Dynamic stabilization of the lumbar spine

Robert W. Molinari

Purpose of review

This is a review of the recent literature involving dynamic posterior stabilization in the lumbar spine.

Recent findings

As an alternative to fusion, a mobile, dynamic stabilization restricting segmental motion would be advantageous in various indications, allowing greater physiological function and reducing the inherent disadvantages of rigid instrumentation and fusion. Dynamic stabilization may provide benefit by altering the transmission of abnormal loads across the degenerative disc space without the elimination of movement. Further study is required to determine optimal design, clinical indications, and clinical outcomes.

Summary

Much of the experience with dynamic lumbar stabilization is from Europe. There has been little experience with these devices in the USA and data on long-term clinical outcomes are lacking. Much of the European experience has been with two dynamic stabilization devices, the Graf ligament and Dynesys. Biomechanical testing of newer posterior fulcrum-assisted dynamic systems has been recently reported. Short-term follow-up data on the X-STOP device, which is another alternative to lumbar fusion, has been recently reported.

Keywords

dynamic stabilization, lumbar, soft stabilization, spine, X-STOP

Curr Opin Orthop 18:215–220. © 2007 Lippincott Williams & Wilkins.

Department of Orthopaedic Surgery, Division of Spinal Surgery, University of Rochester, Rochester, New York, USA

Correspondence to Robert W. Molinari, MD, University of Rochester Medical Center, Box 665, 601 Elmwood Ave, Rochester, NY 14642, USA
Tel: +1 585 275 1733; fax: +1 585 756 4726; e-mail: bobmol@aol.com

Current Opinion in Orthopaedics 2007, 18:215–220

Abbreviation

TOPS total posterior element-replacement system

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Introduction

Spinal fusion remains the gold standard for surgical management of instability and mechanical low-back pain. However, even in carefully selected patients, successful clinical results can be difficult to achieve. Reasons for failure include pseudarthrosis and adjacent segment disease. Although dynamic stabilization seems promising in some clinical reports, one should take a cautious approach to any new spinal-implant system. An implant for fusion only has to serve a temporary stabilization until fusion has taken place; on the other hand, a dynamic stabilization system has to provide stability throughout its life. Implant loosening following fusion surgery is common in the presence of pseudarthrosis. With dynamic stabilization, the implant has to stay anchored to the bone despite allowing movement. Any mismatch between the kinematics of the implant system and the motion segment, in particular any discrepancy between their instantaneous axis of rotation, would result in the implant bearing unexpected load at certain ranges of motion. The need for strict bench testing in the laboratory, therefore, cannot be over-emphasized. The few dynamic stabilization systems that have had clinical applications so far have produced some clinical outcomes comparable to that of fusion. Most importantly, no prospective randomized controlled trial has been reported yet, which is an essential requirement for practice of evidence-based medicine. The need for more clinical outcomes data was recently emphasized by Nockels [1] in his review of dynamic lumbar stabilization in the management of painful lumbar disorders.

