinal fusion has been the primary surgical option for the treatment of degenerative lumbar spinal disease over the past several decades; however, many studies have demonstrated that such surgeries result in subsequent mechanical and physiological changes, such as the acceleration of adjacent segments, loss of motion, and changes in the centers of intervertebral rotation [1,2]. Previous studies have shown that rigid spinal systems may cause abnormal changes in the load transfer and stresses, which may lead to the degeneration of the intervertebral disc and bony structures [3–5]. This can result in several unwanted problems, including spinal stiffness and acceleration of adjacent segment degeneration. To avoid these adverse effects, less rigid spinal stabilization systems have recently been introduced for use in the treatment of lumbar degenerative spinal diseases [6–8]. These systems are clinically categorized as dynamic stabilization systems. The pedicle-based dynamic stabilization system (PBDS) is one such dynamic stabilization system that provides flexibility of a motion segment and induces more load transfer across the spine than conventional rigid stabilization devices [9]. Recent studies have suggested that dynamic stabilization may provide better surgical alternatives to conventional fusion for the treatment of patients with chronic low back pain [8,9]. As a result, various types of PBDS have been developed for the treatment of lumbar degenerative spinal diseases [10–14]. These devices use more compliant materials (such as Nitinol, polymers, or polyetheretherketone [PEEK]) or design changes (coiled, twisted rods, or joint rods). It is thought that they are capable of maintaining or restoring the load-sharing characteristics to the level of the intact spine with less stress shielding.

Successful clinical outcomes in patients with PBDS have been reported [15–19]. Some clinical reports have revealed that PBDS could not prevent the acceleration of adjacent segment degeneration despite their theoretical advantages over rigid fixation [20–22], and reoperation associated with hardware failure has been reported [23–26]. The ideal PBDS should simulate the normal functional spinal unit, which has normal kinematics, a normal load transfer pattern with load sharing, and active change in the instantaneous center of rotation (COR). In addition, the normal spine has a unique pattern of motion on the sagittal plane as well as the coronal and axial planes. The distance between the upper and lower pedicle (DBP) changes during flexion-extension. Thus, PBDSs can be compatible with this change of DBP. Most PBDSs except NFlex (Synthes Spine, West Chester, PA, USA) in the current market are designed with a fixed DBP when they are implanted. This design flaw can contribute to abnormal kinematics, abnormal loading, and unwanted clinical outcome. Recently developed PBDSs have a more sophisticated design and claim to simulate a functional spinal unit [27–31]. However, only a few studies have compared the biomechanical responses of PBDS despite its distinct design characteristics.

In this study, the biomechanical effects of various PBDS implantations were investigated using the nonlinear three-dimensional finite element (FE) model of L4–L5. NFlex, Dynesys (Zimmer Spine, Warsaw, IN, USA), and PEEK rods were chosen as the representative PBDS and compared with the intact and rigid titanium (Ti) rod fixation model of the functional spinal unit.

Materials and methods

A three-dimensional, intact, osteoligamentous L4–L5 FE model, an upgraded version of the previously validated model [32] and used for the artificial disc applications [33], was used for this study. In the model, the shape of the vertebrae was modified slightly based on the data from Man8 (Human Anatomy; Digimation, Inc., Lake Mary, FL, USA) [34], and the number of elements was increased. Mesh sensitivity analysis was carried out and it was determined that an acceptable compromise between the solution accuracy and solution time was achieved. (Nucleus pressure and axial displacement difference was only 3.3% and 5.7% under 400 N of compressive load, and angular rotation difference was 5.73% and 4.78% under 6 Nm flexion and extension moment, respectively, when the mesh density was increased eightfold. The calculation time was increased 27 times, despite this small change.)

With this model, meshes in the vertebral body and pedicles were further modified to incorporate the pedicle screw insertion. Responses in the modified motion segment model (eg, load-displacement relationship, nucleus pressure, facet contact force, and ligament stains) were also similar to our previously validated model.

