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Surgical versus Nonsurgical Treatment for Lumbar Degenerative Spondylolisthesis

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ABSTRACT

BACKGROUND

Management of degenerative spondylolisthesis with spinal stenosis is controversial. Surgery is widely used, but its effectiveness in comparison with that of nonsurgical treatment has not been demonstrated in controlled trials.

METHODS

Surgical candidates from 13 centers in 11 U.S. states who had at least 12 weeks of symptoms and image-confirmed degenerative spondylolisthesis were offered enrollment in a randomized cohort or an observational cohort. Treatment was standard decompressive laminectomy (with or without fusion) or usual nonsurgical care. The primary outcome measures were the Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36) bodily pain and physical function scores (100-point scales, with higher scores indicating less severe symptoms) and the modified Oswestry Disability Index (100-point scale, with lower scores indicating less severe symptoms) at 6 weeks, 3 months, 6 months, 1 year, and 2 years.

RESULTS

We enrolled 304 patients in the randomized cohort and 303 in the observational cohort. The baseline characteristics of the two cohorts were similar. The one-year crossover rates were high in the randomized cohort (approximately 40% in each direction) but moderate in the observational cohort (17% crossover to surgery and 3% crossover to nonsurgical care). The intention-to-treat analysis for the randomized cohort showed no statistically significant effects for the primary outcomes. The as-treated analysis for both cohorts combined showed a significant advantage for surgery at 3 months that increased at 1 year and diminished only slightly at 2 years. The treatment effects at 2 years were 18.1 for bodily pain (95% confidence interval [CI], 14.5 to 21.7), 18.3 for physical function (95% CI, 14.6 to 21.9), and −16.7 for the Oswestry Disability Index (95% CI, −19.5 to −13.9). There was little evidence of harm from either treatment.

CONCLUSIONS

In nonrandomized as-treated comparisons with careful control for potentially confounding baseline factors, patients with degenerative spondylolisthesis and spinal stenosis treated surgically showed substantially greater improvement in pain and function during a period of 2 years than patients treated nonsurgically. (ClinicalTrials. gov number, NCT00000409.)

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D EGENERATIVE SPONDYLOLISTHESIS IS the slipping forward of one lumbar vertebra on another with an intact neural arch. It rarely occurs before the age of 50 years, and it disproportionately affects women, particularly black women, with a male:female ratio of approximately 1:6.[1] Slippage most commonly occurs at the L4–L5 level and rarely exceeds 30% of vertebral width.[1] Degenerative spondylolisthesis is generally asymptomatic, but it can be associated with symptomatic spinal stenosis.[1]

Spinal stenosis, the most common reason for lumbar surgery in adults over the age of 65, is a narrowing of the spinal canal with encroachment on the neural structures by surrounding bone and soft tissue. Patients typically present with neurogenic claudication — pain in the buttocks or legs with walking or standing that resolves with sitting or lumbar flexion. However, anatomical spinal stenosis is frequently detected by imaging studies in asymptomatic patients; thus, clinical correlation between symptoms and imaging is critical.[2]

Two studies have compared surgery with nonsurgical treatment for spinal stenosis, but both of these studies included patients with and those without degenerative spondylolisthesis.[3-5] Several studies have compared surgical techniques in cohorts with degenerative spondylolisthesis; however, these studies had small samples with limited geographic participation and lacked nonsurgical controls and validated outcome measures.[6-8] The optimal treatment strategy for symptomatic degenerative spondylolisthesis remains unclear.

The Spine Patient Outcomes Research Trial (SPORT) was designed to compare the effectiveness of surgical and nonsurgical treatment among participants with confirmed diagnoses of intervertebral disk herniation,[9,10] spinal stenosis, and degenerative spondylolisthesis.[11] Here we report the 2-year outcomes of patients with degenerative spondylolisthesis.

METHODS

STUDY DESIGN

The SPORT was conducted in 11 states at 13 medical centers in the United States that have multidisciplinary spine practices. The SPORT included both a randomized cohort and a concurrent observational cohort with identical selection criteria and outcomes assessment.[12] The standardized protocol was approved by human subjects committees at each participating institution, and an independent data and safety monitoring board monitored the results of the trial. The principal investigator had full access to all the data in the study and takes responsibility for the accuracy and integrity of the data analysis. Additional background information has been published previously.[9-11,13]

PATIENT POPULATION

All patients had neurogenic claudication or radicular leg pain with associated neurologic signs, spinal stenosis shown on cross-sectional imaging, and degenerative spondylolisthesis shown on lateral radiographs obtained with the patient in a standing position. The patients had had persistent symptoms for at least 12 weeks and had been confirmed as surgical candidates by their physicians. Patients with adjacent levels of stenosis were eligible; patients with spondylolysis and isthmic spondylolisthesis were not. The nature of nonsurgical care before enrollment was not prespecified but included physical therapy in 68% of patients, epidural injections in 55%, chiropractic treatment in 25%, antiinflammatory agents in 63%, and opioid analgesic agents in 30%.

Research nurses at each site identified potential participants and verified their eligibility. The patients were offered enrollment in either cohort and gave written informed consent after viewing videotapes explaining the expected benefits, risks, and uncertainties of the treatments.[14,15] Participants in the randomized cohort received computer-generated random treatment assignments blocked according to center; those in the observational cohort chose their treatment with their physician. Enrollment began in March 2000 and ended in February 2005.

STUDY INTERVENTIONS

The protocol surgery consisted of a standard posterior decompressive laminectomy with or without bilateral single-level fusion (iliac crest bone grafting with or without posterior pedicle-screw instrumentation).[11] The nonsurgical protocol was usual care, recommended to include at least active physical therapy, education or counseling including instructions for exercising at home, and nonsteroidal antiinflammatory agents if tolerated.[11,13]

STUDY MEASURES

The primary end points were the Medical Outcomes Study 36-Item Short-Form General Health Survey

(SF-36) bodily pain and physical function scores[16-19] and the Oswestry Disability Index (American Academy of Orthopaedic Surgeons/Modems version)[20] measured at 6 weeks and at 3, 6, 12, and 24 months after enrollment. Secondary outcomes included patient-reported improvement, satisfaction with current symptoms and care,[21] the Stenosis Bothersomeness Index,[22,23] and the Low Back Pain Bothersomeness Scale.[3] The SF-36 scores range from 0 to 100, with higher scores 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; and the Low Back Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms.

