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Lumbar Spinal Stenosis: Conservative or Surgical Management?

A Prospective 10-Year Study

Tom Amundsen, MD,* Henrik Weber, MD, DrMed,* Helge J. Nordal, MD, DrMed,* Bjørn Magnaes, MD, DrMed,† Michael Abdelnoor, MPH, PhD,‡ and Finn Lilleås, MD§

Study Design. A cohort of 100 patients with symptomatic lumbar spinal stenosis, characterized in a previous article, were given surgical or conservative treatment and followed for 10 years.

Objectives. To identify the short- and long-term results after surgical and conservative treatment, and to determine whether clinical or radiologic predictors for the treatment result can be defined.

Summary of Background Data. Surgical decompression has been considered the rational treatment. However, clinical experience indicates that many patients do well with conservative treatment.

Methods. In this study, 19 patients with severe symptoms were selected for surgical treatment and 50 patients with moderate symptoms for conservative treatment, whereas 31 patients were randomized between the conservative (n = 18) and surgical (n = 13) treatment groups. Pain was decisive for the choice of treatment group. All patients were observed for 10 years by clinical evaluation and questionnaires. The results, evaluated by patient and physician, were rated as excellent, fair, unchanged, or worse.

Results. After a period of 3 months, relief of pain had occurred in most patients. Some had relief earlier, whereas for others it took 1 year. After a period of 4 years, excellent or fair results were found in half of the patients selected for conservative treatment, and in four fifths of the patients selected for surgery. Patients with an unsatisfactory result from conservative treatment were offered delayed surgery after 3 to 27 months (median, 3.5 months). The treatment result of delayed surgery was essentially similar to that of the initial group. The treatment result for the patients randomized for surgical treatment was considerably better than for the patients randomized for conservative treatment. Clinically significant deterioration of symptoms during the final 6 years of the follow-up period was not observed. Patients with multilevel afflictions, surgically treated or not, did not have a poorer outcome than those with single-level afflictions. Clinical or radiologic predictors for the final outcome were not found. There were no dropouts, except for 14 deaths.

Conclusions. The outcome was most favorable for surgical treatment. However, an initial conservative approach seems advisable for many patients because those with an unsatisfactory result can be treated surgically later with a good outcome. [Key words: lumbar spinal stenosis, conservative or surgical treatment, sciatica] **Spine 2000;25:1424–1436**

The clinical entity "lumbar spinal stenosis" can be defined as a narrowing of the lumbar spinal canal, resulting in symptoms and signs caused by entrapment and compression of intraspinal vascular and nervous structures. Herniated intervertebral discs and space-occupying lesions (caused by inflammation or neoplasm) are in the strictest sense also causes of stenosis, but they usually are regarded as separate entities. Clinical and radiologic features are described and discussed in a previous article.[4] Pain in the back and leg(s) and, in particular, claudication caused by compression and ischemia of nerve roots are the main symptoms.

Lumbar spinal stenosis has been known for more than 100 years, but for a long time it was regarded as "the forgotten spinal disease." This neglect occurred because the association between herniated vertebral discs and sciatica received most of the attention after it was discovered by Mixter and Barr[37] in 1934. However, since the early 1950s, starting with the studies of Verbiest,[52] this has changed, and lumbar spinal stenosis now is an accepted clinical entity. The space in the vertebral canal is limited, usually because of degenerative changes, supposed to be progressive, and sometimes in combination with a congenital narrow bony canal. Symptoms and signs are related to this limited canal space. Surgical decompression was considered as the natural treatment, and the results of this were reported in several publications.[7,9,13,14,23,25,38,52,53,57] However, over time, clinical experience indicated that many patients obviously did well without surgery.[10,19,24,35,41,42,44]

Medical publications deal largely with results after surgical treatment. In a meta-analysis by Turner et al,[51] successful results after surgical treatment are reported for 26% to 100% of the subjects, but the mean follow-up time was less than 4 years. Herno et al[18] reported good surgical results for 68% of patients after a mean follow-up time of 12 years. Postacchini et al[43] examined the

From the *Department of Neurology, †Department of Neurosurgery, ‡Clinical Research Forum, and §Department of Neuroradiology, Ullevål Hospital, Oslo, Norway.
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surgical long-term results, making a distinction between results from patients with short-term unsatisfactory and satisfactory outcomes. After an average follow-up time of 8 years the proportion of unsatisfactory results was 33%, but this decreased to 20% when only the patients who had satisfactory short-term results were considered. None of the patients with an unsatisfactory short-term result improved with time. Literature dealing with results after nonsurgical treatment are scanty.

In a study comparing surgically and conservatively treated patients, Johnsson et al[25] found that 60% of the patients treated surgically improved and 25% deteriorated, whereas of the conservatively treated patients, 30% improved and 60% were unchanged. Mean observation time was 53 and 31 months, respectively. In another study Johnsson et al[24] studied the natural course of spinal stenosis and found after a mean observation period of 49 months that the symptoms were unchanged in 70%, improved in 15%, and worsened in 15% of the patients. No proof of deterioration was found after 4 years, and it was concluded that expectant observation could be an alternative to surgical treatment.

