

A Comparison Between Two Physical Therapy Treatment Programs for Patients With Lumbar Spinal Stenosis

A Randomized Clinical Trial

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Study Design. Multicenter randomized, controlled trial.

Objective. To compare two physical therapy programs for patients with lumbar spinal stenosis.

Summary of Background Data. Scant evidence exists regarding effectiveness of nonsurgical management programs for lumbar spinal stenosis.

Methods. Fifty-eight patients with lumbar spinal stenosis were randomized to one of two 6-week physical therapy programs. One program included manual physical therapy, body weight supported treadmill walking, and exercise (Manual Physical Therapy, Exercise, and Walking Group), while the other included lumbar flexion exercises, a treadmill walking program, and subtherapeutic ultrasound (Flexion Exercise and Walking Group). Perceived recovery was assessed with a global rating of change scale. Secondary outcomes included: Oswestry, a numerical pain rating scale, a measure of satisfaction, and a treadmill test. Testing occurred at baseline, 6 weeks, and 1 year. Perceived recovery, pain, and other healthcare resources used were collected with a long-term follow-up questionnaire.

Results. A greater proportion of patients in the manual physical therapy, exercise, and walking group reported recovery at 6 weeks compared with the flexion exercise and walking group ($P = 0.0015$), with a number needed to treat for perceived recovery of 2.6 (confidence interval,

1.8–7.8). At 1 year, 62% and 41% of the manual therapy, exercise, and walking group and the flexion exercise and walking group, respectively, still met the threshold for recovery. Improvements in disability, satisfaction, and treadmill walking tests favored the manual physical therapy, exercise, and walking group at all follow-up points.

Conclusions. Patients with lumbar spinal stenosis can benefit from physical therapy. Additional gains may be realized with the inclusion of manual physical therapy interventions, exercise, and a progressive body-weight supported treadmill walking program.

Key words: lumbar spine, stenosis, spinal stenosis, physical therapy, rehabilitation, physiotherapy, RCT, clinical trial. **Spine 2006;31:2541–2549**

Lumbar spinal stenosis (LSS) is a prevalent and disabling condition in the aging population that often results in substantial physical burden for individuals with the disorder, and is associated with significant healthcare costs.^{1–4} An estimated 13% to 14% of those patients who seek help from a specialty physician, and 3% to 4% who seek care from a general practitioner for low back pain (LBP), are diagnosed with LSS.^{1,3,5,6} Just over a decade ago, LSS was noted as the most common diagnosis associated with spinal surgery in patients over 65 years of age, with an estimated total annual inpatient expense of 1 billion dollars for over 30,000 surgical procedures performed.^{2,4,7} A recent report by Deyo *et al* reveals that this trend has continued: the number of fusion procedures performed for LSS has continued to grow steadily into the 21st century.⁸ As the population continues to age, providing medical care for patients with LSS will continue to adversely affect healthcare resources, thus identifying effective treatment options for these patients is an important research priority.

It has been suggested that patients with LSS should receive a trial of conservative management before surgery is considered.^{1,9} However, a recent report revealed that only 10% of the clinical trials investigating outcomes from surgery for LSS reported that patients received, and did not improve with, a period of conservative management.¹ To date, we have not identified any randomized clinical trial (RCT) evidence to inform nonsurgical treatment-related decision-making. Of the three studies specifically investigating nonsurgical clinical outcomes of care in patients with LSS,^{10–12} the study with

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the largest cohort of patients¹⁰ was limited to short-term outcomes. Other studies^{11,12} did report longer-term outcomes but were retrospective, and interpretation is confounded by the use of highly variable interventions. Further, these studies failed to incorporate patient-centered outcome measures. Despite methodologic limitations, these studies reveal that roughly one half to two thirds of patients treated nonsurgically either improve or remain in status quo at the time of follow-up.^{11,12} Despite a commonly held belief that patients with LSS may be at risk for an inevitable decline in health status over time, the peer-reviewed literature related to nonsurgical management of these patients does not support this concern.^{13–17}

Given the prevalence and cost associated with LSS, and the lack of strong evidence for nonsurgical care for these patients, developing optimal nonoperative management strategies is a high priority. Therefore, the purpose of this study was to compare the clinical outcomes achieved by patients receiving two different programs. Based on preliminary work,^{18,19} we hypothesized that patients receiving a program, including manual physical therapy, exercise, and a body weight supported ambulation program, would achieve better outcomes compared with the patients receiving lumbar flexion exercises, subtherapeutic ultrasound, and a treadmill walking program without body weight support.

■ Materials and Methods

Patients with a clinical presentation consistent with LSS were recruited from referral sources within medical centers in San Antonio, TX. Referring clinicians ordered lumbar spine MRIs of potential study participants, who were subsequently screened for eligibility by one of two physician specialists within the orthopedic and neurosurgery departments to establish a diagnosis of LSS based on the clinical examination and MRI findings. These physician specialists also provided MRI readings, including information regarding degrees of central and foraminal stenosis, anterolisthesis and retrolisthesis, and degree of scoliosis. Inclusion criteria included: pain in the lumbopelvic region and lower extremities, ≥ 50 years of age, MRI findings consistent with LSS (evidence of compression of lumbar spinal nerve root(s) by degenerative lesions of the facet joint, disc, and/or ligamentum flavum), and patient rating of sitting as a better position for symptom severity than standing or walking.

Patients meeting any of the following criteria were excluded: severe vascular, pulmonary, or coronary artery disease limiting participation in a walking tolerance test or walking program (including presence of absolute contraindications to submaximal exercise testing)²⁰; previous lumbar spinal surgery that included fusion; history of spinal tumors or infection, or lumbar vertebral fractures other than spondylolysis or spondylolisthesis; contraindications for lumbar spine MRI; and signs/symptoms suggestive of potential nonbenign or pathologic condition as the origin of symptoms. All patients provided informed consent before participation. The study was approved by the Institutional Review Boards at Wilford Hall Medical Center and Brooke Army Medical Center in San Antonio, TX.

