# Dynamic Stabilization in Addition to Decompression for Lumbar Spinal Stenosis with Degenerative Spondylolisthesis

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Study Design. Prospective clinical study.

**Objective.** To test whether elastic stabilization with the Dynesys system (Zimmer Spine, Minneapolis, MN) provides enough stability to prevent further progression of spondylolisthesis as well as instability after decompression for spinal stenosis with degenerative spondylolisthesis.

Summary of Background Data. In spinal stenosis with degenerative spondylolisthesis, decompression and fusion is widely recommended. However, patients have donor site pain. In 1994, a dynamic transpedicular system (Dynesys) was introduced to the market, stating that stabilization is possible without bone grafting.

Methods. A total of 26 patients (mean age 71 years) with lumbar spinal stenosis and degenerative spondylolisthesis underwent interlaminar decompression and dynamic stabilization with the Dynesys system. Minimum follow-up was 2 years. Operative data, clinical outcome, and plain and flexion/extension radiographs were obtained and compared to preoperative and postoperative data.

**Results.** Mean leg pain decreased significantly (P < 0.01), and mean walking distance improved significantly to more than 1000 m (P < 0.01). There were 5 patients (21%) who still had some claudication. A total of 21 patients (87.5%) would undergo the same procedure again. Radiographically, no significant progression of spondylolisthesis could be detected. The implant failure rate was 17%, and none of them were clinically symptomatic.

Conclusions. 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. It maintains enough stability to prevent further progression of spondylolisthesis or instability. With the Dynesys system, no bone grafting is necessary, therefore, donor site morbidity can be avoided.

**Key words:** spinal stenosis, degenerative spondylolisthesis, dynamic stabilization, Dynesys, decompression. **Spine 2006;31:442–449** 

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Degenerative lumbar spondylolisthesis commonly affects older people at the level L4–L5 and is a frequent cause for spinal stenosis. The forward slipping of the affected vertebra, which unlikely exceeds 30% of the body width, combined with the degenerative enlarged facet joints can cause central or lateral recess, or neuroforaminal stenosis as well as a combination of those findings. Although the majority of patients can be treated conservatively, 10% to 15% require surgical treatment because of severe and incapacitating back pain and/or leg symptoms, such as claudication or radicular pain, or cauda equina syndrome. 4-7

Several studies could show that decompression combined with arthrodesis (posterolateral or interbody) significantly improved patient outcome compared to decompression alone. Interestingly, even patients with pseudarthrosis had good or excellent results, probably because motion was restricted enough. Controversy exists if the addition of transpedicular instrumentation further improves clinical outcome. Although additive instrumentation leads to higher fusion rates and less progression of spondylolisthesis, it is unlikely to improve clinical outcome. Spondylolisthesis, it is unlikely to improve clinical outcome. In conclusion, to obtain good clinical results in surgery for spinal stenosis with degenerative spondylolisthesis, decompression and stabilization can be recommended, while fusion seems to be dispensable.

The main drawback of posterolateral or interbody fusion with autogenous iliac crest graft is donor site morbidity in up to 39% of patients. Persistent donor site pain in 55% of patients 1 year after the operation has been described. Wound problems, neurovascular damage, infections, pelvic fractures, and bleeding are other possible complications. <sup>21</sup>

In 1994, Dubois *et al*<sup>22</sup> introduced a new dynamic stabilization system (Dynesys; Zimmer Spine, Minneapolis, MN) to the market, stating that stabilization is possible with this implant without bone grafting. However, few studies exist regarding the clinical and radiologic outcome of patients who underwent Dynesys implantation.<sup>23,24</sup> We conducted this clinical and radiologic study to prove our hypothesis: that in lumbar spinal stenosis with degenerative spondylolisthesis, dynamic stabilization provides enough stability to prevent progression of spondylolisthesis, leading to comparable clinical results as seen after instrumented fusion. If so, it would be the preferable surgical treatment because it would eliminate the donor site problems entirely.