The screw section in the pedicle screw was simplified as a beam element that had the same bending stiffness as the actual screw section. Because our models were designed to simulate the biomechanical behavior of long-term statuses after instrumentation, the bone-screw interface was assumed to be completely bonded via the node sharing condition. A screw head model was attached at the end of those beam elements.

The implanted models were constructed after modifying the intact model to simulate postoperative changes using four different fixation systems. Four models instrumented with PBDS (Dynesys, NFlex, and PEEK) and rigid fixation systems (conventional Ti rod), which are all commercially available, were developed for comparison. The rigid Ti rod contained a circular cross section (diameter=6.0 mm), and the PEEK rod had an ellipsoidal cross section (major diameter=7.0 mm, minor diameter=6.2 mm, and rod radius of curvature=120.0 mm).

The Dynesys was comprised of pedicle screws, polyethylene terephthalate cords, and polycarbonate urethane (PCU) spacers. To withstand compressive loads, the spacers were placed bilaterally between the pedicle screw heads. The cords were run through the hollow core of the spacers,
and the construct was stabilized by 300 N of tensile preload. The tensile preload was assigned using a prestrained spring element.

The NFlex dynamic stabilization system consists of polyaxial Ti alloy pedicle screws that are fixed to a semirigid PCU-sleeved rod. The composite Ti and PCU sleeve is captured on a solid Ti core by a Ti end cap, which is fixed in place. The PCU spacer of NFlex acted as a bumper, allowing the Ti ring to slide up and down the core and to toggle against the tapered core. Sliding and contact between the Ti core and sliding ring, combined with the double PCU spacers was modeled using surface contact elements. The rigid Ti rod section of NFlex had a circular cross section (diameter = 6 mm). The material properties of Ti, PEEK, and PCU were assigned as 110 GPa, 3.2 GPa, and 50 Mpa, respectively. Fig. 1 shows the complete instrumented L4–L5 motion segment with the Dynesys, PEEK, NFlex, and rigid Ti rod.

A cross type rigid bar element was attached at the superior end plate of the L4 vertebra as a loading frame and its center was located at the two-third of L4 vertebral body from the end of the anterior surface. 400 N of compressive preload was assigned to the superior end plate of L4 and superior facet at a rate of 18 to 1 [32,35]. An additional flexion/extension and lateral bending moment up to 6 Nm was applied on the L4 vertebra via loading frame. Axial rotation was simulated by applying a load in the horizontal direction. ABAQUS (ver. 6.10; Hibbitt Karlsson & Sorensen, Inc., Pawtucket, RI, USA) was used to carry out the nonlinear structural analysis on the detailed lumbar spinal motion segment model.

Results

Compared with the intact spine model, the PBDS-implanted models showed decreased range of motion (ROM) in all motion planes as shown in Fig. 2. The flexion motion was limited most and the axial rotation was limited the least, after device implantation. In flexion-extension, the ROM gradually increased in all tested implants with an increase of moment. Under a moment of 6 Nm, ROM decreased in the following order: rigid fixation, PEEK rod, Dynesys, and NFlex. The decrease in ROM during flexion was greater than that during extension. In the case of NFlex, ROM was 42% in flexion and 56% in extension of that of the intact spine. Flexion-extension ROM was the largest in the NFlex implant, followed by Dynesys, PEEK rod, and rigid fixation. In lateral bending, ROM was in the following order for both the flexion/extension motion:

![Intact](image1)

![PEEK](image2)

![Ti](image3)

![NFlex](image4)

![Dynesys](image5)

Fig. 1. L4–L5 finite element models of intact and implanted with various pedicle-based dynamic stabilization. PEEK, polyetheretherketone; Ti, titanium; PCU, polycarbonate urethane.
NFlex, Dynesys, PEEK rod, and rigid rod. Approximately 59% of the intact motion was preserved in NFlex. Of particular interest, the PEEK rod produced a ROM similar to that of the rigid rod except for axial rotation. In axial rotation, NFlex showed greater motion (81% of intact spine motion) when compared with the other devices. Contrary to lateral bending, the PEEK rod showed the greatest ROM in the axial rotation.