All baseline information was obtained before randomization. Research assistants (experienced physical therapists) confirmed satisfaction of inclusion/exclusion criteria, obtained informed consent, collected self-report questionnaires, completed historical examinations, and conducted treadmill walking tolerance tests.²¹ All research assistants received individual training and written instruction on all procedures by the primary investigator. Patients were assigned to a treating physical therapist, and that therapist completed baseline physical examinations. Random assignment to treatment groups was performed using a computer-generated randomization scheme prepared in blocks of 20 patients. Before beginning the study, opaque, sequentially numbered sealed envelopes were prepared indicating the group assignment. After completion of the physical examination, the treating therapist opened the envelopes revealing the results of randomization. Research assistants, blinded to group allocation, readministered self-report questionnaires and treadmill tests at completion of the treatment period and at 1 year.

In addition to the 6-week and 1-year follow-up testing sessions, a long-term follow-up questionnaire was sent to patients in the spring of 2004 to collect information regarding subsequent utilization of health care and medication, current pain levels, and perceived recovery. For patients not responding to the first mailing and for those who had not yet completed their treatment programs at the time of the first mailing, repeat questionnaires were sent in the spring of 2005. A research assistant who was blind to group allocation attempted to contact remaining nonresponders *via* telephone.

Interventions. Patients were scheduled for twelve 45- to 60-minute physical therapy sessions over 6 weeks (twice weekly). In addition to the physical therapy visits, all patients were asked to take a daily walk at a pace and distance that did not irritate lower extremity symptoms and to perform a home exercise program. The patients completed exercise logs during the 6-week treatment duration, and also provided a self-report of their exercise compliance during both the 6-week intervention period and from 6 weeks to 1 year. The eight treating physical therapists in this study were experienced manual physical therapists, 7 of whom were Fellows of the American Academy of Orthopedic Manual Physical Therapists. These therapists performed all interventions except for the treadmill walking programs, which were supervised by Physical Therapy Assistants who were trained in study procedures.

Flexion Exercise and Walking Group (FExWG). Treatment for this group included lumbar flexion exercises, performance of a progressive treadmill walking program, and subtherapeutic ultrasound. Specifically, patients received 10 minutes of 3 MHz, 0.1 W/cm² intensity, pulsed ultrasound with the intention of minimizing the possible therapeutic effects of the treatment²² and mitigating the potential for an attention effect to occur. Flexion exercises included three 30-second bouts of both single- and double-knee-to-chest exercises performed during physical therapy visits and as part of the home exercise program. This program also included a level treadmill walking session during each visit. Patients were encouraged to maintain a self-selected comfortable walking pace for the duration of the session and were advised to stop walking when symptoms reached the point that would typically cause them to stop walking during normal community ambulation. The du-

ration of each treadmill session was based on that patient's tolerance on that specific day and could extend up to 45 minutes.

Manual Physical Therapy, Exercise, and Walking Group (MPTEWG). Patients in this group received manual physical therapy to the thoracic and lumbar spine, pelvis, and lower extremities. The manual therapy was eclectic and included techniques such as those described by Maitland,²³ Greenman,²⁴ and Whitman *et al.*¹⁸ Selection of specific manual physical therapy interventions and exercise techniques was based on the underlying impairments identified by the treating physical therapist, and included both thrust and nonthrust manipulation of the spine and lower extremity joints, manual stretching, and muscle strengthening exercises. Therapists instructed patients in specific exercises to address impairments in mobility, strength, and/or coordination, including instruction in the same flexion exercises for the lumbopelvic region as prescribed for the FEXWG. Exercises were performed in the clinic and as part of a home exercise program. The typical dosage for exercises addressing mobility was three bouts of 30 seconds, and typical dosage for stretching exercises was 3 repetitions of 30 seconds of stretching. Strengthening exercises were tailored to fit the individual patient's needs. Finally, patients participated in a body-weight supported (BWS) treadmill ambulation program. BWS systems use a cable and trunk harness system to unload a specific amount of weight from the patient while the patient walks on a treadmill. Compressive forces, or axial loading, has been demonstrated to decrease the cross-sectional area (CSA) of the neuroforamen and central spinal canal and non-weight-bearing positions have been demonstrated to increase CSAs.^{25–30} Because BWS systems decrease the downward excursion of the center of gravity and decrease the ground reaction forces associated with gait,^{31,32} BWS should theoretically decrease axial compression forces, increase CSAs, and improve

walking tolerance. We included BWS treadmill walking based on this theoretical background, preliminary evidence from two small case series,^{18,19} and based on our clinical experience with this intervention. The amount of support used for each treadmill session was the minimum amount of unloading required to minimize the patient's symptoms and to allow the patient to walk as comfortably as possible. The overall goal was to decrease the amount of body weight support used over the duration of the study and gradually increase walking pace and distance.

All patients were allowed to continue with previously prescribed medications or over-the-counter medications for their symptoms associated with LSS but were advised not to change the dosage of these medications in the 6 weeks before the baseline testing or during the 6-week treatment period. No epidural steroid injections were performed from 6 weeks before the baseline testing session through the end of the treatment period. Any cointerventions were recorded by research assistants at the 1-year follow-up testing session and by the patients in their long-term follow-up questionnaires. See the online Appendix (flash file) for further description and video illustration of the intervention programs used in this study.

Outcome Measures. Data regarding perceived recovery, disability, pain, satisfaction, and function were collected at baseline, at the end of the treatment program (6 weeks), and at 1 year. Long-term follow-up questionnaires were used to collect data regarding healthcare utilization, medication usage, pain, and perceived recovery. The patient global rating of change scale (GRC) as described by Jaeschke *et al.*, served as the primary outcome measure.³³ The GRC is a 15-point Likert scale whereby patients rate their own perceived amount of improvement.³³ The scale ranges from -7 ("a very great deal worse") to zero ("about the same") to $+7$ ("a very great deal better").

