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The Surgical Treatment of the Lumbar Disc Prolapse

Nucleotomy With Additional Transpedicular Dynamic Stabilization *Versus* Nucleotomy Alone

Michael Putzier, MD, Sascha V. Schneider, MD, Julia F. Funk, MD, Stephan W. Tohtz, MD, and Carsten Perka, PhD

Study Design. Clinical and radiologic study evaluating the outcome after nucleotomy with dynamic stabilization compared with nucleotomy alone.

Objectives. To investigate the effect of dynamic stabilization on the progression of segmental degeneration after nucleotomy.

Summary of Background Data. Nucleotomy as treatment for lumbar disc prolapse in combination with initial segment degeneration may lead to segmental instability. Dynamic stabilization systems restrict segmental motion and thus prevent further degeneration of the lumbar spine. They are designed to avoid the disadvantages of rigid fixation, such as pseudarthrosis and adjacent segment degeneration.

Methods. Eighty-four patients underwent nucleotomy of the lumbar spine for the treatment of symptomatic disc prolapse. Additional dynamic stabilization (DYNESYS) was performed in 35 of those cases. All patients showed signs of initial disc degeneration (MODIC I). They underwent evaluation before surgery, 3 months after surgery, and at follow-up. The mean duration of follow-up was 34 months. Examinations included radiographs, magnetic resonance imaging (MRI), physical examination, and subjective patient evaluation using Oswestry score and visual analog scale (VAS).

Results. Clinical symptoms, Oswestry score, and VAS improved significantly in both groups after 3 months. At follow-up, a significant increase in the Oswestry score and in the VAS was seen only in the nonstabilized group. In the dynamically stabilized group, no progression of disc degeneration was noted at follow-up, whereas radiologic signs of accelerated segmental degeneration existed in the solely nucleotomized group. There were no implant-associated complications.

Conclusions. The applied dynamic stabilization system is useful to prevent progression of initial degenerative disc disease of lumbar spinal segments after nucleotomy.

Key words: dynamic stabilization, lumbar spine, nucleotomy, segmental instability. **Spine 2005;30:E109–E114**

From the Department of Orthopaedics, Center for Muskuloskeletal Surgery, Charité - University Medicine Berlin, Germany.
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Address correspondence to Michael Putzier, MD, Center for Muskuloskeletal Surgery, Department of Orthopaedics, Charité - University Medicine Berlin, Campus Mitte, Schumannstrasse 20/21, 10117 Berlin, Germany; E-mail: michael.putzier@charite.de

The therapy of a disc prolapse with accompanying degenerative changes is subject to controversial discussion. Solitaire nucleotomy as well as the spondylodesis of the affected segments are recommended.[1–3] On the one hand, segmental fusion leads to an irreversible loss of function of the treated segment with the resulting risks of adjacent segment degeneration and pseudarthrosis, whereas a simple nucleotomy is not able to stop the continuing segmental degeneration but can even cause an acceleration of this process.[4–8] The reduction of the intradiscal pressure,[9] and the surgically induced alteration of osseous and ligamentous structures after nucleotomy combined with the simultaneously nearly missing potential of healing of the intervertebral disc and the adjacent endplates,[10–15] leads to progressive instability.

Thus, beside the successful symptomatic treatment, the aim of the surgical treatment should be the permanent inhibition of the progression of the degeneration with extensive preservation of the function of the affected segment.

The dorsal transpedicularly fixed dynamic implant device DYNESYS used in this study proved in biomechanical tests *in vitro* a reduction of the segment affecting bending moments and the horizontal translation.[16] The aim of this investigation was to examine this effect concerning the relief of the ventral and dorsal columns of the segment to avoid a progressive degeneration following nucleotomy.

Materials and Methods

In a prospective study, clinical and radiologic data of patients treated with nucleotomy and implanted with the DYNESYS device (Centerpulse, Winterthur, Switzerland) because of a diagnosed symptomatic nucleus pulposus prolapse with accompanying initial segment degeneration were investigated (group 1). These data were retrospectively compared with the prospective recorded results of a study including patients with respective diagnoses treated solely with nucleotomy before the introduction of the DYNESYS and the same evaluation parameters (group 2).

Population. Eighty-four patients who had been suffering from therapy-resistant lumbar radicular complaints and who showed a disc prolapse on MRI were enrolled in this study. The patients were evaluated before surgery, 3 months after surgery, and at a follow-up examination after an average of 34 months (range 24–47 months).