### **■** Materials and Methods

The Dynesys Spinal System. The Dynesys system consists of titanium alloy pedicle screws (Protasul 100), with sandblasted

surface, polyethylen-terephthalat cords (Sulene-PET), and polycarbonate urethane spacers (Sulene-PCU), which fit between the pedicle screw heads. The system has been tested biomechanically and clinically elsewhere. 24-26

Operative Technique. Three experienced spine surgeons of the University of Basel, Switzerland performed all operations. Patients were operated on while under general anesthesia in a prone position and received an antibiotic prophylaxis for 48 hours. After midline incision and subperiosteal preparation of the muscles, the affected segment was exposed. The interlaminar decompression of the stenotic levels was performed containing removal of the supraspinal and interspinal ligament, as well as the thickened flavum ligament. The dura was exposed, and an undercutting laminotomy was performed. Usually, the medial part of the facet joints was removed up to the pedicles.

After adequate decompression, the titanium alloy pedicle screws (5.2 or 6 mm) were inserted, and their correct positions were controlled by AP (anteroposterior) and lateral fluoroscopy. The polycarbonate urethane spacers were cut to accurate size and installed together with the polyester cord. The system was tightened with the specified preload. No further distraction or lordosis was applied to the segment, and no attempt to reduce the spondylolisthesis was made. A deep Redon drainage was inserted, and the fascia was closed meticulously. Finally, the wound was closed, and patients were allowed to get up at first postoperative day. All patients received a lumbar orthosis for 12 weeks. The intention of wearing a brace was to allow an unhindered ingrowth of the pedicle screws and for the patient's comfort.

Patient Selection. Between November 1999 and November 2000, a total of 26 consecutive patients undergoing decompression for lumbar spinal stenosis in the presence of degenerative spondylolisthesis were selected for the study. All patients were selected and treated at the Department for Spinal Surgery, University of Basel, Switzerland. In all patients, the spondylolisthetic segment was stabilized with the Dynesys system at the same level. Patients had claudication with back, buttock, and/or leg pain and had had conservative treatment before surgery without improvement. No patient had a prior attempt at fusion. All were Swiss residents who spoke German or French fluently and gave their written consent. Indications were spinal stenosis combined with degenerative spondylolisthesis at L3/L4 in 4 patients and at L4/L5 in 22. All patients underwent functional myelography and/or magnetic resonance imaging to prove diagnosis.

Preoperative Patient Data. The following patient data were collected: age, gender, body mass index (BMI), location and duration of pain, intensity of pain according to the visual analog scale (VAS), neurologic symptoms, walking distance, pain medication, previous treatment, former spinal operations, occupation, and activity status.

Preoperative Diagnostic Imaging. Plain radiographs (AP and lateral) and functional myelography or magnetic resonance imaging were obtained from all patients. An independent radiologist confirmed diagnosis of spinal stenosis with degenerative spondylolisthesis. The spondylolisthesis was measured in percent. The segmental angle was determined according to Cobb, and the anterior and posterior disc height were measured in millimeters. Accompanying alterations at other levels such as disc protrusions, spondylosis, osteochondrosis, scoliosis, spinal stenosis, synovial cysts, former fractures, and operations were noted.

Perioperative Data. Duration of operation, blood loss, hospital stay, and intraoperative and perioperative major and minor complications were assessed. Postoperative plain radiographs in AP and lateral view were obtained.

Clinical Follow-up. An independent surgeon (K.J.S) collected and evaluated all data. The minimum follow-up was 2 years. The following data were collected: location of pain; intensity of pain according to the VAS; neurologic symptoms; walking distance; finger-toe distance; and Schober measurement to assess lumbar mobility, pain medication, complications caused by the operation, subsequent spinal surgery, occupation, and activity status, according to Prolo et al.27

To indicate their treatment satisfaction, patients were asked "Would you have the same treatment again for the same outcome?" According to the NASS Patient Satisfaction Index,<sup>28</sup> they could answer: definitely yes, probably yes, not sure, probably not, or definitely not.

Radiologic Follow-up. After a minimum of 2 years, plain radiographs (AP and lateral standing) and functional radiographs with flexion and extension views were obtained. On plain radiographs, the spondylolisthesis was measured in percent. Implant failure, such as screw loosening or breakage, was noted. The segmental angle, and the anterior and posterior disc height were measured. Results were compared to preoperative and postoperative data. On functional radiographs, the segmental angle of the stabilized segment was measured according to Cobb. In addition, any anterior or posterior translation was noted to detect instability. Changes of more than 5° or 3 mm were stated as significant. 29 Finally, degenerative alterations at adjacent levels were evaluated and compared to preoperative radiographs.

