SPINE Volume 35, Number 14, pp 1329–1338

Surgical *Versus* Nonoperative Treatment for Lumbar Spinal Stenosis Four-Year Results of the Spine Patient Outcomes Research Trial

James N. Weinstein, DO, MS,*†‡ Tor D. Tosteson, ScD,*†‡ Jon D. Lurie, MD, MS,*†‡ Anna Tosteson, ScD,*†‡ Emily Blood, MS,*†‡ Harry Herkowitz, MD,§ Frank Cammisa, MD,¶ Todd Albert, MD,‖ Scott D. Boden, MD,** Alan Hilibrand, MD,‖ Harley Goldberg, DO,†† Sigurd Berven, MD,‡‡ and Howard An, MD§§

Study Design. Randomized trial and concurrent observational cohort study.

Objective. To compare 4 year outcomes of surgery to nonoperative care for spinal stenosis.

Summary of Background Data. Surgery for spinal stenosis has been shown to be more effective compared to nonoperative treatment over 2 years, but longer-term data have not been analyzed.

Methods. Surgical candidates from 13 centers in 11 US states with at least 12 weeks of symptoms and confirmatory imaging were enrolled in a randomized cohort (RC) or observational cohort (OC). Treatment was standard decompressive laminectomy or standard nonoperative care. Primary outcomes were SF-36 bodily pain (BP) and physical function scales and the modified Oswestry Disability index assessed at 6 weeks, 3 months, 6 months, and yearly up to 4 years.

Results. A total of 289 patients enrolled in the RC and 365 patients enrolled in the OC. An as-treated analysis combining the RC and OC and adjusting for potential confounders found that the clinically significant advantages for surgery previously reported were maintained through 4 years, with treatment effects (defined as mean change in surgery group minus mean change in nonoperative group) for bodily pain 12.6 (95% confidence interval [CI], 8.5–16.7); physical function 8.6 (95% CI, 4.6–12.6); and Oswestry Disability index −9.4 (95% CI, −12.6 to −6.2). Early advantages for surgical treatment for secondary measures such as bothersomeness, satisfaction with symptoms, and self-rated progress were also maintained.

Conclusion. Patients with symptomatic spinal stenosis treated surgically compared to those treated nonoperatively maintain substantially greater improvement in pain and function through 4 years.

Key words: spinal stenosis, randomized trial, surgery, nonoperative, SPORT, outcomes. **Spine 2010;35:1329–1338**

From the *Department of Orthopaedics, Dartmouth Medical School, Hanover, NH; †The Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, NH; ‡Dartmouth-Hitchcock Medical Center, Lebanon, NH; §Department of Orthopaedic Surgery, William H. Beaumont Hospital, Royal Oak, MI; ¶Hospital for Joint Diseases, New York, NY; ‖Department of Orthopaedic Surgery, Rothman Institute at Thomas Jefferson University, Philadelphia, PA; **Emory Spine Center, Emory University, Atlanta, GA; ††Kaiser-Permanente, San Francisco, CA; ‡‡Department of Orthopaedic Surgery, University of California, San Francisco, CA; and §§Rush-Presbyterian-St. Luke's Medical Center, Chicago, IL.

Acknowledgment date: June 26, 2009. First revision date: September 25, 2009. Acceptance date: January 11, 2010.

The manuscript submitted does not contain information about medical device(s)/drug(s).

Federal funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

Spine Patient Outcomes Research Trial (SPORT): Spinal Stenosis; #NCT00000411; available at: http://www.clinicaltrials.gov/.

Supported by The National Institute of Arthritis and Musculoskeletal and Skin Diseases (U01-AR45444) and the Office of Research on Women's Health, the National Institutes of Health, and the National Institute of Occupational Safety and Health, the Centers for Disease Control and Prevention.

Address correspondence and reprint requests to James N. Weinstein, DO, MS, Department of Orthopaedics, The Dartmouth Institute for Health Policy & Clinical Practice, Dartmouth Medical School, One Medical Center Dr. Lebanon, NH 03756; E-mail: SPORT@dartmouth.edu

Spinal stenosis (SpS) patients typically present with radicular leg pain or neurogenic claudication (*i.e.*, pain in the buttocks/legs with walking or standing that resolves with sitting down or lumbar flexion). Lumbar decompression surgery is commonly performed in the United States for patients having back and leg symptoms due to SpS.[1] Studies have compared surgery to nonoperative treatment in SpS; however, these studies typically included a mixed group with and without degenerative spondylolisthesis,[2–4] had small sample sizes, limited geographic participation, or lacked nonoperative controls and validated outcome measures.[5–7]

The special methodologic challenges of surgical trials (*e.g.*, compliance with treatment[2,5–7]) were addressed by Spine Patient Outcomes Research Trial (SPORT) design, with a randomized cohort (RC) and a concurrent observational cohort (OC) using identical selection criteria and outcomes assessment.[8–12] In the SPORT study, as-treated comparisons with careful control for potentially confounding baseline factors showed that patients with SpS who were treated surgically had substantially greater improvement in pain and function during a period of 2 years than patients treated nonoperatively. In this article, we assess the stability of pain and functional outcomes out to 4 years for patients with SpS.

Materials and Methods

Study Design

SPORT was conducted in 11 states at 13 US medical centers with multidisciplinary spine practices. SPORT included both a RC and a concurrent OC of patients who declined randomization.[8,9,12–14] This design allows for improved generalizability.[15] Additional information is available in previous publications.[2,8,10,11,16,17]