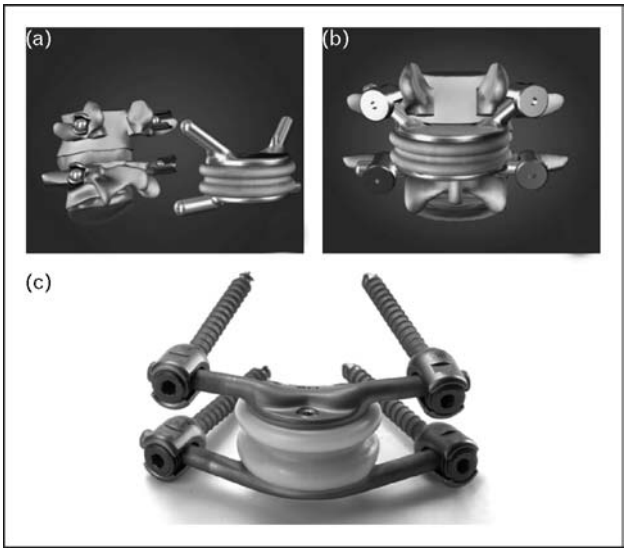
Biomechanics

Schmoelz *et al.* [2] investigated the Dynesys dynamic posterior nonfusion system to determine the magnitude of the stabilization and the effect of the stabilization on the adjacent lumbar segment. Six lumbar cadaver spines were fixed in a spine tester and loaded in pure moments in three main motion planes. For each spine, four different stages were tested: intact spine, defect in the middle segment, Dynesys stabilization, and fixation with rigid pedicle screws. Intersegmental motions were measured at all levels. For the bridged segment, Dynesys stabilized the spine and was more flexible than rigid internal fixation. This difference was most pronounced in extension, with the Dynesys restoring motion back to the level of the intact spine. Interestingly, the motion in the adjacent segments was not influenced by either stabilization method. The study suggests that Dynesys provides substantial stability in cases of degenerative

spinal pathologies but may not produce any difference on adjacent segment motion [2].

Schmoelz *et al.* [3] performed a study *in vitro* of intradiscal pressure to determine the influence of dynamic stabilization on the load bearing of the bridged disc. Using six cadaver spines, four different states of the specimens were studied: intact, destabilized, Dynesys-stabilized, and rigidly fixed with an internal fixator. In the neutral position, there were no significant differences in the disc pressure for the four conditions. During the course of loading, both the Dynesys and the internal fixator significantly reduced the pressure change from neutral to extension in comparison to the intact spine. However, there was no significant pressure changes noted from neutral to flexion. Only the internal fixator demonstrated slightly reduced discal pressure change in axial rotation. Dynesys showed no significant difference in axial-rotation disc pressure when compared to the intact spine. No changes were seen in adjacent disc pressures for either Dynesys or the internal fixator. The results demonstrated that the intradiscal pressures for both Dynesys and rigid internal fixation were similar, but altered compared to the intact disc [3].

Figure 1 Schematic diagrams (a, b) and posterior view (c) of the total posterior element-replacement system (TOPS) implant, which is fixed with regular polyaxial transpedicular screws to the spinal segment



Taken from [4••].

Recently Wilke *et al.* [4••] reported the biomechanical evaluation of a new total posterior-element-replacement system at the L4–L5 segment in cadaver spines. The total posterior element-replacement system (TOPS) implant is designed to replace the entire posterior elements while providing flexible restabilization. It consists of bilateral pedicle screws attached to an elastic disc element capable of transmitting tensile and compressive loads (Fig. 1). In this study the implant almost ideally restored range of motion in lateral bending and axial rotation compared to the intact spine. In the sagittal plane, 85% of the intact range of motion could be obtained. The authors conclude that the TOPS implant almost ideally restored range of motion and loading of the anterior disc. The implant mimics the biomechanical behavior of the posterior complex of the spine after laminectomy and facetectomy [4••].

Clinical outcomes of posterior dynamic stabilization

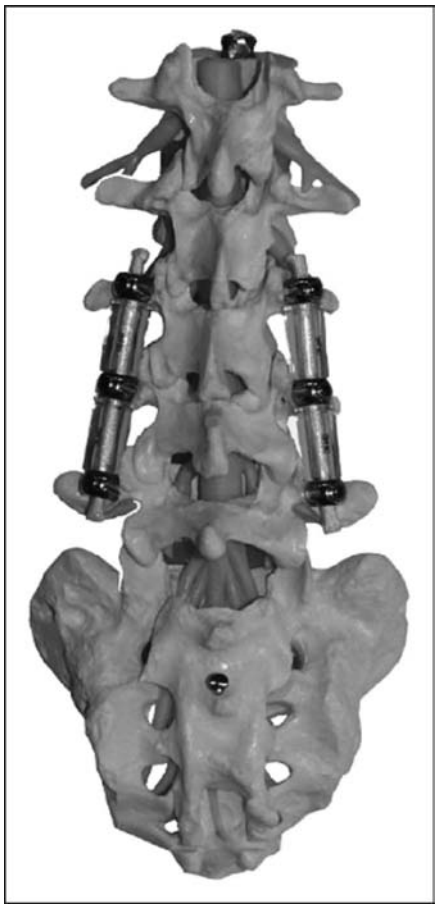
There has been little clinical experience with posterior dynamic stabilization devices in the USA. Much of the reported European clinical experience has been with two dynamic stabilization devices, Dynesys and the Graf ligament.