Patients were enrolled if their MRI showed stage I disc degeneration according to Modic et al in a maximum of 2 segments and additionally a considerable morphologic change of the ventral spinal column such as nucleus pulposus prolapse or reprolapse showing the alteration of at least 1 nerve root.[17]

Table 1. Characteristics of Both Study Groups

	DYNESYS Group 1	Nucleotomy Group 2	Total
No. of patients	35	49	84
female	13	20	33
male	22	29	51
Age at time of surgery	39 (23–58) y.	36 (21–59) y.	37 (21–59) y.
Duration of symptoms	6 (1–11) weeks	7 (0–10) weeks	7 (0–11) weeks

For age and duration of radicular symptoms, mean as well as minimum and maximum are shown.

Table 2. Group 1, Segments Treated with DYNESYS and Nucleotomy; Group 2, Segments Treated with Solitaire Nucleotomy

Treated Segments	DYNESYS Group 1	Nucleotomy Group 2	Total
L3/4	1	0	1
L4-S1	2	1	3
L4/5	12	14	26
L5/S1	20	34	54

Clinical symptoms equivalent to a radicular syndrome were another prerequisite for inclusion in this study.

Thirty-five cases were allocated to group 1 and treated with the dorsal dynamic stabilization system DYNESYS described below in addition to the minimally invasive nucleotomy performed. They were compared with 49 age- and symptom-matched patients belonging to group 2 who underwent exclusive nucleotomy (Table 1).

Patients presenting with the following local pathomorphological findings were not included: epidural adhesions and/or periradicular fibrosis after precedent nucleotomy depicted on MRI, significant changes in the posterior section of the motion segment like marked facet joint arthritis, absolute spinal stenosis according to the definition of Verbiest,[18] spondylolisthesis, lumbar scoliosis >10°, and stage II and III degenerative changes according to Modic et al.[17] Further exclusion criteria were a chronification of pain greater than stage II according to Gerbershagen[19]; clinical, laboratory and/or radiologic signs of osteoporosis or other metabolic bone diseases; the presence of malignant tumors; a BMI > 30 kg/m^2; and chronic alcohol or drug abuse. Table 2 shows the number and level of spinal segments treated and the allocation to the groups.

Surgical Technique, Implant Design, and Biomechanics. The minimally invasive nucleotomy in the solely nucleotomized patients was performed using an approximately 4 cm long incision directly lateral to the corresponding spinous processes. After mobilization of the paravertebral musculature, a sparing interlaminar fenestration with ablation of a small amount of the cranial or caudal vertebral arch depending on the localization of the prolapsed disc tissue was performed. Subsequently, the flavous ligament was incised, dura and nerve root were mobilized, and the underlying disc prolapse was recovered. Following irrigation, the wound was closed in layers.

When the dynamic stabilization system DYNESYS was used, an approximately 7 cm long medial incision was made. After mobilization of the paravertebral musculature bilaterally, the pedicle screws were positioned under image intensifier control and by preservation of the facet joints. Afterwards, the nucleotomy was performed as described above. Following this, the cylindrical spacers, made of polycarbonate urethane were positioned on both sides between the screw heads. Stabilizing cords consisting of polyethylene terephthalate and forming the core of the spacers were fixed under tension using the adjustment screws in the heads of the pedicle screws. While the cords limit inclination, reclination is restricted by the spacers. The compression stiffness of the DYNESYS is approximately 200 N/mm.[20] Assuming the proper fixation of the cord in the screw head with the stipulated torque of 4 Nm, the required pullout force is 1060 N.[21,22]

Subjective Symptoms and Clinical Examination. The Oswestry low back pain disability questionnaire according to Fairbank was used to assess subjective functional impairment.[23] This questionnaire rates the following 10 parameters: pain intensity, personal care, lifting, walking/walking aids, sitting, standing, sleeping, sex life, social life, and traveling. Additionally, the entire quantity of pain was evaluated using a visual analog scale (VAS) without further subdivision into leg and back pain.[24]

The neurologic findings were classified with regard to sensory, motor, and sensomotor deficits (Table 3).

Perioperatively, the duration of surgery, blood loss during surgery, and the duration of inpatient treatment were recorded. The intra- and postoperative, implant- and nonimplant-associated complications were determined until follow-up. At the time of follow-up examination, the patients were additionally questioned about their level of satisfaction and their willingness to undergo the operation again under the same conditions.