In normal intact spine modeling, COR was located in posterior three-fifth from the anterior to posterior direction of the disc and moved posteriorly and downwardly with extension in the disc space. Although it was not the same as the intact spine model, NFlex had the closest COR to the intact spine and showed a similar pattern in COR changes.

Contact force on the facet joint was investigated under each loading condition. 400 N of compressive preload produced an initial facet contact in the intact spine, Nflex, and Dynesys models as seen in Fig. 5. 300 N of initial tensile preload during Dynesys application increased the facet contact force to 177.1 N. The additional flexion moment gradually reduced the facet contact force. The contact force on the facet joint during extension motion increased with an increase of moment in Dynesys and NFlex; however, no facet contact force was observed for rigid or PEEK rod fixation. As shown in Fig. 6, the facet contact force changed during right lateral bending and right axial rotation. During lateral bending, the facet contact force on the right side increased with a decrease in the left side as the moment increased in the normal spine. Only a right side facet contact force was observed for NFlex, and it was much smaller than the normal spine (40.5% of intact spine at 6 Nm). Rigid fixation with the Ti rod produced no contact force on both sides. The PEEK rod only produced a small contact force on the right side at a moment of 6 Nm. For the Dynesys, the facet contact force was much greater than the normal spine on both sides, and it was slightly higher on the right side with almost no change on the left side. During right axial rotation, the facet contact force increased on the left side with no contact force on the right side for the normal spine, and it gradually increased with an increase of moments. All other devices, except Dynesys, showed a similar pattern, but it was little bit larger than the normal spine at a moment of 6 Nm. The Dynesys generated a greater contact force than the normal spine on the rotating side as well as the opposite side, which gradually decreased on the rotating side with an increase of overall contact force when the moment was increased.

The stress distribution in the spinal motion segment and the device is illustrated in Figs. 7 and 8. In the intact spine model, a relatively high stress was generated mainly in the superior portion of the upper vertebral body during flexion. Application of a stabilizing device changed its load transfer. During rigid fixation with the Ti rod, a higher stress was generated in the rod. Among PBDS, the NFlex produced the highest stress in the rod.

During extension, a relatively high stress was generated in the posterior element of the intact model. Some of the stress was distributed to posterior column of the vertebral body, especially on the facet joints of the upper vertebrae and lamina of the lower vertebrae. In rigid fixation with the Ti rod, a higher stress was generated in the rod than that observed during flexion motion. For the Dynesys implantation, the stress distribution at the vertebrae during flexion and extension was similar to that of the intact spine. For the NFlex implantation, a high stress was distributed to the PCU spacer beneath the upper pedicular screw. The
stress produced by the PEEK rod implantation was located at the upper end of the PEEK rod during extension, but the overall stress on the PEEK rod was relatively small.

Discussion

Spinal instrumented fusion has been the primary method of surgical treatment for lumbar degenerative spinal diseases, such as spinal stenosis and spondylolisthesis. Historically, simple decompression has been known as a problem of instability and mechanical back pain; thus, fusion has been used to improve stability. In the 1980s, pedicle screw fixation was added to fusion to support postoperative instability and enhance spinal fusion. Although instrumented fusion has been widely accepted as the standard treatment for degenerative lumbar diseases, many studies have demonstrated unwanted effects of spinal fusion, including chronic back pain, loss of motion, and degeneration of adjacent segment [2–5]. Because of the realization of these fusion-related problems, less rigid stabilization was thought to be an alternative to avoid these problems. Theoretically, a dynamic stabilization system can preserve some ROM and produce a favorable change in the loading pattern [8,9]. Although interspinous devices have claimed that their biomechanical effects can act as a dynamic stabilization system, the actual biomechanical effects were limited. Pedicle-based dynamic stabilization systems are the major compatible devices that can effectively influence spinal functional segments without fusion.