Dynesys

In 1994, a dynamic transpedicular system (Dynesys) was introduced to the market, promoting the concept that stabilization is possible without bone grafting. This dynamic neutralization system for the posterior spine is a pedicle screw system for mobile stabilization, consisting of titanium-alloy screws connected by an elastic synthetic compound, controlling motion in any plane (Fig. 2). Several recent European studies have reported short-term clinical outcomes.

Schnake *et al.* [5] evaluated whether elastic stabilization with the Dynesys system provides enough stability to prevent instability after decompression for spinal stenosis with degenerative spondylolisthesis. Twenty-six patients with lumbar spinal stenosis and degenerative spondylolisthesis underwent interlaminar decompression and dynamic stabilization with the Dynesys system. Minimum follow-up was 2 years. Mean leg pain decreased significantly ($P < 0.01$), and mean walking distance improved significantly to more than 1000 m ($P < 0.01$). There were five patients (21%) who still had some claudication. A total of 21 patients (87.5%) were satisfied and indicated that they would undergo the same procedure again. Radiographically, no significant progression of spondylolisthesis could be detected. The implant failure rate was 17%, and none of the implant failures was clinically symptomatic. In elderly patients with spinal stenosis with degenerative spondylolisthesis, dynamic stabilization with the Dynesys system in addition to decompression leads to similar clinical results as seen in established protocols using decompression and fusion with pedicle screws. Dynesys also maintains enough stability to prevent further progression of spondylolisthesis or instability [5].

Figure 2 Dynesys with the pedicle screws connected by the synthetic flexible cords, and spacers



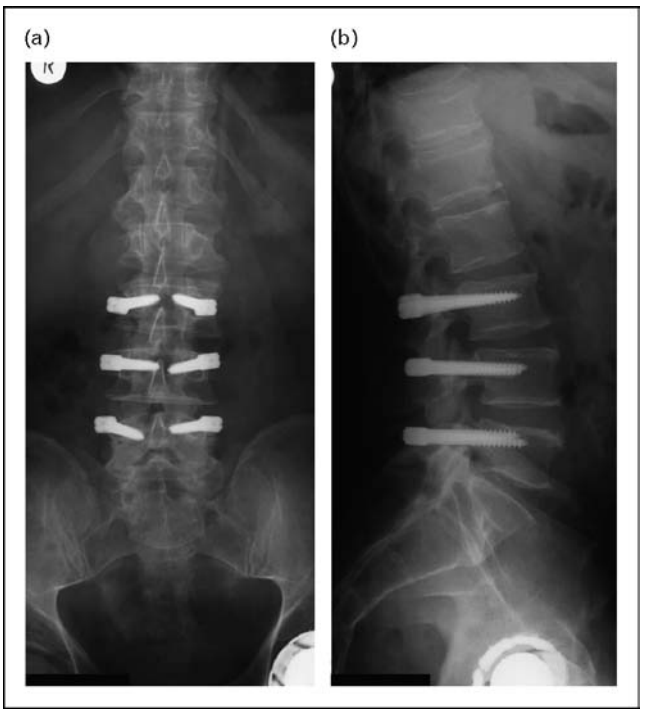
Taken from [2].