Table 1. Baseline Variables: Demographics, Outcome Measures, and Physical Impairments

Variable	Flexion Exercise and Walking Group (n = 29)	Manual Physical Therapy, Exercise, and Walking Group (n = 29)	Significance (P)
Age (yr)	70.0 (7.2)	68.9 (8.7)	0.60
Female [n (%)]	17 (56.7)	10 (33.3)	0.06*
Race [n (%)]			0.15*
White	26 (89.8)	20 (69.0)	
Black	1 (3.4)	3 (10.3)	
Hispanic	2 (6.9)	6 (20.7)	
Body mass index (kg/m ²)	27.60 (4.38)	28.27 (4.51)	0.63
Median duration LBP (mo)	108 (0–804)	60 (6–744)	0.69†
Median duration LE symptoms (mo)	48 (3–804)	24 (3–744)	0.40†
Patients with bilateral LE symptoms [n (%)]	16 (55.2)	16 (55.2)	1.00
Modified Oswestry Disability Index	39.3 (13.6)	35.8 (13.8)	0.40
Numeric Pain Rating Scale (for Lower Extremity Pain)	5.48 (2.11)	5.05 (2.45)	0.49
SSS_Symptom Severity Subscale	3.10 (0.48)	3.08 (0.55)	0.83
SSS_Function Subscale	2.40 (0.52)	2.24 (0.51)	0.33
Beck Depression Inventory	7.12 (4.25)	6.10 (4.92)	0.40
Treadmill walking distance (m)	639.30 (457.88)	673.05 (436.93)	0.74
Standing total flexion range of motion (°)	82.0 (22.2)	79.8 (18.8)	0.68
Standing extension range of motion (°)	16.1 (6.6)	17.5 (6.3)	0.42
Average straight leg raise (°)	64.7 (16.6)	63.3 (12.8)	0.73
Abnormal neurologic findings (L4, L5, or S1) [n (%)]	16 (55.2)	16 (55.2)	1.00

Mean (SD) reported unless otherwise stated.

* χ^2 test.

†Mann-Whitney U test; Modified Oswestry Disability Index: range, 0%–100%; higher scores represent higher levels of disability. Numeric Pain Rating Scale: range, 0–10; 0 = "no pain"; 10 = "worst pain imaginable." SSS = Spinal Stenosis Scale. Symptom Severity Subscale: range, 1–5; lower scores represent lower levels of symptoms. Function Subscale: range, 1–4; lower scores represent greater levels of function.

Table 2. Self-Reported Demographics General Health and Comorbidities at Baseline

Variable	Flexion Exercise and Walking Group (n = 29)	Manual Physical Therapy, Exercise, and Walking Group (n = 29)
Self-reported general health		
Poor	2 (6.9)	1 (3.4)
Fair	7 (24.1)	7 (24.1)
Good	18 (62.1)	21 (72.4)
Excellent	1 (3.4)	0 (0)
Not reported	1 (3.4)	0 (0)
Hypertension	21 (72.4)	21 (72.4)
Diabetes	6 (20.7)	5 (17.2)
Cancer	4 (13.8)	7 (24.1)
Cerebrovascular accident or transient ischemic attack	3 (10.3)	2 (6.9)
Chronic obstructive pulmonary disease or asthma	5 (17.2)	5 (17.2)
Prior cardiac procedures	6 (20.7)	9 (31.0)
History of falls	6 (20.7)	5 (17.2)
Hip or knee osteoarthritis	18 (62.1)	12 (41.4)
Hip or knee replacement	3 (10.3)	1 (3.4)
Prior lumbar spine surgery (laminectomy)	0 (0)	1 (3.4)

Values are n (%).

We dichotomized scores on the GRC based on “perceived recovery,” with scores of +3 (“somewhat better”) or greater defining “improvement.”

Secondary outcomes included the Modified Oswestry Disability Index (OSW),³⁴ the Satisfaction Subscale of the Spinal Stenosis Scale (SSS),^{35,36} a Numerical Pain Rating Scale (NPRS)³⁷ for average thigh/leg pain, a walking tolerance test, and other healthcare resources used. The SSS Satisfaction Subscale was modified from the original scale^{35,36} by replacing the word “surgery” with the word “treatment” in each question. For the measure of walking tolerance, patients walked at a self-selected pace for up to 15 minutes on a level surface, rested for 10 minutes in a seated posture, then walked again for up to 15 minutes at a 15% grade incline. The combined distance walked was used as a marker of walking tolerance. Because the OSW, SSS, and NPRS have not been validated in this population of patients treated with nonsurgical intervention strategies, these self-report questionnaires were not used as primary outcomes.

Sample Size Determination and Statistical Analysis. Sample size was calculated based on the dichotomized score of the primary outcome measure, “perceived recovery.” A difference of 30% or more in success rate (“perceived recovery”) was considered to be clinically important. Power was set *a priori* at 0.8, alpha = 0.05, a minimum of 30 patients per treatment group was required to achieve significance using a one-tailed Pearson χ^2 test. All analyses were performed using SPSS statistical software, version 11.5 (SPSS Inc., Chicago, IL). All patients meeting inclusion/exclusion criteria were included in all analyses according to intention-to-treat principles (last available score forward). Baseline status of the treatment groups and compliance with the home exercise program were compared using two-tailed independent samples *t* tests, χ^2 tests of independence, and Mann-Whitney U tests as indicated. A one-tailed Pearson χ^2 test was used to identify significant associations between group membership and perceived recovery at 6-week, 1-year, and long-term follow-up. Alpha was set at 0.05 for all analyses. To further illustrate the value of our findings to clinicians, we calculated number needed to treat statistics for perceived recovery at 6-week, 1-year, and at the long-term follow-up. Mean improvements and differences between groups with 95% confidence intervals were calculated for each of the secondary outcome measures.