Controlled clinical studies comparing conservative and surgical treatment are rare, and few studies deal with long-term results.[23,51] In an effort to shed light on this important problem, the current study was initiated in 1983 under the auspices of Dr. Henrik Weber and in close collaboration with the departments of neuroradiology and neurosurgery at Ullevål Hospital, Oslo, Norway. It has been influenced heavily by the experience Dr. Weber attained with patients who have lumbar disc herniation, as presented in his doctoral thesis in 1978.[55,56]

The first task was to define a study population and to characterize the clinical features and radiologic aspects of patients with symptomatic lumbar spinal stenosis. For this purpose, 100 patients were recruited over a 3-year period from December 1984 to September 1987. The patients fulfilled certain criteria that reflected the prevailing definition of lumbar spinal stenosis. The results from this initial part of the research project are presented in a previous article.[4]

The core of the problem, addressed in this report, is to find guidelines applicable for the individual patient on how to choose between conservative and surgical treatment. The working hypothesis of the authors was that conservative treatment is a realistic alternative to surgery, at least under certain circumstances. They defined the following aspects of the problem:

> Conservative treatment seems to be the natural choice when symptoms are mild. Little is known about the short- and long-term prognosis of this approach. How often does conservative treatment give an acceptable result? Will the clinical condition deteriorate as the patient ages? This might be anticipated if a simple causal relation exists between symptoms and degenerative changes of the spine.
>
> When symptoms are severe, it is tempting to suggest surgery. Decompression seems logical and has the potential to give the patient immediate relief. How effective is surgical treatment? What is the price for a beneficial long-term effect of surgery? Will spinal "instability" after surgery take its toll over the years in the form of an acceleration of increasing symptoms? Which symptoms benefit most from surgery?
>
> An important problem pertains to the timing of surgery. Is an early operation important to secure a good result, or should all patients initially be offered conservative treatment, with surgery reserved for the failures of such treatment?
>
> Is it possible to find clinical or radiologic predictors that can be used as guidelines in the decision between conservative and surgical treatment?

Materials and Methods

Participants. From December 1984 to September 1987 (34 months), 100 patients with symptomatic lumbar spinal stenosis were recruited consecutively to the study from the Department of Neurology at Ullevål Hospital, Oslo, Norway. The long recruitment period resulted from the strict exclusion criteria. The Department of Neurology is a referral center for the 500,000 inhabitants of Oslo. During the same period, 1900 patients with low back pain and sciatica were admitted to the department, from which candidates for the current study were selected by two of the authors (T.A. and H.W.).

Inclusion criteria required that participants have sciatic pain in the leg(s), with or without pain in the back, together with radiologic signs of stenosis and compression of the clinically afflicted nerve root(s). Patients were excluded from the study if they had a bulging or herniated disc, spondylolysis, coxarthosis, gonarthosis, arterial insufficiency in the legs, polyneuropathy, concomitant serious disease, or previous surgery on the back.

The participants in this study included 54 men and 46 women whose median age was 59 years (range, 16–77 years). The median age of the women was 1.5 years less than that of the men. The clinical characteristics and radiologic features of the patients are described in detail in a previous report.[4] The study procedures were as follows:

> From these patients, a group S (n = 19) (Figure 1) was selected for surgical treatment because of the severity of their symptoms. Most important was the intensity of their pain. The physical findings were usually mild. The severity of the radiologic findings was not decisive. Six patients had mild clinical signs of cauda equina (perianal numbness). None had serious motor disturbances of the leg(s) or anal sphincter or reduced bladder function. Candidates for surgery were chosen by two of the authors (T.A., H.W.). After a conference between a neurosurgeon (B.M.), a neurologist (T.A. or H.W.), and the patient, the latter gave final consent for surgery.
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> Another cohort of patients, group C (n = 50), with milder pain considered too moderate to justify surgery, was selected for conservative treatment. None had serious neurologic deficits.

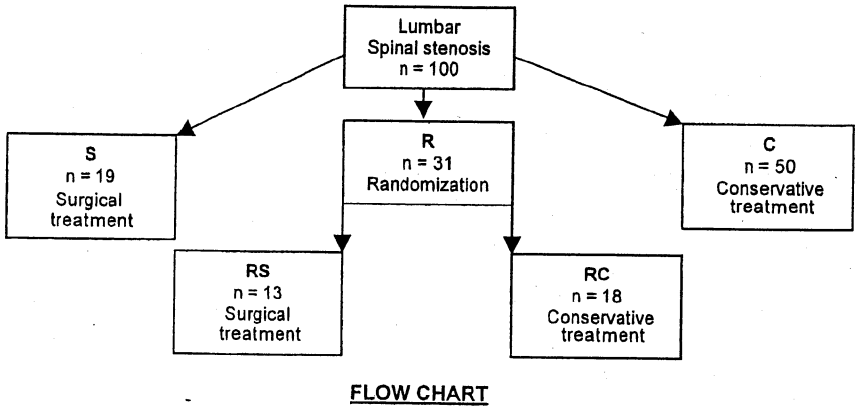

Figure 1. Flow chart of the treatment given to 100 patients with symptomatic lumbar spinal stenosis. Depending on the severity of symptoms, patients were selected for surgical treatment (group S, n = 19), for conservative treatment (group C, n = 50), or for randomization between surgical treatment or conservative treatment (group R, n = 31). Of the 31 patients selected for randomization, 13 were randomized to surgery (group RS) and 18 to conservative treatment (group RC).