Statistical Evaluation. Statistical analysis was performed with the assistance of computer statistics programs (SPSS 10.0.7 [SPSS, Inc., Chicago, IL] and StatXact-5.0.3 [Cytel Software, Cambridge, MA]). The clinical and radiologic results were analyzed using the analysis of variance chi-square test, Fisher exact test, Kruskal-Wallis test, and McNemar test.

#### ■ Results

# **Preoperative Patient Data**

A total of 26 patients (18 females, 8 males) with a mean age of 71 years (range 47–87) were included. Average BMI was 26.4 (range 19–35). All patients complained of leg pain while walking. There were 9 patients who had diffuse paresthesia at 1 or both legs, additionally. Twentyone patients (81%) complained of back pain also. There was 1 patient who had urinary and fecal incontinence caused by multiple sclerosis. On average, patients had symptoms for 35 months (range 2–180), with a mean of 80 on the VAS (range 55–100). There were 18 patients on pain killers; 6 of these patients were on opiates. Mean walking distance was 250 m (range 10–2000). The only patient (No. 12) with a walking distance of 2000 m was included because of intolerable back, buttock, and leg pain over a period of 40 months. Former therapy had included physiotherapy in 6 of 26 patients and/or steroid injections in 8 of 26. There were 3 patients who had undergone a previous spine operation, including 2 decompressions and 1 discectomy. Because of the high average age, 17 patients were already retired, 2 disabled, and 7 were working full time. Comorbidities were seen in 14 patients. There were 8 patients who had 1 comorbidity and 6 who had ≥2. One patient had multiple sclerosis and a gait disorder with a strong left-sided limp.

There were 22 patients who had degenerative spondylolisthesis at the L4/L5 level, and 4 at the L3/4 level. The mean value of spondylolisthesis was 17% (range 6% to 31%). There were 3 patients who had more than a 25% slip. The average height of the intervertebral disc was 4.3 mm anteriorly (range 0–8) and 7.5 mm posteriorly (range 0–13). The average Cobb angle of the affected level was 21° lordosis (range 3–32).

## Perioperative Data

Mean operating time was 137 minutes (range 90–210). Mean blood loss was 415 cc (range 100–700). There were 14 patients (54%) who required additional decompression at adjacent levels because of multilevel spinal stenosis. No patient underwent stabilization at more than 1 level. The overall complication rate was 11.5%. There were 2 patients who had a transient leg paresthesia

and 1 required revision surgery secondary to insufficient decompression. There were no implant correlated complications. Mean hospital stay was 16 days (range 10–43). Patients had to wear a lumbar orthosis for 12 weeks. Spondylolisthesis remained unchanged, with 17% on average (range 4% to 29%). The average anterior and posterior height of the intervertebral disc did not change significantly either. Average Cobb angle was slightly reduced to 18° (range 1°–28°).

#### Clinical Follow-up

A total of 24 patients (92%) could be evaluated after 2 years (Table 1). There were 2 patients who had to be excluded: 1 had subsequent surgery because of a traumatic vertebral fracture at L4 (patient No. 8), and 1 died of an unrelated pathology (patient No. 6). Average follow-up was 26 months (range 24–33).

Mean pain on VAS decreased significantly to 23 (range 0-82) (P=0.00001). Mean walking distance improved significantly to >1000 m (range 100 to infinite) (P=0.00001) (Table 2). Of the 2 patients with a walking distance of 100 m, 1 of them (patient No. 10) had multiple sclerosis, while the other (No. 26) did not benefit from the operation. Mean finger-toe distance was 9.5 cm (range 0-30). Mean Schober test distance was 3.6 cm (range 2-6).

