

Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine

Surgical and Patient-Oriented Outcome in 50 Cases After an Average of 2 Years

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Study Design. Retrospective study on a consecutive series of patients.

Objectives. To examine patient-oriented outcome after Dynesys implantation.

Summary of Background Data. The dynamic neutralization system for the spine, Dynesys, is a nonfusion pedicle screw stabilization system, which was developed in an attempt to overcome the inherent disadvantages of rigid instrumentation and fusion. Although the system has been in clinical use for more than 5 years, no studies from disinterested research groups have reported on patient-oriented outcome after surgery with Dynesys.

Methods. A total of 50 consecutive patients instrumented with Dynesys over the preceding 40 months were invited to complete a postal, patient-oriented follow-up questionnaire. The data from 31 of 31 of these, with at least 2 years' follow-up, were analyzed (mean age, 50 years; SD, 13 years; 20 women, 11 men). The primary indication for surgery was degenerative disease (disc/stenosis) with associated "instability"; 11 of 31 (35%) patients had had prior spinal surgery. In 32% cases, 1 level was instrumented, in 52% 2 levels, 13% 3 levels, and 3% 4 levels. Thirteen of 31 (42%) patients underwent additional decompression.

Results. Within the 2-year follow-up period, 6 of 31 (19%) patients had required or were scheduled for a further surgical intervention. At follow-up, mean (SD) back and leg pain (0–10 VAS) were 4.7 (3.2) and 3.8 (3.6), respectively. The following global outcomes were reported: back symptoms, 67% improved, 30% same, 3% worse; leg symptoms, 64% improved, 21% same, 14% worse; ability to do physical activities/sports, 40% improved, 33% same, 27% worse; quality of life, 50% improved, 37% same, 13% worse; how much the operation helped, 29% helped a lot, 23% helped, 10% only helped a little, 35% didn't help, 3% made things worse.

Conclusion. The results of the present study indicate that both back and leg pain are, on average, still moderately high 2 years after instrumentation with the Dynesys system. Only half of the patients declared that the operation had helped and had improved their overall quality

of life; less than half reported improvements in functional capacity. The reoperation rate after Dynesys was relatively high. The results provide no support for the notion that semirigid fixation of the lumbar spine results in better patient-oriented outcomes than those typical of fusion.

Key words: semirigid instrumentation, Dynesys, fusion, patient-oriented outcome, degenerative disorders, back pain, leg pain. **Spine 2005;30:324–331**

Fusion is a widespread and accepted treatment for painful degenerative conditions of the lumbar spine. However, the inconsistent results reported in the literature indicate a basic lack of understanding regarding the exact mechanism of pain relief. Overall, the outcome after fusion appears to be quite inconsistent: a systematic review of mainly retrospective case series reported that satisfactory clinical outcomes ranged from just 16% to as high as 95%, with an average of around 68%.¹ Although technical errors and inaccurate indications might be responsible for failure in some instances, there is some suggestion that additional factors may play a role in governing the outcome.

In the course of the degenerative process, during which the segment undergoes various anatomic alterations, there are significant changes in both the motion characteristics of, and the load distribution across, the affected (and possibly also neighboring) segments.² The loading pattern and motion are to a certain extent interdependent, and alterations in either (or both) may contribute to the generation of pain.³ The concept of spinal fusion originally arose from the notion that a degenerated motion segment is often "unstable" or shows "movement abnormalities," and that accordingly, the elimination of motion in the affected segment would prevent it from undertaking the movements associated with the generation of pain. Recent thinking, however, suggests that the prevention of movement per se may not be the most important factor accounting for the success of fusion.

For a long time, solid fusion was thought to be a requirement for a successful outcome: however, the results of many recent studies have challenged this concept by showing that patients' self-rated improvements in pain and function after surgery are unrelated to the attainment of solid fusion.^{4–8} It is now well accepted that degeneration of the spine is often, but not invariably, associated with pain. It has been noted that back pain is

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primarily related to position or posture, rather than movement of the lumbar spine, and it has thus been hypothesized that it is the abnormal pattern of loading associated with degeneration, rather than the abnormal movement itself, which accounts for disc degeneration causing back pain in some patients.³ The fact that, in a given patient, the precise position that provokes an abnormal loading pattern is rarely known may explain why the results of fusing the spine in one position appear to be somewhat “random” as regards clinical success.³