The remaining patients, group R (n = 31), whose severity of pain left the physician in doubt concerning which treatment to recommend, were randomized for surgical treatment (group RS [n = 13]) or conservative treatment (group RC [n = 18]).

In this way, four treatment groups were defined: two surgical treatment groups (S and RS) and two conservative treatment groups (C and RC). The patients were given the option to withdraw from the study at any time without giving any reason. The age and gender distribution are shown in Table 1. There were more men randomized to surgery, and more women to conservative treatment. The difference was not statistically significant. The intensity of pain is shown in Table 2, and the degree of narrowness in relation to intensity of pain in Table 3. The procedures for defining the intensity of pain and the degree of narrowness are described in a previous article.[4]

The patients were randomized by block randomization[2] using tables of random numbers. They gave informed consent to participation in the study and to randomization.

For some patients, the pain was so severe during the follow-up period that they were reconsidered for surgery. The same procedure was followed for the delayed consideration of surgery as for the initial deliberation when the patients were recruited to the study. This led to surgery for 21 patients up to the 4-year assessment (10 from group C (20%), 10 from group RC (55%) and 1 from group S), increasing to 25 patients (4 more from group C) up to the end of the 10-year period.

The patients crossing over from conservative to surgical treatment were recorded as treatment failures in their original treatment groups on the "intention-to-treat" analysis during the first 4 years. All crossover patients up to April 1988 (n = 20) were followed in the same way as "new" patients until the final evaluation of all the patients in 1996. The median time lag for crossover was 3.5 months (range, 3–27 months). There were 10 crossover patients from group C, who formed a new group designated as group C+, and the 10 crossover patients from group RC designated as group RC+. The remaining patients in groups C and RC were designated as groups "C" and "RC," respectively. Three patients from group C+ and three patients from group RC+ later had a second operation. These patients were all recorded as treatment failures, irrespective of the result after the second operation.

Table 1. Age and Gender Distribution of All Patients in the Groups Shown in Figure 1

	S		RS		RC		C	
Age, yr	M	W	M	W	M	W	M	W
≤20	0	0	0	0	0	0	1	0
21–40	1	1	1	1	0	2	1	2
41–60	5	3	4	3	4	5	10	11
61–70	5	2	4	0	2	4	11	5
≥71	0	2	0	0	1	0	4	5
Total	11	8	9	4	7	11	27	23

S = selected for surgical treatment, RS = randomized to surgical treatment, RC = randomized to conservative treatment, C = selected for conservative treatment, M = men, W = women.

Table 2. Number of Patients and Degree of Pain in the Various Treatment Groups Shown at the Start, and After the Follow-Up Evaluations (see also Figures 1 and 5)

	S	R			C	
Selected Treatment Groups	S	RS	"RC"	RC+	"C"	C+
At the start						
Light pain	0	0	0	0	2	0
Moderate pain	5	6	2	3	20	4
Severe pain	14	7	6	7	18	6
Total (100)	19	13	8	10	40	10
After 3 mo						
No or light pain	8	2	2	5	10	3
Moderate pain	8	11	5	4	28	5
Severe pain	3	0	1	1	2	2
Total (100)	19	13	8	10	40	10
After 4 yr						
No or light pain	6	5	1	1	13	3
Moderate pain	9	7	7	3	22	5
Severe pain	3	0	0	4	3	2
Total (94)	18	12	8	8	38	10
After 10 yr						
No or light pain	8	5	2	2	12	3
Moderate pain	3	6	6	2	14	4
Severe pain	5	0	0	2	1	0
Total (75)	16	11	8	6	27	7

Because of reoperation or death 6 patients were not counted after 4 years and 25 after 10 years.
S = selected for surgery, R = randomized to surgical (RS) or conservative ("RC" + RC+) treatment, C = selected for conservative treatment, "RC" = randomized to conservative treatment except for the cross-over patients to surgery (RC+), "C" = selected for conservative treatment except for the cross-over patients to surgery (C+).

Table 3. Distribution of Patients With Different Degrees of Stenosis (Light, Moderate, or Severe) in the Various Treatment Groups at the Start of the Study

	A						B				
Group	S	RS	"RC"	RC+	"C"	C+	S	R	RS	RC	C
All 100 patients	19	13	8	10	40	10	19	31	13	18	50
Light pain (2)											
Severe stenosis					2						2
Moderate pain (40)											
Light stenosis	0	2	0	2	4	1	0	4	2	2	5
Moderate stenosis	3	3	1	0	10	2	3	4	3	1	12
Severe stenosis	2	1	1	1	6	1	2	3	1	2	7
Severe pain (58)											
Light stenosis	2	2	2	2	2	1	2	6	2	4	3
Moderate stenosis	9	4	2	2	9	4	9	8	4	4	13
Severe stenosis	3	1	2	3	7	1	3	6	1	5	8

The "*de facto* treatment" groups are shown in the left (A) and the "intention to treat" groups in the right (B) set of columns. S = selected for surgery, R = randomized to surgical or conservative treatment, C = selected for conservative treatment, RS = randomized to surgery, "RC" = randomized to conservative treatment except for the later cross-over patients to surgery (RC+), "C" = selected for conservative treatment except for the later cross over-patients to surgery (C+).