There were 5 patients (21%) who still had some claudication, but only 2 of them (8%) had no benefit at all

Table 1. List of All Patients

Patient No.	Age (ys)	Gender	Stabilized Level	Postoperative Progression of Spondylolisthesis (%)	Change of Cobb Angle in Flexion/ Extension (°)	Implant Failure	Miscellaneous
1	71	Male	L3/4	0	3	No	
2	76	Male	L4/5	1.3	8	Screw loosening	
3	79	Female	L4/5	0	0	No	
4	47	Female	L4/5	0	4	Screw loosening	
5	87	Female	L4/5	2	3	No	
6	56	Male	L4/5	n/a	n/a	n/a	Death caused by unrelated pathology
7	76	Female	L4/5	6.5	2	No	
8	71	Female	L4/5	n/a	n/a	n/a	Osteoporotic L4 fracture and Dynesys removal
9	74	Male	L3/4	0	2	No	
10	52	Female	L4/5	4	12	Screw loosening breakage	Multiple sclerosis
11	76	Male	L4/5	1	1	No	
12	76	Female	L4/5	0	2	No	
13	81	Female	L4/5	0	1	No	
14	69	Male	L4/5	0	2	No	
15	77	Male	L4/5	0	9	Screw loosening	
16	73	Female	L4/5	0	3	No	
17	78	Female	L3/4	0	0	No	
18	71	Female	L4/5	0	6	No	
19	72	Female	L4/5	2	0	No	
20	65	Male	L4/5	0	0	No	Adjacent level instability
21	52	Female	L4/5	0	7	No	
22	58	Female	L4/5	2	0	No	
23	84	Female	L4/5	5	0	No	
24	73	Female	L3/4	9	2	No	
25	73	Female	L4/5	12	3	No	
26	73	Female	L4/5	1.5	5	No	

n/a indicates not applicable.

**Table 2. Clinical Outcome** 

	Preoperatively (n = 26)	2-Year Follow-up (n = 24)	Р
Pain (VAS)	80	23	0.00001
Mean walking distance (m)	250	>1000	0.00001
No. patients using analgetics	19	6	0.013

from the operation. Five patients (21%) still complained of paresthesia. The neurologic improvement was statistically significant (P = 0.0005) as well as the pain improvement (P = 0.0005). There were 19 patients (79%) who had no more claudication, and 14 (58%) were completely free of back and leg pain. Eighteen patients (75%) did not use pain killers any more (P = 0.013) (Table 2). There were 5 patients who needed nonsteroidal antiinflammatory drugs, and 1 was still in need of opiates. No patient reported on complications caused by the operation.

A total of 15 patients (62.5%) stated that they were active at their previous level without restriction according to Prolo Economic Scale. This statement means that they had activities as they had before the onset of their symptoms. There were 6 patients (25%) who stated their activity was at their previous level with limitation. Three patients (12.5%) were active but not at premorbid level (Table 3). There were 21 patients (87.5%) who would undergo the same operative procedure again. Age, gender, BMI, comorbidities, and complications had no statistical effect on postoperative activity status or pain improvement (all P > 0.08).

### Radiologic Follow-up

Plain and functional radiographs of 24 patients (92%) could be obtained after 2 years (Figure 1, Table 1). Overall progression of spondylolisthesis was 2.1% (range 0% to 12%) and not significant (P = 0.056). Only 4 patients (17%) had visible progression of more than 5% (patient Nos. 7, 23, 24, and 25). Implant failure was seen in 4 patients (17%). There were 3 screws that showed radiolucent lines in terms of loosening. One patient with multiple sclerosis had screw loosening and screw breakage (Figure 2). Implant failure was not related to patient satisfaction (P = 1.0) or back pain (Table 4).

The average height of anterior intervertebral discs was 4.8 mm (range 0–9) and showed no significant alteration (P = 0.47). In contrast, the average height of the posterior intervertebral disc space was reduced significantly from 7.5 to 6.6 mm (range from 0 to 12) (P = 0.012). However, only 2 patients had more than a 3-mm lowering of the posterior height. The average Cobb angle was

Table 3. Activity Level at 2 Years Postoperatively

Activity Level (mean age 71 ys)	No. Patients (%)
Activity at previous level without restriction Activity at previous level with limitation Active but not at premorbid level	15 (62.5) 6 (25) 3 (12.5)

reduced significantly from 20.9° before surgery to 17.3° at the 2-year follow-up (range 0-28) (P = 0.005). On the other hand, the postoperative change of the Cobb angle was not significant (P > 0.05). Regarding the itemized data of each patient, there was only 1 patient with a decreased Cobb angle of more than 5°. Mean segmental motion on flexion/extension views was 3° (range 0°-12°). There were 5 patients (21%) who had motion of more than 5° (Table 1). Therefore, their stabilized segment was stated as still mobile.