■ Results

Sixty patients were enrolled over a 43-month period (June 2001 to December 2004). The mean time of follow-up for the long-term follow-up questionnaire was 29 months (± 10.5) for the FExWG and 27.4 months (± 10.1) for the MPTEWG. No significant baseline differences were identified for demographics, baseline physical impairment, or outcomes (Table 1). Patient self-reported health status and comorbidities are reported in Table 2, and baseline MRI findings for central and foraminal stenosis are reported in Tables 3 and 4. At the baseline examination, 32 subjects were noted to have scoliosis (7 subjects $<10^\circ$; 21 subjects 11° – 30° ; 4 subjects 30° – 50°), 12 subjects had identified lumbar spine retrolisthesis (4 in the FExWG, 8 in the MPTEWG), and 24 had lumbar anterolisthesis (9 in the FExWG, 15 in the MPTEWG). Finally, there was no difference in self-reported home exercise compliance between groups during the 6-week treatment period or in the time period between the 6-week and 1-year follow-up session.

Table 3. No. of Patients With Central Spinal Stenosis at Each Spinal Level

	Flexion Exercise Walking Group (n = 28)			Manual Physical Therapy Exercise Walking Group (n = 28)		
	Mild Stenosis (12–15 mm)	Moderate Stenosis (10–12 mm)	Severe Stenosis (<10 mm)	Mild Stenosis (12–15 mm)	Moderate Stenosis (10–12 mm)	Severe Stenosis (<10 mm)
L1–L2	6 (20.7)	1 (3.4)	0 (0)	6 (20.7)	1 (3.4)	0 (0)
L2–L3	7 (25.0)	5 (17.9)	2 (7.1)	2 (7.1)	7 (25.0)	3 (10.7)
L3–L4	5 (17.9)	7 (25.0)	8 (28.6)	9 (32.1)	7 (25.0)	4 (14.3)
L4–L5	6 (21.4)	5 (17.9)	12 (42.9)	1 (3.6)	10 (35.7)	15 (53.6)
L5–S1	7 (25.0)	3 (10.7)	5 (17.9)	7 (25.0)	3 (10.7)	4 (14.3)

Values are no. of patients with findings at respective spinal levels (percentage of sample in parentheses).

Table 4. No. of Patients With Lateral Foraminal Stenosis at Each Spinal Level

	Flexion Exercise and Walking Group (n = 20)			Manual Physical Therapy, Exercise, and Walking Group (n = 24)		
	Mild Stenosis	Moderate Stenosis	Severe Stenosis	Mild Stenosis	Moderate Stenosis	Severe Stenosis
L1–L2 left	1 (5.0)	0 (0)	0 (0)	1 (4.2)	0 (0)	1 (4.2)
L1–L2 right	1 (5.0)	0 (0)	0 (0)	1 (4.2)	0 (0)	0 (0)
L2–L3 left	5 (25.0)	1 (5.0)	0 (0)	3 (12.5)	3 (12.5)	0 (0)
L2–L3 right	6 (30.0)	0 (0)	0 (0)	3 (12.5)	2 (8.3)	1 (4.2)
L3–L4 left	2 (10.0)	4 (20.0)	3 (15.0)	7 (29.2)	6 (25.0)	0 (0)
L3–L4 right	5 (25.0)	3 (15.0)	3 (15.0)	6 (25.0)	7 (29.2)	0 (0)
L4–L5 left	4 (20.0)	2 (10.0)	4 (20.0)	7 (29.2)	6 (25.0)	4 (16.7)
L4–L5 right	6 (30.0)	1 (5.0)	5 (25.0)	5 (20.8)	9 (37.5)	3 (12.5)
L5–S1 left	4 (20.0)	3 (15.0)	5 (25.0)	8 (33.3)	2 (8.3)	6 (25.0)
L5–S1 right	4 (20.0)	4 (20.0)	2 (10.0)	7 (29.2)	2 (8.3)	5 (20.8)

Values are no. of patients with findings at respective spinal levels (percentage of sample in parentheses).

Two patients were excluded in the first week of enrollment due to detection of previously missed exclusion criteria as the primary source of their symptoms (peripheral vascular disease, cancer). These patients were considered to have not enrolled in the study and were not included in any analyses. Three patients who met the inclusion/exclusion criteria dropped out after the 6-week follow-up for reasons unrelated to the study (2 from the FExWG, 1 from the MPTEWG). For the long-term follow-up questionnaire, 3 patients in each group were lost to follow-up, 2 patients in the MPTEWG had died, and

1 patient failed to respond to the mailing and phone contact. See Figure 1 for the CONSORT diagram regarding patient flow through the study.³⁸

Several patients did not perform the treadmill (TM) testing portion of the testing sessions. One patient requested not to complete TM testing due to concerns about hypertension. Two patients did not perform the 6-week or 1-year TM tests due to: 1) seasonal allergy exacerbation and 2) unrelated grand mal seizure. Nine other patients did not perform the TM test at 1 year: 1 died, 3 developed cardiac conditions classified as abso-