Treatment Procedures. After admission to the hospital, all patients remained in the Department of Neurology for a period of 2 weeks, undergoing clinical evaluation and diagnostic procedures (described in a previous article[4] and experiencing 1 week of bed rest. The obtained information formed the basis for the selection of treatment group, as previously described.

The patients offered surgical treatment were transferred to the surgical department for operation. The surgical procedure was standardized for the purpose of nerve decompression by partial or total laminectomy, medial facetectomy, discectomy, and/or removal of osteophytes from the vertebral margins or facet joints. Hypertropic ligamenta flava were removed if necessary. No fusions were performed. The eight surgeons who performed the operations all were instructed to adhere strictly to the same procedure.

The selection of operative level(s) was made by considering primarily the clinically defined level(s), not the severity of the radiologic findings. The operation was performed at one to four levels, unilaterally or bilaterally, depending on the degree of stenosis. Most were multilevel operations: Only 8% (4/52) were one-level operations, whereas 52% (27/52) were two-level, 29% (15/52) three-level, and 11% (6/52) four-level operations. The mean was 2.4 levels. Most operations were at the lower levels: 10% at L2–L3, 40% at L3–L4, 90% at L4–L5, and 90% at L5–S1.

The patients were mobilized within 1 to 2 days and fitted with a 3-point brace (a hyperextension thoracolumbar orthosis with pelvic support/Camp). The orthosis was believed to stabilize the spine and facilitate wound healing after surgery. After 1 week, the patients were transferred to the rehabilitation department for a period of 1 month. Sitting was not allowed during this period, and no specific physiotherapy was given except for instruction and "back school."[58] The patients were encouraged to walk around and move as normally as possible.

The patients selected for conservative treatment also were fitted with the same type of orthosis and transferred to the rehabilitation department for 1 month. The orthosis was worn during the day for all activities, and these patients were encouraged to walk and move around as normally as possible. No regular physiotherapy was given, except for instruction and "back school."[58] The patients who were uncomfortable with the bracing (because of the extended position of the back) were encouraged to bend slightly forward in the orthosis. The physiotherapist and physician (T.A.) collaborated in adjusting of the orthosis.

During the stay in the rehabilitation department, the patients were observed daily by the physiotherapists and three times a week by a physician (T.A.). All the patients, both in the surgical and conservative treatment groups, were discharged from the hospital after 1 month. Further treatment was identical for all groups. The patients continued to wear the orthosis for two more months, whereupon it was removed gradually over a period of 1 month. Thereafter, physiotherapy was started, which consisted of general physical training in the form of ambulation and stabilizing exercises. No attempt was made to improve mobility of the spine, and the patients were instructed to try holding the back in a slightly kyphotic position.

Evaluation During the 10-Year Follow-Up Period. The patients were seen at regular intervals for 10 years by the same physician (T.A.). The follow-up assessments were made at 6 months, 12 months, 4 years, and 10 years. Several additional consultations were necessary for many of the patients. The final assessment, intended to be after 10 years, was carried out in 1996. The observation time was 9 years for the final patients who entered the study (patients in groups C+ and RC+), but a minimum of 10 to 13 years for the others. Additionally, all patients completed questionnaires at 3 months, 2 years, and 3 years.

Most patients entering the study were elderly, and some died during the observation period. During the first 4 years, 3 patients died, and an additional 11 died during the last 6 years of the study. All the deaths resulted from natural causes (*e.g.*, cardio- or cerebrovascular diseases, cancer) seemingly unrelated to the patients' back problems. None of the patients died under circumstances suspicious for suicide. The deaths were distributed rather evenly among the various treatment groups. Otherwise, no dropouts occurred because patient contact was lost.

Because the number of surviving patients in the treatment groups dropped during the long follow-up period, the results were recorded as a fraction. The numerator is the number of patients with a certain treatment result in a given group, and the denominator is the number of surviving patients in that group. This implies that an apparent change of treatment result with time may be the result of deaths in that group.

At the regular follow-up assessments, certain data were recorded. Particular emphasis was laid on the presence of pain and the level of daily activities. The patients told about their different symptoms, stating the intensity of their pain verbally and indicating it on a visual analog scale.[4] Any change from the previous assessment was noted. The patients reported their claudication distance, and the effect of bending forward or backward was recorded. Note was made on whether the patients were working, sick listed, unemployed, disability pensioned, or retired. Activities of daily living, at home and away from work, also were recorded. The consumption of analgesics was noted, but because the authors believed this information to

be unreliable, it was not subjected to further analysis. Finally, a neurologic examination was performed and any change in physical findings recorded.