The dynamic neutralization system for the spine (Dynesys) is a nonfusion pedicle screw stabilization system, which was developed more than 10 years ago.⁹ In view of the arguments presented above, and the suggestion that prevention of all movement within fused segments may not only be detrimental to sagittal balance and overall function, but may also elicit accelerated degenerative changes in neighboring segments, “soft stabilization” was developed. Although the system has now been in clinical use for almost a decade, there are few studies in the literature that report on patient-oriented outcome after Dynesys implantation. A recent report from the originators of the system reported marked reductions in average pain and disability in a group of 73 patients, approximately 3 years after Dynesys instrumentation.⁹ However, neither the proportion of patients declaring a successful global outcome nor the proportion attaining a clinically relevant change in pain or Oswestry disability was reported. Furthermore, the complications reported with the 3-year period were quite considerable. To date, only one study from a disinterested research group has been published in the peer-reviewed literature.¹⁰ In this small, retrospective study, patient-oriented outcomes after dynamic stabilization ($n = 10$) were compared with those of historical controls ($n = 10$) who had undergone dorsoventral fusion. Before surgery, all patients had radiographically demonstrable “instability,” defined as antelisthesis or retrolisthesis of 2 to 5 mm recorded in sagittal images.¹⁰ Similar improvements in Oswestry disability scores and generic health status (SF-36) were recorded in each group after an average 15 months, suggesting that the Dynesys showed promise as an alternative to fusion. However, by the authors’ own admission, because of the small sample size (and consequent lack of any statistical analyses) and the retrospective nature of the study, it was difficult to draw any firm conclusions from this work.

The aim of the present study was to examine patient-oriented outcomes in a group of 50 patients in whom the Dynesys system had been implanted over the preceding 40 months; in 31 patients, the system had been implanted at least 2 years earlier. The study was primarily retrospective, as far as the patient-oriented outcome was concerned, but the clinical data documented before surgery were used to examine whether certain preoperative factors bore any association to the later outcome.

■ Materials and Methods

Patients. A total of 50 consecutive patients (from the Spine Unit of the authors’ hospital), who had undergone semirigid fixation of the lumbar spine with the Dynesys system between September 1999 and January 2003, took part in the study. The main results are presented for the first 31 patients with at least 2 years follow-up (and the results for the whole group of 50 patients (regardless of follow-up duration) are briefly described at the end of the results section).

Three surgeons were involved, although one of them carried out the majority of the operations (surgeon 1, 71% cases; surgeon 2, 26%; surgeon 3, 3%). The mean age of the patients at operation was 50 years (SD, 13 years; range, 30–80 years); there were 20 women and 11 men.

The primary indication for surgery was degenerative disease (disc/stenosis/spondylosis) resulting in some form of instability associated with neurogenic or radicular pain and/or chronic back pain. The main diagnosis was in 7 of 31 cases (23%) stenosis, in 11 of 31 (35%) spondylosis, in 7 of 11 (23%) disc degeneration, in 4 of 11 (13%) failed back surgery, 1 of 31 (3%) degenerative listhesis, and 1 of 31 (3%) extradural tumor. For 20 of 31 (65%) patients, the Dynesys fixation was their first spinal operation. Eleven of 31 (35%) patients had previously undergone decompression of the same or neighboring segments and/or fusion of neighboring segments: 8 of 31 (26%) patients had had 1 previous operation, 2 of 31 (6%) had had 2 prior operations, and 1 of 31 (3%) had had 3 prior operations.

Preoperative Evaluation. Preoperative evaluation included patient history, imaging, and clinical and neurologic evaluation by the treating surgeon. On admission to the hospital for the surgery, the patients underwent reexamination by one of the Spine Unit residents; a summary of the findings and the clinical history were then documented on a standardized evaluation form and entered into the hospital’s computerized patient-records system. The results of these examinations are shown in Table 1.

Surgery. The dynamic neutralization system claims to restabilize unstable segments keeping them mobile within a controlled range. The system consists of pedicle screws made of Ti-Al-Nb forge alloy Protasul 100. The screws are connected with a polyethylene terephthalate cord (Sulene PET) that runs in the center cylindrical spacer made of a polycarbonate urethane (Sulene PCU). By tethering the cord and selecting the appropriate length of the spacer between the screws, segmental distraction or compression may be applied (Figure 1).