The average vertebral translation anteriorly or posteriorly of the stabilized segment was 0.8 mm (range 0-4). Only 1 patient had translation of more than 3 mm. The same patient had the highest motion in flexion/extension views with 12°. Therefore, we concluded an instability, which was caused by an implant failure (patient No. 10). There were 7 patients (29%) who had signs of adjacent level degeneration in terms of osteochondrosis or arthritis of facet joints. Six patients (25%) had degeneration at the level above and 1 (4%) at the level below. Degenerative instability at the adjacent segment developed in 1 patient.

#### ■ Discussion

Our data confirm that a dynamic stabilization system may maintain enough stability to prevent further translation of the vertebra without fusion. The progression of spondylolisthesis was not significant (P = 0.056). Visible progression occurred in 4 patients only and was not higher than 12%, which, in fact, means 4 mm on plain radiographs. The intervertebral height could be maintained in 92% of the patients also. Only 2 patients had more than a 3-mm lowering of posterior intervertebral height. The segmental angle measured with the Cobb technique decreased in 1 patient more than 5°. On functional radiographs, 5 patients (21%) had more than 5° of motion. However, only the patient with the broken screw (patient No. 10) had anterior translation of more than 3 mm.

In conclusion, 1 patient (4%) had instability at the stabilized segment caused by implant failure, while 4 (17%) still had mobile segments. To our knowledge, no comparable data are yet available in the current literature. Guigui and Chopin<sup>30</sup> used the Graf ligamentoplasty system for the treatment of spinal stenosis with degenerative instability. After surgery, 27% of 26 patients had destabilization of the operated segments. The Graf system could not prevent postoperative instability. Our data suggest that the use of the Dynesys system can stabilize the olisthetic segment sufficiently. Schmoelz et al,<sup>26</sup> who investigated the Dynesys biomechanically, supports this impression. Their in vitro study compared the Dynesys system with an internal fixator. The investigators concluded that "Dynesys provides substantial stability in case of degenerative spinal pathologies and can therefore be considered as an alternative method to fusion surgery."

One argument against a dynamic stabilization system is possible implant failure. In our study, 4 patients had potential implant failure (17%). We saw 4 pedicle screws



Figure 1. A 76-year-old female. Lumbar myelography in AP (A) and lateral (B) views showing degenerative spondylolisthesis at L4/L5 with severe compression of the dural sack. Two-year postoperative radiographs in AP (C) and lateral (D) views illustrating stable implant and no progression of spondylolisthesis.

with radiolucent lines and 1 broken pedicle screw (6% of 96 screws). Two patients with screw loosening had degenerative lumbar scoliosis. Patient No. 10 had multiple sclerosis and an abnormal gait with a strong right-sided

limp (Table 4). We found 1 screw with radiolucent lines and 1 broken screw on her radiographs (Figure 2). For this reason, we recommend not using the Dynesys system in patients with severe gait deviation. Other inves-





Figure 2. A 52-year-old female with an abnormal gait with a strong right-sided limp caused by multiple sclerosis. Two-year postoperative AP (A) and lateral (B) views showing broken cranial (arrows) and loose cranial screws (arrow).

tigators who used the Dynesys reported similar rates of implant failure. Stoll et al24 described 4% loose screws of a total number of 280 screws. Cakir et al<sup>23</sup> did not detect any implant failure in a series of 10 patients. Therefore, the screw-loosening rates with the Dynesys system seem to be similar to studies using rigid pedicle screw systems.31-34

Some investigators have mentioned that a dynamic stabilization system could prevent degeneration of the adjacent segment.<sup>24,35</sup> Our data do not support this theory. We found signs of degeneration adjacent to the stabilized segment in 7 patients (29%) after 2 years. Adjacent instability developed in 1 of these patients (patient No. 20) and was treated with an extension of the Dynesys system. Rahm and Hall<sup>36</sup> described adjacent-segment degeneration in 35% of 49 patients after instrumented lumbar fusion. Lehmann et al<sup>37</sup> found segmental instability above the fusion in 45% of 33 patients during a long-term follow-up. We believe that the Dynesys system acts similar to rigid pedicle screw systems because of its high intrinsic stability.<sup>26</sup> Therefore, overloading of the adjacent segments is possible.