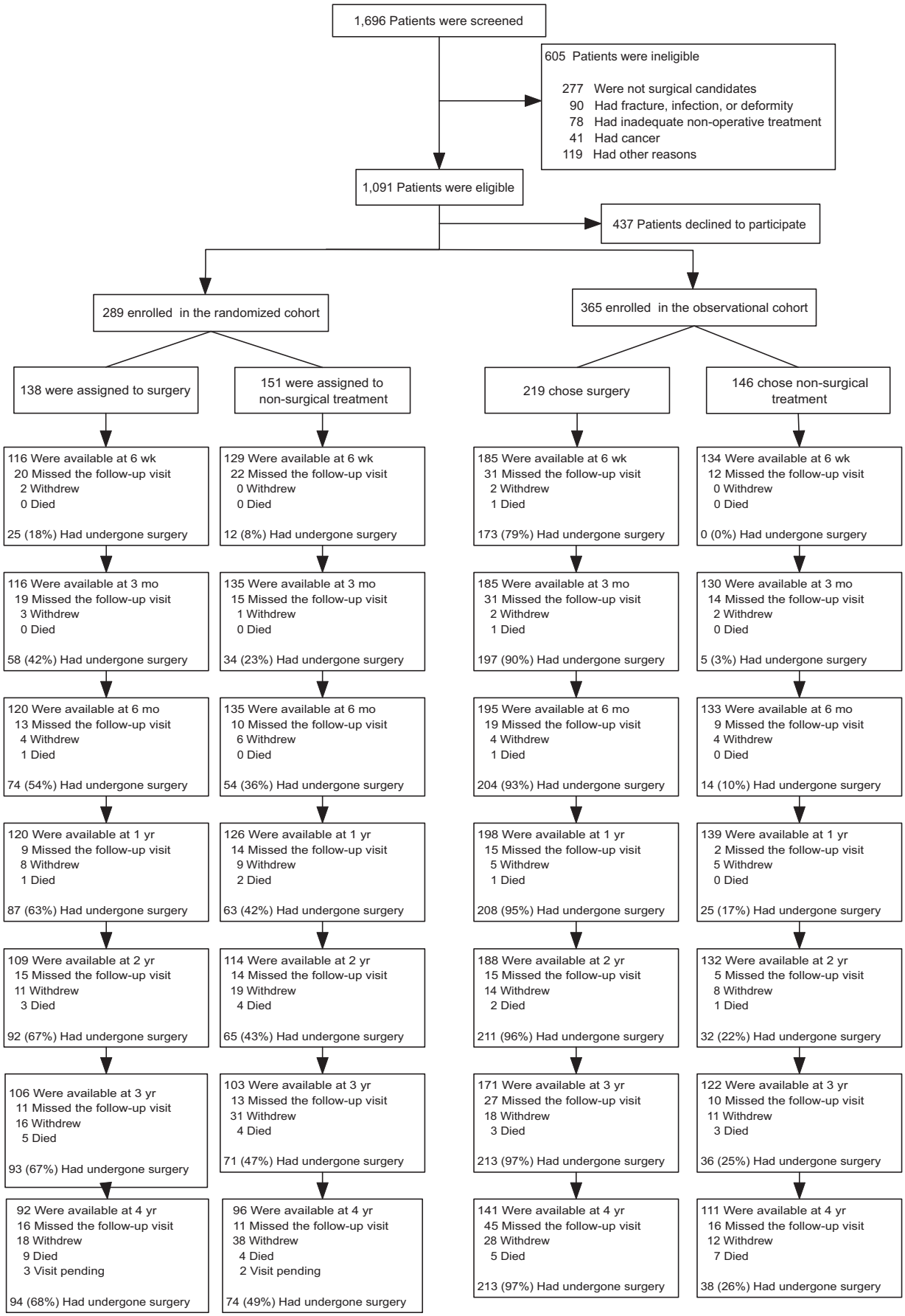

Figure 1. Exclusion, Enrollment, Randomization, and Follow-up of Trial Participants. The values for surgery, withdrawal and death are cumulative over 4 years. For example, a total of nine patients in the group assigned to surgery died during the 4-year follow-up period.

Table 1. Patient Baseline Demographic Characteristics, Comorbidities, and Health Status Measures According to Study Cohort and Treatment Received

	SPORT Study Cohort			Randomized and Observational Cohorts Combined: Treatment Received*		
	Randomized (n = 278)	Observational (n = 356)		Surgery (n = 413)	Nonoperative (n = 221)	
Mean age (stdev)	65.5 (10.5)	63.9 (12.5)	0.098	63.8 (12.2)	66.1 (10.4)	0.019
Female	106 (38%)	143 (40%)	0.66	159 (38%)	90 (41%)	0.64
Ethnicity: not Hispanic†	259 (93%)	346 (97%)	0.027	396 (96%)	209 (95%)	0.58
Race–white	238 (86%)	295 (83%)	0.41	349 (85%)	184 (83%)	0.77
Education–at least some college	176 (63%)	225 (63%)	0.96	259 (63%)	142 (64%)	0.77
Marital status–married	197 (71%)	249 (70%)	0.87	300 (73%)	146 (66%)	0.10
Work status			0.12			0.32
Full or part time	88 (32%)	128 (36%)		147 (36%)	69 (31%)	
Disabled	24 (9%)	36 (10%)		40 (10%)	20 (9%)	
Retired	144 (52%)	152 (43%)		182 (44%)	114 (52%)	
Other	22 (8%)	40 (11%)		44 (11%)	18 (8%)	
Compensation–any‡	21 (8%)	27 (8%)	0.89	30 (7%)	18 (8%)	0.81
Mean Body Mass Index (BMI), (stdev)§	29.8 (5.6)	29.3 (5.6)	0.31	29.4 (5.3)	29.8 (6.1)	0.44
Smoker	34 (12%)	28 (8%)	0.089	37 (9%)	25 (11%)	0.42
Comorbidities						
Hypertension	134 (48%)	154 (43%)	0.25	175 (42%)	113 (51%)	0.043
Diabetes	50 (18%)	46 (13%)	0.098	57 (14%)	39 (18%)	0.24
Osteoporosis	22 (8%)	38 (11%)	0.30	32 (8%)	28 (13%)	0.061
Heart problem	80 (29%)	85 (24%)	0.19	102 (25%)	63 (29%)	0.34
Stomach problem	60 (22%)	79 (22%)	0.93	86 (21%)	53 (24%)	0.41
Bowel or intestinal problem	36 (13%)	50 (14%)	0.78	50 (12%)	36 (16%)	0.18
Depression	36 (13%)	34 (10%)	0.22	46 (11%)	24 (11%)	0.98
Joint problem	158 (57%)	188 (53%)	0.35	222 (54%)	124 (56%)	0.63
Other¶	95 (34%)	125 (35%)	0.87	143 (35%)	77 (35%)	0.97
Time since most recent episode >6 mo	158 (57%)	210 (59%)	0.64	245 (59%)	123 (56%)	0.42
Bodily Pain (BP) score‖	31.9 (17.5)	31.4 (17.4)	0.73	28.9 (16.2)	36.6 (18.6)	<0.001
Physical Functioning (PF) score	35.4 (22.6)	34.3 (23.8)	0.55	31.8 (21.8)	40.5 (24.8)	<0.001
Mental Component Summary (MCS) score	49.8 (12.4)	49.1 (11.6)	0.47	48.6 (12)	50.9 (11.7)	0.023
Oswestry (ODI)**	42.7 (17.9)	42.1 (19)	0.70	45.6 (17.9)	36.3 (18.1)	<0.001
Stenosis Frequency Index (0–24)††	13.5 (5.7)	14.2 (5.8)	0.13	15 (5.5)	11.8 (5.7)	<0.001
Stenosis Bothersome Index (0–24)‡‡	13.9 (5.7)	14.7 (5.8)	0.084	15.4 (5.4)	12.4 (5.8)	<0.001
Back pain bothersomeness§§	4 (1.9)	4.2 (1.8)	0.19	4.2 (1.8)	3.8 (1.8)	0.012
Leg pain bothersomeness¶¶	4.3 (1.7)	4.4 (1.7)	0.44	4.5 (1.6)	3.9 (1.8)	<0.001
Satisfaction with symptoms–very dissatisfied	183 (66%)	250 (70%)	0.27	320 (77%)	113 (51%)	<0.001
Problem getting better or worse			0.48			<0.001
Getting better	18 (6%)	28 (8%)		14 (3%)	32 (14%)	
Staying about the same	95 (34%)	108 (30%)		115 (28%)	88 (40%)	
Getting worse	160 (58%)	218 (61%)		277 (67%)	101 (46%)	
Treatment preference			<0.001			<0.001
Definitely prefer nonsurg	37 (13%)	86 (24%)		38 (9%)	85 (38%)	
Probably prefer nonsurg	61 (22%)	45 (13%)		43 (10%)	63 (29%)	
Not sure	95 (34%)	26 (7%)		67 (16%)	54 (24%)	
Probably prefer surgery	51 (18%)	36 (10%)		75 (18%)	12 (5%)	
Definitely prefer surgery	33 (12%)	163 (46%)		190 (46%)	6 (3%)	
Pseudoclaudication–any	219 (79%)	289 (81%)	0.51	334 (81%)	174 (79%)	0.59
SLR or femoral tension	41 (15%)	91 (26%)	0.001	89 (22%)	43 (19%)	0.61
Pain radiation–any	215 (77%)	284 (80%)	0.52	322 (78%)	177 (80%)	0.60
Any neurological deficit	146 (53%)	203 (57%)	0.29	223 (54%)	126 (57%)	0.52
Reflexes–asymmetric depressed	76 (27%)	92 (26%)	0.74	109 (26%)	59 (27%)	0.99
Sensory–asymmetric decrease	68 (24%)	114 (32%)	0.046	122 (30%)	60 (27%)	0.59
Motor–asymmetric weakness	71 (26%)	106 (30%)	0.28	109 (26%)	68 (31%)	0.28
Stenosis levels						
L2–L3	77 (28%)	102 (29%)	0.86	123 (30%)	56 (25%)	0.27
L3–L4	183 (66%)	237 (67%)	0.91	278 (67%)	142 (64%)	0.49
L4–L5	255 (92%)	324 (91%)	0.86	380 (92%)	199 (90%)	0.49
L5–S1	72 (26%)	101 (28%)	0.55	105 (25%)	68 (31%)	0.18
Stenotic levels (mod/severe)			0.45			0.15
None	4 (1%)	11 (3%)	—	6 (1%)	9 (4%)	—
One	106 (38%)	128 (36%)	—	148 (36%)	86 (39%)	—
Two	109 (39%)	132 (37%)	—	162 (39%)	79 (36%)	—
Three+	59 (21%)	85 (24%)	—	97 (23%)	47 (21%)	—

