Stabilization of the Lumbar Spine Using the Dynamic Neutralization System

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The records of 68 patients (42 men and 26 women) who underwent spine stabilization with a dynamic neutralization system were reviewed. Mean patient age at operation was 42.8 years. The primary indication for surgery was degenerative spine disease and instability with neurogenic or radicular pain and/or chronic back pain. Forty-one (60.2%) patients had degenerative diskopathy or disk herniation, and 27 (39.8%) patients had lumbar spine stenosis. One-motion segment spine stabilization was performed in 30 patients, 2-motion segment spine stabilization in 32 patients, and 3-motion segment spine stabilization in 6 patients. Within a mean follow-up of 36.2 months (range, 12.9-75.3 months), there were 2 re-operations, and 3 patients with screw loosening. Re-operations were for a deep infection in 1 patient and left leg pain in another patient. Both patients were managed with early implant removal and spinal arthrodesis. Self-assessment questionnaires showed improvement of patients’ clinical and functional status. The Oswestry Disability Index and the Roland-Morris Disability Questionnaire score improved from a mean preoperative score of 55.4% (severe disability) and 52% respectively to a mean postoperative score of 22.9% (moderate disability) and 35% respectively. The overall results of this study are highly comparable to fusion procedures. The dynamic neutralization system can be a safe and effective alternative technique to spine arthrodesis in selected cases of degenerative lumbar spine instability.

An arthrodesed spine is not a normal state. When lumbar spine segments are fused together, either as a congenital abnormality or by surgery, significant stresses are directed to the adjacent spinal segments. This could result in failure of the instrumentation or degenerative changes of the spine and significant disability of the patient. Recent studies showed that solid fusion can generate a considerable amount of morbidity, high rates of complications, a high frequency of re-operations, and variable patient satisfaction regardless of the quality of fusion. The future of spine stabilization needs to involve more physiologic and patient-friendly methods. Flexible stabilization is a commonly used term to describe various developed systems that allow a restricted spine motion.

The dynamic neutralization system for spine stabilization (Dynesys; Centerpulse Ltd, Zurich, Switzerland) is a pedicle screw system for flexible stabilization of the spine. This system consists of titanium alloy screws connected by an elastic synthetic compound that controls motion in any plane (nonfusion system) (Figure 1). The Dynesys instrumentation system re-stabilizes unstable segments (“neutralization”) without involving the intervertebral disks and the facet joints; the segments remain mobile within a controlled range (“dynamic stabilization”) permitting limited motion of the arthrodesed lumbar vertebrae. The spine is thus returned to an anatomical function that is closer to the healthy status.

This study evaluated the effectiveness and safety of the dynamic neutralization pedicle screw system in the treatment of patients with spine instability associated with degenerative lumbar disease who have failed conservative treatment. All patients would have been considered for solid spine fusion if a flexible instrumentation system such as the Dynesys system was unavailable.

Materials and Methods

The medical records of 68 patients who had spine stabilization using the Dynesys instrumentation system were retrospectively reviewed. These were 42 men and 26 women, with a mean age at operation of 42.8 years (range, 25-65 years). All patients presented with low back pain, with or without radicular leg pain that was resistant to conservative treatment over at least three months. Twenty-five of the patients had neurologic impairment.

The primary indication for surgery was degenerative spine disease associated with degenerative disk disease or disk herniation in 41 (60.2%) patients and lumbar stenosis in 27 (39.8%) patients. These conditions resulted in instability associated with neurogenic or radicular leg pain and/or chronic back pain.
The criteria of instability included well-defined spondylolisthesis or dynamic instability with translation >3 mm and/or angle change between the vertebral end plates >10° on flexion and extension views. These radiographic findings were well correlated with the clinical and intraoperative signs of spine instability.29

Eight patients had a previous operation: 5 of the 8 patients had one level discectomy, and 3 patients had decompressive lumbar laminectomy without spine arthrodesis. All patients fulfilled the aforementioned criteria to stabilize the spine with the Dynesys instrumentation system.

