Outcome of a Dynamic Neutralization System for the Spine

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abstract

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One hundred fourteen patients (66 men and 48 women; mean age, 49 years) underwent spine stabilization using a dynamic neutralization system between January 1999 and August 2010 for degenerative disk disease, spinal instability, or spinal stenosis. Mean follow-up was 6.8 years (range, 1-11 years). Seven patients were lost to follow-up. Radiological examination and clinical evaluation, including the Oswestry Disability Index, the Roland-Morris Disability Questionnaire, and patient satisfaction, were performed.

Mean Oswestry Disability Index score improved from 57% (severe disability) preoperatively to 22% (moderate disability) postoperatively. Mean Roland-Morris Disability Questionnaire score improved from 52% preoperatively to 35% postoperatively; 79 (74%) patients declared themselves very satisfied with the end result of the operation. Postoperatively, 27 (25%) patients experienced complications, including screw loosening (n=22), infection (n=2), back (n=5) and leg (n=2) pain, and endplate vertebral fracture (n=1). Three patients with screw loosening, 2 with deep infection, and 1 with severe persistent back and leg pain underwent rigid spine arthrodesis.

Dynamic neutralization systems can be considered for degenerative disk disease, spinal instability, and stenosis. Patient satisfaction with the procedure is excellent. However, in the long term, the complication rate, most commonly screw loosening, is high and reoperations are common. In this setting, long-term follow-up is recommended, and the use of this system should be reconsidered.

Figure: Preoperative lateral radiograph of the lower lumbar spine of a 45-year-old man with low back pain and right L5 and S1 radiculopathy showing L5-S1 degenerative disk disease (A). Preoperative magnetic resonance image of the lumbar spine showing L4-L5 disk protrusion and L5-S1 degeneration (B). Anteroposterior (C) and lateral (D) radiographs of the lumbar spine 5 years after L4-S1 laminotomy and stabilization using the Dynesys system (Centerpulse Ltd, Zurich, Switzerland) showing no evidence of implant-related complications and minimum progression of L5-S1 degeneration. The patient was asymptomatic.
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Arthrodesis offers the desired stability and prevents

movement associated with pain deterioration.1 However, arthrodesis of the lumbar

spine eliminates motion of the functional spinal segment and subsequently overloads

the adjacent segments.2 This could result in transition syndrome,1,3 instrumentation failure,

4-15 degenerative changes of the spine, reoperations,2,16-19 and significant patient

disability,2,16,17 with variable patient satisfaction with the end result of the operation,

regardless of the quality of fusion.7,13,20,24 Therefore, the prevention of movement

may not be the most important factor accounting for the success of fusion.25,26

Flexible or dynamic stabilization is a phrase commonly used to describe vari

ous developed systems that allow restricted spine motion.3,25,27-35 Based on the concept

that abnormal spinal loading patterns are responsible for low back pain and spinal
degeneration,25 a dynamic stabilization system can restrict motion to a zone of

normal or near-normal loading or prevent the spine from adopting a position where

abnormal loading may occur.1,3,31 Various dynamic stabilization systems have been

developed over the past 2 decades to address more biologic (nonfusion systems) and patient-friendly treatment.1,28,36-40 The dynamic neutralization system for spine stabilization is a pedicle screw system connected by an elastic synthetic compound. It stabilizes unstable segments (neutralization), sparing the intervertebral disks and facet joints; the segments remain mobile within a controlled range (dynamic stabilization), permitting limited motion of the arthrodesed lumbar vertebrae.27,28 Thus, the spine is returned to an anatomical function that is closer to healthy status.

A theoretical advantage of the dynamic neutralization system is a more progressive load transition to the adjacent segments, preventing high stress forces to the adjacent disks.27,30 Advocates of the system claim that an arthrodesed spine is not in a normal state; by controlling the abnormal motion and unloading the disks, pain is reduced and the disks restore their normal biology.27-30 Opponents of the system consider solid spinal fusion as the gold standard when surgery is indicated because it can prevent abnormal motion and restore spinal coronal and sagittal alignment.2,16,17,26,35 To address these conflicting reports, this retrospective study was performed to evaluate the clinical outcome of a series of consecutive patients with lumbar spine degenerative disease treated with a dynamic neutralization system and followed for the long term.