Radiologic Diagnostics. Anteroposterior and lateral radiographs of the lumbar spine and MRI examination of all patients

Table 3. Development of Neurological Deficits Preoperative, at 3 Months Postoperative and at Follow-up

			3 Months Postoperative			Follow-up		
Neurologic Deficits		Preoperative	Sensory	Motor	Sensomotor	Sensory	Motor	Sensomotor
Sensory	Group1	22	6	0	0	4	0	0
	Group2	31	10	0	0	6	0	0
Motor	Group1	2	0	1	0	0	1	0
	Group2	5	0	1	0	0	1	0
Sensomotor	Group1	11	2	1	2	2	0	2
	Group2	13	3	1	4	2	1	4
Total	Group1	35		12			9	
	Group2	49		19			14	

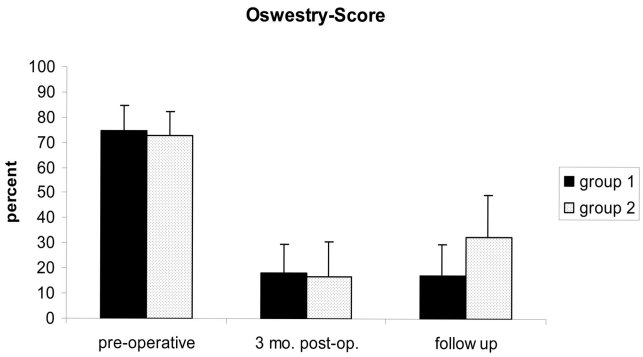

Figure 1. Subjective function evaluated with the Oswestry low back pain disability questionnaire before surgery, 3 months after surgery, and at follow-up for both groups.

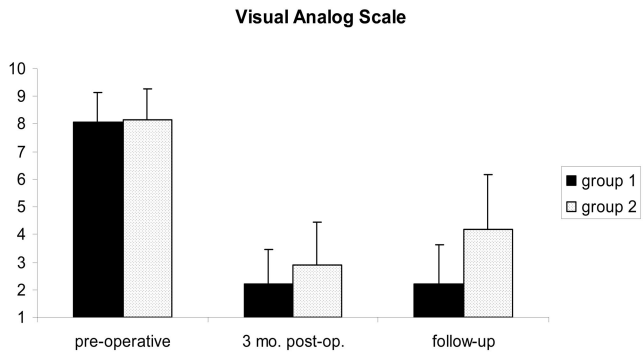

Figure 2. Pain intensity evaluated with a VAS before surgery, 3 months after surgery, and at follow-up for both groups.

were conducted before surgery, 3 months after surgery, and at the time of follow-up.

In the course of this study, degeneration of the treated segments as well as of the adjacent segments was assessed by determining the degree of hydration of the intervertebral discs on T2 weighted sagittal MRIs according to Luoma,[25] and by measuring the height of the intervertebral space based on a modified method of Colloca et al and Mimura et al.[26,27] Furthermore, cancellous and cortical bone reactions in the area of the cranial and caudal endplates according to Modic et al and in the facet joints based on general arthrosis criteria were recorded.[17] Novel disc herniations, stenotic changes resulting from bone or ligament structures, or axial deviations in the frontal and sagittal plain were documented. In addition, alterations in cortical bone caused by the pedicle screws were evaluated, as were loosening, dislocation, or breaking of the implant.

Statistics. Duration of surgery and blood loss were compared using the Student *t* test. Other than that, two-factorial analysis of variance with repetitive calculation for dependent and independent variables was performed for statistical evaluation. The results were verified by the Friedman test. The level of significance was set at $P < 0.05$.

Results

Perioperative Data

The mean duration of surgery in the DYNESYS group was 118 minutes (range 75–155), with an average blood loss of 190 ml (range 80–440). The duration of surgery in the solely nucleotomized group was significantly shorter with a mean of 47 minutes (range 35–70; $P < 0.05$) as was the blood loss averaging 135 ml (range 40–380) without instrumentation. Intraoperatively, 2 patients of group 1 and 3 patients of group 2 sustained damage to the dura, which was closed immediately with a primary suture and fibrin glue. The only specific early postoperative complication observed was a superficial wound healing disorder in 1 patient of Group 1.