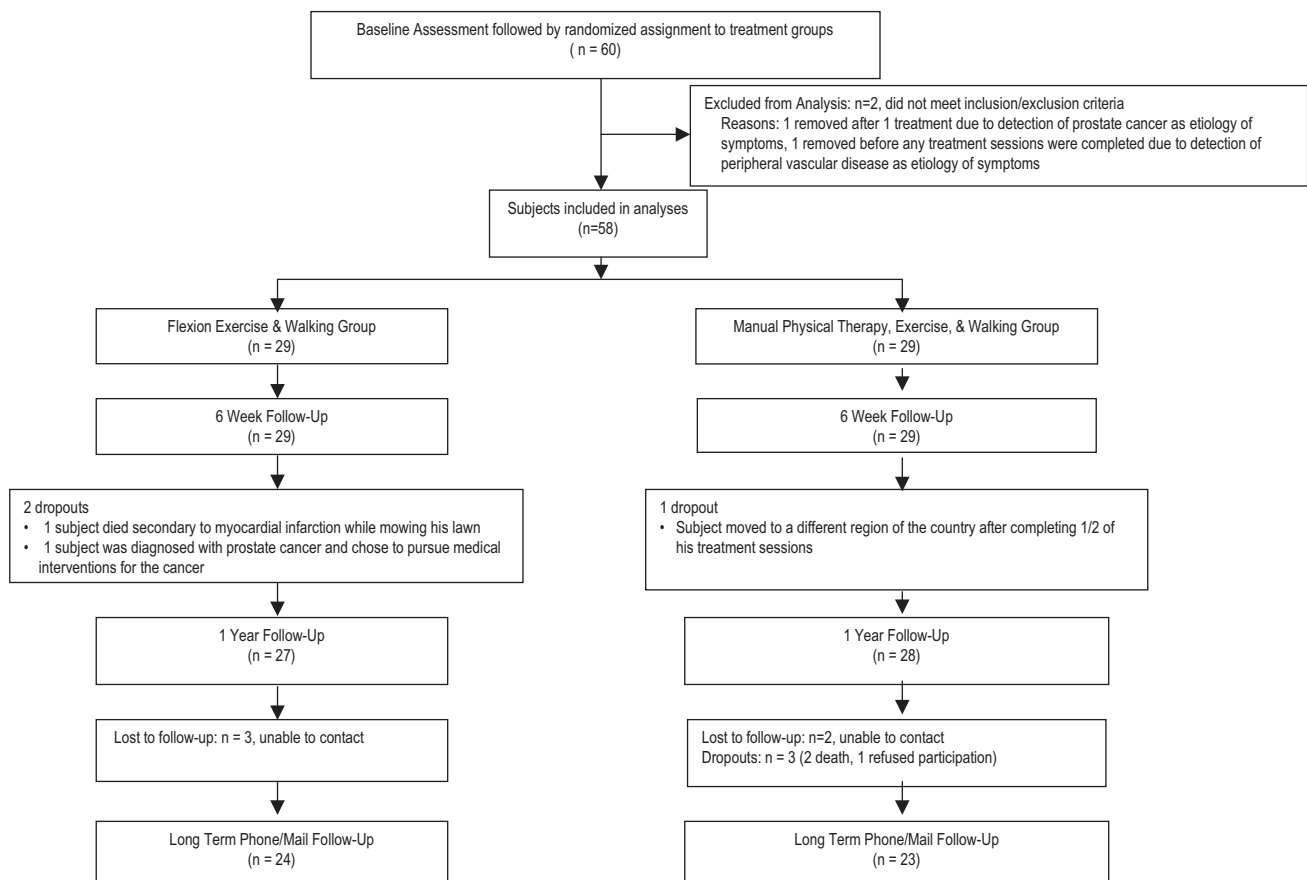


Figure 1. Flow chart depicting the flow of subjects through the trial.

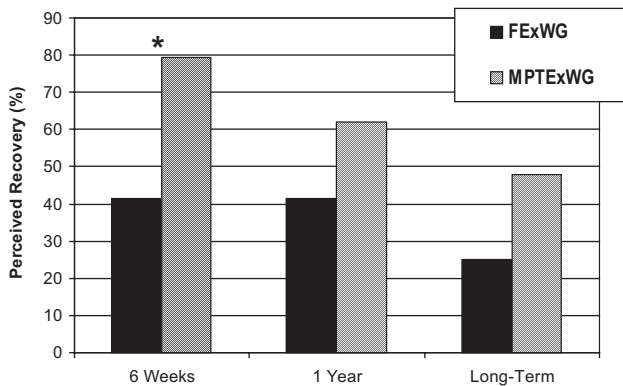


Figure 2. Perceived recovery at 6 weeks and 1 year: percent of each group meeting threshold for perceived recovery. *Significant association between treatment group and perceived recovery ($P = 0.0015$). Long term = data from long-term follow-up questionnaire. Mean time of follow-up: 29 months (+10.5 months) for the FExWG and 27.4 months (+10.1 months) for the MPTEExWG.

lute contraindications per ACSM guidelines,¹⁶ and 5 refused (1 unknown reason, 1 to stay with terminally ill wife, 1 with recent injury, 1 receiving care for prostate cancer, 1 did not want to exacerbate his LBP).

At 6 weeks, there was a significant association between treatment group and perceived recovery ($P =$

0.0015) (Figure 2), with 79% of patients in the MPTEExWG meeting the threshold for perceived recovery compared with 41% of patients in the FExWG. At 1 year, 62% of the MPTEExWG and 41% of the FExWG continued to report recovery, and 38% and 21% of the MPTEExWG and FExWG, respectively, still met the threshold for recovery at long-term follow-up. However, there was no longer a significant association between group and perceived recovery at either time period. The number needed to treat for benefit for perceived recovery was 2.6 (confidence interval [CI], 1.8 to 7.8) at 6 weeks, 4.8 (CI, -2.3 to 21.3) at 1 year, and 4.4 (CI, -2.1 to 22.7) at the long-term follow-up. All of the secondary outcomes favored the MPTEExWG at 6 weeks and 1 year except improvements in NPRS for lower extremity symptoms from baseline to 1 year; however, these differences were not statistically significant (Figure 3; Table 5). Lastly, Table 6 shows the healthcare utilization data acquired from the long-term follow-up questionnaires.

All patients who met the inclusion/exclusion criteria were included in all analyses regardless of their dropout status or completion of TM testing per intention-to-treat principles by carrying the last available value forward.