The procedure was performed in the prone position. A midline approach, with dissection of the erector spinae muscles, provided access to the bony anatomy of the lumbar spine. If indicated, decompression of the spinal canal was performed first. Insertion of the pedicle screws was carried out under radiographic control using a C-arm, or with computer assistance (in 12 of 50 patients, 24%). The polycarbonate urethane spacer was cut according the measured distance between the screws, with the length being chosen to compensate any existing lordosis or kyphosis. The central cord and the spacer were then locked within the screw heads. A soft brace was administered after surgery until wound healing had occurred (Figure 2).

Table 1. Clinical Findings Before Surgery

	N*				
Duration of symptoms	25	4% (0–6 wk)	8% (7 wk to 6 mo)	84% (6–12 mo)	4% (1–3 yr)
Frequency of pain: back	31	0% never	3% occasional	49% often	48% constant
Frequency of pain: leg	26	4% never	27% occasional	42% often	27% constant
Pain at rest	28	11% no	89% yes		
Pain on movement	28	7% no	93% yes		
Pain 0–10 VAS (back) [mean (SD)]	29	7.0 (2.1)			
Pain 0–10 VAS (leg) [mean (SD)]	22	6.6 (2.4)			
Sensory deficits	30	77% no	23% yes		
Claudication	30	50% none	13% yes > 1000 m	24% yes 100–1000 m	13% yes < 100 m
Pseudoradicular pain	25	60% no	40% yes		
Radicular pain	25	68% no	32% yes		
Fingertip-floor distance > 10 cm	23	48% no	52% yes		
Lasegue test	29	90% negative	10% positive		

* N < 31 for some tests, as not all were carried out/documented in every patient.

In 33% cases, 1 level was instrumented; in 52%, 2 levels; in 13%, 3 levels; and in 3%, 4 levels. The most frequently performed instrumentation (39% of all cases) was of both L4–L5 and L5–S1. A total of 42% of patients underwent decompression surgery in addition to Dynesys instrumentation.

Short-term Radiologic and Clinical Follow-up. The first postsurgical radiographs, taken 4 to 6 days after surgery, were examined by one of the surgeons and rated in terms of the presence or absence of “technical errors” (such as loose or misplaced screws). Any other early complications were also documented. All this information was entered into the hospital’s computerized patient-records system.

Questionnaire Follow-up Assessment. In April 2003, all the patients were contacted by letter and invited to complete a short questionnaire (to be returned in the post) regarding their perceptions of the outcome of surgery. The questionnaire enquired about: pain intensity (0–10 VAS) in the preceding week (separate scales for back pain and leg pain); changes in overall back symptoms and leg symptoms as a result of the operation (categorized in each case as “much improved,” “improved,” “no change,” “worse”); reoperations undergone since the Dynesys implantation (number and nature of operation); removal of the Dynesys system (yes, no, don’t know); change in work status, quality of life, and ability to perform free-time/sporting activities as a result of the operation (in each case, “much improved,” “improved,” “same,” “worse”); global outcome after surgery (categorized as “helped a lot,” “helped,” “helped a little,” “no change,” “made things worse”); and whether, in hindsight, the same decision would be made to undergo surgery (yes, no). Our pilot studies (as yet unpublished) have shown that the results of the global outcome questionnaire correlate significantly with prospectively collected changes in pain and Roland Morris disability.

Data Analysis. Descriptive and frequency analyses were used to describe the baseline patient characteristics and categorical outcomes; relationships between categorical variables were examined using contingency tables with χ^2 /Fishers exact test (for 2×2 categories). The Mann Whitney U test was used to examine differences between two main outcome groups (good/bad). Statistical significance was accepted at the $P < 0.05$ level.

■ Results

Complications/Technical Errors

There were four intraoperative/immediate-postoperative complications. One patient developed pleural effusion, following an allergic reaction to the pain medication. In another patient, prolonged hospitalization was required due to transitory postoperative mental confusion. One patient required treatment due to postoperative cardiac insufficiency. In another patient, a dural tear required suturing and sealing with fibrinogenic material. Examination of the first postoperative radiographs in relation to positioning of the Dynesys screws revealed 4 cases of “technical error”: in 1 case, the screws were positioned extrapedicularly; in 2 cases, too far laterally (in both these cases, computer assistance had been used); and in 1 case, the screws on the right-hand side showed loosening. None of these technical errors per se caused significant symptoms or necessitated reintervention.