Follow-up Examinations

All 35 patients of group 1 were available for the 3-month as well as the follow-up evaluation. Implant-associated complications in group 1 were not observed during the course of follow-up. The neurologic examination at follow-up showed in 74.3% of group 1 (26 of 35 patients) and in 71.4% of group 2 (35 out of 49 patients) a complete remission of the preoperative symptoms (no significant difference). In 2 further cases of group 1 and 3 further cases of group 2 with a preexisting sensomotor radicular syndrome, the impairment was reduced to a sensory deficit (Table 2). Neither surgery related nor, during the postoperative follow-up period, novel neurologic symptoms has been observed.

The Oswestry score improved significantly from preoperative to 3-month postoperative findings in both

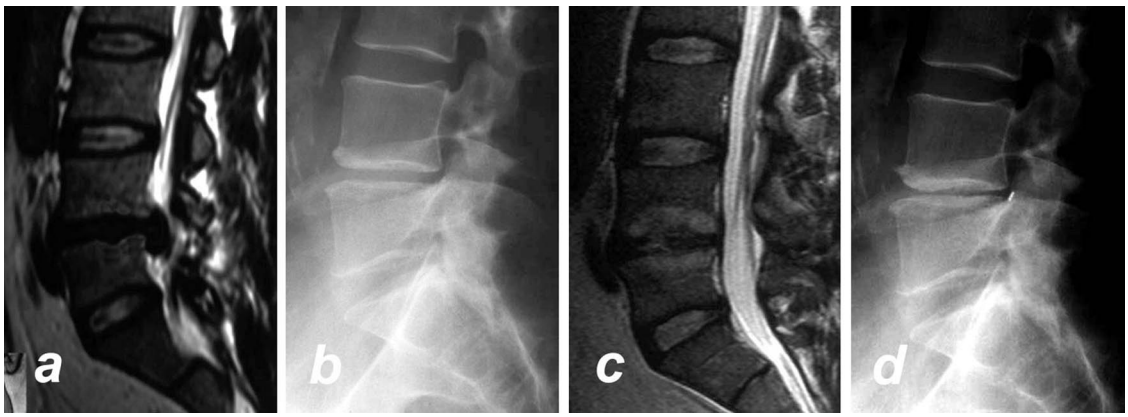

Figure 3. **a-d,** MRI and radiograph of a 49-year-old male with nucleus pulposus prolapse L4/5 and initial osteochondrosis (MODIC I) preoperative (**a, b**). Twenty-six months after minimal invasive nucleotomy, advanced disc degeneration is seen (**c, d**).

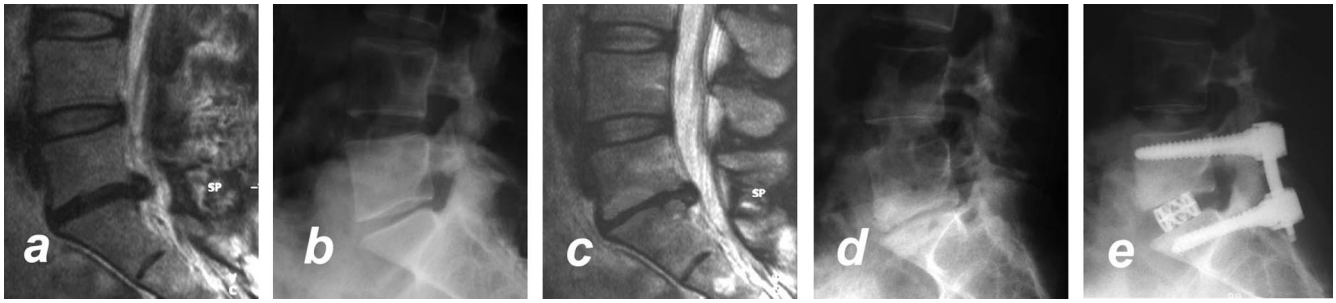

Figure 4. **a-e,** MRI and radiograph of a 32-year-old female with reprolapse L5/S1 and initial disc degeneration (MODIC I) accompanied by a new neurological deficit (**a, b**). The patient presented with progredient disc degeneration (MODIC II) at follow-up examination (**c, d**). Consecutively, a ventro-dorsal spondylodesis was performed.

groups ($P < 0.05$). The power of this improvement was equal in both groups. Between the scores of the first and the second follow-up a significant increase of the Oswestry score was found in group 2 ($P < 0.05$), whereas no significant changes were seen in group 1 (Figure 1).