(*Continued*)

Table 1. Continued

	SPORT Study Cohort			Randomized and Observational Cohorts Combined: Treatment Received*		
	Randomized (n = 278)	Observational (n = 356)	*P*	Surgery (n = 413)	Nonoperative (n = 221)	*P*
Stenosis locations						
Central	241 (87%)	302 (85%)	0.58	357 (86%)	186 (84%)	0.51
Lateral recess	236 (85%)	267 (75%)	0.003	334 (81%)	169 (76%)	0.23
Neuroforamen	88 (32%)	119 (33%)	0.70	124 (30%)	83 (38%)	0.066
Stenosis severity			0.24			0.006
Mild	4 (1%)	11 (3%)	—	6 (1%)	9 (4%)	—
Moderate	131 (47%)	151 (42%)	—	171 (41%)	111 (50%)	—
Severe	143 (51%)	194 (54%)	—	236 (57%)	101 (46%)	—

*Patients in the 2 cohorts combined were classified according to whether they received surgical treatment or only nonsurgical treatment during the first 4 yrs of enrollment.
†Race or ethnic group was self-assessed. Whites and blacks could be either Hispanic or non-Hispanic.
‡This category includes patients who were receiving or had applications pending for workers compensation, Social Security compensation, or other compensation.
§The body-mass index is the weight in kilograms divided by the square of the height in meters.
¶Other = problems related to stroke, cancer, fibromyalgia, CGS, PTSD, alcohol, drug dependency, lung, liver, kidney, blood vessel, nervous system, migraine, or anxiety.
‖The SF-36 scores range from 0 to 100, with higher score indicating less severe symptoms.
**The Oswestry Disability Index ranges from 0 to 100, with lower scores indicating less severe symptoms.
††The Stenosis Frequency Index ranges from 0 to 24, with lower scores indicating less severe symptoms.
‡‡The Stenosis Bothersomeness Index ranges from 0 to 24, with lower scores indicating less severe symptoms.
§§The Low Back Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms.
¶¶The Leg Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms.

Patient Population

All patients had neurogenic claudication and/or radicular leg symptoms; confirmatory cross-sectional imaging showing lumbar SpS at one or more levels; and were judged to be surgical candidates. Patients with degenerative spondylolisthesis were studied separately.[9,11] Patients with lumbar instability defined as greater than 4 mm translation or 10° of angular motion between flexion and extension on upright lateral radiographs were excluded. All patients had ongoing symptoms for a minimum of 12 weeks. The content of pre-enrollment nonoperative care was not prespecified but included physical therapy (68%), epidural injections (56%), chiropractic (28%), anti-inflammatories (55%), and opioid analgesics (27%). Enrollment began from March 2000 and ended by March 2005.

Study Interventions

The protocol surgery consisted of a standard posterior decompressive laminectomy.[8] The nonoperative protocol was "usual care" recommended to include at least active physical therapy, education/counseling with home exercise instruction, and nonsteroidal anti-inflammatories if tolerated.[8,18]

Study Measures

Primary end points were the SF-36 Bodily Pain (BP) and Physical Function (PF) scales,[19–22] and the AAOS/Modems version of the Oswestry Disability Index (ODI)[23] measured at 6 weeks, 3 months, 6 months, and yearly out to 4 years. If surgery was delayed beyond 6 weeks, additional follow-up data were obtained 6 weeks and 3 months after surgery. Secondary outcomes included patient self-reported improvement; satisfaction with current symptoms and care[24]; stenosis bothersomeness[3,25]; and low back pain bothersomeness.[3] Treatment effect was defined as the difference in the mean changes from baseline between the surgical and nonoperative groups (difference of differences).

The SF-36 scores range from 0 to 100, with higher scores indicating less severe symptoms; the ODI ranges from 0 to 100, with lower scores indicating less severe symptoms; the Stenosis Bothersomeness Index ranges from 0 to 24, with lower scores indicating less severe symptoms; and the Low Back Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms.

Statistical Considerations

Statistical methods for the analysis of this trial have been reported in previous publications,[9–14] and these descriptions are repeated here. Initial analyses compared the baseline characteristics of patients in the RC with those in the OC and between surgical and nonoperative groups in the combined cohorts. The extent of missing data and the percentage of patients undergoing surgery were calculated according to study group for each scheduled follow-up. Baseline predictors of the time until surgical treatment (including treatment crossovers) in both cohorts were determined through a stepwise proportional-hazards regression model with an inclusion criteria of $P < 0.1$ to enter and $P > 0.05$ to exit. Predictors of adherence to treatment and missing follow-up visits at 1, 2, 3, and 4 years were determined through stepwise logistic regression. Primary analyses compared surgical and nonoperative treatments with the use of changes from baseline at each follow-up visit, with a mixed effects model of longitudinal regression that included a random individual effect to account for correlation between repeated measurements. The RC was initially analyzed on an intention-to-treat basis. Because of crossover, subsequent analyses were based on treatments actually received.

In the as-treated analyses, the treatment indicator was a time-varying covariate, allowing for variable times of surgery. For the intention-to-treat analyses, all times are from enrollment. For the as-treated analysis, the times are from the beginning of treatment (*i.e.*, the time of surgery for the surgical group and the time of enrollment for the nonoperative group). Therefore, all changes from baseline before surgery were included in the estimates of the nonoperative treatment effect. After surgery, changes were assigned to the surgical group, with follow-up measured from the date of surgery.

Repeated measures of outcomes were used as the dependent variables, and treatment received was included as a time-varying covariate. Adjustments were made for the time of surgery with respect to the original enrollment date so as to approximate the designated follow-up times. Treatment comparisons were made at designated follow-up time. In addition, a global significance test was based on the time-weighted average/area under the curve analysis over all time periods.[26]

As-treated estimates of treatment effect from the RC and OC were compared to establish comparability. Subsequent analyses combined the 2 cohorts. To adjust for potential confounding, baseline variables that were associated with missing data or treatment received were included as adjusting covariates in longitudinal regression models. Computations were performed with the use of the PROC MIXED procedure for continuous data and the PROC GENMOD procedure for binary and non-normal secondary outcomes in SAS software, version 9.1 (SAS Institute). Statistical significance was defined as $P < 0.05$ on the basis of a 2-sided hypothesis test with no adjustments made for multiple comparisons. Data for these analyses were collected through December 8, 2008.