STATISTICAL ANALYSIS

A sample size of 150 patients in each treatment group for the randomized cohort was determined as sufficient on the basis of a two-sided t-test with a power of 0.85 to detect a 10-point difference in the SF-36 bodily pain and physical function scores or a similar effect size in the Oswestry Disability Index. The sample size allowed for up to 20% of the data to be missing but did not account for any specific levels of nonadherence.

Initial analyses compared baseline characteristics of the patients between the randomized cohort and the observational cohort and between the treatment groups of the combined randomized cohort and the observational cohort. The extent of missing data and the percentage of patients undergoing surgery were calculated for each scheduled follow-up. Baseline predictors of time until surgical treatment in both cohorts (including treatment crossovers) were determined by a stepwise proportional-hazards regression model with an inclusion criterion of P<0.1 to enter and P>0.05 to exit. Predictors of missing follow-up visits at 1 year were determined by stepwise logistic regression with entry and exit criteria of P<0.1 and P>0.05, respectively.

Primary analyses compared surgical and nonsurgical treatments using changes from baseline at each follow-up time for SF-36 bodily pain and physical function and for the Oswestry Disability Index. The randomized cohort was initially analyzed on an intention-to-treat basis. However, because of the extent of crossover, subsequent analyses combined the randomized cohort and the observational cohort and were based on treatments actually received. In these as-treated analyses, the treatment indicator was a time-varying covariate, allowing for variable times to surgery. Before the time of surgery, all changes from baseline were included in the estimates of the nonsurgical treatment effect. After surgery, subsequent changes in outcomes were assigned to the surgical group with follow-up measured from the date of surgery. The randomized cohort and the observational cohort were each analyzed to produce separate as-treated estimates of treatment effect. These results were compared with the use of a Wald test to simultaneously test all follow-up visit times for differences in estimated treatment effects between the randomized and observational groups.[24] Subsequent analyses combined the two cohorts.

To adjust for potential confounding effects, baseline variables associated with missing data or treatment received were included as covariates in longitudinal regression models.[24] A random effect was specified to account for the correlation between the repeated measurements of individual patients. Computations were performed with the use of SAS software (PROC MIXED for continuous data with normal random effects and PROC GENMOD for binary and non-normal secondary outcomes). Statistical significance was defined as P<0.05 on the basis of a two-sided hypothesis test (SAS software, version 9.1). Data for these analyses were collected through October 3, 2006.

RESULTS

Overall, 607 of 892 eligible participants were enrolled in the SPORT (304 in the randomized cohort and 303 in the observational cohort). A total of 601 patients (99%) completed at least one follow-up visit and were included in the analysis; between 83% and 95% of enrollees supplied data at each follow-up visit (Fig. 1).

In the randomized cohort, 159 patients were assigned to surgery and 145 to nonsurgical treatment. Of those assigned to surgery, 57% underwent surgery by 1 year and 64% by 2 years. In the group assigned to nonsurgical care, 44% underwent surgery by 1 year and 49% by 2 years. In the observational cohort, 173 patients initially chose surgery and 130 initially chose nonsurgical care. Of those initially choosing surgery, 97% underwent surgery by 1 year, and one additional pa-
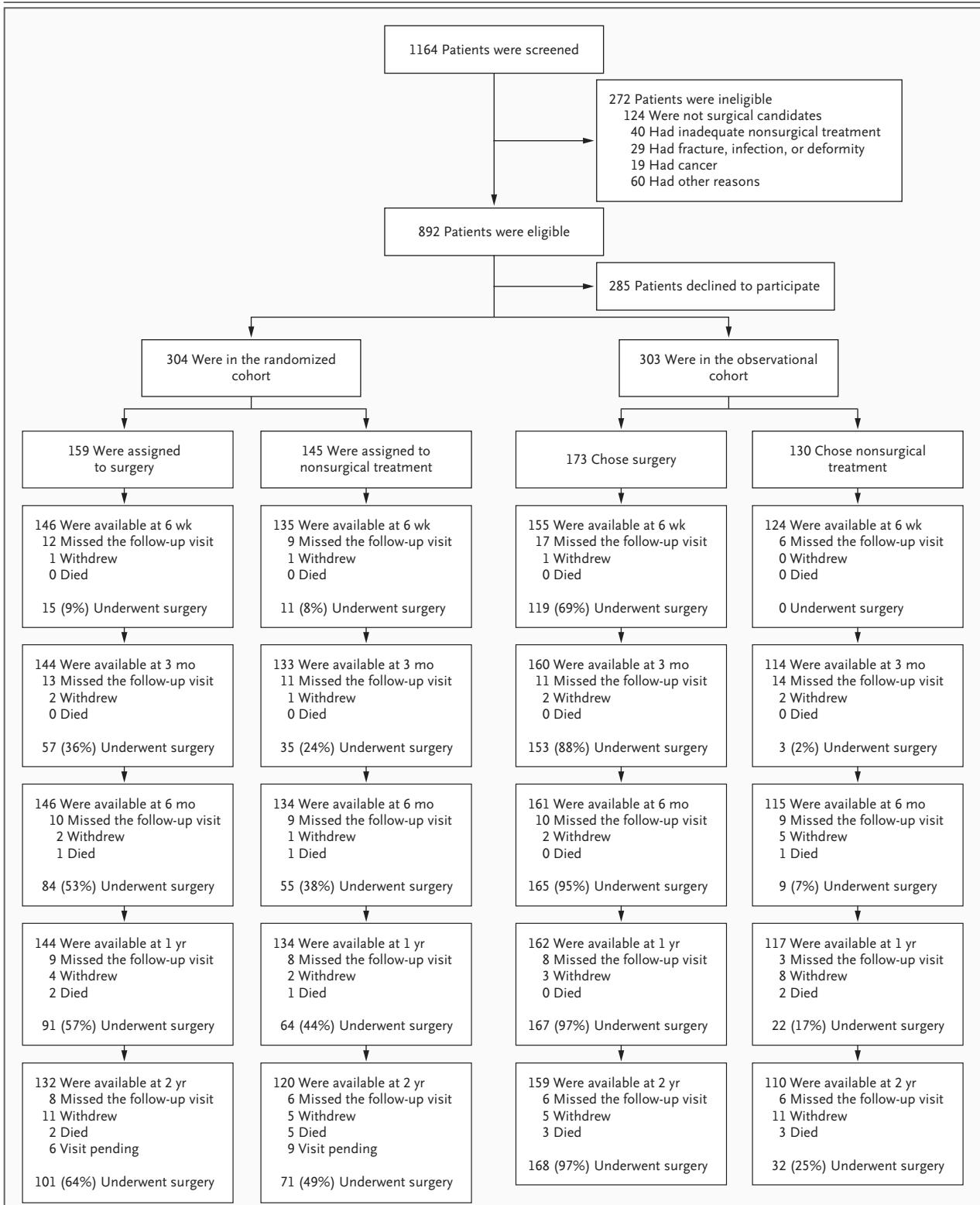
Figure 1. Exclusion, Enrollment, Randomization, and Follow-up of Trial Participants.