Clinical evaluation included the patient's past medical history and complete physical and neurological examination. All patients had a pre- and postoperative clinical and radiological evaluation, and a self-assessment examination using the Oswestry Disability Index30,31 and the Roland-Morris Disability Questionnaire.32-34 The Oswestry Disability Index is scored on a scale of 0%-100%, where 0%-20% means minimal disability, 20%-40% means moderate disability, 40%-60% means severe disability, 60%-80% means crippled, and 80%-100% means either bed-bound or exaggerating symptoms.14 In addition the patients have been questioned regarding their satisfaction from the operation.

All patients had radiological assessment with plain anteroposterior, dynamic lateral radiographs, and MRI or CT-myelography of the lumbar spine. The pre- and postoperative radiographs of each patient were examined and validated by the senior author (G.S.) and 2 independent to the study spine surgeons, separately. In all radiographs, the height of the intervertebral disk space was measured using a standardized distance from the involved spinal level. Screw loosening was defined as the radiological appearance of halo formation and/or screw migration.14

Technical Considerations

The Dynesys system is composed of pedicle screws, polycarbonate urethane spacers, and polyethylene terephthalate cords (Figure 1).26,28 The pedicle screws are made of Ti-Al-Nb forge alloy (Protasul 100).29 The textured surface is sandblasted allowing for bone ingrowth. Due to the conical core diameter, the screw has the advantages of a biggest screw diameter in a highest bending moment, a better bone compression and anchorage in the pedicle canal, and the low notch-factor (low stress-concentration rate) through threads in highest bending moment. The disadvantage of the conical screw is that the back and forth screwing is prohibited.

The polycarbonate urethane spacers (Sulene PCU)28 adapt to the screw head, thereby preventing micromotions and wear debris formation in the contact area.35 The spacer between the screw heads limits the degree of lordosis that can be created, and the two screw heads are approximated to the extent the interposed spacer allows.36 The polyethylene terephthalate cord (Sulene PET)26 connects the pedicle screw heads via the hollow core of the spacer and holds the spacer in place. The stabilizing cord limits bending movements, while the spacers hold the segments in a position of anatomical function and suppress extension and rotational movements.37

Surgical Technique

Under general anesthesia with the patient prone, a posterior midline approach is performed at the area of the affected lumbar levels. After the pedicle screw insertion, the spacers are cut to the proper size. The stabilizing cords are pretensioned separately for each segment before their fixation in the pedicle screw. Hypermobility of the segments is corrected and the screws for fixation of the stabilizing cord in the eyes of the pedicle screws are tightened. The stabilizing cord is cut and the surgical wound closed.

Following the application of the Dynesys system, bilateral laminectomy for a sequestrated and large centrally displaced intervertebral disk in 41 patients, and extensive bilateral laminectomy and foraminotomy for lumbar spinal stenosis in 27 patients was performed. In all cases, the facet joints were preserved. In 30 (44%) patients, one spinal motion was included in the stabilization. In 32 (47%) patients, and in 6 (9%) patients two and three motion segments respectively were stabilized. This either was due to iatrogenic instability caused by extensive bilateral laminectomy and foraminotomy, or initial degeneration of the adjacent intervertebral disks in 11 patients.

Bone grafts were not used. The wound was closed in layers after the application of two suction drains that were removed after 48 hours. Prophylactic antibiotics were given 1 hour prior to the operation and for 3 days postoperatively (Figures 2A-C).

Patients were mobilized on the first postoperative day, and were discharged from the hospital 48 to 72 hours later. Patients were advised to wear a soft lumbar brace for 4 to 6 weeks, and to return to work and activities of daily living.
Results

Sixty-six of the 68 patients were available for re-examination, and their records have been retrospectively reviewed for the purpose of this study. Two patients were lost to follow-up. Mean follow-up was 36.2 months (range, 12.9-75.3 months).