Table 2. Primary Analysis Results for Years 3 and 4: Intent-to-Treat for the Randomized Cohort and Adjusted* Analyses According to Treatment Received for the Randomized and Observational Cohorts Combined†

		2 yr			3 yr			4 yr		
	Baseline Overall Mean	Mean Change (SE) or Percent		Treatment Effect (95% CI)‡	Mean Change (SE) or Percent		Treatment Effect (95% CI)‡	Mean Change (SE) or Percent		Treatment Effect (95% CI)‡
		Surgery	Nonoperative		Surgery	Nonoperative		Surgery	Nonoperative	
Randomized Controlled Trial intent-to-treat										
Primary outcomes		(n = 109)‡‡	(n = 114)‡‡		(n = 106)‡‡	(n = 103)‡‡		(n = 92)‡‡	(n = 96)‡‡	
SF-36 Bodily Pain (BP) (0–100) (SE)§	31.9 (1.1)	23.2 (2.3)	15.4 (2.2)	7.8 (1.4, 14.1)	21 (2.4)	16.6 (2.3)	4.4 (−2.1, 10.9)	15.9 (2.4)	15.7 (2.4)	0.3 (−6.4, 7)
SF-36 Physical Function (PF) (0–100) (SE)§	35.4 (1.4)	16.7 (2.4)	17 (2.3)	−0.3 (−6.7, 6.1)	17.1 (2.4)	14.4 (2.3)	2.6 (−4, 9.2)	12.7 (2.5)	15.9 (2.4)	−3.2 (−9.9, 3.6)
Oswestry Disability Index (ODI) (0–100) (SE)¶	42.7 (1.1)	−16.1 (1.9)	−12.7 (1.8)	−3.4 (−8.5, 1.8)	−14.7 (2)	−13.3 (1.9)	−1.4 (−6.8, 3.9)	−12.2 (2)	−12.4 (1.9)	0.2 (−5.2, 5.7)
Secondary outcomes										
Sciatica Bothersomeness Index (0–24) (SE)‖	13.9 (0.35)	−6 (0.71)	−5.4 (0.69)	−0.5 (−2.5, 1.4)	−6 (0.73)	−4.9 (0.71)	−1 (−3.1, 1)	−5.2 (0.75)	−4.5 (0.73)	−0.7 (−2.8, 1.4)
Leg pain (0–6) (SE)**	4.3 (0.1)	−2 (0.2)	−1.8 (0.2)	−0.2 (−0.8, 0.4)	−2.2 (0.2)	−1.6 (0.2)	−0.6 (−1.2, 0)	−1.8 (0.2)	−1.8 (0.2)	0 (−0.7, 0.6)
Low back pain bothersomeness (0–6) (SE)††	4 (0.1)	−1.2 (0.2)	−1.6 (0.2)	0.4 (−0.2, 0.9)	−1.2 (0.2)	−1.3 (0.2)	0.1 (−0.4, 0.7)	−0.9 (0.2)	−1.3 (0.2)	0.4 (−0.2, 1)
Very/somewhat satisfied w/symptoms (%)	5 (2.2)	53.1	43.3	9.8 (−3.3, 22.9)	56.6	45.2	11.5 (−2.1, 25.1)	48.2	43.8	4.5 (−9.6, 18.6)
Very/somewhat satisfied w/care (%)		75.9	67.6	8.3 (−3.6, 20.2)	79.6	62.8	16.8 (4.5, 29.2)	69.4	70.6	−1.2 (−14.5, 12.2)
Self-rated progress: major improvement (%)		49.4	43.5	5.9 (−7.3, 19.2)	47.2	42.7	4.5 (−9.1, 18.2)	42.3	33.9	8.3 (−5.4, 22.1)
Randomized Controlled Trial/ OC as-treated										
Primary outcomes		(n = 350)‡‡	(n = 199)‡‡		(n = 326)‡‡	(n = 171)‡‡		(n = 275)‡‡	(n = 144)‡‡	
SF-36 Bodily Pain (BP) (0–100) (SE)§	31.4 (0.6)	27 (1.2)	12.9 (1.5)	14 (10.5, 17.6)	26.8 (1.2)	13.4 (1.6)	13.4 (9.6, 17.1)	25.1 (1.3)	12.5 (1.7)	12.6 (8.5, 16.7)
SF-36 Physical Function (PF) (0–100) (SE)§	34.9 (0.8)	22.2 (1.3)	12.7 (1.5)	9.5 (6, 13)	20.9 (1.3)	10.4 (1.6)	10.4 (6.7, 14.1)	20.3 (1.3)	11.6 (1.7)	8.6 (4.6, 12.6)
Oswestry Disability Index (ODI) (0–100) (SE)¶	43.2 (0.6)	−20.3 (0.98)	−9.4 (1.2)	−10.9 (−13.7, −8.1)	−18.6 (0.98)	−9.1 (1.2)	−9.4 (−12.4, −6.5)	−18.7 (1.1)	−9.3 (1.3)	−9.4 (−12.6, −6.2)
Secondary outcomes										
Sciatica Bothersomeness Index (0–24) (SE)‖	14.5 (0.2)	−8 (0.35)	−4.2 (0.43)	−3.8 (−4.9, −2.8)	−7.7 (0.35)	−4.4 (0.46)	−3.2 (−4.3, −2.1)	−7.6 (0.39)	−4.1 (0.49)	−3.5 (−4.7, −2.3)
Leg pain (0–6) (SE)**	4.3 (0.1)	−2.6 (0.1)	−1.3 (0.1)	−1.3 (−1.6, −1)	−2.5 (0.1)	−1.6 (0.1)	−1 (−1.3, −0.6)	−2.5 (0.1)	−1.4 (0.2)	−1.1 (−1.5, −0.7)
Low back pain bothersomeness (0–6) (SE)††	4.1 (0.1)	−2.1 (0.1)	−1 (0.1)	−1.1 (−1.4, −0.8)	−1.9 (0.1)	−0.9 (0.1)	−1 (−1.3, −0.7)	−1.8 (0.1)	−0.9 (0.1)	−0.8 (−1.2, −0.5)
Very/somewhat satisfied w/symptoms (%)	5.8 (2.3)	69.3	28.3	41 (32.5, 49.5)	65.5	35.8	29.7 (20.4, 39.1)	63.1	32.2	31 (20.9, 41)
Very/somewhat satisfied w/care (%)		82.5	66.2	16.3 (7.9, 24.6)	83.6	61.8	21.9 (12.8, 30.9)	77.8	63.6	14.3 (4.1, 24.5)
Self-rated progress: major improvement (%)		63.6	27.9	35.8 (27.3, 44.2)	61	28.5	32.5 (23.6, 41.4)	52.8	23.1	29.6 (20.3, 39)

*Adjusted for center, age, gender, baseline score, income, treatment preference, duration of symptoms, compensation, smoking status, BMI, baseline Sciatica Bothersomeness, joint, stomach and bowel.
†The estimates for 1 yr and 2 yr for IDH Randomized Controlled Trial ITT differ slightly from those presented in NEJM paper 12 due to modeling differences.
‡Treatment effect is the difference between the surgical and nonoperative mean change from baseline.
§The SF-36 scores range from 0 to 100, with higher score indicating less severe symptoms.
¶The Oswestry Disability Index ranges from 0 to 100, with lower scores indicating less severe symptoms.
‖The Stenosis Bothersomeness Index ranges from 0 to 24, with lower scores indicating less severe symptoms.
**The Leg Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms.
††The Low Back Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms.
‡‡The sample sizes for the as-treated analyses reflect the no. of patients contributing to the estimate in a given time-period using the longitudinal modeling strategy explained in the methods section, and may not correspond to the counts provided for each visit time in Figure 1.