**Materials and Methods**

The medical records of 114 patients (66 men and 48 women; mean age at operation, 49 years; range, 21-82 years) who underwent spine stabilization using a dynamic neutralization system (Dynesys; Centerpulse Ltd, Zurich, Switzerland) between January 1999 and August 2010 were retrospectively reviewed. All patients presented with low back pain, with or without radicular leg pain, resistant to conservative treatment for at least 3 months. Fourteen patients had previous spinal surgery, including 1-level diskectomy (8 patients) and decompressive lumbar laminectomy without instrumentation (6 patients). Mean follow-up was 6.8 years (range, 1-11 years). Seven patients were lost to follow-up, leaving 107 patients for further analysis. All patients gave written informed consent to be included in the study. The study was approved by the institutional review board of the authors’ institution.

The indications for surgery were degenerative disk disease in 69 patients, spinal instability in 11 patients, and spinal stenosis in 27 patients. The criteria for spinal instability included well-defined spondylolisthesis or dynamic instability with translation of more than 3 mm or an angle change between the vertebra endplates of more than 10° on flexion and extension radiographs.24

**Clinical Evaluation**

Clinical evaluation included patients’ medical history and complete physical and neurologic examinations. All patients had pre- and postoperative radiographs and underwent self-assessment examination using the Oswestry Disability Index41,42 and the Roland-Morris Disability Questionnaire.43,45 The Oswestry Disability Index is scored on a scale of 0% to 100%, where 0% to 20% means minimal disability, 20% to 40% means moderate disability, 40% to 60% means severe disability, 60% to 80% means crippled, and 80% to 100% means bedbound or exaggerating symptoms.41,42 The Roland-Morris Disability Questionnaire is a health status measure designed to be completed by patients to assess physical disability due to low back pain. It was designed for use in research but has also been found useful for monitoring patients in clinical practice.43,45 In addition, the patients were asked about their satisfaction with the operation and were classified as very satisfied, satisfied, and not satisfied with the end result of the operation.

**Technical Considerations**

The Dynesys system is composed of pedicle screws, polycarbonate urethane spacers, and polyethylene terephthalate cords.28,30 The pedicle screws are made of Ti-Al-Nb alloy (CSF-Gamma, Protasul 100; Zimmer, Winterthur, Switzerland).30 The textured surface is sandblasted for bone ingrowth. Due to the conical core diameter, the screw has the advantages of the largest diameter in the highest bending moment, better bone compression and anchorage in the pedicle canal, and a lower notch factor (low stress concentration rate) through threads in the highest bending moment. The disadvantage of the conical screw is that back-and-forth screwing is prohibited.

The polycarbonate urethane spacers (Sulene PCU; Zimmer)30 adapt to the screw head, thereby preventing micro-
motions and wear debris formation in the contact area. The spacer between the screw heads limits the degree of lordosis that can be created, and the 2 screw heads are approximated to the extent that the interposed spacer allows. The polyethylene terephthalate cords (Sulene PET; Zimmer) connect the pedicle screw heads via the hollow core of the spacer and hold the spacer in place. The cords limit bending movements, and the spacers hold the segments in a position of anatomical function and suppress extension and rotational movements.

**Surgical Technique**

With the patient under general anesthesia and in the prone position, a posterior midline approach was performed at the area of the affected lumbar levels. Pedicle screws were inserted transpedicularly; in all cases, the facet joints were preserved. Then, the spacers were cut to the proper size and the stabilizing cords were pretensioned separately for each segment before their fixation in the pedicle screw. Hypermobility of the segments was corrected, and the locking mechanism of the cords was tightened. The stabilizing cords were cut at the margins of their locking mechanisms.