Late Complications/Repeat Surgery

A total of 6 of 31 (19%) patients either required reintervention in the 2-year follow-up or were undergoing further investigative tests with a view to reoperation in the near future. Three patients required revision surgery at the same spinal level with removal of the system: in 2 of these, a rigid fusion was carried out due to implant loosening (after 6 months and 18 months); and in the third,



Figure 1. In the Dynesys system, pedicle screws are connected with a system of a central cord and cylindrical shaped spacers.



Figure 2. Radiograph with Dynesys of the lumbar spine. In the radiographs, only the pedicle screws are visible.

the Dynesys instrumentation was removed on one side due to infection (after 8 months). One further patient required a morphine pump, 12 months after the Dynesys instrumentation. At the time of the present follow-up study, a further 2 patients with signs of screw loosening were undergoing consultation, with a view to possible revision; both underwent reoperation shortly after (Dynesys removal and fusion).

The findings for all 31 patients are given according to an “intention to treat” analysis, *i.e.*, for all patients in whom the system was implanted. The corresponding data for only those patients in whom the Dynesys was still in place were also analyzed, but as the results were not appreciably different from those for the whole group, only the latter are presented.

Patient-Oriented Outcome Measures After Minimum 2 Years

A total of 30 of 31 (97%) patients completed and returned the patient-oriented follow-up questionnaire. The remaining patient, from whom no questionnaire was received, was contacted by telephone; she explained that she was unwilling to send the questionnaire back because she was most disappointed with the results of the surgery. She did, however, agree to answer the two most important questions concerning the global outcome after surgery and the decision in hindsight to undergo surgery again (last two in the list above, in Methods), and to answer

the question about intervening surgical treatment. The average questionnaire follow-up duration was 2.8 (SD 0.5) years (range, 2.0–3.6 years; median, 2.7 years).

The patients’ mean (SD) preoperative pain intensity, as documented on the preoperative clinical evaluation form during the initial consultation, was 7.0 (2.1) for back pain and 6.6 (2.4) for leg pain. However, as this preoperative evaluation had been completed by the physician in consultation with the patient (rather than the patient completing it independently), it was decided not to make any direct statistical comparison with the results from the patient-self-rated pain at follow-up. At follow-up, the mean (SD) patient self-rated pain intensity was 4.7 (3.2) for back pain and 3.8 (3.6) for leg pain. The values were almost identical when only those patients were considered who still had the implant in place.

In the follow-up questionnaire, the proportions of patients that declared that their back symptoms had resolved, improved, were unchanged, or were worse were 20%, 47%, 30%, and 3%, respectively; the corresponding figures for self-rated leg symptoms were 32%, 32%, 21%, and 14%, respectively.

At the time of follow-up, the patients’ self-rated ability to carry out physical activities (sport/hobbies) had “improved” as a result of the operation in 40% patients, was “unchanged” in 33%, and was “worse” in 27%. Overall quality of life had “improved” in 50%, was “unchanged” in 37%, and was “worse” in 13%.

Table 2. Difference in Outcome Between Patients Receiving Only Dynesys and Those Receiving Dynesys and Decompression

Outcome Variable (and significance [<i>P</i> value] of the Difference in Distribution of Answers in the Two Subgroups, Dynesys Only and Dynesys With Decompression)		Dynesys Only (n = 18) (%)	Dynesys and Decompression (n = 13) (%)
Did the operation help? (<i>P</i> = 0.36)	Helped/helped a lot	39	69
	Helped a little	17	0
	No change/made things worse	44	31
Would you, in hindsight, make the same decision to undergo the operation again? (<i>P</i> = 0.13)	Yes	56	85
	No	44	15
Quality of life after operation? (<i>P</i> = 0.10)	Better	35	69
	Same	53	16
	Worse	12	15
Capacity to do physical activity after operation? (<i>P</i> = 0.33)	Better	30	54
	Same	35	31
	Worse	35	15

In response to a question enquiring as to whether the patients were in the same job now as before the operation, the following replies were recorded: 23% were in the exact same job as before; 20% were in the same job but only able to work part-time; 3% had changed jobs for personal reasons or due to changes in the job market; 13% had retired on the grounds of age; 27% had gone onto a disability pension due to back problems; and 13% had a different employment status for other reasons.

The patients' overall self-rating of the global outcome, *i.e.*, how much the operation had helped, was as follows: 29% helped a lot, 23% helped, 10% only helped a little, 35% didn't help, 3% made things worse; 68% declared that they would, in hindsight, make the same decision to undergo surgery, while the remaining 32% reported that they would not.