■ Results

A total of 654 SPORT participants were enrolled out of 1091 eligible for enrollment (289 in the RC and 365 in the OC) (Figure 1). In the RC, 138 were assigned to surgical treatment and 151 to nonoperative treatment. Of those randomized to surgery, 67% received surgery by 2 years, 68% by 4 years. In the group randomized to nonoperative care, 43% received surgery by 2 years, 49% by 4 years (Figure 1). In the OC group, 219 patients initially chose surgery and 146 patients initially chose nonoperative care. Of those initially choosing surgery, 96% received surgery by 2 years, and 97% by 4 years. Of those choosing nonoperative treatment, 22% had surgery by 2 years, 26% by 4 years (Figure 1). In both cohorts combined, 419 patients received surgery at some point during the first 4 years; 235 remained nonoperative. The proportion of enrollees who supplied data at each follow-up visit interval ranged from 67% to 89% with losses due to dropouts, missed visits, or deaths.

Patient Characteristics

Table 1 shows the baseline characteristics and clinical findings of participants in the randomized and the OCs. The cohorts were remarkably similar except for their preferences for surgery ($P < 0.001$), with more RC patients unsure of their preference (34% *vs.* 7%), and fewer RC patients definitely preferring either surgery (12% *vs.* 46%) or nonoperative treatment (13% *vs.* 24%).

Summary statistics for the combined cohorts are also shown in Table 1 according to treatment received. At baseline, patients in the group undergoing surgery within 4 years from the combined randomized and observational cohorts were younger than those receiving nonoperative treatment. They had worse pain, function, disability, and symptoms than patients in the nonoperative group. Patients in the surgery group were more dissatisfied with their symptoms and at enrollment more often rated their symptoms as worsening and definitely preferred surgery. These observations highlight the need to control for baseline differences in the adjusted models. Based on the selection procedure for variables associated with treatment, missing data, and outcomes, the final as-treated models controlled for the following covariate: center; age; gender; baseline score (for SF-36, ODI); income; treatment preference; current duration of symptoms; compensation; smoking status; body mass index; baseline sciatica bothersomeness; joint; stomach; and bowel (Table 2).

Nonoperative Treatments

Nonoperative treatments used during SPORT included physical therapy (44%); visits to a surgeon (46%); nonsteroidal anti-inflammatory drugs (49%); and opioids (37%). More patients in the RC reported receiving injections (54% *vs.* 41%, $P = 0.02$), while more observational patients reported receiving other medications (74% *vs.* 62%, $P = 0.02$). Before enrollment there were no significant differences in nonoperative treatments received between the Randomized Controlled Trial and Observational cohorts.

Table 3. Operative Treatments, Complications, and Events

	Randomized Cohort (n = 166*)	Observational Cohort (n = 245)	*P*
Procedure			0.53
Decompression only	142 (88%)	213 (88%)	
Non-instrumented fusion	7 (4%)	15 (6%)	
Instrumented fusion	12 (7%)	13 (5%)	
Multilevel fusion	5 (3%)	11 (4%)	0.62
Laminectomy level			
L2–L3	57 (35%)	90 (37%)	0.74
L3–L4	123 (76%)	159 (66%)	0.043
L4–L5	149 (92%)	224 (93%)	0.86
L5–S1	62 (38%)	91 (38%)	1
Levels decompressed			0.81
0	4 (2%)	4 (2%)	—
1	35 (21%)	58 (24%)	—
2	50 (30%)	78 (32%)	—
3+	77 (46%)	105 (43%)	—
Operation time	129 (64.1)	128.6 (67)	0.96
Blood loss	333.2 (515.3)	296.9 (310.4)	0.38
Blood replacement			
Intraoperative replacement	15 (9%)	24 (10%)	1
Postoperative transfusion	7 (4%)	13 (5%)	0.82
Length of stay	3.5 (2.6)	3 (2.2)	0.023
Postoperative mortality (death within 6 weeks of surgery)	0 (0%)	1 (0.4%)†	0.84
Postoperative mortality (death within 3 months of surgery)	0 (0%)	1 (0.4%)†	0.84
Intraoperative complications‡			
Dural tear/spinal fluid leak	15 (9%)	23 (9%)	0.95
Other	1 (1%)	2 (1%)	0.73
None	149 (90%)	219 (90%)	0.99
Postoperative complications/events§			
Wound hematoma	3 (2%)	1 (0%)	0.35
Wound infection	4 (2%)	5 (2%)	0.95
Other	10 (6%)	14 (6%)	0.97
None	141 (87%)	213 (87%)	0.94
Additional surgeries (1 yr rate)¶	7 (4%)	15 (6%)	0.41
Additional surgeries (2 yr rate)¶	11 (7%)	21 (8%)	0.48
Additional surgeries (3 yr rate)¶	17 (10%)	29 (12%)	0.64
Additional surgeries (4 yr rate)¶	22 (13%)	32 (13%)	0.94
Recurrent stenosis/progressive spondylolisthesis	15 (9%)	9 (4%)	
Pseudarthrosis/fusion exploration	0 (0%)	0 (0%)	
Complication or other	6 (4%)	12 (5%)	
New condition	1 (NE)‖	7 (3%)	

*171 Randomized Controlled Trial and 252 Observational patients had surgery; surgical information was available for 166 Randomized Controlled Trial patients and 245 observational patients. Specific procedure information was available on 161 Randomized Controlled Trial and 241 Observational patients.
†Patient died 9 days after surgery of a myocardial infarction. The death was judged probably related to treatment by the DHMC review and not related to treatment by the external review.
‡None of the following were reported: aspiration, nerve root injury, operation at wrong level, vascular injury.
§Any reported complications up to 8 wks postoperation. None of the following were reported: bone graft complication, CSF leak, nerve root injury, paralysis, *cauda equina* injury, wound dehiscence, pseudarthrosis.
¶One-, two-, three- and four-year postsurgical reoperation rates are Kaplan Meier estimates; *P* values are based on the log-rank test. Numbers and percentages are based on the first additional surgery if more than one additional surgery. Surgeries include any additional spine surgery not just reoperation at the same level.
‖Not estimable.