Next, bilateral laminectomy for sequestrated and centrally displaced intervertebral disks was performed in 64 patients, and extensive bilateral laminectomy and foraminotomy for lumbar spinal stenosis were performed in 27 patients. Forty-nine patients underwent 1-level spinal instrumentation; 58 patients underwent 2-level (40 patients) or 3-level (18 patients) instrumentation due to iatrogenic instability caused by extensive bilateral laminectomy and foraminotomy or due to initial degeneration of the adjacent intervertebral disks. Bone grafting was not used. Finally, the surgical wound was closed in layers, and 2 suction drains were placed for 48 hours. Antibiotic prophylaxis was given 1 hour preoperatively and for 3 days postoperatively.

Patients were mobilized on postoperative day 1 and were discharged 48 to 72 hours later with instructions to wear a soft lumbar corset for 4 to 6 weeks. Muscle strengthening exercises, early return to work, and activities of daily living were permitted after postoperative week 6. Routine follow-up clinical and radiological examinations were performed at 6 weeks and 3, 6, and 12 months postoperatively and annually thereafter.

**Results**

**Clinical Outcome**

Mean Oswestry Disability Index score improved from 57% (severe disability) preoperatively to 22% (moderate disability) postoperatively. Mean Roland-Morris Disability Questionnaire score improved from 52% preoperatively to 35% postoperatively. Overall, 79 (74%) patients declared themselves very satisfied with the end result of the operation, and 95 (89%) patients reported that they would undergo the same operation again, if necessary, which outlines their overall satisfaction with the procedure. Of the 89 patients with 1- or 2-level instrumentation, 69 (77.5%) declared themselves very satisfied and 4 (4.5%) declared themselves not satisfied with the operation (Figure 1). Of the 18 patients with 3-level instrumentation, 10 (55.5%) declared themselves very satisfied and 4 (22.2%) declared themselves not satisfied with the operation.

**Complications**

No intraoperative complications occurred. Postoperatively, 27 (25%) patients experienced complications, including screw loosening (n=22), infection (n=2), back (n=5) and leg (n=2) pain, and endplate vertebral fracture (n=1); 6 (5.6%) of these patients underwent rigid spine arthrodesis.

Loosening of at least 1 pedicle screw as evidenced by halo formation or screw migration was observed in 22 patients (Figure 2). Three (2.8%) of these patients...
underwent reoperation for continuous back pain that precluded activities of daily living and return to work; another patient experienced mild back pain associated with spine movements and denied further treatment. The remaining patients with radiographic evidence of screw loosening reported no symptoms (Figure 3). Two (1.86%) patients experienced early deep surgical infection within the first month postoperatively and were treated with staged revision surgery and spine arthrodesis. Two patients experienced leg pain postoperatively; 1 of them experienced persisting symptoms after conservative treatment with pregabalin and was treated with implants removal, thorough foramina decompression, and rigid spine arthrodesis 15 months after the initial operation. One patient experienced severe back pain with local spine tenderness after mobilization on postoperative day 3. Radiographs of the lumbar spine showed fracture of the upper endplate of the L4 vertebra, which was treated conservatively with a 3-point posture thoracolumbar brace without further problems. Spacer or cord breakage was not observed in any patient who underwent reoperation because of complications. For the remaining patients, no spacer or cord breakage was observed in the study period.

**DISCUSSION**

Dynamic or flexible stabilization is a phrase commonly used to describe various nonfusion pedicle screw instrumentation systems that allow limited motion of the instrumented spinal segments. Ideally, these systems would restore normal function of the functional spinal segments while protecting the adjacent segments. The Dynesys system is designed for the treatment of degenerative conditions of the lumbar spine that present with unstable spinal segments, as well as unstable forms of dynamic or permanent patterns of lumbar stenosis. The Dynesys is also capable of halting the progression of minor deformities that are frequently associated with spinal stenosis, including degenerative spondylolisthesis and early degenerative scoliosis. However, reports are conflicting regarding the clinical outcome of patients with degenerative spine disease treated with dynamic systems. Therefore, this retrospective observational study was performed to present the authors’ experience with the Dynesys system. The results show that the majority of patients were satisfied with the operation; however, complications occurred in up to 25% of patients, with 5.6% of them necessitating revision surgery.