The patients were asked to evaluate their own situation and to state whether it was better, worse, or unchanged as compared with their condition on entering the study. This, together with the opinion of the examining physician (T.A.) after recording the aforementioned data, constituted the basis for the statement of overall treatment result. Pain, working ability, walking ability, level of physical activity at leisure, and any change in physical findings were considered. When a disagreement appeared, it was discussed by the treatment team (physician and physiotherapist). "Excellent" meant full or almost full restitution considering pain and physical function. "Fair" was reserved for partial restitution, with lesser problems and clear improvement over the condition at entry to the study. Excellent or fair was considered to be a good result. "Unchanged" or "worse" were used when no change or a worsening in the clinical situation from the start of the study could be seen. Unchanged or worse was designated a bad result (treatment failure).

Statistical Methods. In this longitudinal follow-up study, the association of various clinical and radiologic parameters at the start of the study with later treatment outcome was assessed by using parametric and nonparametric tests: one-way analysis of variance (ANOVA) and the Kruskall-Wallis test in the case of non-Gaussian distribution of the outcome variable and when no homogeneity of variances existed in the different groups. In comparing two independent groups, the Student's t test and the Mann-Whitney test were used. The correlation between two continuous variables was investigated by the Pearson correlation coefficient and its 95% confidence limits. The association between polythomous variables was assessed by using contingency χ^2 tables. Concordance between two methods was tested by the kappa test for polythomous variables.[2,33]

Because the situation was observational, the existence of hidden confounders and selection bias made it mandatory for the authors to be descriptive and noninferential. For database and statistics, D-BASE 3 PLUS (Ashton-Tate Corp., Berkeley, CA) and EPI INFO, version 5 (WHO/GPA/RES/SFI/92.2, Atlanta, GA) were used.

Results

Conservative and Surgical Treatments: The First 4 Years

There were no dropouts in this study except for three deaths after 4 years. A survey of the results (the "intention-to treat-results") as stated by the observer (T.A.) is shown in Figure 2 at 6 months, 1 year, and 4 years. The treatment results also were recorded at the other follow-up evaluations, but the deviation from the presented data were small, so for the sake of simplicity, they are omitted in this article.

In Table 4, the concordance between patient and observer regarding treatment result is shown after 6 months. Kappa was 0.592 (*i.e.*, moderate agreement).[2] Similarly, kappa was 0.55 after 1 year, 0.41 after 4 years, and 0.45 after 10 years. The degree of pain is shown for the different treatment groups in Table 2 (after 3 months, 4 years, and 10 years).

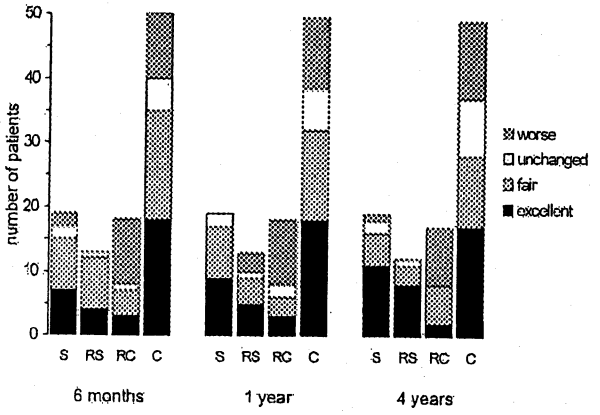

Figure 2. Treatment results after 6 months, 1 year, and 4 years for 100 patients with symptomatic lumbar spinal stenosis. The result for a patient was graded as "excellent," "fair," "unchanged," or "worse" as compared with the start of the study. The height of the vertical columns indicates the number of patients who experienced results in the various categories. Three patients had died after 4 years. The treatment groups correspond to those shown in Figure 1: group S (selected for surgical treatment), group RS (randomized to surgical treatment), group RC (randomized to conservative treatment), group C (selected for conservative treatment).

Conservative Treatment. A good result was reported by 35 (70%) of the 50 patients in group C after 6 months. This dropped to 32 of 50 patients (64%) after 1 year, and further to 28 (57%) of 49 patients (one had died) after 4 years. A poor outcome was not associated with discomfort in using the orthosis.

Surgery. A good result was reported by 15 (79%) of the 19 patients in group S at the first clinical assessment after 6 months, by 17 (89%) of 19 patients after 1 year, and by 16 (84%) of 19 patients after 4 years. Only 2 patients reported being worse after 6 months, none after 1 year, and 1 patient after 4 years. Only 1 of these patients underwent reoperation.

Table 4. Concordance Between Treatment Results After 6 Months as Stated by Examiner and Patient in a Group of 100 Patients With Symptomatic Lumbar Spinal Stenosis

Results (Examiner)	Results (Patient)			
After 6 mo	Worse	Unchanged	Fair	Excellent
Worse	3	0	0	0
Unchanged	2	4	4	0
Fair	1	4	37	4
Excellent	0	0	10	31

Kappa = 0.59, SE (Kappa) = 0.073, Z = Kappa/SE (Kappa) = 8.09, P = 0.0000001. The Kappa indicates good agreement.