A discrepancy between expectation and clinical outcome may be associated with the current design of PBDSs. The early concept of PBDS was simply to allow for flexibility, and this flexibility was thought to permit motion. However, the normal spine can allow motion and absorb shock. Thus, the PBDS design should consider both functions of the spinal unit. Furthermore, spinal motion is a very complex coupled motion. When the spine is flexed or extended, DBP is varied. In addition to flexion/extension motion, DBP on one side will be changed during the lateral bending and axial rotation. Recent studies using the FE model have revealed that the displacement during flexion, axial rotation, and lateral bending was 4.0, 3.7, and 2.1 mm, respectively [36]. Another study reported that the DBP ranges from 2.3 to 2.7 mm during flexion/extension [30]. Unfortunately, most current devices show only simple flexibility and this variation in DBP is not considered. This design flaw can affect biomechanical results, including COR, stress distribution,
facet contacts force, and even ROM, which may lead to screw loosening, fatigue failure, an undesirable effect on the spine, and unexpected clinical outcomes.

In this study, we compared the biomechanical effect of different types of PBDSs using FE modeling. As expected, the PBDS implanted models showed a decreased ROM in all three motion planes. Thus, the tested PBDSs have a definite stabilizing effect on the functional spinal unit with limited extent of motion. NFlex showed more preserved ROM than Dynesys and PEEK rods in all three planes. A recent FE study for the biomechanics of stabilization systems [28] revealed that PBDSs decreased ROM by approximately 40% to 50% relative to the intact spine during flexion-extension. The decrease in ROM for the PEEK rod was about 70% to 90% of the intact spine during extension and lateral bending, but the decrease in ROM during axial rotation was similar to the other PBDSs. Our results were similar to those observed in this study. Another recent study was conducted to compare ROM after stabilization using NFlex, Dynesys, and other coiled PBDS. In that study, a coiled device produced a much larger motion in all three planes when compared with NFlex and Dynesys [36]. Unfortunately, detailed modeling of NFlex, which has the dynamic nature of double spacers, was not conducted. Furthermore, the ROM after PEEK implantation was zero, as was observed for the Ti rod used in their study. This finding was very unusual considering other studies and the flexible nature of the PEEK rod. In our study, greater than 50% of the motion was maintained for the NFlex implantation except during flexion (42%). The ideal level of motion in PBDS has not yet been clearly demonstrated, and some researchers have claimed that 50% of motion was desirable when considering that an aging spine has greater motion [30,36]. The ideal PBDS may have a normal physiologic ROM and unloading capability. However, the motion of most recently developed PBDSs is 30% to 50% of that of the intact spine motion. For stabilizing effects, the extent of motion in all motion planes must be limited. Obviously, an increase in flexibility permits more ROM and produces less effect on adjacent segments; however, the unloading effect is limited. Although some devices have claimed greater motion, more flexible devices have a less effect on load sharing and stability [29]. For these reasons, more sophisticated investigations are needed to determine the ideal ROM and exact amount of unloading, which may be individualized in clinical practice.

Fig. 4. Variations of instantaneous axis of rotation during extension. Ti, titanium; PEEK, polyetheretherketone.
The pattern of motion was investigated in addition to the magnitude of motion. In the normal intact spine model, the predicted location of COR showed little difference when compared with in vivo measurement. In this analysis, only one motion segment model was selected, and the activation of paraspinal deep muscle during the spine motion should further change the location of COR. Although it was not the same as the intact spine model, NFlex had the closest COR to that of the intact spine. Few studies of COR in PBDS have been reported. Noisi et al. [37] examined changes of COR in Dynesys using a cadaveric model. In their study, COR in the Dynesys implant was beyond the posterior body line of the vertebra, whereas COR of the intact spine was at the middle of the disc. Recently, Rao et al. [38] reported that NFlex has a more physiological COR at the adjacent segment when compared with PEEK or rigid rod, when hybrid stabilization was performed. Actually, COR of the normal spine is not fixed, rather it changes during motion. When PBDS has a fixed COR or a COR that is far away from the physiological COR, it may cause adverse biomechanical stress on stabilizing segments, adjacent segments, and implants.