Stoll *et al.* [6] reported the results of a prospective, multicenter study evaluating the safety and efficacy of Dynesys in the treatment of lumbar instability conditions. The authors evaluated pre and postoperative pain, function, and radiographic data on a consecutive series of 83 patients. Indications consisted of unstable segmental conditions mainly combined with spinal stenosis (60.2%) and with degenerative discs (24.1%), in some cases with disc herniation (8.4%), and with revision surgery (6%). Thirty-nine patients had degenerative spondylolisthesis, and 30 patients had previous lumbar surgery. In 56 patients, the instrumentation was combined with direct decompression. The mean age at operation was 58 years and the mean follow-up time was 38 months. Additional surgery in the follow-up period included implant removal and conversion into spinal fusion with rigid instrumentation for persistent pain in three cases, laminectomy of an index segment in one case and screw removal due to loosening in one case. In seven cases, radiographic signs of screw loosening were observed. In seven cases, adjacent segment degeneration necessitated further surgery. Mean pain and function scores improved significantly from baseline to follow-up and Oswestry Disability Scores improved from 55.4 to 22.9%. These study results compare well with those obtained by conventional procedures. Dynamic neutralization may be a safe and effective alternative in the treatment of unstable lumbar conditions [6].

Dynamic stabilization may prevent further degeneration of the lumbar spine. Putzier *et al.* [7] evaluated the addition of dynamic stabilization to lumbar discectomy procedures in an attempt investigate the effect of dynamic stabilization on segmental degeneration after discectomy. Eighty-four patients with initial-stage disc degeneration (Modic 1) underwent discectomy for symptomatic disc herniation and 35 had the addition of Dynesys stabilization. At mean 34-month follow-up a significant increase in Oswestry Disability Scores and Visual Analog Scale results was observed only in the nonstabilized group. No progression of disc degeneration was noted in the Dynesys group at follow-up, whereas radiographic signs of accelerated degeneration were noted only in the discectomy group. The authors concluded that dynamic stabilization is useful to prevent progression of initial disc degeneration in segments after lumbar discectomy [7].

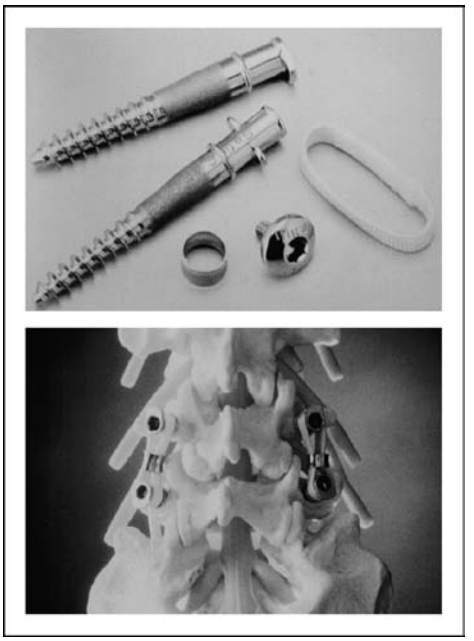
Although the Dynesys semirigid fixation system has been in clinical use for more than 5 years, only one study from a disinterested research group has reported on patient-oriented outcome after surgery with Dynesys. Grob *et al.* [8] reported the clinical experience with Dynesys semirigid lumbar fixation in 31 patients with follow-up of more than 2 years. The primary indication for surgery was degenerative disc with stenosis and associated instability and 35% of the patients had prior spinal surgery. In 23% of cases, one level was instrumented, in 52% two levels, 13% three levels, and 3% four levels. Forty-two percent of the patients also had decompression. Within the 2-year follow-up period, six of 31 (19%) patients had required or were scheduled for further surgical intervention. The following global outcomes were reported: back symptoms, 67% improved, 30% same, 3% worse; leg symptoms, 64% improved, 21% same, 15% worse; ability to do physical activity and sports, 40% improved, 33% same, 27% worse; quality of life, 50% improved, 37% same, 13% worse; how much the operation helped, 29% helped a lot, 23% helped, 10% only helped a little, 35% didn't help, 3% made things worse. The results of this study indicate that both back and leg pain are, on average, still moderately high 2 years after instrumentation with the Dynesys system. Only half of the patients declared that the operation had helped and had improved their overall quality of life. Less than half of the patients reported improvement in their functional capacity. The reoperation rate after Dynesys was relatively high. The results

Figure 3 Radiograph with Dynesys of the lumbar spine



In the radiographs, only the pedicle screws are visible. Taken from [8].