The values are cumulative over 2 years. For example, a total of two patients in the group assigned to surgery died during the 2-year follow-up period.

tient underwent surgery between 1 and 2 years from the time of enrollment. Of those initially choosing nonsurgical treatment, 17% underwent surgery by 1 year and 25% by 2 years. In both cohorts combined, 372 patients underwent surgery within the first 2 years and 235 received only nonsurgical treatment.

PATIENT CHARACTERISTICS

Table 1 shows the baseline characteristics and clinical findings of participants in the randomized and the observational cohorts. The cohorts were remarkably similar; however, patients in the observational cohort had more L4–L5 involvement, less involvement of L3–L4, and less lateral recess stenosis.

Summary statistics for the combined cohorts are also shown in Table 1 according to treatment received; the mean age was 66 years. Eighty-five percent of patients had neurogenic claudication, and 77% had associated dermatomal pain radiation. Most of the degenerative slips and associated stenoses were at L4–L5. On imaging, stenosis was graded as severe in 60% of patients, and 35% had multiple levels of stenosis.

At baseline, patients in the group undergoing surgery from the combined randomized and observational cohorts were younger and more likely to be receiving compensation (e.g., workers' compensation or social security) than those receiving nonsurgical treatment. They had worse pain, function, disability, and symptoms than patients in the nonsurgical group. Patients in the surgery group were more dissatisfied with their symptoms and at enrollment more often rated their symptoms as worsening. This observation highlights the need to control for baseline differences in the adjusted models. The final model controlled for the following covariates, selected as described in the Methods section: age, sex, work status, depression, osteoporosis, joint problems, duration of current symptoms, reflex deficit, number of moderate or severe stenotic levels, baseline score (for the SF-36, the Oswestry Disability Index, and the Stenosis Bothersomeness Index), and the center where the patient was treated. SF-36 and the Oswestry Disability Index scores were also adjusted for the baseline Stenosis Bothersomeness Index score.

Lateral radiographs obtained with the patient in a neutral standing position were available for independent review for 169 patients. The percentage of slip as measured by the method of Mor-gan and King[25] ranged from 1 to 37% (median, 15%; interquartile range, 10 to 21%). Eighty-six percent of patients had grade 1 slip and 14% had grade 2.

NONSURGICAL TREATMENTS

Nonsurgical treatments used during the SPORT included physical therapy (42%), epidural steroid injections (45%), nonsteroidal antiinflammatory drugs (51%), and opioids (34%). Nonsurgical treatments were similar in the randomized cohort and the observational cohort, though more patients in the randomized cohort reported visits to a surgeon (44% vs. 34%, P=0.04), receiving injections (49% vs. 37%, P=0.02), and narcotics use (40% vs. 26%, P=0.007).

SURGICAL TREATMENT AND COMPLICATIONS

The median surgical time was 199 minutes, with a mean blood loss of 589 ml (Table 2). There were no significant differences between the cohorts in rates of intraoperative blood replacement, but there was a difference in the postoperative transfusion rates (16% in the randomized cohort vs. 26% in the observational cohort, P=0.04). The most common surgical complication was dural tear (10%). The 2-year reoperation rate was 12%.

MAIN TREATMENT EFFECTS

The intention-to-treat analysis of the randomized cohort showed no statistically significant effects for the primary outcomes, on the basis of a global hypothesis test for differences in mean changes from baseline between the treatment groups including all time periods. Treatment effects at 2 years were 1.5 for SF-36 bodily pain (95% confidence interval [CI], −4.2 to 7.3; P=0.52), 1.9 for physical function (95% CI, −3.7 to 7.5; P=0.71), and 2.2 for the Oswestry Disability Index (95% CI, −2.3 to 6.8; P=0.68).

As-treated effects for the combined cohorts were statistically significant in favor of surgery for all primary and secondary outcomes (Table 3 and Fig. 2). Treatment effects were stable for 2 years and were significant for all time periods, with treatment effects at 2 years of 18.1 for SF-36 bodily pain (95% CI, 14.5 to 21.7), 18.3 for physical function (95% CI, 14.6 to 21.9), and −16.7 for the Oswestry Disability Index (95% CI, −19.5 to −13.9). The results of the intention-to-treat and the as-treated analyses of the randomized and the observational cohorts are compared in Figure 2. The as-treated treatment effects at 2 years were nearly