The VAS showed a significant pain reduction in both groups at 3 months after surgery ($P < 0.05$). A significant difference of the power of this improvement between both groups was not found. At follow-up, group 2 showed a significant increase of the VAS ($P < 0.05$), which was not noticed in group 2 (Figure 2).

At the time of follow-up, 73 patients were very (n = 43) or considerably satisfied (n = 30) with the results of the treatment, 6 patients were not satisfied, and 3 patients were completely dissatisfied. Of these 9 patients, 6 belonged to group 2. One patient of group 1 and 4 patients of group 2 stated that they would not be willing to undergo the operation again under the same circumstances.

The radiologic evaluation showed a central position of all of the implanted pedicle screws. No loosening or breaking of screws was observed. No case of progressive height reduction of the intervertebral space, disc protrusion, or prolapse was detected in the instrumented segments. However, 5 of the non-instrumented patients showed a loss of height of at least 20% of the operated intervertebral space. Furthermore, a reprolapse was seen in 1 patient of group 2 at follow-up. Transformation of cancellous bone to fatty tissue or sclerotic bone reactions as a sign of progressive degeneration were depicted in 8 solely nucleotomized patients (Figure 3 and 4) and did not appear in group 1 (Figures 5 and 6). Stenosing osseous or ligamentous changes were not observed in any of the groups. No new appearance or progression of preexisting spondylarthrosis was noticed in group 1, whereas 6 patients of group 2 presented with new or increasing signs of spondylarthrosis as an indication of progressive segmental degeneration. In the adjacent segments, neither axis deviation nor osseous remodeling processes, stenoses, or spondyloarthroses were seen. A degeneration or herniation of vertebral disc tissue could not be determined.

■ Discussion

The minimally invasive nucleotomy currently is the state of the art treatment for symptomatic disc prolapses. Nevertheless, it increases the probability of an accelerated degeneration of the treated motion segment.[28] In particular concerning the immanent instability, a segmental fusion operation is often the only option for the treatment of recurrent prolapses.[29]

In accordance with that, this study showed a morphologic increase of degenerative changes along with a clinical increase of functional restrictions and pain quantity in the nonstabilized nucleotomy group after an initially equal improvement in both groups. The increasing insta-

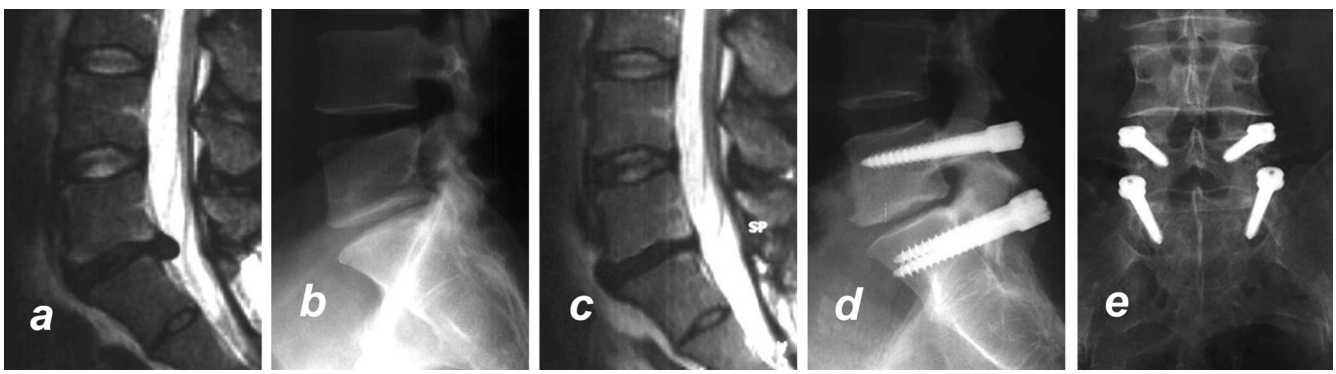

Figure 5. **a-e,** MRI and radiograph of a 36-year-old female with primary nucleus pulposus prolapse L5/S1, initial osteochondrosis and sensomotor radicular syndrome preoperative (**a, b**). Twenty-five months after nucleotomy and DYNESYS stabilization (**c-e**), no further progression is seen.