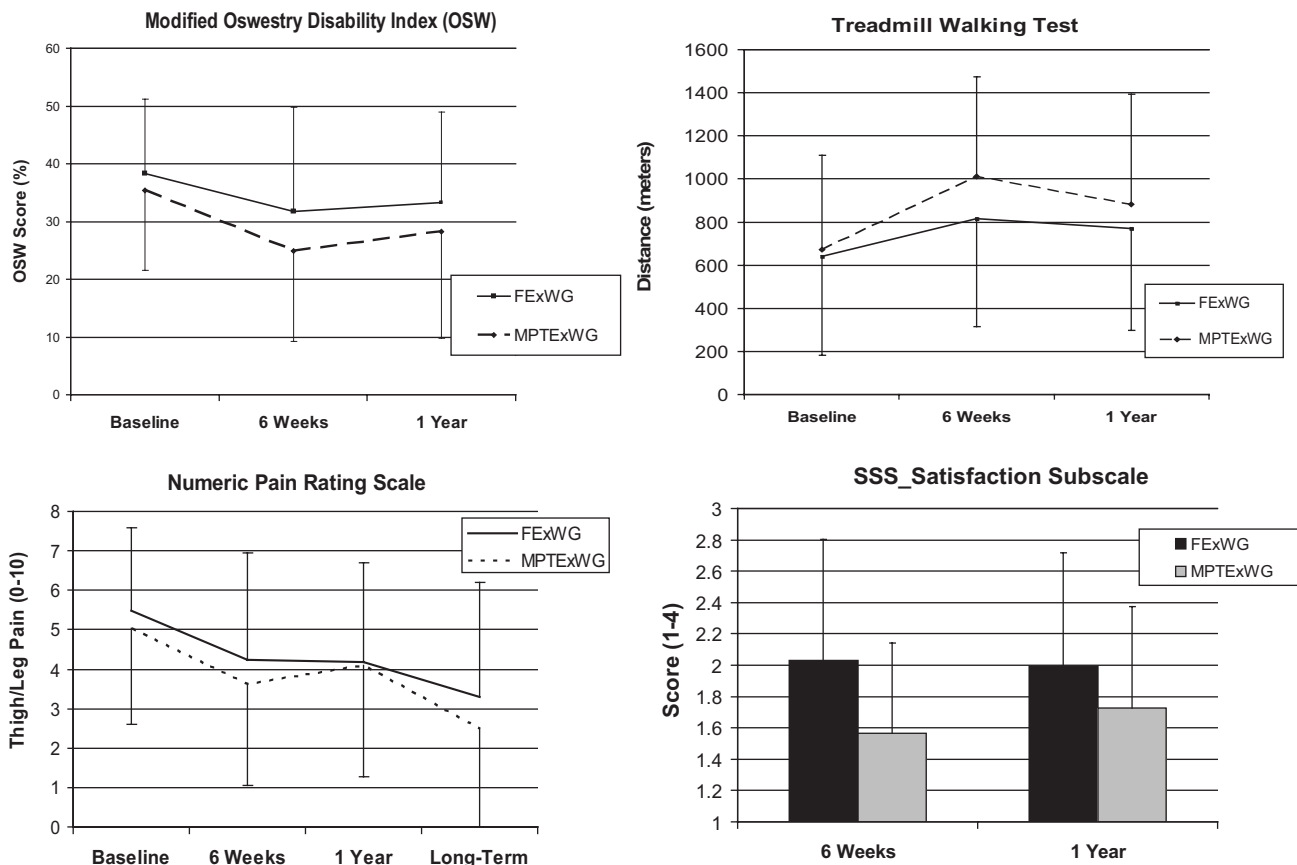


Figure 3. Changes in secondary outcomes over the course of the study. OSW = Modified Oswestry Disability Questionnaire: range 0–100, higher scores represent greater disability. Numeric Pain Rating Scale for thigh/leg pain: range 0–10 (0 = no pain, 10 = worst pain imaginable); SSS = Satisfaction Subscale: range 1–4 (1 = very satisfied, 4 = very dissatisfied). Long term = data from long-term follow-up questionnaire. FExWG: mean 29 months (+10.5); MPTEExWG: mean 27.4 months (+10.1).

Table 5. Mean Improvement From Baseline and Difference of Mean Improvement Between Groups for Secondary Outcomes

Secondary Outcomes	Flexion Exercise and Walking Group (n = 29) (95% CI)	Manual Physical Therapy, Exercise, and Walking Group (n = 29) (95% CI)	Between-Group Differences (95% CI)
Mean improvement in OSW			
Baseline to 6-week follow-up	6.55 (1.87 to 11.23)	10.48 (6.5 to 14.4)	3.93 (–2.07 to 9.93)
Baseline to 1-year follow-up	5.03 (1.71 to 8.35)	7.14 (1.5 to 12.8)	2.10 (–8.50 to 4.32)
Modified SSS_Satisfaction Subscale			
6-week follow-up [mean (SD)]	2.03 (1.8 to 2.31)	1.57 (1.36 to 1.78)	0.46 (0.09 to 0.82)
1-year follow-up [mean (SD)]	1.99 (1.71 to 2.27)	1.73 (1.49 to 1.97)	0.26 (–0.09 to 0.62)
Mean improvement in treadmill walking distance (m)			
Baseline to 6-week follow-up	176.5 (–9.5 to 362.4)	339.7 (218.4–461.0)	163.1 (–55.6 to 381.8)
Baseline to 1-year follow-up	130.4 (–55.3 to 316.2)	209.8 (67.5 to 352.1)	79.3 (–150.7 to 309.4)
Mean improvement in NPRS for lower extremity symptoms			
Baseline to 6-week follow-up	1.1 pts (0.2–2.0)	1.5 pts (0.5 to 2.5)	0.34 (–0.97 to 1.66)
Baseline to 1-year follow-up	1.2 pts (0.4 to 1.9)	1.0 pts (–0.2 to 2.2)	0.19 (–1.56 to 1.19)
Baseline to long-term follow-up	1.8 pts (0.6 to 3.0)	2.0 pts (0.7 to 3.4)	0.47 (–1.23 to 2.18)

OSW = Modified Oswestry Disability Index: range, 0–100; higher scores represent higher levels of disability. SSS = Spinal Stenosis Scale: range on satisfaction subscale, 1–4; lower scores represent greater levels of satisfaction. Treadmill walking distance: distances for up to 15-minute level treadmill walking plus up to 15 minutes inclined treadmill. NPRS = Numeric Pain Rating Scale: range, 0–10; higher scores represent higher levels of pain.