Comparison of Outcome in Patients Undergoing Just Dynesys Versus Dynesys and Decompression

Approximately 40% patients underwent decompression in addition to the Dynesys instrumentation, making it somewhat difficult to separate out the relative effects of the decompression and those of the stabilization on the patients' self-ratings of pain, disability, quality of life, *etc.* measured at follow-up. Thus, the various outcome variables were compared between the patients who received Dynesys instrumentation only (D) and those who received Dynesys in addition to decompression (DDec). There was an overall trend for poorer results in the D group compared with the DDec group, with the differences for some of the variables (change in quality of life after the operation; and "would you, in hindsight, make the same decision again to undergo the operation?") approaching statistical significance, even with the small numbers involved (Table 2).

Association Between Outcome and Various Baseline Variables

To examine factors that were associated with the global outcome, the answer to the question "would you make the same decision to undergo surgery" was used to dichotomize the outcomes as "good" (= yes, would make

the same decision) and "poor" (= no, would not make the same decision). In general, this classification tended to correspond to the same groupings as for "operation helped a lot, helped, helped little" (= good) *versus* "no change/worse" (= poor) on the 5-point Likert scale (Table 3), although interestingly, 27% of the patients who declared that the operation "didn't help" reported that they would still, in retrospect, make the same decision to undergo this surgery again.

Only few of the variables recorded and documented before surgery showed any notable association with the global outcome. Those patients with a "good" global outcome after surgery (n = 21) did not differ from those with a "poor" outcome (n = 10) in terms of gender, age at surgery, or number of previous spine operations. Outcome tended to be better in patients who had no neurogenic claudication before surgery (Fisher's exact test, *P* = 0.005) and in whom only 1 or 2 levels had been instrumented (*P* = 0.29).

Whole-Group Analysis

None of the results for the patient self-rated outcomes were notably different from those reported in the preceding sections, when the whole group of 50 patients was examined (mean [SD] follow-up duration, 25 [13]

Table 3. Relationship Between the Answers to the Questions "How Much Did the Operation Help?" and "Would You, in Retrospect, Make the Same Decision to Undergo Surgery?"

How much did the operation help?	No. in Each Answer Category	Would You, in Retrospect, Make the Same Decision to Undergo Surgery?	
		Yes	No
Helped a lot	9	9/9 (100%)	0/9 (0%)
Helped	7	7/7 (100%)	0/7 (0%)
Only helped little	3	2/3 (67%)	1/3 (33%)
Didn't help	11	3/11 (27%)	8/11 (73%)
Made things worse	1	0/1 (0%)	1/1 (100%)
Total	31	21/31 (68%)	10/31 (32%)

months; range, 3–43 months; median, 27 months), as opposed to only those with a minimum 2-year follow-up. There was no association between outcome and duration of follow-up ($P = 0.8$).

■ Discussion

Fusion is generally considered to be the treatment of choice for painful degenerative conditions of the lumbar spine that have proven unresponsive to nonoperative therapy. The results reported in the literature for the outcome after fusion vary according to patient selection and indication; satisfactory results have been reported to range from 16% to 95%, with an average of about 68%.¹ More recent, large-scale studies confirm these figures (57% good/excellent;¹² 63% patients “better” or “much better”⁷). For a long time, good results were thought to be dependent on radiologically confirmed solid fusion, although recent studies in which patients with pseudarthrosis showed the same clinical outcome as patients with solid fusion^{4,8,11,12} have challenged this notion. It might therefore be hypothesized that it is the reduction in (rather than the elimination of) segmental motion — brought about by partial fusion, or perhaps even simply by an alteration of the structure of the spinal tissues, induced by the surgery itself — that results in the alleviation of pain. As pain relief represents one of the most important outcomes in achieving a good result after surgery for degenerative spinal disorders, it would thus appear that solid fusion no longer represents a prerequisite for achieving this goal. If this were so, it would present several advantages, including a reduction in the extensiveness of surgery required and the number of complications, as well as the elimination of undesirable late side effects of fusion, such as adjacent segment degeneration^{13,14} and consequent hypermobility.^{15,16}

It was on this basis that “nonfusion” concepts for treating painful degenerative disorders of the lumbar spine were developed. Initial *in vitro* studies were able to confirm the potential biomechanical advantages of a “dynamic neutralization system” (Dynesys) for the spine: bending angles and horizontal translations were significantly reduced, although not abolished, while vertical translations were increased and bulging of the posterior anulus was reduced.¹⁷ Clinical use of the Dynesys semirigid instrumentation began in 1994. Since then, various individual case studies have been presented, showing restoration of disc height and improvements in Modic changes after Dynesys (Dubois, personal communication, 2003¹⁸), and the clinical results from some case series have been evaluated and presented at local research meetings.^{19,20} Based on promising preliminary findings, the system now enjoys wide clinical application in Europe, despite the fact that its mechanism of action is still far from clear.