Surgical Treatment and Complications

The mean surgical time was 129 minutes, with a mean blood loss of 311 mL (Table 3). There was no significant

Table 4. Statistically Significant Predictors of Adherence to Treatment Among Randomized Controlled Trial Patients

	Assigned to Surgery			Assigned to Nonoperative		
	Treatment Received Within 4 yr			Treatment Received Within 4 yr		
	Surgery (n = 91)	Nonoperative (n = 41)	*P*	Surgery (n = 73)	Nonoperative (n = 73)	*P*
Race–white	81 (89%)	28 (68%)	0.008	67 (92%)	62 (85%)	0.30
Comorbidities						
Hypertension	41 (45%)	27 (66%)	0.04	31 (42%)	35 (48%)	0.62
Mental Component Summary (MCS) score*	50 (12.1)	50.3 (14.2)	0.88	47.1 (12.7)	52 (10.9)	0.012
Oswestry (ODI)†	44.7 (18)	38.3 (19.1)	0.07	46 (18.3)	39.3 (15.8)	0.019
Stenosis Frequency Index (0–24)‡	14.6 (5.4)	11.8 (6.3)	0.009	14.3 (5.5)	12.1 (5.5)	0.019
Stenosis Bothersome Index (0–24)§	14.9 (4.9)	12.1 (6.1)	0.007	15 (5.5)	12.5 (6.1)	0.011
Leg pain bothersomeness	4.5 (1.6)	4 (1.9)	0.08	4.5 (1.5)	3.9 (1.8)	0.049
Satisfaction with symptoms–very dissatisfied	67 (74%)	23 (56%)	0.07	56 (77%)	37 (51%)	0.002
Problem getting better or worse			0.007			0.15
Getting better	2 (2%)	6 (15%)		2 (3%)	8 (11%)	
Staying about the same	28 (31%)	17 (41%)		25 (34%)	25 (34%)	
Getting worse	58 (64%)	18 (44%)		44 (60%)	40 (55%)	
Treatment preference			0.02			<0.001
Definitely prefer nonsurg	9 (10%)	8 (20%)		7 (10%)	13 (18%)	
Probably prefer nonsurg	16 (18%)	14 (34%)		12 (16%)	19 (26%)	
Not sure	32 (35%)	12 (29%)		19 (26%)	32 (44%)	
Probably prefer surgery	23 (25%)	7 (17%)		17 (23%)	4 (5%)	
Definitely prefer surgery	11 (12%)	0 (0%)		18 (25%)	4 (5%)	

*The SF-36 scores range from 0 to 100, with higher score indicating less severe symptoms.
†The Oswestry Disability Index ranges from 0 to 100, with lower scores indicating less severe symptoms.
‡The Stenosis Frequency Index ranges from 0 to 24, with lower scores indicating less severe symptoms.
§The Stenosis Bothersomeness Index ranges from 0 to 24, with lower scores indicating less severe symptoms.

difference between the cohorts in rates of intraoperative blood replacement, or postoperative transfusion rates. The most common surgical complication was dural tear (9%). The 4-year reoperation rate was 13%.

Over 4 years, there were 12 deaths in the nonoperative group within 4 years of enrollment compared to 23 expected based on age-gender specific mortality rates, and 15 deaths in the surgery group within 4 years of surgery, compared to 29 expected. The hazard ratio based on a proportional hazards model adjusted for age was 0.7 (95% CI: 0.32, 1.6); $P = 0.43$. All 27 deaths were independently reviewed and 23 were judged not to be treatment-related. Four deaths were of unknown cause and unknown treatment relation but occurred 1203, 1192, 855, 501 days postsurgery/enrollment. Three of these deaths were in patients who had had surgery and one was in a patient who had not had surgery.

Cross Over

Nonadherence to treatment assignment affected both arms: patients chose to delay or decline surgery in the surgical arm and crossed over to surgery in the nonoperative arm (Figure 1). The characteristics of cross over patients, which were statistically different from patients who did not cross over are shown in Table 4. Patients who crossed over to nonoperative care were less likely to be white; less bothered by their symptoms; more likely to judge their symptoms as improving at baseline; and had stronger baseline treatment preferences for nonoperative care. Patients crossing over to surgery had lower mental component summary scores, were more disabled and bothered by their symptoms, were less satisfied by their symptoms, and had stronger baseline preference for surgery.

Main Treatment Effects

The intent-to-treat analysis of the RC showed no statistical differences between surgery and nonoperative care based on overall global hypothesis tests for differences in mean changes from baseline (Figure 2). The randomized and observational cohorts as-treated treatment effects were similar at 4 years (Figure 2):

- Bodily Pain: RC 11.4 (95% CI, 5.1–17.6) *versus* OC 14.9 (95% CI, 9.3–20.5);
- PF: RC 8.0 (95% CI, 1.7–14.3) *versus* OC 10.1 (95% CI, 4.7–15.5); and
- ODI: RC −7.8 (−12.9, −2.6) *versus* OC −11.5 (−15.8, −7.3).

The global hypothesis test comparing the as-treated RC and OC treatment effects over all time periods showed no difference between the cohorts ($P = 0.27$ for BP; $P = 0.56$ for PF; and $P = 0.25$ for ODI).

Results from the intent-to-treat and as-treated analyses of the 2 cohorts are compared in Figure 2. The as-treated treatment effects significantly favored surgery in both cohorts. In the combined analysis, treatment effects were statistically significant in favor of surgery for all primary and secondary outcome measures at each time point out to 4 years (Table 2 and Figure 3). At 4 years, the treatment effect for BP was 12.6 (95% CI, 8.5–16.7) for PF was 8.6 (95% CI, 4.6–12.6) and for ODI was −9.4 (95% CI, −12.6 to −6.2).