■ Discussion

To our knowledge, this is the first randomized clinical trial comparing nonsurgical intervention programs for patients with lumbar spinal stenosis. Our results suggest that patients treated with nonsurgical physical therapy programs may achieve clinically important improvements at 6 weeks and 1 year. However, patients receiving a program of manual physical therapy, exercise, and BWS treadmill walking reported greater rates of perceived recovery following treatment than those receiving a program of flexion exercises, walking, and subtherapeutic ultrasound. The number needed to treat for benefit with the MPTE_xWG was 2.6 at 6 weeks, indicating

that only about 3 patients need to be treated with this program to prevent 1 patient from not achieving perceived recovery based on the GRC scale.

The results of this trial are encouraging and lend support to the premise that patients with LSS can achieve clinically important improvements with a physical therapy management program. We think that the study results are generalizable, as our patients had similar levels of baseline status (age, sex, duration/location of symptoms, general health status, disability, *etc.*) as reported in other studies for patients with LSS.^{16,39,40} Additionally, we had a high follow-up rate, increasing the stability of our findings. Only 2 patients dropped from the study during the 1-year study period, both for reasons unrelated to the research study. Finally, because of the morbidity and mortality rates associated with surgical interventions for patients in this population,^{9,39,41} it is promising that physical therapy may be a viable lower risk alternative form of care for older adults with LSS.

There are many avenues for continued research in the area of nonsurgical interventions for patients with LSS, especially continued work to identify the most optimal and cost-effective intervention programs. Further work should identify the components of the physical therapy intervention that result in the greatest reduction in symptoms and improvement in function. Nonsurgical treatment programs should be compared with pharmacologic or medical management programs or natural history, especially since the natural history of LSS has not been well established. A preliminary report of patients treated with a physical therapy program with a more defined strengthening program, aerobic exercise, and flexion exercises suggests that perhaps the addition of a more developed strengthening program could be important.⁴² Although an initial RCT did not demonstrate long-term advantages of epidural steroid injections,⁴³ preliminary

Table 6. Healthcare Resources Used for Lumbar Spinal Stenosis After 6-Week Physical Therapy Program

Intervention for LSS	FExWG	MPTE _x WG
Epidural steroid injection	9	5
Surgery	2	2
Other medical providers (from end of physical therapy treatment until long-term follow-up questionnaire)		
General practitioner	2	0
Physical therapist	2	0
Chiropractor	1	0
Physiatrist	0	1
Orthopaedic surgeon	0	1
Pain clinic	3	1
Frequency of medication use at time of long-term follow-up		
None	8	8
Weekly or every couple of days	4	6
At least once daily	12	9

FExWG = Flexion Exercise and Walking Group; MPTE_xWG = Manual Physical Therapy, Exercise, and Walking Group. Information compiled from both 1-year follow-up and long-term follow-up for epidural steroid injection and surgery. Data for other medical providers and medication usage collected from long-term follow-up questionnaire. The sample sizes for the long-term follow-up questionnaires are: FExWG, n = 24; MPTE_xWG, n = 23. The 1-year sample sizes were: FExWG, n = 27; MPTE_xWG, n = 28.

work by Hunter *et al*⁴² suggests that combining ESI and physical therapy may be promising. Ultimately, RCTs comparing a well-designed, comprehensive nonsurgical treatment programs to surgical interventions and cost-analysis studies are needed.

■ Conclusion

The results of our study suggest that patients with LSS can benefit from a course of physical therapy, which includes lumbar flexion exercises and a walking program. Furthermore, additional gains may be realized with the inclusion of manual physical therapy interventions, exercise, and a progressive body-weight supported treadmill walking program.

■ Key Points

- Patients with lumbar spinal stenosis can benefit from physical therapy interventions.
- Additional improvements may be realized with the inclusion of manual physical therapy interventions, exercise, and a progressive body-weight supported treadmill walking program (MPTE_xWG).
- In this study, a greater proportion of patients receiving MPTE_xWG reported recovery at 6 weeks compared with those receiving flexion exercises and a walking program (FExWG) ($P = 0.0015$).
- Only about 3 patients need to be treated with the MPTE_xWG program to prevent 1 patient from not achieving perceived recovery at 6-weeks (NNT = 2.6).
- Improvements in disability, satisfaction, and treadmill walking tests favored the MPTE_xWG at all follow-up points.