The preoperative data did not give any hint of limitations of using the Dynesys system. Neither the BMI, age,

Table 4. Data of Patients With Implant Failure

	Patient No.			
	2	4	10	15
No. loose screws	1	1	1	1
No. broken screws	0	0	1	0
Patient age (ys)	76	47	52	77
BMI	26	21	29	28
Comorbidities	Lumbar scoliosis	None	Multiple sclerosis	Lumbar scoliosis
Postoperative back pain	Yes (VAS 60)	No	No	Yes (VAS 27)

gender, comorbidities, nor duration of symptoms influenced patient outcome. However, it can be assumed that patients with BMI higher than 35 or severe osteoporosis are not suitable for the use of the Dynesys. In our opinion, people who are too active (i.e., typically younger than 60 years) may encounter implant failure because of their high activity level. Although we cannot prove this with our data. Concerning the perioperative data, we can assume that decompression and stabilization with the Dynesys system may reduce operating time and complication rate because bone grafting is not necessary. The overall complication rate was 11.5% in our study, but no implant correlated complications occurred.

Clinical outcome of patients with spinal stenosis and degenerative spondylolisthesis mainly relies on the efficacy of neural decompression. Clinical data of our patients improved significantly. Pain on VAS (P < 0.001) and the use of pain medication (P = 0.013) could be reduced, and walking distance (P < 0.001) and neurologic symptoms (P < 0.001) improved. Of patients, 87.5% were active at their previous level without restriction or with limitation. Only 12.5% of patients did not reach the premorbid level. Overall, patient satisfaction was high. Of patients, 87.5% stated that they would undergo the same operative procedure again.

A review of the literature revealed only 1 study concerning the Dynesys and degenerative instability. Cakir et al<sup>23</sup> compared 10 patients with dynamic stabilization because of spinal stenosis and degenerative instability, with 10 undergoing anterior-posterior fusion because of the same diagnosis. They found comparable clinical improvement in both groups evaluated with the SF-36 and Oswestry Questionnaire after 1 year. Konno et al<sup>38</sup> used a soft tissue stabilization system according to Graf in comparison to decompression alone in patients with degenerative spondylolisthesis. There was no statistical difference in the clinical outcome, except that low back pain was lower in the Graf system group. However, several studies revealed worse outcome and higher revision rates using the Graf ligamentoplasty procedure for treating low back pain or degenerative disc disease. 30,39,40

Our clinical data match favorably with the published results of decompression and instrumented fusion for degenerative spondylolisthesis. Nork et al<sup>14</sup> used the SF-36 to assess patient satisfaction and found a 93% satisfaction rate. Booth et al<sup>16</sup> reported an 83% satisfaction rate after 5 years; 77% of patients would have undergone the same procedure again. Fischgrund et al<sup>15</sup> conducted a randomized study comparing decompression and arthrodesis with or without fusion. Of patients with additional instrumentation, 76% had excellent or good results.

#### ■ Conclusions

Despite the fact that our data are restricted because of the low number of patients and short follow-up, we can conclude that decompression and stabilization with the Dynesys leads to comparable clinical and radiologic results seen with established protocols. After 2 years, the radiologic evaluation showed no significant progression of spondylolisthesis and also stable implant in 83% of the patients. The Dynesys is a safe stabilization system in elderly patients with spinal stenosis and degenerative spondylolisthesis. Because no bone grafting is necessary, using the Dynesys system eliminates donor site morbidity entirely. Further long-term and randomized studies are necessary to confirm our 2-year data.

#### ■ Key Points

- A total of 26 patients with spinal stenosis and degenerative spondylolisthesis underwent dynamic stabilization with the Dynesys system in addition to decompression. There were 24 patients (92%) who completed a 24-month follow-up.
- Pain on VAS and walking distance improved significantly (P < 0.01). No significant progression of spondylolisthesis occurred.
- Dynamic stabilization with the Dynesys in addition to decompression for the treatment of spinal stenosis with degenerative spondylolisthesis showed similar results as compared to decompression and fusion reported in the literature.
- No bone graft is necessary when using dynamic stabilization with the Dynesys system, therefore, donor site morbidity can be avoided.

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