Table 1. Characteristics of the Patients According to Study Cohort at Baseline.*

Characteristic	Randomized Cohort (N=301)	Observational Cohort (N=300)	P Value	Surgical Treatment (N=368)†	Nonsurgical Treatment (N=233)†	P Value
Age — yr	66.0±10.0	66.1±10.6	0.86	64.7±10.1	68.2±10.3	<0.001
Female sex — no. (%)	200 (66)	212 (71)	0.30	255 (69)	157 (67)	0.69
Race or ethnic group — no. (%)‡						
Non-Hispanic	292 (97)	295 (98)	0.42	359 (98)	228 (98)	0.97
White	259 (86)	247 (82)	0.26	316 (86)	190 (82)	0.19
Black	29 (10)	32 (11)	0.78	30 (8)	31 (13)	0.06
Any college education — no. (%)	201 (67)	199 (66)	0.98	247 (67)	153 (66)	0.78
Married — no. (%)	198 (66)	198 (66)	0.98	249 (68)	147 (63)	0.29
Work status — no. (%)			0.42			0.96
Working full- or part-time	116 (39)	102 (34)		133 (36)	85 (36)	
Disabled	21 (7)	30 (10)		33 (9)	18 (8)	
Retired	129 (43)	128 (43)		156 (42)	101 (43)	
Other	35 (12)	40 (13)		46 (12)	29 (12)	
Compensation — no. (%)§	21 (7)	20 (7)	0.99	34 (9)	7 (3)	0.005
Body-mass index¶	29.1±5.7	29.2±6.7	0.91	29.4±6.5	28.8±5.7	0.22
Current smoker — no. (%)	23 (8)	28 (9)	0.55	34 (9)	17 (7)	0.49
Coexisting conditions — no. (%)						
Hypertension	141 (47)	134 (45)	0.65	164 (45)	111 (48)	0.51
Diabetes	39 (13)	41 (14)	0.89	48 (13)	32 (14)	0.90
Osteoporosis	33 (11)	36 (12)	0.79	40 (11)	29 (12)	0.65
Heart problem	61 (20)	61 (20)	0.94	65 (18)	57 (24)	0.055
Stomach problem	64 (21)	69 (23)	0.68	79 (21)	54 (23)	0.70
Bowel or intestinal problem	17 (6)	26 (9)	0.20	30 (8)	13 (6)	0.30
Depression	56 (19)	42 (14)	0.16	63 (17)	35 (15)	0.57
Joint problem	175 (58)	169 (56)	0.72	202 (55)	142 (61)	0.17
Other‖	121 (40)	113 (38)	0.58	146 (40)	88 (38)	0.70
Symptom duration >6 mo — no. (%)	185 (61)	176 (59)	0.54	227 (62)	134 (58)	0.35
SF-36 scores**						
Bodily pain	30.7±16.4	31.7±17.5	0.44	29.2±16.8	34.4±16.7	<0.001
Physical function	34.4±21.5	34.3±23.3	0.98	30.5±20.5	40.3±23.9	<0.001
Mental component summary	49.9±11.9	50.5±11.2	0.53	49.5±11.6	51.3±11.3	0.06
Oswestry Disability Index††	41.8±16.5	41.3±19.1	0.72	45.0±16.6	36.2±18.5	<0.001
Stenosis Frequency Index‡‡	14.2±5.5	13.8±5.7	0.36	14.8±5.5	12.6±5.4	<0.001
Stenosis Bothersomeness Index§§	14.8±5.6	14.6±5.6	0.79	15.6±5.5	13.3±5.4	<0.001
Low Back Pain Bothersomeness Scale¶¶	4.3±1.8	4.3±1.8	0.99	4.4±1.8	4.0±1.9	0.01
Very dissatisfied with symptoms — no. (%)	203 (67)	213 (71)	0.39	287 (78)	129 (55)	<0.001
Self-assessment of health trend — no. (%)‖‖			0.73			<0.001
Problem getting better	17 (6)	21 (7)		17 (5)	21 (9)	
Problem staying about the same	100 (33)	94 (31)		89 (24)	105 (45)	
Problem getting worse	179 (59)	182 (61)		258 (70)	103 (44)	
Treatment preference at baseline — no. (%)***			<0.001			<0.001
Definitely prefer nonsurgical treatment	44 (15)	83 (28)		32 (9)	95 (41)	
Probably prefer nonsurgical treatment	71 (24)	37 (12)		40 (11)	68 (29)	
Not sure	117 (39)	20 (7)		83 (23)	54 (23)	
Probably prefer surgery	30 (10)	31 (10)		51 (14)	10 (4)	
Definitely prefer surgery	38 (13)	129 (43)		162 (44)	5 (2)	

Table 1. (Continued.)

Characteristic	Randomized Cohort (N=301)	Observational Cohort (N=300)	P Value	Surgical Treatment (N=368)†	Nonsurgical Treatment (N=233)†	P Value
Pseudoclaudication — no. (%)	259 (86)	252 (84)	0.56	319 (87)	192 (82)	0.19
Straight-leg–raising test or femoral-tension sign — no. (%)	44 (15)	41 (14)	0.83	48 (13)	37 (16)	0.39
Dermatomal pain radiation — no. (%)	239 (79)	229 (76)	0.42	288 (78)	180 (77)	0.85
Any neurologic deficit — no. (%)	142 (47)	152 (51)	0.44	185 (50)	109 (47)	0.45
Asymmetric reflex depression	53 (18)	40 (13)	0.18	65 (18)	28 (12)	0.08
Asymmetric sensory decrease	79 (26)	90 (30)	0.35	108 (29)	61 (26)	0.45
Asymmetric motor weakness	74 (25)	72 (24)	0.94	87 (24)	59 (25)	0.71
Listhesis level — no. (%)			0.17			0.69
L3–L4	34 (11)	23 (8)		33 (9)	24 (10)	
L4–L5	267 (89)	277 (92)		335 (91)	209 (90)	
Stenosis level — no. (%)						
L2–L3	31 (10)	22 (7)	0.26	33 (9)	20 (9)	0.99
L3–L4	136 (45)	100 (33)	0.004	145 (39)	91 (39)	1.00
L4–L5	285 (95)	295 (98)	0.03	357 (97)	223 (96)	0.54
L5–S1	27 (9)	30 (10)	0.77	29 (8)	28 (12)	0.12
No. of moderate or severe stenotic levels — no. (%)			0.10			0.14
0	7 (2)	16 (5)		9 (2)	14 (6)	
1	179 (59)	191 (64)		231 (63)	139 (60)	
2	96 (32)	76 (25)		104 (28)	68 (29)	
≥3	19 (6)	17 (6)		24 (7)	12 (5)	
Stenosis location — no. (%)						
Central	277 (92)	272 (91)	0.65	341 (93)	208 (89)	0.20
Lateral recess	286 (95)	260 (87)	<0.001	338 (92)	208 (89)	0.36
Neuroforamen	123 (41)	120 (40)	0.89	152 (41)	91 (39)	0.64
Stenosis severity — no. (%)			0.08			0.08
Mild	7 (2)	16 (5)		9 (2)	14 (6)	
Moderate	116 (39)	99 (33)		131 (36)	84 (36)	
Severe	178 (59)	185 (62)		228 (62)	135 (58)	
Instability — no. (%)†††	26 (9)	21 (7)	0.55	35 (10)	12 (5)	0.07

*   Plus–minus values are means ±SD.