Neurological deficits completely resolved in all patients. The mean preoperative Oswestry Disability Index score was 55% (severe disability). This improved to a mean postoperative score of 25% (moderate disability) in patients with <9 months follow-up, and to a mean postoperative score of 22% (moderate disability) in patients with >18 months follow-up. The Roland-Morris Disability Questionnaire score improved from a mean preoperative value of 52% to a mean postoperative value of 35%. Fifty-seven (86%) of the 66 patients reported that they would undergo the operation again and 53 (80%) of the 66 patients reported having a satisfactory postoperative result. Eight patients, who had a previous lumbar surgery, reported the poorest results. Sixty-four of the 66 patients returned to work and previous activities of daily living after a maximum of 3 months.

In the 41 patients with disk disease, the mean postoperative disk height was 2 mm (range, 1-3 mm) wider compared to the respective mean preoperative disk height. In the 27 patients with lumbar stenosis, the disk height changes were negligible. The postoperative dynamic flexion-extension radiographs showed spinal stability in all patients.

Complications

No intraoperative complications were reported. Within a mean follow-up of 36.2 months, no late complications were observed related to the implants and mechanical failure or instability, such as breakage of the pedicle screws, the spacer or the cord, and alteration of the initial postoperative height of the intervertebral space (Figures 2D-E).
However 3 cases of screw loosening were reported.

Deep spine infection occurred 1 month postoperatively in one patient. This has been treated with implant removal and reoperation for rigid spine arthrodesis 3 months later. Another patient had persistent leg pain because of nerve root compression, and had a reoperation 15.6 months after the initial operation for implant removal, thorough foraminal decompression and rigid spine arthrodesis.

Discussion

Degenerative spondylosis can create spinal instability predisposing to axial low-back pain radicular pain or neurological deficits. Moreover decompressive procedures may aggravate preexisting instability or cause iatrogenic spine instability. Traditional surgical treatments of degenerative or iatrogenic instability is non-instrumented, instrumented, or pedicular fusion, posterior lumbar interbody fusion, transforminal lumbar interbody fusion, anterior lumbar interbody fusion. Considering spinal fusion as the optimal treatment was based on the assumption that a degenerated motion segment either is unstable or moves out of normal range. This has been associated with generation of pain; therefore fusion offers the desired stability and subsequently prevents movement associated with pain deterioration.

However recent studies showed that spine fusion surgery can generate a considerable amount of morbidity, high complication rate, high frequency of reoperation, and variable patient satisfaction of the end-result of the operation. Moreover fusion eliminates motion of the functional spinal segment and subsequently overloads the adjacent segments, thereby generating the "transition syndrome." The above results show that the prevention of movement per se may not be the most important factor accounting for the success of fusion, challenging the original assumption. The aforementioned drawbacks led to alternative procedures and techniques for stabilization without fusion, nonfusion systems.

In 2002 Mulholland and Sengupta proposed a concept where abnormal loading patterns due to disk disorganization occurring in degenerative disk disease were responsible for low back pain. Range of motion usually is not increased after disk degeneration, and motion by itself is not the cause of pain. According to these authors, the cause of pain is the abnormal quality of motion that may be in abnormal direction or in an increased degree of translation thus distributing abnormal loads across the disk space. The authors suggested that a dynamic stabilization system either restricts motion to a zone where normal or near normal loading may occur, or prevents the spine from adopting a position where abnormal loading may occur. A dynamic stabilization system would ideally restore normal function of the functional spinal segments on one hand, and protect the adjacent segments on the other.

Dynamic stabilization is a commonly used term to describe various systems that have been developed thus far, and that permit only restricted movement within the range of normal motion. In recent years, ideas of dynamic neutralization of the lumbar spine have become more popular. Proposed systems range from complete replacement of the disk to replacing the disk while maintaining the annulus, or maintaining the disk with a controlled motion of the segment.