Dynamic instrumentation systems such as the Dynesys have several advantages compared with rigid spine arthrodesis. The Dynesys provides a more physiological condition compared with the sole decompression or fusion of an unstable segment. It is able to compensate initial morphologic changes and prevent progression of segment degeneration by reducing movement in flexion and extension. The intervertebral disks and vertebral joints of the affected segments remain intact, and the adjacent spine segments are protected. If a decompressive procedure is required, the Dynesys system reestablishes stability and prevents postoperative iatrogenic instability; bone grafting is not necessary. A precondition for dynamic systems is that the disk should not be completely degenerated; if a spontaneous arthrodesis of the vertebrae or the facet joints has already occurred, rigid arthrodesis is recommended.

Previous studies reported contradictory results regarding the clinical outcome of patients with degenerative lumbar spine disease treated with the Dynesys system. Most studies reported better outcomes and shorter operation times and hospital stays compared with spine fusion, significant improvement of Oswestry Disability Index scores from a mean preoperative range of 43% to 58.5% to a mean postoperative range of 20% to 22.9%, and improvement in the percentage of patients with low back and leg pain from a mean preoperative range of 47.8% to 80% to a mean postoperative range of 25% to 41.9%.

**Figure 2:** Anteroposterior radiograph of the lumbar spine of a 44-year-old man 21 months after discectomy and Dynesys (Centerpulse Ltd, Zurich, Switzerland) stabilization for L4-L5 and L5-S1 degenerative disk disease and disk protrusion showing loosening of the proximal screws. The patient was asymptomatic.

**Figure 3:** Lateral radiograph (A) and sagittal magnetic resonance image (B) of the lumbar spine of a 44-year-old woman 15 months after discectomy and Dynesys (Centerpulse Ltd, Zurich, Switzerland) stabilization for L4-L5 and L5-S1 degenerative disk disease and disk protrusion showing loosening of the proximal screws. The patient was asymptomatic.
The infection rate is usually low because the Dynesys system is less invasive compared with most posterior arthrodesis procedures. The reoperation rate due to complications ranges from 4.8% to 19%. In a previous series of 68 patients treated with the Dynesys system for degenerative spine disease and instability with neurogenic or radicular pain or chronic back pain and followed for a mean of 36.2 months (range, 12.9-75.3 months), the current authors reported a 6% complication rate and 3% reoperation rate; 3 patients experienced screw loosening, 1 patient experienced deep infection, and 2 patients underwent reoperation for complications.56

In the current study, with a higher number of patients and a longer-term follow-up, the overall complication rate was 25% and the reoperation rate due to complications was 5.6%; the most common complication was screw loosening. In agreement with the literature, screw loosening can be expected over time; the implantation of a nonfusion, dynamic instrumentation system may excessively distress the screws, leading to loosening or migration. This study had 2 limitations. First, it was a retrospective study with the inherent limitations. However, single-institution retrospective studies are often useful to draw conclusions for a treatment approach. Second, the study lacked a control group of patients treated with an alternative dynamic or rigid spinal instrumentation system. The authors acknowledge this limitation and consider the study observational.

**Conclusion**

The Dynesys system can be considered for degenerative disk disease, spinal instability, and stenosis. The ease of application and preservation of adjacent spinal segments are the major advantages of the system. Patient satisfaction with the operation is excellent. However, in the long term, the complication rate, most commonly screw loosening, is high and reoperations are common. In this setting, long-term follow-up is recommended and the use of this system should be reconsidered.

**References**