†   Patients in the two cohorts combined were classified according to whether they received surgical treatment or only nonsurgical treatment during the first 2 years 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 included those related to stroke, cancer, lung disease, fibromyalgia, chronic fatigue syndrome, post-traumatic stress disorder, alcohol abuse, drug dependency, liver disease, kidney disease, vascular disease, neurologic disease, migraine, or anxiety.

** The SF-36 scores range from 0 to 100, with higher scores 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.

‖‖ Data were not available for eight patients.

*** Data were not available for one patient.

†††Instability is defined as a change of more than 10 degrees of angulation or more than 4 mm of translation of the vertebrae between flexion and extension of the spine.

Table 2. Surgical Treatments and Complications.*

Variable	Randomized Cohort (N=172)	Observational Cohort (N=200)	P Value
Specific procedure — no. (%)†			0.92
Decompression only	10 (6)	10 (5)	
Fusion without instrumentation	35 (21)	43 (21)	
Fusion with instrumentation‡	123 (73)	147 (74)	
Multilevel fusion — no. (%)	46 (27)	40 (20)	0.13
Decompression level — no. (%)			
L2–L3	25 (15)	17 (8)	0.08
L3–L4	92 (54)	84 (42)	0.02
L4–L5	165 (98)	190 (95)	0.34
L5–S1	60 (36)	47 (24)	0.01
No. of levels decompressed — no. of patients (%)			0.01
0	1 (1)	2 (1)	
1	56 (33)	98 (49)	
2	65 (38)	65 (32)	
≥3	47 (28)	35 (18)	
Operation time — min	210.5±81.7	202.7±85.8	0.37
Blood loss — ml	570.0±425.7	606.2±511.2	0.47
Blood replacement — no. (%)			
Intraoperative replacement	60 (36)	67 (34)	0.71
Postoperative transfusion	27 (16)	51 (26)	0.04
Length of hospital stay — days	6.9±28.7	4.8±3.3	0.30
Intraoperative complications — no. (%)§			
Dural tear or cerebrospinal fluid leak	19 (11)	18 (9)	0.59
Vascular injury	1 (1)	0	0.93
Other	3 (2)	6 (3)	0.67

identical in the randomized and the observational cohorts. For SF-36 bodily pain, the effect was 17.8 (95% CI, 12.5 to 23.0) in the randomized cohort as compared with 18.5 (95% CI, 13.4 to 23.6) in the observational cohort; for SF-36 physical function, the effect was 16.7 (95% CI, 11.4 to 22.1) in the randomized cohort as compared with 19.9 (95% CI, 14.8 to 24.9) in the observational cohort; and for the Oswestry Disability Index, the effect was −15.9 (95% CI, −20.2 to −11.7) in the randomized cohort as compared with −17.7 (95% CI, −21.6 to −13.7) in the observational cohort. The global hypothesis test comparing the treatment effects in the randomized and the observational cohorts over all time periods revealed no significant difference between the cohorts: P=0.29 for SF-36 bodily pain, P=0.28 for SF-36 physical function, and P=0.97 for the Oswestry Disability Index.

SUBGROUP ANALYSES

Models fitted for selected subgroups were examined for evidence of modification of treatment efficacy. Participants less than 65 years old at baseline had larger treatment effects in favor of surgery at 3 months (21.3 vs. 14.6 for bodily pain, P=0.02) but not at 1 or 2 years. The treatment effect for a degenerative spondylolisthesis level of L3–L4 was larger than that for a level of L4–L5 (33.1 vs. 16.8 for SF-36 bodily pain, P=0.01) at 2 years but not at 3 months or 1 year. Participants with no more than a high-school education had smaller treatment effects for surgery at 3 months (12.8 vs. 20.5 for SF-36 bodily pain, P=0.02) and 2 years (11.5 vs. 21.6 for SF-36 bodily pain, P=0.01). Other subgroups (defined according to sex, smoking history, severity of symptoms at baseline, duration of symptoms, treatment preference,

Table 2. (Continued.)

Variable	Randomized Cohort (N = 172)	Observational Cohort (N = 200)	P Value
Postoperative complications and events — no. (%)¶			
Nerve-root injury	1 (1)	0	0.93
Wound dehiscence	0	1 (1)	0.93
Wound hematoma	0	1 (1)	0.93
Wound infection	8 (5)	3 (2)	0.12
Other	21 (12)	14 (7)	0.10
Death within 3 mo after surgery — no. (%)	1 (1)	1 (1)	0.55
Additional spine surgeries within 1 yr — no. (%)‖**	13 (8)	11 (6)	0.40
Recurrent stenosis or progressive listhesis	1 (1)	1 (1)	
Pseudarthrosis or fusion exploration	0	1 (1)	
Complication	11 (6)	7 (4)	
New condition	1 (1)	1 (0.5)	
Additional spine surgeries within 2 yr — no. (%)‖	18 (11)	23 (12)	0.84
Recurrent stenosis or progressive listhesis	5 (3)	5 (2)	
Pseudarthrosis or fusion exploration	0	3 (2)	
Complication	13 (8)	11 (6)	
New condition‖	1 (1)	4 (2)	

* A total of 172 patients in the randomized cohort and 200 patients in the observational cohort underwent surgery with-in 2 years after enrollment. Information about the surgery was available for 169 patients from the randomized cohort and 200 from the observational cohort. Plus–minus values are means ±SD.
† Data on specific procedures were available for 168 patients in the randomized cohort and 200 in the observa-tional cohort.
‡ All 270 patients undergoing fusion with instrumentation had pedicle screws; 46 underwent additional interbody fusion.
§ No cases were reported of aspiration into the respiratory tract, nerve-root injury, or operation at the wrong level.
¶ Complications or events occurring up to 8 weeks after surgery are listed. There were no reported cases of bone-graft complication, cerebrospinal fluid leak, paralysis, cauda equina injury, or pseudarthrosis.
‖ The postsurgical reoperation rates are Kaplan–Meier estimates.
** One new stenosis occurred in the randomized cohort, and two new herniations and two new stenoses occurred in the observational cohort.

number of stenotic levels, severity of stenosis on imaging, number of coexisting conditions, and baseline SF-36 mental component summary score) did not show significant effect modification. These results should be considered cautiously, be-cause the study was not designed or powered to examine subgroup differences.