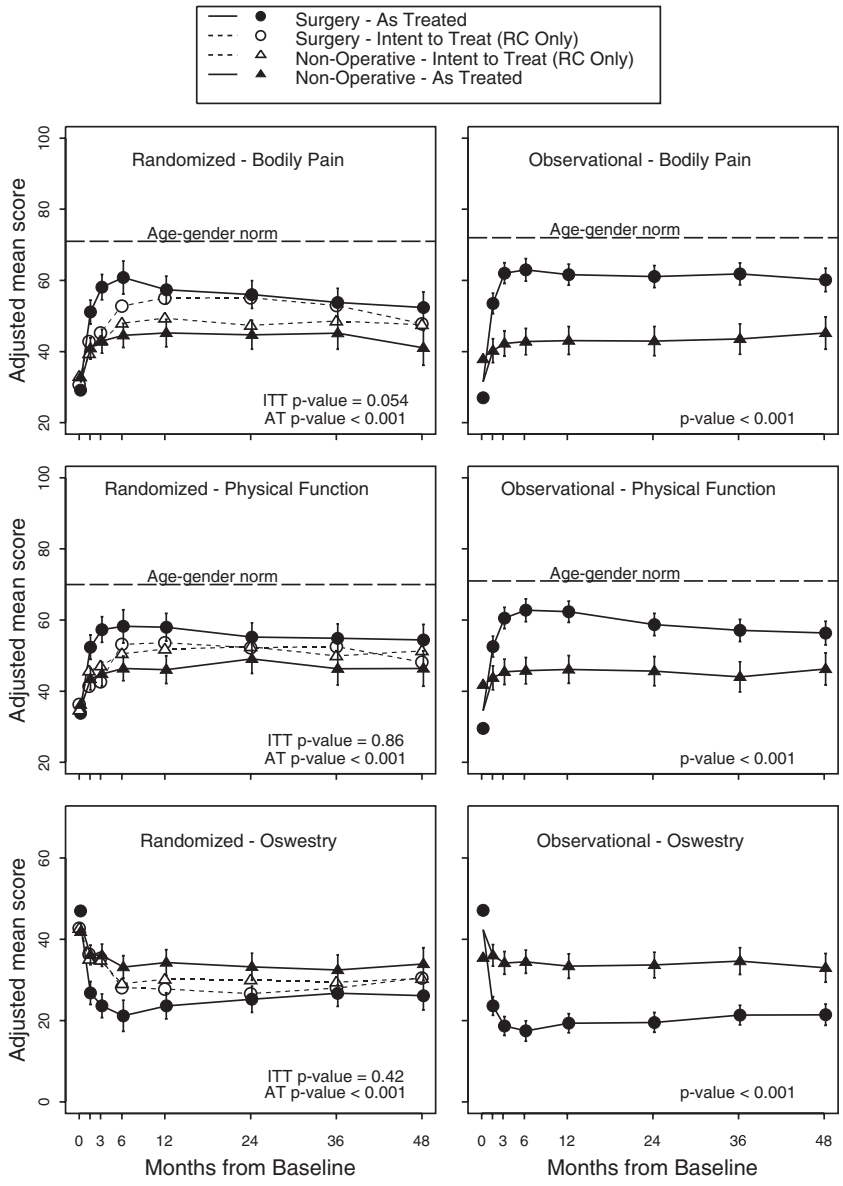

Figure 2. Primary outcomes over 4 years for the spinal stenosis randomized and observational cohorts. Intention-to-treat and As-Treated Results over Time for the Primary Outcome Measures of SF-36 Bodily Pain, SF-36 Physical Function, and the Oswestry Disability Index. The horizontal dashed line in each of the four SF-36 graphs represents the age- and sex-adjusted norms. I bars represent the 95% confidence intervals. The floating symbols at 0 months represent the observed mean scores for each treatment group, whereas the plotline at 0 months originates from the overall means used in the adjusted analyses.

Table 5 shows the proportion of patients in the as-treated comparison of surgery *versus* nonoperative care who achieved at least a 15-point improvement in the ODI at 1 and 4 years, respectively.[23] These proportions at 4 years (61% in surgery group, 32% in nonoperative group) are quite similar to the proportions rating themselves as being very/somewhat satisfied with their symptoms (63% in the surgery group, 32% in the nonoperative group) and having had a major improvement (53% in surgery group, 23% in nonoperative group).

■ Discussion

In patients presenting with signs and symptoms of image confirmed SpS persisting for at least 12 weeks, the intention-to-treat analysis found no significant advantage for surgery over nonoperative treatment. These results must be viewed in the context of substantial rates of nonadherence to the assigned treatment. This mixing of treatments generally biases treatment effect estimates towards the null.[8–14]

In the as-treated analysis, the treatment effect in favor of surgery suggests the intention-to-treat analysis underestimates the true effect of surgery. The effect was seen as early as 6 weeks, appeared maximal by 3 to 12 months and has persisted over 4 years. The nonoperative treatment group demonstrated only modest improvement over time. The results in both treatment groups were maintained between 2 and 4 years.

This study provides an opportunity to compare results involving patients who were willing to participate in a randomized study (randomized cohort) and those who were unwilling to participate in such a study (observational cohort). These 2 cohorts were remarkably similar at baseline. Other than treatment preference the only significant differences at baseline were small ones: location of stenosis, tension signs, and sensory findings. The cohorts also had similar outcomes, with no significant differences between the treatment effects in the as-treated analyses, supporting the validity of the combined analy-

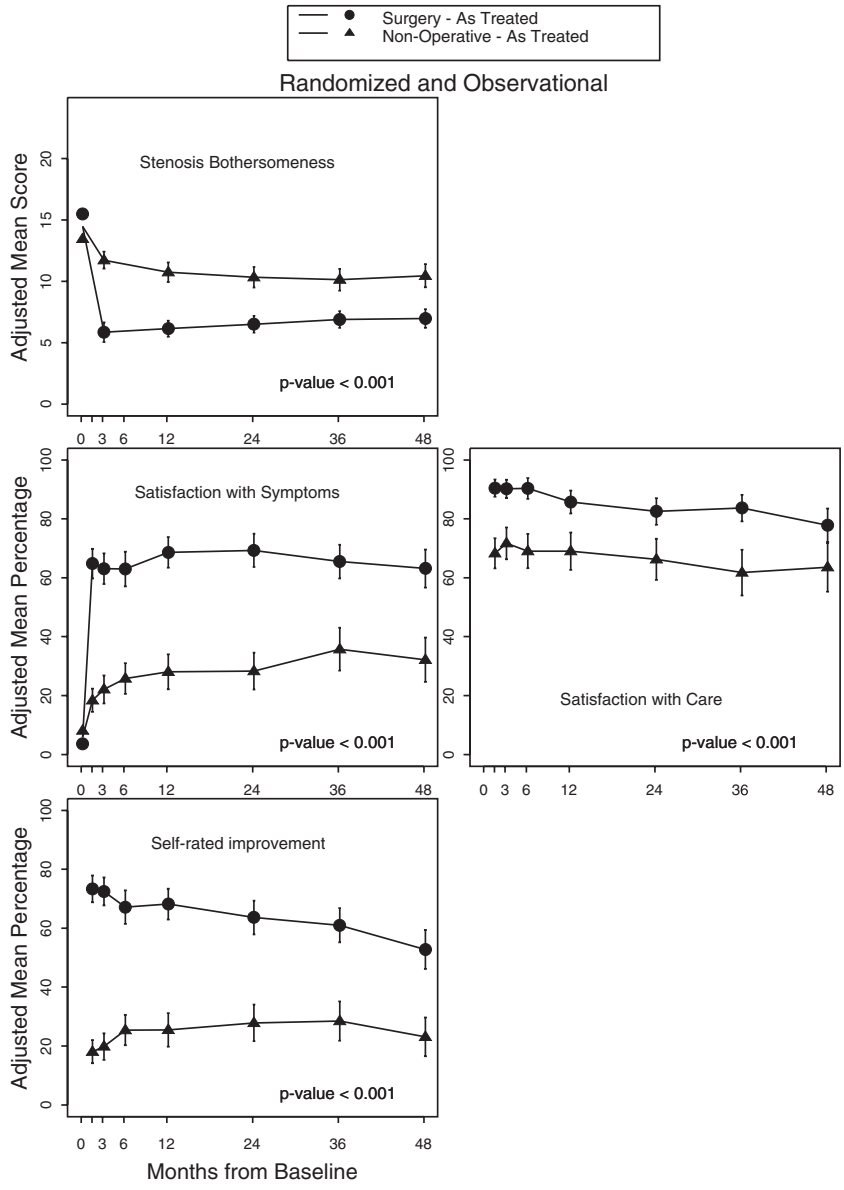

Figure 3. Secondary outcomes over 4 years for the spinal stenosis randomized and observational cohorts (As-Treated analyses). I bars represent the 95% confidence intervals. The floating symbols at 0 months represent the observed mean scores for each treatment group, whereas the plotline at 0 months originates from the overall means used in the adjusted analyses.

sis. Although these analyses are not based entirely on randomized treatment assignments, the results are strengthened by the use of specific inclusion and exclusion criteria, the sample size, and the adjustment for potentially confounding baseline factors.[10–12]

Comparisons to Other Studies

SPORT represents the largest study of its kind, and the largest study to isolate SpS from stenosis secondary to degenerative spondylolisthesis. Its cohort was recruited from 13 centers in 11 states, making it the most heterogeneous study of stenosis, and its inclusion and exclusion criteria were the most rigorous to date. The characteristics of the participants and the short-term outcomes of SPORT as previously reported are comparable to studies both of isolated SpS and of mixed cohorts of patients with and without degenerative spondylolisthesis with stenosis.[9,11,12]

Table 5. Proportion of Patients Who Had a Change of ≥15 on the ODI at 1-Year and 4-Year From Baseline

	Surgery	Nonoperative	Treatment Effect (95% CI)	*P*
At 1 yr	64.7%	30.7%	33.9% (26.1, 41.7)	<0.001
At 4 yr	60.6%	32.4%	28.2% (18.6, 37.7)	<0.001

Based on the adjusted as-treated analysis for the randomized and observational cohorts combined, according to treatment received.