The present study represents the first published report on patient-rated outcomes after Dynesys from a disinter-

ested research group, and the generally rather poor results may well serve to dampen current enthusiasm for the system. Overall, approximately two thirds of the patients reported some improvement in their leg/back pain. However, only 40% reported an improvement in their ability to perform physical activities and just 50% an improvement in their quality of life.

Only 52% declared that the operation had helped or helped a lot. In an analysis of the results of a group of 347 historical controls, who had undergone fusion in our hospital and were followed up an average 3 years later (74% follow-up rate), approximately 70% declared that the operation had helped/helped a lot.²¹ It could be argued that there is a bias for patients with a better outcome to respond to such questionnaires, *i.e.*, that in the study of Dvorak *et al.*,²¹ the 26% who did not respond were more likely to have had a poorer outcome. In an attempt to address this issue, we analyzed separately the data from the first 74% questionnaires to be returned in the present study (mostly those individuals who did not need a second or third reminder): 51% reported that the operation helped/helped a lot, more or less the same proportion as in the whole group. Thus, we tentatively suggest that the results after Dynesys were no better, and possibly even worse than those of historical controls undergoing fusion for similar indications within our own hospital. Naturally, randomized controlled trials would be necessary to investigate this with the scientific rigor required to make definitive statements about the relative merits of the two techniques.

In our patient series, the average preoperative leg and back pain VAS scores (recorded by the clinician in consultation with the patient) were similar to those reported by Stoll *et al.*⁹ However, the back and leg pain intensities reported in the present study 2 years after surgery were 1 to 2 U higher than those reported by Stoll *et al.*⁹ and most likely accounted for the generally poor global outcomes.

The better results of Stoll *et al.*⁹ may have been a reflection of the greater proportion of patients undergoing the (typically more successful) procedure of decompression in their study (68%, compared with 42% in the present study). Notably, in the present study, when the patients who underwent decompression in addition to Dynesys were compared with those who only received Dynesys, the results were generally more favorable for the former group. In the face of such potential confounding factors, caution must be exercised in attributing the results to the Dynesys per se. A further difference between the present study and that of Stoll *et al.*⁹ was the greater number of unisegmental instrumentations performed in their study (66% *vs.* just 32% in the present study; see later for discussion of the effects of multilevel instrumentation). The proportion of patients who had previously undergone lumbar spine surgery was similar in the two studies (35%–40%).

Although the group results presented here are not very favorable, there are some patients who clearly benefited

from the surgery. No previous studies have identified predictors of success for the Dynesys implant system, either in relation to the surgical indication or to other baseline factors (such as age, gender, diagnostics used, previous operations, baseline pain levels, *etc.*). The sample size in the present study was not large enough to carry out meaningful multivariate analyses to accurately identify predictor variables. From bivariate analyses, however, there was some suggestion that patients in whom only one or two levels were instrumented had a better outcome, in keeping with the findings for “ordinary” spinal surgery.²² Further, it was noted that patients with no neurogenic claudication before surgery tended to have a better outcome. Nonetheless, in practice, this does not help to solve the problem of accurately defining indications for the procedure. Further, as “instability” and “movement abnormalities” are vague, poorly defined terms, and the phenomenon evades accurate and clinically meaningful measurement *in vivo*,²³ these are also not suitable as indicators for Dynesys instrumentation. The variable individual outcomes might possibly be related to factors that were not analyzed before and after surgery in the present study, for example, the degree of osteoarthritis of the facet joints or the presence of discogenic pain as determined using discography. Further studies investigating these factors might provide more information in this respect.