Figure 4 Graf ligamentoplasty with the implant shown disassembled (top) and *in situ* (bottom)



The components include a nonelastic band, which is secured around two pedicle screw heads with a metal band. Taken from [1].

provide no support for the notion that dynamic fixation of the lumbar spine results in better patient-oriented outcomes than those typical of fusion [8] (Fig. 3).

Graf ligamentoplasty

The Graf ligament stabilizes the lumbar segment through the coaptation of the bilateral facet joints, and it is the first posterior dynamic stabilization device to be widely clinically evaluated. The Graf procedure reportedly has the potential to treat flexion instability but cannot correct vertebral slippage or deformity. The most common surgical indication is degenerative lumbar disorder with less than 25% of vertebral slip, minimal disc space narrowing, and facet arthrosis (Fig. 4).

In the mid and long term, Graf ligamentoplasty may reduce the risk of adjacent segment degeneration. Kanayama *et al.* [9] reported the adjacent-segment morbidity after Graf ligamentoplasty compared to posterolateral lumbar fusion at a minimum of 5-year follow-up in 45 patients. Although there was no difference in the preoperative adjacent-segment disc condition between the two groups, radiographic evidence of adjacent-segment degeneration at final follow-up was more frequent in the posterolateral-lumbar-fusion group than the Graf group (25 and 6% at L1–L2, 38 and 6% at L2–L3, 38 and 18% at L3–L4, and 43 and 18% at L5–S1, respectively). One case in the Graf group (6%) and and five cases in the posterolateral-lumbar-fusion group (19%) required additional surgery for adjacent-segment degeneration. The authors concluded that in well selected patients, Graf ligamentoplasty lowers the rate of adjacent-segment degeneration [9].

Rigby *et al.* [10] reported the mid and long-term follow-up of Graf ligament stabilization. A retrospective review of 51 patients with a mean follow-up time of 4 years was reported. The average age of the patients was 41 years. The Oswestry Disability Score only improved an average of six points with longer follow-up. There were 12 complications and four required additional surgery. Seven patients (14%) went on to require bony-fusion procedures. Forty-one percent of the group would have chosen not to have the operation again. The authors concluded that longer-term results of this technique are not as encouraging as earlier studies and that the continued use of the procedure should be viewed with caution [10].

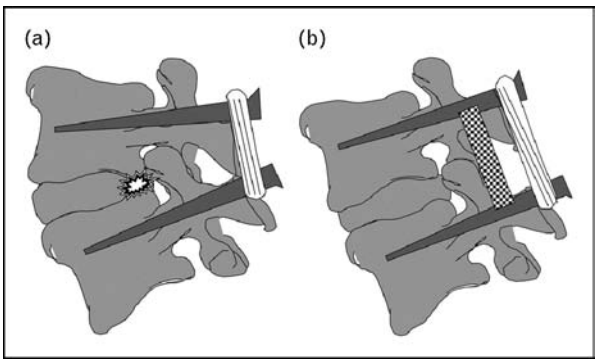
Although series have been reported showing encouraging results with the use of the Graf ligamentoplasty for low-back pain no comparative data are available on outcomes when compared with more conventional treatments. A retrospective case–control study compared Graf ligamentoplasty and instrumented posterolateral fusion in a consecutive series of 83 patients operated on by a single surgeon. Patients underwent either soft-tissue stabilization using the Graf ligament or posterolateral fusion with

pedicle-screw instrumentation. There was a significantly better outcome, when measured by the Low Back Outcome Score, in the group of patients managed by posterolateral fusion at 1 year ($P = 0.02$), although at 2 years the difference was less ($P < 0.34$). This study demonstrated that the outcome after soft-tissue stabilization was associated with a worse outcome at 1 year and a significantly higher revision rate at 2 years. Revision was associated with a poor outcome similar to that seen in revision after fusion [11].