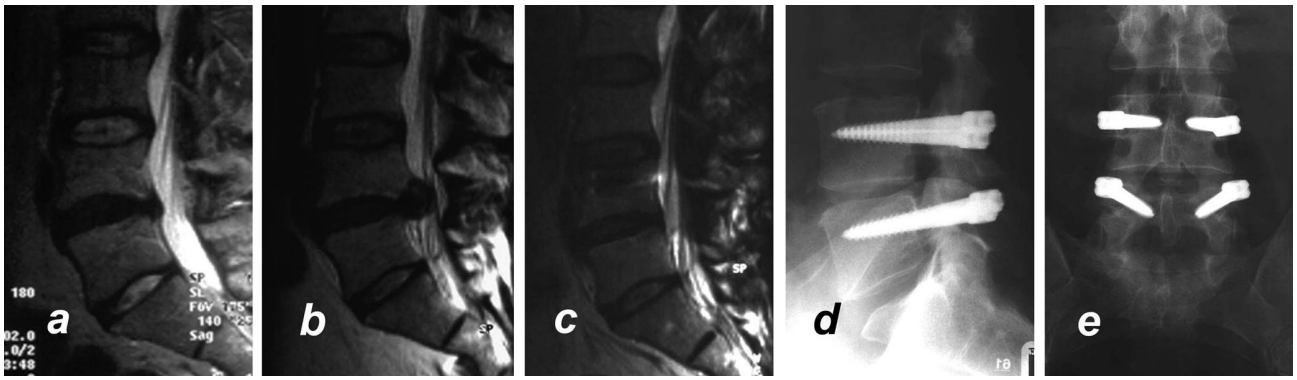

Figure 6. **a-e,** MRI after primary nucleotomy (**a**) and 14 months postoperative showing a large medial reprolapse L4/5 (**b**). Twenty-seven months after renucleotomy and DYNESYS stabilization (**c-e,**), no progressive disc degeneration is seen. The 43-year-old male patient is very satisfied; sensomotor deficits are no longer detectable.

bility seems to be crucial for this development,[30,31] and it is referred to in the literature as the main reason for dissatisfying surgery outcomes.[28] Up to 38% of the patients describe unsatisfactory results after lumbar nucleotomy.[32–35]

The presented short- to medium-term results after application of the DYNESYS show the ability of this dorsally implanted system to prevent a progression of degeneration of the anterior as well as the posterior spinal section during the course of this study. This is because of the biomechanical characteristics of this device, which are comparable to the intact dorsal section of a motion segment concerning its stiffness, and thus correspond to approximately 20% of a stable-angle screw-rod connection.[20]

Furthermore, the restriction of inclination and reclination leads to a neutralization of the intradiscal pressure and to an unloading of the facet joints.[21] This explains the ability of the DYNESYS to slow down the progressive or even accelerated degeneration after nucleotomy, which is caused by compression forces as shown in animal experiments as well as in finite element model simulations.[14] Through the preservation of the function of the treated segment, an increased loading of the adjacent segments can also be avoided.

Additional studies need to be performed to determine to what extent the evaluated significantly better results, after implantation of the DYNESYS compared with nucleotomy alone, persist until long-term follow-up. Only a prolonged success, especially concerning clinical results and the reduction of fusion operations, will be able to justify the disadvantages of the system: such as an initially increased duration of surgery, the higher risk of iatrogenic lesions attributable to the implantation of a transpedicular system, and the additional cost of the device.

Additionally, the durability of the implant properties *in vivo* has to be assessed in long-term follow-up examinations. Long-term stress tests *in vitro* showed a nonsignificant plastic deformation of the cord by 1.2% and of the spacer by 6.5% after 5 million cycles of distraction-compression.[22] Should more significant deformation or compression occur, as for example in athletes or excessively obese patients, restrictions for the implantation of this device will need to be reconsidered.

■ Key Points

- Nucleotomy in combination with segmental degeneration may lead to segmental instability. Spondylodesis, on the other hand, bares the risks of adjacent segment degeneration and pseudarthrosis.
- This study compared nucleotomy alone with nucleotomy combined with the dynamic stabilization system DYNESYS as treatments for symptomatic disc prolapse with initial segmental degeneration.
- At follow-up (34 months) the patients with additional stabilization showed significantly less signs of progressive degeneration.
- The DYNESYS presents a device that stabilizes the motion segment after nucleotomy to prevent further disc degeneration.

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