The patients who described their treatment result as "worse" were, in the opinion of the observer (T.A.), not poorer than the "worse patients" in the conservative treatment groups. No serious complications (*e.g.*, deep venous thrombosis or cardiac problems) were encountered.

Patients Randomized to Conservative Treatment. Of the 18 patients in group RC, the results were good for only 7 (39%) patients after 6 months. As many as 10 patients (56%) were worse after 6 months. The results were good for 6 (33%) of 18 patients after 1 year, and for 8 (47%) of 17 patients (one had died) after 4 years. In this group, discomfort from the use of the orthosis was not associated with a poor outcome.

Patients Randomized to Surgery. In group RS, a good result was reported for 12 (92%) of 13 patients after 6 months, 9 (69%) of 13 patients after 1 year, and 11 (92%) of 12 patients (one had died) after 4 years. None got worse and none underwent reoperation.

Comparison of the Treatment Results For the First and Last 50 Patients Recruited to the Study. Selection bias during the recruitment period was anticipated, and did indeed occur. Early in the study, a more favorable outcome than expected was noted in the conservatively treated patients. This observation led to an increase in the number of patients selected for conservative treatment in the last half of the patients recruited to the study (increase in threshold for selection to surgery or randomizaton) (Table 5). The treatment results for the first and last 50 patients are shown in Figure 3. The ratio of bad to good results (surgical and nonsurgical treatments counted together), respectively, after 6 months was 15 to 35 for the first 50 patients and 16 to 34 for the last 50 patients. After 1 year, the corresponding ratio, respectively, was 17 to 33 and 19 to 31, and after 4 years 13 to 35 and 21 to /28. Therefore, the best treatment result was achieved by the selection mode used for the first 50 patients. The results in the individual treatment groups are shown in Table 6.

Does a Delay of Surgery Entail a Poorer Prognosis?

Results for the Crossover Patients From Conservative to Surgical Treatment. For the 10 patients in group C+, the results were good for 9 patients (90%) after 6 months, for all 10 patients (100%) after 1 year, and for 7 patients (70%) after 4 years. None had undergone reoperation (Figure 4).

Of the 10 patients in group RC+ the results were good for 9 patients (90%) after 6 months, for 8 patients (80%) after 1 year, and for 4 (44%) of 9 surviving patients after 4 years. One had undergone reoperation.

The results at the 4-year assessment for the 68 patients who received conservative treatment initially (50 in group C and 18 in group RC) also were evaluated. Up to that time, the development of pain had been so unfavorable for 20 of the patients (*i.e.*, approximately one third of the group) that they had to be given surgical treatment. However, because of the favorable result also of

Table 5. Number of Patients in the Different Treatment Groups for the First 50 (Nos. 1–50) and last 50 (Nos. 51–100) Patients Recruited to the Study

Group	Nos. 1–50	Nos. 51–100
S	12	7
RS	10	3
RC	11	7
C	17	33

S = selected for surgical treatment, RS = randomized to surgical treatment, RC = randomized to conservative treatment, C = selected for conservative treatment.

Table 6. Number of Good Results (Numerator) for the Patients Still Alive (Denominator) After 6 Months and 1 and 4 Years for the First 50 (Nos. 1–50) and Last 50 (Nos. 51–100) Patients in All Treatment Groups (See Figure 1) of 100 Patients With Symptomatic Lumbar Spinal Stenosis

	Treatment Groups							
	S		RS		RC		C	
	1–50	51–100	1–50	51–100	1–50	51–100	1–50	51–100
6 mo	10/12	5/7	9/10	3/3	6/11	1/7	10/17	25/33
1 yr	12/12	5/7	7/10	2/3	5/11	1/7	9/17	23/33
4 yr	9/12	7/7	8/9	3/3	7/10	1/7	11/17	17/32

S = selected for surgical treatment, RS = randomized to surgical treatment, RC = randomized to conservative treatment, C = selected for conservative treatment.

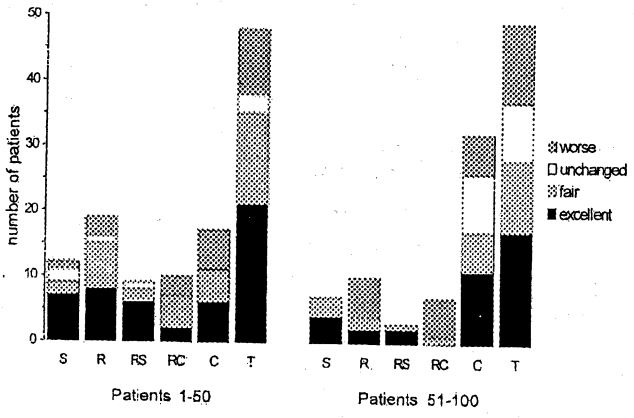

Figure 3. Treatment results after 4 years compared with the start of the study as stated by the observer for the first 50 patients (numbers 1–50) and the last 50 patients (numbers 51–100). Three patients died. The treatment groups correspond to those shown in Figure 1: group S (selected for surgical treatment), group R (selected for randomization between surgical or conservative treatment), group RS (randomized to surgical treatment), group RC (randomized to conservative treatment), group C (selected for conservative treatment). T (total) indicates the result in all patients from 1 to 50 or from 51 to 100.