Examination of the purported mechanism of action of the Dynesys system may also shed some light on the issue of the varying individual responses to its implantation. When Dynesys first appeared on the market, it was promoted as a device that would allow motion to be “preserved” and “modulated,” *i.e.*, movement would be retained, but at a moderated level in relation to the otherwise unphysiologic, hypermobility displayed by the degenerated segment(s). Although precise figures regarding the extent of the residual motion were not proffered, it was expected to be considerably greater than that associated with rigid fixators, in an attempt to circumvent the (suspected) problem of accelerated degeneration in the otherwise overloaded adjacent segment. However, two recent biomechanical studies have shown that, at least *in vitro*, the range of intersegmental motion after Dynesys instrumentation is much lower than expected.^{24,25} Independently, both these studies showed that for flexion/extension and lateral bending almost identical ranges of motion were observed for Dynesys instrumentation and a rigid internal fixator. Only in axial rotation did the Dynesys allow a significantly greater range of motion compared with rigid fixation. These findings appear to contradict those from *in vivo* testing,²⁶ in which 4° to 5° of intersegmental motion in the sagittal plane was recorded in patients instrumented with the device. This could be the result of *in vitro* tests failing to accurately simulate the conditions *in vivo* (although it seems unlikely that this would result in less movement in the *in vitro* situation, since *in vivo* the posterior struc-

tures of the spine (muscles, fascia, *etc.*) can be expected to offer additional resistance to bending over and above that offered by the osteoligamentous spine), or may simply be the consequence of the known, interindividual variation in range of motion coupled with the small sample sizes in each study (*i.e.*, in each experimental situation, insufficient cases were examined to provide an accurate representation of “typical” behavior for the given testing situation). Either way, it seems that the biomechanical effect of instrumentation of the lumbar spine with Dynesys must, at present, be summarized as “the alteration of motion to an extent that is not yet well characterized *in vivo*.” Interestingly, as far as the restriction in motion is concerned, Graf ligamentoplasty²⁷ appears to demonstrate similar results, with least stabilization being provided in axial rotation.²⁸

According to Mulholland and Sengupta,³ pain in association with degenerative disease may arise as a result of high spot-loading associated with the adoption of certain positions, rather than movement per se. In one sense, solid fusion of the unstable segment negates the problem of having to identify which particular positions are painful and why, by eliminating all movement in the painful segment in a “sledge-hammer to crack a nut” approach (being sure to include the painful postures, but at the cost of eliminating those that may not be associated with pain). It would be interesting to hypothesize that the benefits of Dynesys and Graf ligamentoplasty may—paradoxically—lie in their ability to markedly reduce movement in the sagittal and frontal planes (thereby emulating fusion, or at least pseudoarthrosis) but that the systems fail those patients whose pain is typically provoked by rotational movements or the adoption of postures in which the spine is rotated. In this sense, the failure of these systems to sufficiently restrict mobility in the horizontal plane, rather than their inability to sufficiently retain motion in flexion/extension, may indeed be their downfall. Obviously, such a hypothesis remains to be tested and requires considerably more investigation using accurate *in vivo* three-dimensional segmental motion analysis, before and after instrumentation, coupled with corresponding pain measurements. In the meantime, since both the Graf and Dynesys semirigid stabilization systems appear to demonstrate similar clinical and biomechanical results, it might be useful to compare the common effects of both systems using data pooled from the very many studies carried out to date, in an attempt to identify their respective benefits and drawbacks in comparison with conventional fusion procedures. One recent study with Graf ligamentoplasty has shown less adjacent segment disc degeneration compared with posterolateral fusion²⁹; no comparable data are currently available for the Dynesys system, but it would seem that such data are urgently required if its continued use is to be advocated; at present, there is no overwhelming evidence to suggest that the system per-

forms better than traditional fusion as far as the mid-term results are concerned.

■ Key Points

- Semirigid instrumentation of the lumbar spine represents a new alternative to fusion in the treatment of chronic low back pain due to degenerative disorders of the lumbar spine.
- The dynamic neutralization system (“Dynesys”) has been in clinical use for more than 5 years, but the associated outcome (patient-oriented) has not been reported by any disinterested research groups.
- A total of 31 of 31 patients answered a follow-up questionnaire 2 years after being instrumented with Dynesys. Improvements in functional capacity and quality of life were only moderate. Only approximately 50% patients declared that the operation “helped” or “helped a lot.”
- The overall results are poorer than those for historical controls undergoing fusion for similar indications in our hospital.
- There is still insufficient evidence to suggest that semirigid fixation of the lumbar spine results in better patient-oriented outcomes than does fusion.

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