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References

1. ECRI Health Technology Assessment Group. Treatment of Degenerative Lumbar Spinal Stenosis. Evidence report/Technology Assessment No. 32 [Prepared by ECRI under Contract No. 290-97-0020; AHRW Publication No. 01-E048]. Rockville, MD: Agency for Healthcare Research and Quality, 2001.
2. Ciol MA, Deyo RA, Howell E, et al. An assessment of surgery for spinal stenosis: time trends, geographic variations, complications, and reoperations. *J Am Geriatr Soc* 1996;44:285-90.
3. Fanuele J, Birkmeyer N, Abdu W, et al. The impact of spinal problems on the health status of patients: have we underestimated the effect? *Spine* 2000;25:1509-14.
4. Taylor V, Deyo R, Cherkin D, et al. Low back pain hospitalization: recent United States trends and regional variations. *Spine* 1994;19:1207-13.
5. Long D, BenDebba M, Torgerson W, et al. Persistent back pain and sciatica in the United States: patient characteristics. *J Spinal Disord* 1996;9:40-58.
6. Hart L, Deyo R, Cherkin D. Physician office visits for low back pain: frequency, clinical evaluation, and treatment patterns from a U.S. national survey. *Spine* 1995;1:11-9.
7. Turner J, Ersek M, Herron L, et al. Surgery for lumbar spinal stenosis: attempted meta-analysis of the literature. *Spine* 1992;17:1-8.
8. Deyo R, Gray D, Kreuter W, et al. United States trends in lumbar fusion surgery for degenerative conditions. *Spine* 2005;30:1441-5.
9. Reindl R, Steffen T, Cohen L, et al. Elective lumbar spinal decompression in the elderly: is it a high-risk operation? *Can J Surg* 2003;46:43-6.
10. Onel D, Sari H, Donmez C. Lumbar spinal stenosis. Clinical/radiologic therapeutic evaluation in 145 patients: conservative treatment or surgical intervention? *Spine* 1993;18:291-8.
11. Simotas A, Dorey F, Hansraj K, et al. Nonoperative treatment for lumbar spinal stenosis: clinical and outcome results and a 3-year survivorship analysis. *Spine* 2000;25:197-203.
12. Swezey R. Outcomes for lumbar stenosis: a 5-year follow-up study. *J Clin Rheumatol* 1996;2:129-34.
13. Mariconda M, Zanforlino G, Celestino GA, et al. Factors influencing the outcome of degenerative lumbar spinal stenosis. *J Spinal Disord* 2000;13:131-7.
14. Johnsson K, Uden A, Rosen I. The effect of decompression on the natural course of spinal stenosis: a comparison of surgically treated and untreated patients. *Spine* 1991;16:615-9.
15. Hurri H, Slati P, Soini J, et al. Lumbar spinal stenosis: assessment of long-term outcome 12 years after operative and conservative treatment. *J Spinal Disord* 1998;11:110-5.
16. Atlas SJ, Keller RB, Wu YA, et al. Long-term outcomes of surgical and nonsurgical management of lumbar spinal stenosis: 8 to 10 year results from the Maine Lumbar Spine Study. *Spine* 2005;30:936-43.
17. Amundsen T, Weber H, Nordal H, et al. Lumbar spinal stenosis: conservative or surgical management? A prospective 10-year study. *Spine* 2000;25:1424-36.
18. Whitman JM, Flynn TW, Fritz JM. Nonsurgical management of patients with lumbar spinal stenosis: a literature review and a case series of three patients managed with physical therapy. *Phys Med Rehabil Clin North Am* 2003;14:77-101.
19. Fritz JM, Erhard RE, Vignovic M. A nonsurgical treatment approach for patients with lumbar spinal stenosis. *Phys Ther* 1997;77:962-73.
20. *ACSM's Guidelines for Exercise Testing and Prescription*, 5th ed. Baltimore: Williams & Wilkins, 1995.
21. Fritz JM, Erhard RE, Delitto A, et al. Preliminary results of the use of a two-stage treadmill test as a clinical diagnostic tool in the differential diagnosis of lumbar spinal stenosis. *J Spinal Disord* 1997;10:410-6.
22. Ziskin M, McDiarmid T, Michlovitz S. Therapeutic ultrasound. In: Michlovitz S, ed. *Thermal Agents in Rehabilitation*, 2nd ed. Philadelphia: Davis, 1990:134-69.
23. Maitland G. *Peripheral Manipulation*, 3rd ed. Oxford: Butterworth-Heinemann, 1991.
24. Greenman P. *Principles of Manual Medicine*, 2nd ed. Philadelphia: Lippincott Williams & Wilkins, 1996.
25. Dai LY, Xu YK, Zhang WM, et al. The effect of flexion-extension motion of the lumbar spine on the capacity of the spinal canal: an experimental study. *Spine* 1989;14:523-5.
26. Infusa A, An HS, Lim TH, et al. Anatomic changes of the spinal canal and intervertebral foramen associated with flexion-extension movement. *Spine* 1996;21:2412-20.
27. Panjabi M, Takata K, Goel V. Kinematics of the lumbar intervertebral foramen. *Spine* 1983;3:348-57.
28. Penning L, Wilmink J. Posture-dependent bilateral compression of L4 or L5 nerve root in facet hypertrophy: a dynamic CT-myelographic study. *Spine* 1987;12:488-500.
29. Schonstrom N, Lindahl S, Willen J, et al. Dynamic changes in the dimensions of the lumbar spinal canal: an experimental study in vitro. *J Orthop Res* 1989;7:115-21.
30. Willen J, Danielson B, Gaulitz A, et al. Dynamic effects on the lumbar spinal canal: axially loaded CT-myelography and MRI in patients with sciatica and/or neurogenic claudication. *Spine* 1997;22:2968-76.



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31. Flynn T, Canavan P, Cavanagh P, et al. Plantar pressure reduction in an incremental weight-bearing system. *Phys Ther* 1997;410–6.
32. Finch L, Barbeau H, Arsenault B. Influence of body weight support on normal human. *Phys Ther* 1991;71:842–56.
33. Jaeschke R, Singer J, Guyatt G. Measurement of health status: ascertaining the minimally clinically important difference. *Control Clin Trials* 1989;10:407–15.
34. Fritz J, Irrgang J. A comparison of a modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. *Phys Ther* 2001;81:776–88.
35. Stucki G, Liang MH, Fossel AH, et al. Relative responsiveness of condition-specific and generic health status measures in degenerative lumbar spinal stenosis. *J Clin Epidemiol* 1995;48:1369–78.
36. Stucki G, Daltroy L, Liang M, et al. Measurement properties of a self-administered outcome measure in lumbar spinal stenosis. *Spine* 1996;21:796–803.
37. Childs J, Piva S, Fritz J. Responsiveness of the numeric pain rating scale in patients with low back pain. *Spine* 2005;30:1331–4.
38. Moher D, Schulz K, Altman D, et al. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001;285:1987–91.
39. Ragab A, Fye M, Bohlman H. Surgery of the lumbar spine for spinal stenosis in 118 patients 70 years of age or older. *Spine* 2003;28:348–53.
40. Jolles BM, Porchet F, Theumann N. Surgical treatment of lumbar spinal stenosis: five-year follow-up. *J Bone Joint Surg Br* 2001;83:949–53.
41. Carreon L, Puno R, Dimar J II, et al. Perioperative complications of posterior lumbar decompression and arthrodesis in older adults. *J Bone Joint Surg Br* 2003;85:2089–92.
42. Hunter S, Fritz J, Brennan G. Variables associated with outcomes of physical therapy for patients with lumbar spinal stenosis. *J Orthop Sports Phys Ther* 2005;35:A14.
43. Fukusaki M, Kobayashi I, Hara T, et al. Symptoms of spinal stenosis do not improve after epidural steroid injection. *Clin J Pain* 1998;14:148–51.