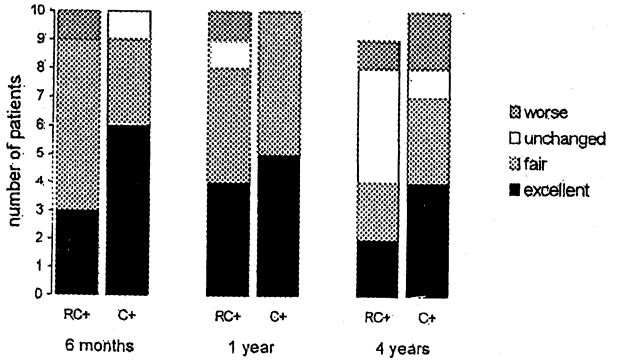

Figure 4. Treatment results for crossover patients from conservative to surgical treatment compared with the start of the study. group RC+ (n = 10) includes crossover patients from patients randomized to conservative treatment (group RC; see Figure 1). One patient had died at the 4-year control assessment. group C+ (n = 10) includes crossover patients from patients selected for conservative treatment (group C; see Figure 1).

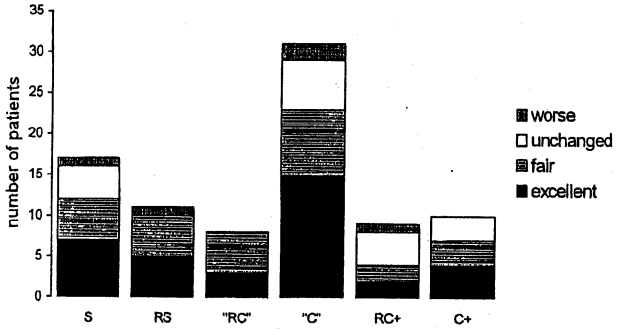

Figure 5. Treatment results after 10 years compared with the start of the study. Fourteen patients died. The treatment groups S (selected for surgery) and RS (randomized to surgery) correspond to those shown in Figure 4. The remaining patients in groups RC and C are designated groups "RC" and "C".

delayed surgery, the final result of initial conservative treatment followed by surgery was not greatly inferior to that of initial surgical treatment. Therefore, the outcome after 4 years for the 50 patients selected to group C was that 21 patients reported an excellent result, 14 a fair result, 10 an unchanged result, and 4 a worse result, meaning that 35 (71%) of 49 patients got a good result. One had died dead. Similarly, of the 18 patients in group RC, 4 reported an excellent result, 8 a fair result, 4 an unchanged result, and 1 a worse result at the 4-year assessment, giving a good result for 12 (71%) of the 17 patients. One had died.

Results After 10 Years

Except for death, there were no dropouts. After 10 years, 14 patients had died: 2 in group S, 9 in group C, 2 in group RS, and 1 in group RC. In addition groups C and RC were reduced by the crossover patients to delayed surgery. The number of patients after 10 years was 17 in group S, 31 in group "C," 11 in group RS, 8 in group "RC," 9 in group RC+, and 10 in group C+.

The treatment results were relatively stable during the final 6 years of the observation period (Figure 5). Group S showed a modest decrease in good results, from 16 (84%) of 19 to 12 (71%) of 17 patients, but this is explained partly by the death of two patients who had good treatment results up to their death. In the other groups, good results were experienced by 10 (91%) of 11 patients in group RS, 8 (100%) of 8 patients in group "RC," 4 (44%) of 9 patients in group RC+, 23 (74%) of 31 patients in group "C," and 7 (70%) of 10 patients in group C+.

In the original conservative treatment groups, the good "de facto results" were experienced by 12 (71%) of 17 patients in group RC ("RC" and RC+ combined) and 30 (73%) of 41 patients in group C ("C" and C+ combined). There were two more reoperations in group RC+, and three in group C+, but in the tables mentioned in this article, they have been counted as treatment failures, independently of the final treatment result.

The good "de facto results" in the original selected treatment groups after 4 and 10 years, respectively, were 84% and 71% for group S, 77% and 79% for group R (randomized group), and 71% and 73% for group C.

Changes in Clinical Parameters During the Follow-Up Period

Pain. According to the completed questionnaires, the pain was greatly relieved already after 3 months. For most of the patients, the relief of pain occurred earlier than 3 months, whereas for others it took a year. The reduction of pain for the patients in the different treatment groups during the follow-up period is shown in Table 2.

No pain was experienced by 16 of all 100 patients after 3 months, by 22 of 97 surviving patients after 4 years, and by 35 of 86 surviving patients after 10 years. These changes were distributed evenly in the surgical and conservative treatment groups (not shown in Table 2). After 3 months, 19 patients felt pain in the back, 19 in the leg(s), and 46 in both areas. Similarly, after 4 years the numbers, respectively, were 14, 4, and 56, and finally after 10 years 15, 5, and 31. At the follow-up assessments up to 4 years, the surgically treated patients reported more pain from the back than the conservatively treated patients. However, after 10 years there was no difference.