DISCUSSION

In patients with image-confirmed degenerative spondylolisthesis and symptoms persisting for at least 12 weeks, the intention-to-treat analysis found no significant advantage for surgery over nonsurgical care, but the analysis was severely limited by treatment crossover. As-treated analy-ses showed that surgery was superior to nonsur-gical treatment in relieving symptoms and im-

proving function. This treatment effect was seen as early as at the 6-week follow-up and persisted over 2 years. The nonsurgical-treatment group showed only moderate improvement over time. The smaller treatment effect for surgery seen in less-educated subjects is intriguing but unex-plained and may be a chance finding in a post hoc subgroup.

The randomized and observational cohorts were remarkably similar at baseline. The only significant differences were small ones in level and location of stenosis on baseline imaging. The cohorts also had similar outcomes, with no sig-nificant differences between the treatment effects in the as-treated analyses. These similarities sup-port the validity of the combined analysis pre-sented here.

There was little evidence of harm from either

Table 3. Change Scores and Treatment Effects for Primary and Secondary Outcomes in the Randomized and Observational Cohorts Combined, According to Treatment Received.*

Outcome	3 Mo			1 Yr			2 Yr		
	Surgery (N=385)†	Nonsurgical Treatment (N=320)	Treatment Effect of Surgery (95% CI)‡	Surgery (N=286)	Nonsurgical Treatment (N=234)	Treatment Effect of Surgery (95% CI)‡	Surgery (N=324)	Nonsurgical Treatment (N=187)	Treatment Effect of Surgery (95% CI)‡
Primary outcomes									
SF-36 bodily pain§	28.1±1.1	10.3±1.1	17.8 (14.9 to 20.6)	31.5±1.2	12.7±1.3	18.8 (15.5 to 22.1)	29.9±1.2	11.7±1.5	18.1 (14.5 to 21.7)
SF-36 physical function§	21.5±1.1	7.6±1.2	13.9 (11.1 to 16.8)	29.0±1.2	9.6±1.3	19.4 (16.1 to 22.7)	26.6±1.3	8.3±1.5	18.3 (14.6 to 21.9)
Oswestry Disability Index¶	−20.8±0.9	−6.2±0.9	−14.6 (−16.8 to −12.4)	−25.4±1.0	−7.5±1.1	−17.9 (−20.5 to −15.3)	−24.2±1.0	−7.5±1.2	−16.7 (−19.5 to −13.9)
Secondary outcomes									
Stenosis Bothersomeness Index‖	−10.2±0.5	−3.3±0.3	−6.9 (−8.0 to −5.9)	−9.5±0.4	−4.0±0.4	−5.5 (−6.5 to −4.5)	−8.9±0.4	−4.0±0.4	−4.9 (−6.0 to −3.8)
Leg Pain Bothersomeness Scale**	−3.2±0.1	−1.1±0.1	−2.1 (−2.5 to −1.8)	−3.1±0.1	−1.4±0.1	−1.6 (−1.9 to −1.3)	−2.9±0.1	−1.4±0.1	−1.5 (−1.8 to −1.1)
Low Back Pain Bothersomeness Scale**	−2.2±0.1	−1.0±0.1	−1.2 (−1.5 to −0.9)	−2.4±0.1	−1.1±0.1	−1.4 (−1.6 to −1.1)	−2.2±0.1	−1.2±0.1	−1.0 (−1.3 to −0.7)
Very or somewhat satisfied with symptoms (%)	69.6	24.0	45.6 (39.1 to 52.1)	73.2	26.8	46.4 (39.0 to 53.9)	68.8	32.2	36.6 (28.0 to 45.1)
Very or somewhat satisfied with care (%)	90.8	68.3	22.5 (16.4 to 28.5)	90.8	68.2	22.6 (15.6 to 29.6)	89.2	67.3	21.9 (13.9 to 29.9)
Self-rated major improvement in progress (%)	77.5	19.9	57.7 (51.8 to 63.5)	77.2	24.8	52.4 (45.3 to 59.6)	74.1	24.1	50.0 (42.2 to 57.9)

* Scores are adjusted for age, sex, work status, depression, osteoporosis, joint problems, duration of current symptoms, reflex deficit, number of moderate or severe stenotic levels, baseline scores (for the SF-36, Oswestry Disability Index, and Stenosis Bothersomeness Index), and the center where the patient was treated. Plus–minus values are means ±SE and represent changes from baseline. Percentages represent the proportion of patients giving positive responses at each follow-up examination.
† For secondary outcomes, the total number of patients was 263.
‡ The global P value based on a Wald test assessing all time points simultaneously is less than 0.001 for all measures.
§ The SF-36 scores range from 0 to 100, with higher scores 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 and the Low Back Pain Bothersomeness Scales range from 0 to 6, with lower scores indicating less severe symptoms.

treatment. Often patients fear they will get worse without surgery, but the patients receiving nonsurgical treatment, on average, showed moderate improvement in all outcomes. No patients undergoing surgical or nonsurgical treatment had cauda equina syndrome; 89% of surgical patients had no operative complications.