Future direction

Studies have demonstrated that soft stabililization with the Graf ligament restricts abnormal spinal segment motion but increases the segmental disc pressure. The Dynesys system, which uses a plastic cylinder around the ligament to prevent overloading the disc, has been shown to restrict extension. It can also cause loss of lordosis with excessive distraction. The ideal system for dynamic stabilization of the lumbar spine does not exist. Recently, Sengupta and Mulholland [12] described fulcrum-assisted dynamic stabilization as a new concept in the surgical treatment of degenerative low-back pain. The device consisted of pedicle screws attached to a ligament with the addition of a fulcrum in front of the ligament to unload the disc. It was hypothesized that the fulcrum should transform the compressive force of the ligament behind into a distraction force in front and unload the disc. The new dynamic stabilization device was evaluated in cadaver spines. The results indicated that the fulcrums reduced disc pressure and maintained lordosis. Increasing fulcrum length resulted in progressive unloading of the disc. As the fulcrum length approximated the height of the motion segment, the lordosis was lost, and the disc was completely unloaded. The authors concluded that the novel fulcrum-assisted soft stabilization (FASS) system can unload the disc, control range of motion, and maintain lordosis. These parameters may be controlled with a suitable combination of ligament and fulcrum system. The study indicates the desirable biomechanical properties of the fulcrum and ligament for future development of a clinically applicable prototype [12] (Fig. 5).

Figure 5 The concept of the fulcrum-assisted soft stabilization (FASS) system



(a) A diagram of a normal-motion segment in the lumbar spine. Application of a ligament to the pedicle screws across the motion segment increases the load at the posterior aspect of the disc. (b) Introduction of a fulcrum in front of the ligaments in the FASS system may unload the disc. Taken from [12].

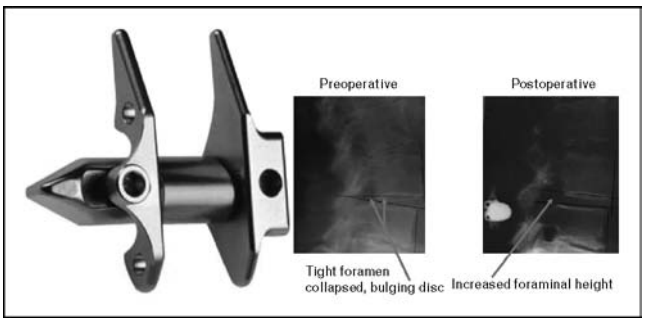
X-STOP

Another alternative to lumbar fusion is the X-STOP interspinous process distraction device. The X-STOP implant is a rigid titanium-alloy device that is placed between the spinous processes to reduce the canal and foraminal narrowing that occurs in extension. The X-STOP device is designed to distract the posterior elements of the stenotic lumbar segment and place it in flexion to treat neurogenic claudication (Fig. 6).

Kondrashov *et al.* [13] recently reported the 4-year follow-up outcomes of X-STOP in 18 patients with lumbar spinal stenosis. The mean improvement in Oswestry Disability Score was 29 points. The overall success rate of the X-STOP device was 78% (14 of 18 patients) and the rate of clinical success remained consistent with the 2-year follow-up results previously reported by the same authors. The authors concluded that the intermediate-term outcomes of X-STOP are stable over time [13].