Clinically, increases in facet loading could potentially lead to low back pain, facet joint osteoarthritis, or other pathologies. In normal subjects, the facet contact force during extension is 10% to 40% of loading [39]. Several researchers have investigated facet contact force in PBDS.
Niosi et al. [40] reported that Dynesys had a lesser effect on facet contact force. Liu et al. [41] revealed that facet stress decreased at the operated level but increased at the adjacent level under extension after Dynesys implantation. Rohlmann et al. [42] reported that facet contact force showed a larger decrease on a rigid fixator than a dynamic implant. In our model, NFlex showed a similar pattern of facet contact force in lateral bending, but it was much less than the normal intact spine. The rigid rod and PEEK rod showed little facet contact force during lateral bending. Dynesys produced a greater facet contact force than the normal spine under all loading conditions. During axial rotation, the facet contact force increased on the opposite side with no contact force on the rotating side in the normal spine, and it gradually increased with an increase in moments. All other devices, except Dynesys, showed a similar pattern but were slightly larger than the normal spine. Dynesys produced a greater facet contact force on both sides. Cord pretension force applied during the implantation procedure produced extension motion of the L4 vertebra, and this induced a relatively small facet contact force under the other loading condition.

Stress (von Mises) distributions at a flexion/extension moment of 6 Nm were observed in the posterior column of the vertebral body and the stress on the facet joints of the upper vertebrae and lamina of the lower vertebrae were very similar between the intact and Dynesys implantation model. The facet contact force shown in Fig. 5 is consistent with these results. In the rigid fixation with the Ti rod, most of the stress on the Ti rod occurred during flexion, and it was more concentrated on the rod during extension. This suggests that rigid fixation unloads most of the stress on the vertebral body during flexion/extension motion. Only a slight change in stress was observed for the PEEK rod implantation during the flexion/extension motion and the overall stress on the PEEK rod was low. The NFlex implant was the only device that showed a change in stress during the flexion/extension motion, which suggests that the NFlex was incorporated into normal spinal motion and moved dynamically with the load-sharing capability. Interestingly, Dynesys spacer and PEEK rod stress loading was minimal during either flexion or extension. Although the level of unloading that is better for patients has not yet been determined, an active change of unloading during flexion/extension motion may be of greater importance than the predetermined fixed unloading in a specific motion.

In a recent study by Galbusera et al. [28], the authors suggested distinguishing “flexible” devices, which are able to preserve only a minor fraction (e.g., at most 50%) of the physiological ROM, from “dynamic” devices, which induce a smaller ROM restriction. Unfortunately, this simple classification is unsuitable in terms of biomechanical behaviors of the normal functional spinal unit. In the author’s opinion, flexible devices mean that they are not rigid regardless of whatever mechanism of flexibility it has. Dynamic devices mean that they can act and vary with normal spinal movement instead of simple flexibilities. Range of motion is not the only significant feature of dynamic PDPS but also COR, stress distribution, and facet contact force, and so forth. In this study, we could confirm the dynamic nature of devices, although it was not very physiological. The current PDPS may be insufficient for dynamic devices so far considering our results. Some of the undesirable outcomes of PDPS may be related with this biomechanical discrepancy and design flaw. For example, the development of adjacent segment degeneration after Dynesys implantation is due to the stiffness and less ROM of stabilized segments. Similarly, the unexplained pain around the buttocks is thought to be the effect of increased facet contact force with Dynesys. In this viewpoint, a recent article by Liu et al. [41] is important and meaningful for the surgeons who implant Dynesys stabilization system. They found that the alteration of cord pretension affects the ROM and facet contact force and annulus stress at the stabilized segment. In addition, the use of a 300 N cord pretension causes a much higher stiffness at the implanted level compared with the intact lumbar spine [43].
In this study, a detailed three-dimensional FE model of the lumbar spinal segment (L4–L5) with different PBDS, which has unique design characteristics, were developed. It was clearly demonstrated that the PBDS implant preserves more ROM than the Ti rod with more physiological COR even though there were some differences among the PBDSs. These biomechanical effects produced nonphysiological stress on the functional spinal unit when they were implanted and may be related with undesirable results. A more sophisticated design is needed to limit unwanted effects on spinal functional segments. Further studies on adjacent segment effects using multilevel modeling will help clarify the further effect of PBDS on spinal functional units.

References