The dynamic neutralization system for the spine (Dynesys) is a nonfusion pedicle screw stabilization system for the stabilization of the lumbar spine. This system provides flexible stabilization while controlling motion in any plane. It is designed for the treatment of degenerative conditions of the lumbar spine that present with unstable motion segments, as well as unstable forms of dynamic or permanent patterns of lumbar stenosis. 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.

In view of the above mentioned arguments, the implantation of flexible instrumentation systems such as the Dynesys system have several advantages compared to rigid spine arthrodesis. Dynesys provides a more physiological condition compared to the sole decompression or fusion of an unstable segment. This system reduces movement both in flexion and extension. Moreover, the intervertebral disks and vertebral joints of the affected segments remain intact, and the adjacent spine segments are protected. The mobility obtained after flexible spine stabilization has a role in keeping up the patient's quality of life. However, in spine arthrodesis a cushioning element is removed from the spine, and the load on the remaining disks of the adjacent segments is greatly increased leading to the "transition syndrome."

If a decompressive procedure is required, the Dynesys system re-establishes stability and prevents postoperative iatrogenic instability. In addition to restricting the range of motion, the Dynesys flexible instrumentation system may also unload the disk; this is an important feature of a flexible stabilization system. Neural elements are indirectly decompressed and the loads are not transferred to the adjacent spinal levels avoiding early degenerative evolution.

Dynesys instrumentation is less complicated than rigid spine arthrodesis. Among other advantages, bone grafting is

not necessary. The patient is mobilized on postoperative day 1 and is discharged from the hospital within 3 to 4 days. The implant is relatively flat and does not irritate the patient. However, a precondition for implanting Dynesys is that the disk is not completely degenerated. If a spontaneous arthrodesis of the vertebrae or the facet joints has already occurred, rigid arthrodesis is recommended. Dynesys usually is used as a monosegmental implant; however, up to 4 segments can be treated.

The system has now been in clinical use for almost a decade, with a number of relevant studies reporting on patient-oriented outcome after Dynesys implantation.

Schwarzenbach et al operated on 54 patients with a mean patient age 60.5 years, for spinal stenosis (24), degenerative spondylolisthesis (4), low back diskogenic pain (12), primary disk herniation (2), and failed low-back pain surgery syndrome (6). Dynesys instrumentation operation consisted of decompression (27), decompression and arthrodesis (12), or arthrodesis of a single level alone (2). Within 26.8 months, the Oswestry Disability Index improved from a mean preoperative score of 43% to a mean postoperative score of 20%. They also reported that the pain scale for low back pain improved from a mean preoperative value of 47.8% to a mean postoperative value of 32%, and the pain scale for leg pain also improved from a mean preoperative value of 63.2% to a mean postoperative value of 24.3%.

Stoll et al. presented their first results with Dynesys in a prospective study of 83 consecutive patients. In this series, spinal instability was mainly associated with spinal stenosis (60.2%) and degenerative diskopathy (24.1%), and in some cases with disk herniation (8.4%) and spine revision surgery (6.0%). Thirty-nine patients additionally had degenerative spondylolisthesis, and 30 patients had previous lumbar surgery. In 56 patients instrumentation was combined with direct spine decompression. Mean patient age at operation was 53.2 years (range, 26.8-85.3 years), mean follow-up was 38.1 months (range, 11.2-79.1 months). Nine complications were unrelated to the implant, and 1 was due to a screw misplacement. Mean pain and function scores improved significantly from baseline to follow-up; back pain scale improved from 7.4 to 3.1 points, leg pain scale improved from 6.9 to 2.4 points, and Oswestry Disability Index improved from 55.4% to 22.9%.