The characteristics of the participants in the SPORT were similar to those in previous studies of degenerative spondylolisthesis and mixed cohorts of patients with stenosis. The mean age of 66 years was similar to that in the cohorts reported by Herkowitz and Kurz[8] (63.5 years), Fischgrund et al.[7] (67 years), the Maine Lumbar Spine Study (MLSS)[3] (66 years), Yukawa et al.[26] (63 years), and Malmivaara et al.[5] (63 years). At enrollment, 60% of the SPORT participants reported having had symptoms for more than 6 months, as did 60% of the participants in the MLSS. Baseline functional status in the SPORT was similar to that in the MLSS (mean SF-36 physical function scores, 34 and 35, respectively) and in the randomized trial by Malmivaara et al. (mean Oswestry Disability Index scores, 41.5 and 35.0, respectively).

The surgical outcomes in the SPORT were generally similar to those in previous surgical series. Herkowitz and Kurz[8] reported absolute improvements of 33% for back pain and 55% for leg pain (6-point scales) at 3 years, similar to the changes of 31% and 41%, respectively (7-point scales), seen in the SPORT at 2 years. Also, the improvement at 1 year in the patients in the SPORT who were undergoing surgery for degenerative spondylolisthesis was similar to the outcomes of surgery in the MLSS mixed-stenosis (those with and those without degenerative spondylolisthesis) cohort. The improvement in the SF-36 bodily pain score was 32 in the SPORT and 43 in the MLSS, and the improvement in the SF-36 physical function score was 29 in the SPORT and 27 in the MLSS.[3]

The nonsurgical outcomes in the SPORT were similar to those in the study by Malmivaara et al.[5] and in the MLSS.[3] Malmivaara et al. reported absolute improvements in back pain at 2 years of 18% on an 11-point scale, as compared with 17% on a 7-point scale in the SPORT, and an improvement in leg pain of 16%, as compared with 17% in the SPORT. Similarly, at 1 year the MLSS reported an improvement of 12.0 points in SF-36 bodily pain, as compared with 12.7 in the SPORT. The nonsurgical functional outcomes, however,

were better in the SPORT than in these previous studies. SF-36 physical function improved by 9.6 points in the SPORT nonsurgical group, as compared with 1.0 point in the MLSS, and the Oswestry Disability Index improved by −7.5 points in the SPORT, as compared with −4.5 points in the study by Malmivaara et al. The somewhat greater improvement in the SPORT may be related to the nonsurgical treatments received. The SPORT participants had higher rates of epidural steroid injections than did the MLSS participants (44% vs. 18%), similar rates of physical therapy, and much lower use of activity restriction (16% vs. 29%) and transcutaneous electrical nerve stimulation (2% vs. 14%). Differences in nonsurgical outcomes might also be due to differences in the underlying disease process in patients with degenerative spondylolisthesis as compared with a mixed stenosis population in the study by Malmivaara et al. and in the MLSS.

We can directly compare estimates of treatment effect in the SPORT with those in the MLSS and the study by Malmivaara et al. The estimated 1-year treatment effects for surgery in the SPORT were smaller than those in the MLSS (18.8 vs. 30.4 points for SF-36 bodily pain, and 19.4 vs. 25.5 points for SF-36 physical function). However, the MLSS did not adjust treatment effects for baseline differences between the treatment groups, which probably explains these discrepancies. The estimated 1-year treatment effects were similar in the SPORT and in the study by Malmivaara et al. (Oswestry Disability Index, −17.9 vs. −11.3, respectively; leg pain, 23% [7-point scale] vs. 15% [11-point scale], respectively; and back pain, 20% [7-point scale] vs. 21% [11-point scale], respectively).

The 1-year rate of reoperation for recurrent stenosis or spondylolisthesis was 0.6%, less than the rates reported by Malmivaara et al. (2%) and the MLSS (1.2%). The reoperation rate increased to 3% at 2 years. The perioperative mortality rate was 0.6%, which is less than the 1.3% seen in Medicare patients after fusion surgery for spondylolisthesis.[27] The 2-year mortality rate was similar in both treatment groups and less than actuarial projections.

A limitation of this study is the marked degree of nonadherence to randomized treatment. The protocol stipulated that patients assigned to surgery have their surgery within 3 to 6 months after enrollment, a period thought to be appro-
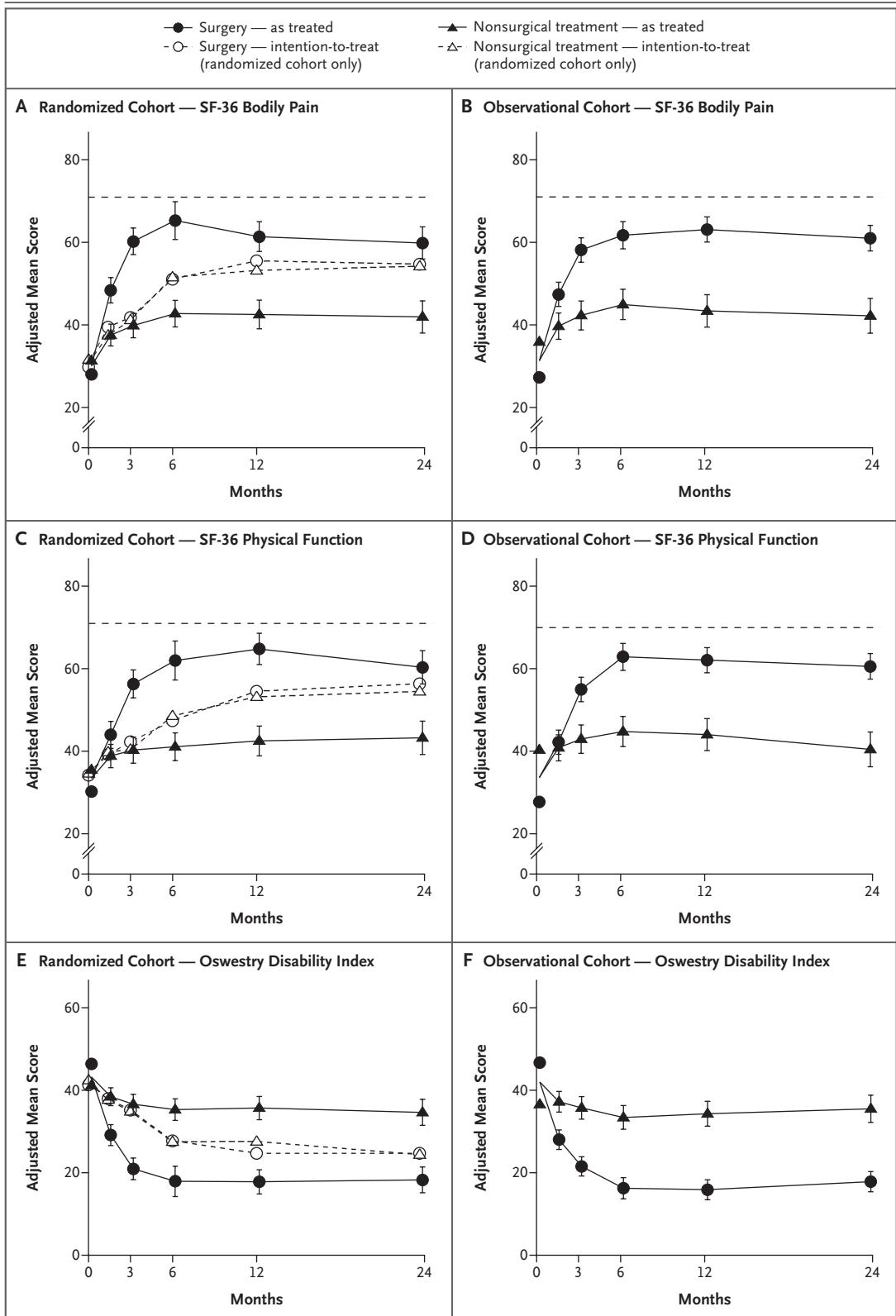
priate in the clinical experience of the investigators. Although patients consented to this protocol, as in all clinical trials this consent could be changed at the request of the patient, and many chose to do so. This reduced the power of the intention-to-treat analysis to demonstrate a treatment effect. Although the as-treated analysis lost the strong protection from confounding conferred by randomization, these analyses were carefully controlled for important covariates and yielded results similar to previous studies.