Anderson *et al.* [14] reported the results of X-STOP for the treatment of neurogenic claudication in patients with degenerative spondylolisthesis. Forty-two patients underwent X-STOP surgery and 33 patients were treated nonoperatively. Two-year follow-up data were obtained in 70 of the 75 patients. There was statistically significant improvement in the SF-36 scores of the X-STOP device-treated patients but not in those of the nonoperative controls. Overall clinical success occurred in 63% of the X-STOP-treated patients and only 13% of the controls. Spondylolisthesis and segmental kyphosis were unaltered. The authors concluded that the X-STOP

Figure 6 The X-STOP rigid interspinous process distraction device and case example



Taken from [13].

device was more effective than nonoperative management of neurogenic claudication secondary to degenerative lumbar spondylolisthesis [14].

Conclusion

Many questions remain unanswered regarding the safety and efficacy of dynamic stabilization over the long term. Will dynamic stabilization be superior to lumbar decompression or fusion for a select group of patients? How long can we expect these devices to last before failing? While theoretical advantages exist, additional outcomes data are certainly required to establish the clinical efficacy of these devices.

The few posterior dynamic stabilization systems that have had clinical applications so far have produced outcomes somewhat comparable with fusion. No severe adverse events caused by these implants have been reported. Long-term follow-up data and well controlled, prospective randomized studies do not exist, but are essential to prove the safety, efficacy, appropriateness, and economic viability of these methods.

References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:

- • of special interest
- •• of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 290).

1 Nockels RP. Dynamic stabilization in the surgical management of painful lumbar spinal disorders. Spine 2005; 30 (16 Suppl):S68–S72.

2 Schmoelz W, Huber JF, Nydegger T, *et al.* Dynamic stabilization of the lumbar spine and its effects on adjacent segments: an in vitro experiment. J Spinal Disord Tech 2003; 16:418–423.

3 Schmoelz W, Huber JF, Nydegger T, *et al.* Influence of a dynamic stabilisation system on load bearing of a bridged disc: an in vitro study of intradiscal pressure. Eur Spine J 2006; 15:1276–1285.

4 •• Wilke HJ, Schmidt H, Werner K, *et al.* Biomechanical evaluation of a new total posterior-element replacement system. Spine 2006; 31:2790–2796.
The TOPS implant almost ideally restored range of motion and loading of the anterior disc. The implant mimics the biomechanical behavior of the posterior complex of the spine after laminectomy and facetectomy.

5 Schnake KJ, Schaeren S, Jeanneret B. Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis. Spine 2006; 31:442–449.

6 Stoll TM, Dubois G, Schwarzenbach O. The dynamic neutralization system for the spine: a multicenter study of a novel nonfusion system. Eur Spine J 2002; 11 (suppl 2):S170–S178.

7 Putzier M, Schneider SV, Funk JF, *et al.* The surgical treatment of the lumbar disc prolapse: nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone. Spine 2005; 30:E109–E114.

8 Grob D, Benini A, Junge A, Mannion AF. 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 2005; 30:324–331.

9 Kanayama M, Hashimoto T, Shigenobu K, *et al.* Nonfusion surgery for degenerative spondylolisthesis using artificial ligament stabilization: surgical indication and clinical results. Spine 2005; 30:588–592.

10 Rigby MC, Selmon GP, Foy MA, Fogg AJ. Graf ligament stabilisation: mid- to long-term follow-up. Eur Spine J 2001; 10:234–236.

11 Hadlow SV, Fagan AB, Hillier TM, Fraser RD. The Graf ligamentoplasty procedure. Comparison with posterolateral fusion in the management of low back pain. Spine 1998; 23:1172–1179.

12 Sengupta DK, Mulholland RC. Fulcrum assisted soft stabilization system: a new concept in the surgical treatment of degenerative low back pain. Spine 2005; 30:1019–1029.

13 Kondrashov DG, Hannibal M, Hsu KY, Zucherman JF. Interspinous process decompression with the X-STOP device for lumbar spinal stenosis: a 4-year follow-up study. J Spinal Disord Tech 2006; 19:323–327.

14 Anderson PA, Tribus CB, Kitchel SH. Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar degenerative spondylolisthesis. J Neurosurg Spine 2006; 4:463–471.