Many patients felt support by wearing the orthosis and continued to wear it periodically. These patients were evenly distributed in the surgical and conservative treatment groups. Some preferred the hyperextension orthosis, others a simple elastic support. The use of an orthosis declined during the follow-up period. At the final 10-year assessment, 52 patients, mostly men, still used an orthosis periodically.

Claudication. At the start of the treatment period, claudication was reported by 90% of the patients. For 60 of these patients, the symptoms were relieved by bending slightly forward in the back (thereby reducing the lumbar lordosis). After treatment, claudication was much reduced, both in occurrence and intensity. During the first 4 years, one third of the patients reported some degree of claudication, but from 4 to 10 years, this proportion was reduced to one fifth (14 patients). Eleven of these patients felt relief of the pain by bending forward. There was no difference between surgically and conservatively treated patients. At the start of the study, the median walking distance was 300 m in the surgically treated groups and 500 m in the conservatively treated groups, but with large variations. After 3 months, the median walking distance was 1000 m and remained stable thereafter.

Level of Daily Activity. When the patients entered the study, 19 were at work: 12 in the conservative treatment groups and 7 in the surgical treatment groups. This was unchanged after 3 months (13 and 6, respectively). After 6 months, 37 patients were at work (20 in the conservative treatment groups and 17 in the surgical treatment groups). The patients at work after 1 year were 34 (17 in each group), after 4 years 21 (9 and 12, respectively), and after 10 years 13 (6 and 7, respectively). These figures represent the "*de facto* figures," which means that the patients with delayed surgery are included in the surgical treatment group. After 10 years, 40 patients had retired from work because of advanced age, as compared with 15 patients at the start of the study.

Neurologic Deficits. Neurologic deficits were modest at the start of this study.[4] The changes during the 10 years were minimal. Six patients had mild signs of cauda equina (perianal numbness), and these patients all underwent surgery. The numbness disappeared in five of these patients after surgery, but persisted in one patient (also after a second operation 5 years later). Before treatment, a positive Lasègue's sign was found in 24 patients (9 from the conservative treatment groups and 15 from the surgical treatment groups), after 4 years in 5 patients (1 and 4, respectively) and after 10 years in 4 patients (1 and 3, respectively).

Interrelation Between Treatment Results and Clinical or Radiologic Features at the Start of the Study

Treatment Results and Clinical Features. The age, gender, social status (married/not married), type of work/physical loading, satisfaction at home and at work, duration of pain, length of sick listing, level of physical activity, smoking habits, physical findings, Lasègue's sign, and level of spinal protein were compared with the treatment results. No convincing associations were observed. Multilevel surgery did not entail a poorer outcome than single-level operations (Table 7).

Table 7. Lack of Association Between Treatment Result and Number of Surgically Treated Levels for 50 Early- and Delayed-Surgery Patients With Symptomatic Lumbar Spinal Stenosis 4 Years After Treatment

	Number of Surgically Treated Levels				
Result	1	2	3	4	Total
Worse	0	3	0	1	4
Unchanged	1	3	4	0	8
Fair	2	4	6	1	13
Excellent	1	16	5	3	25
Total	4	26	15	5	50

The number of patients was too small for statistical χ^2 tests even after grouping.

Treatment Results and Radiologic Features. An attempt was made to discover an association between results of treatment and different radiologic parameters. The following were examined and compared with the treatment results: degenerative changes (spondylosis, osteochondrosis) at different parts of the vertebral segment (disc, facet joint, vertebral canal, lateral recesses), occurrence of pseudospondylolisthesis (slip), occurrence of transition vertebrae, type of stenosis (central or lateral, congenital, developmental, acquired), occurrence of redundant nerve roots, degree of narrowness, root affliction (degree, number of afflicted roots, uni- or bilateral disorder), and measures of different dimensions in the spinal canal (sagittal diameter, interpedicular distance, pedicle length). No convincing associations were found. The lack of association between the results after 4 years and the degree of narrowness in the spinal canal of the surgically treated patients is shown in Table 8.

Discussion

The protocol outlined for the current study was intended to ensure that each patient was given the treatment best for him or her at all times during the long follow-up period. The authors believed that it was unethical to operate on patients with mild symptoms, or to deny surgery for patients with severe symptoms. Randomization between conservative treatment and surgery was acceptable only for patients about whom serious doubt existed concerning which treatment should be recommended.

Table 8. Lack of Association Between Results and Degree of Narrowness for 50 Early- and Delayed-Surgery Patients With Symptomatic Lumbar Spinal Stenosis 4 Years After Treatment

	Degree of Narrowness			
Result	Light	Moderate	Severe	Total
Bad	4	6	2	12
Good	8	20	10	38
Total	12	26	12	50

$\chi^2 = 0.94$, 2 degrees of freedom, $P = 0.625$.