Another limitation is the heterogeneity of the treatment interventions. The choice of nonsurgical therapies was at the discretion of the treating physician and the patient. However, with limited evidence regarding efficacy for most nonsurgical treatments for degenerative spondylolisthesis, creating a fixed protocol for nonsurgical treatment was neither clinically feasible nor generalizable. The nonsurgical treatments used were consistent with published guidelines.[28,29] Similarly, the surgeries performed varied in terms of the presence, method, and extent of spinal fusion accompanying the decompression. We cannot make direct conclusions regarding the comparison between the effect of surgery and any specific nonsurgical treatment, nor do we directly compare the efficacy of nonsurgical treatment with one specific surgical technique.

The magnitudes of the mean changes reported here after surgery for degenerative spondylolisthesis are less than those reported for patients in a SPORT observational cohort undergoing surgery for intervertebral disk herniation. The mean change scores after 2 years were as follows: SF-36 bodily pain, 29.9 for degenerative spondylolisthesis versus 42.6 for intervertebral disk herniation; SF-36 physical function, 26.7 for degenerative spondylolisthesis versus 43.9 for intervertebral disk herniation; Oswestry Disability Index, −24.2 for degenerative spondylolisthesis versus 37.6 for intervertebral disk herniation.[9,10] However, the treatment effects for surgery in the degenerative-spondylolisthesis group were larger than those in the study of intervertebral disk herniation (18.4 for bodily pain in the degenerative-spondylolisthesis group vs. 10.2 in the intervertebral-disk-herniation study) because of dramatic improvements in the nonsurgical group with intervertebral disk herniation not seen in the degenerative-spondylolisthesis group.

In these nonrandomized comparisons with careful control of potentially confounding baseline factors, patients with persistent neurogenic claudication from degenerative spondylolisthesis treated surgically showed substantially greater improvement in pain and function, as well as satisfaction, for 2 years. Characteristics of the patients and treatment outcomes were similar in the randomized and observational cohorts.

APPENDIX

In addition to the authors, the following investigators participated in the Spine Patient Outcomes Research Trial (institutions are in order from highest to lowest enrollment): *Dartmouth Medical School, Hanover, NH* — J. Forman, B. Butler-Schmidt, J.J. Hebb, P. Bernini. R. Hazard, P. Ball, C. Murray, M. Splaine, D. Sengupta, H. Schmidek, R. Rose, C. Olson, P. McDonough, H. Magnasdottir; *William Beaumont Hospital, Royal Oak, MI* — G. Bradley, M. Lurie, L. Kurz, J. Fischgrund, D. Montgomery, E. Truumees; *Rothman Institute at Thomas Jefferson Hospital, Philadelphia* — C. Simon, T. Conliffe; *Hospital for Special Surgery, New York* — B. Green, J. Farmer, H. Sandhu; *Nebraska Foundation for Spinal Research, Omaha* — N. Fullmer, A.M. Fredericks, R. Woodward, J. Fuller, E. Phillips, J. McClellan, P. Bowman, T. Burd; *Emory University–Emory Clinic, Atlanta* — S. Boden, S. Lashley, H. Levy, D. Hubbell, M. Schaufele, J. Rhee, S.T. Yoon, S. Dreyer, J. Heller; *Washington University, St. Louis* — G. Stobbs, K. Bridwell, A. Margherita, K.D. Riew, B. Taylor, J. Metzler; *University Hospitals of Cleveland and Case Western Reserve University, Cleveland* — C. Furey, K. Higgins, J.X. Yoo, E.B. Marsolais, H. Bohlman; *Hospital for Joint Diseases, New York* — A. Lee, J. Bendo, J. Goldstein, J. Spivak, R. Perry, R. Schoenfeldt, R. Moskovich, J. Dryer; *Kaiser Permanente, Oakland, CA* — H. Goldberg, P. Malone, F. Massimino; *University of California, San Francisco, San Francisco* — P. Malone, S. Berven, T. Smith; *Rush–Presbyterian–St. Luke's Medical Center, Chicago* — G. Andersson, H. An, M. Hickey, E. Goldberg, F. Philips; *Maine Spine and Rehabilitation, Scarborough* — R. Keller, L. Thibodeau, J. Florman.

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