The surgical outcomes in SPORT were generally similar to those in previous surgical series. Herkowitz and Kurz[7] reported absolute improvements of 33% for back pain and 55% for leg pain (6-point scales) at an average of 3 years, similar to the changes of 26% and 36%, respectively (7-point scales), seen in SPORT at 4 years. The improvement at 4 years in the patients in SPORT who were undergoing surgery for isolated SpS were also similar to the outcomes of surgery in the Maine Lumbar Spine Study (MLSS) mixed-stenosis (those with and those without degenerative spondylolisthesis) cohort.[27] The improvement in the stenosis

bothersomeness index, leg pain, and low back pain bothersomeness respectively were −7.6, −2.5, and −1.8 in SPORT *versus* −9.4, −3.5, and −1.7 in the MLSS.

There was little evidence of harm from either treatment. In the interval between 2 and 4 years, there have not been any cases of paralysis in either the surgical or nonoperative group. The 4-year rate of reoperation for recurrent stenosis was 6% and the overall reoperation rate increased from 8% at 2 years to 13% at 4 years; compared to 6.2% at 4 years in the MLSS. The perioperative mortality rate remained unchanged at 0.2%, nearly identical to 0.24% seen in Washington State Commission Hospital Abstract Reporting System patients after surgery.[28]

The 4-year mortality rate was similar in both treatment groups and was lower than actuarial projections. It should be noted that higher rates of complications have been reported with increasing age and coexisting medical conditions.[29]

■ Conclusion

In the as-treated analysis combining the randomized and observational cohorts of patients with SpS, those treated surgically showed significantly greater improvement in pain, function, satisfaction, and self-rated progress over 4 years compared to patients treated nonoperatively. Results in both groups were stable between 2 and 4 years.

■ Key Points

- Many previous trials of spinal stenosis surgical treatment have had one or more important limitations: mixed diagnosis, small sample size, no nonoperative control, or lack of validated outcome measures.
- In both cohorts combined, 419 patients received surgery at some point during the first 4 years; 235 remained nonoperative. The proportion of enrollees who supplied data at each follow-up visit interval ranged from 67% to 89% with losses due to dropouts, missed visits, or deaths.
- An as-treated analysis combining the randomized and observational cohorts and adjusting for potential confounders found that the clinically significant advantages for surgery previously reported were maintained through 4 years.

References

1. Weinstein JN, Lurie JD, Olson PR, et al. United States' trends and regional variations in lumbar spine surgery: 1992–2003. *Spine* 2006;31:2707–14.
2. Malmivaara A, Slatis P, Heliovaara M, et al. Surgical or nonoperative treatment for lumbar spinal stenosis? A randomized controlled trial. *Spine* 2007; 32:1–8.
3. Atlas SJ, Deyo RA, Keller RB, et al. The Maine Lumbar Spine Study, Part III. 1-year outcomes of surgical and nonsurgical management of lumbar spinal stenosis. *Spine* 1996;21:1787–94; discussion 1794–5.
4. Arega A, Birkmeyer NJ, Lurie JD, et al. Racial variation in treatment preferences and willingness to randomize in the Spine Patient Outcomes Research Trial (SPORT). *Spine* 2006;31:2263–9.
5. Bridwell KH, Sedgewick TA, O'Brien MF, et al. The role of fusion and instrumentation in the treatment of degenerative spondylolisthesis with spinal stenosis. *J Spinal Disord* 1993;6:461–72.
6. Fischgrund JS, Mackay M, Herkowitz HN, et al. 1997 Volvo Award winner in clinical studies. Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective, randomized study comparing decompressive laminectomy and arthrodesis with and without spinal instrumentation. *Spine* 1997;22: 2807–12.
7. Herkowitz HN, Kurz LT. Degenerative lumbar spondylolisthesis with spinal stenosis. A prospective study comparing decompression with decompression and intertransverse process arthrodesis. *J Bone Joint Surg Am* 1991;73:802–8.
8. Birkmeyer NJ, Weinstein JN, Tosteson AN, et al. Design of the Spine Patient outcomes Research Trial (SPORT). *Spine* 2002;27:1361–72.
9. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis. *N Engl J Med* 2007; 356:2257–70.
10. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus nonoperative treatment for lumbar disc herniation: four-year results for the Spine Patient Outcomes Research Trial (SPORT). *Spine* 2008;33:2789–800.
11. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus non-operative treatment for lumbar degenerative spondylolisthesis: four-year results of the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts. *J Bone Joint Surg Am* 2009;91:1295–304.
12. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical versus nonsurgical therapy for lumbar spinal stenosis. *N Engl J Med* 2008;358:794–810.
13. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT) observational cohort. *JAMA* 2006;296:2451–9.
14. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT): a randomized trial. *JAMA* 2006;296:2441–50.
15. Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: increasing the value of clinical research for decision making in clinical and health policy. *JAMA* 2003;290:1624–32.
16. Johnsson KE, 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.
17. Malmivaara A, Statis P, Heliovaara M, et al. Surgical treatment for moderate lumbar spinal stenosis: a randomized controlled trial. In: Proceedings of the International Society for Study of the Lumbar Spine (ISSLS); May 30–June5, 2004; Porto, Portugal.
18. Cummins J, Lurie JD, Tosteson TD, et al. Descriptive epidemiology and prior healthcare utilization of patients in The Spine Patient Outcomes Research Trial's (SPORT) three observational cohorts: disc herniation, spinal stenosis, and degenerative spondylolisthesis. *Spine* 2006;31:806–14.
19. McHorney CA, Ware JE Jr, Lu JF, et al. The MOS 36-item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. *Med Care* 1994;32:40–66.
20. Stewart AL, Greenfield S, Hays RD, et al. Functional status and well-being of patients with chronic conditions. Results from the Medical Outcomes Study. *JAMA* 1989;262:907–13.
21. Ware J, Sherbourne D. The MOS 36-item short-form health survey. *Med Care* 1992;30:473–83.
22. Ware JJ. *SF-36 Health Survey: Manual and Interpretation Guide*. Boston, MA: Nimrod Press; 1993.
23. Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine* 25:2940–52, 2000; discussion 2952.
24. Deyo RA, Diehl AK. Patient satisfaction with medical care for low-back pain. *Spine* 1986;11:28–30.
25. Patrick DL, Deyo RA, Atlas SJ, et al. Assessing health-related quality of life in patients with sciatica. *Spine* 1995;20:1899–908; discussion 1909.
26. Fitzmaurice G, Laird N, Ware J. *Applied Longitudinal Analysis*. Philadelphia, PA: John Wiley & Sons; 2004.
27. Atlas SJ, Keller RB, Robson D, et al. Surgical and nonsurgical management of lumbar spinal stenosis: four-year outcomes from the maine lumbar spine study. *Spine* 2000;25:556–62.
28. Deyo RA, Cherkin DC, Loeser JD, et al. Morbidity and mortality in association with operations on the lumbar spine. The influence of age, diagnosis, and procedure. *J Bone Joint Surg Am* 1992;74:536–43.
29. 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.