In another study, Stoll et al. evaluated the safety and efficacy of Dynesys in a consecutive series of 83 patients. In 56 patients, instrumentation was combined with direct decompression. Within a mean follow-up of 38.1 months, 9 complications were unrelated to the implant and 1 was due to screw misplacement. Four required early reoperation. In 7 cases, there were radiological signs of screw loosening. In 7 cases, adjacent segment degeneration required further surgery. Mean pain and function scores improved significantly during the follow-up.

Satisfactory results of the application of the Dynesys in patients with degenerative disk disease have been reported by Putzier et al. They concluded that Dynesys is able to compensate initial morphologic changes and prevent progression of segment degeneration.

Cakir et al. presented the results of a retrospective analysis of the outcome of patients with degenerative lumbar instability and spinal stenosis who underwent decompression surgery combined with dorsalventral fusion, or decompression surgery combined with posterior dynamic stabilization. In 20 patients, the Dynesys group showed a slightly better outcome, and shorter operation time and hospital stay.

Grob et al. in a retrospective study of 50 consecutive patients with a mean patient age of 50 years reported less encouraging results. The primary indication for surgery was degenerative disk disease or spinal stenosis associated with instability. Only half of the patients reported satisfaction from the operation and improvement of their overall quality of life. Less than half reported functional improvement.

Putzier et al. evaluated the outcome after nucleotomy combined with dynamic stabilization compared with nucleotomy alone. Eighty-four patients underwent nucleotomy of the lumbar spine for the treatment of symptomatic disk prolapse. Dynamic stabilization using the Dynesys instrumentation system was performed in 35 of the 84 patients. Mean follow-up was 34 months. At 3-month follow-up, Oswestry Disability Index and VAS improved significantly in both groups. However, at long-term follow-up, Oswestry Disability Index and VAS improved significant only in the nonstabilized group. In the dynamically stabilized group, no progression of disk degeneration was observed, whereas radiographic signs of accelerated segmental degeneration were found in the nucleotomized-only group. There were no implant-associated complications.

In the present series, the primary indication for a stabilization procedure using the Dynesys system was degenerative spine disease associated with degenerative diskopathy, disk herniation, and lumbar stenosis. These conditions resulted in instability associated with neurogenic or radicular pain and/or chronic back pain. A substantial improvement in the patient's functional status was demonstrated postoperatively, at least for the first 2 years. The
fact that 86% of the patients reported that they would undergo the operation again indicates their overall satisfaction.

In this series, the overall complication rate was 3%. This rate is lower than the previously reported rates in rigid spine arthrodesis studies.6,10,56 There were no serious implant-related complications compared to those reported in rigid pedicle systems, such as screw misplacement,2,8,57 or screw failure.13,56 However, in line with the literature, implant loosening related complications can be expected in time.14 In this series, the implantation of a dynamic instrumentation system without fusing the bridged segment may excessively distress the screws leading to loosening or migration. Infection rate was low and this was explained by the fact that Dynesys is less invasive compared to most posterior arthrodesis procedures.

The overall results of the present study are in accordance with the results of previously published studies, and highly comparable to the results of fusion procedures.

Conclusion

The Dynesys mobile spine stabilization system can be considered for all types of spinal instability, including excessive or pathologic motion and gradually developing deformity and iatrogenic instability. The results of the present study favor the aforementioned technique. The dynamic neutralization system can be a safe and effective alternative technique to spine arthrodesis in selected cases of degenerative or iatrogenic lumbar spine instability.

What is already known on this topic

- Rigid spine fusion can generate a considerable amount of morbidity, high complication rates, high frequency of reoperations, and variable patient satisfaction regardless of the quality of fusion.
- The future of spine stabilization needs to involve more physiologic and patient-friendly methods.

What this article adds

- The dynamic neutralization pedicle screw system is a flexible spine stabilization system that allows a restricted spine motion.
- The dynamic neutralization system can be a safe and effective alternative technique to spine arthrodesis in selected cases of degenerative or iatrogenic lumbar spine instability.

References


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