

Degenerative Spondylolisthesis

Does Fusion Method Influence Outcome? Four-Year Results of the Spine Patient Outcomes Research Trial

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Study Design. Clinical trial subgroup analysis.

Objective. To compare outcomes of different fusion techniques treating degenerative spondylolisthesis (DS).

Summary of Background Data. Surgery has been shown to be more effective than nonoperative treatment out to 4 years. Questions remain regarding the differential effect of fusion technique.

Methods. Surgical candidates from 13 centers in 11 states with at least 12 weeks of symptoms and confirmatory imaging showing stenosis and DS were studied. In addition to standard decompressive laminectomy, 1 of 3 fusion techniques was employed at the surgeon's discretion: posterolateral in situ fusion (PLF); posterolateral instrumented fusion with pedicle screws (PPS); or PPS plus interbody fusion (360°). Main outcome measures were the SF-36 bodily pain (BP) and physical function (PF) scales and the modified Oswestry Disability Index (ODI) assessed at 6 weeks, 3 months, 6 months, and yearly to 4 years. The as-treated analysis combined the randomized and observational cohorts using mixed longitudinal models adjusting for potential confounders.

Results. Of 380 surgical patients, 21% (N = 80) received a PLF; 56% (N = 213) received a PPS; 17% (N = 63) received a 360°; and 6% (N = 23) had decompression only without fusion. Early outcomes varied, favoring PLF compared to PPS at 6 weeks (PF: 12.73 vs. 6.22, $P < 0.020$) and 3 months (PF: 25.24 vs. 18.95, $P < 0.025$) and PPS compared to 360° at 6 weeks (ODI: -14.46 vs. -9.30, $P < 0.03$)

and 3 months (ODI: -22.30 vs. -16.78, $P < 0.02$). At 2 years, 360° had better outcomes: BP: 39.08 versus 29.17 PLF, $P < 0.011$; and versus 29.13 PPS, $P < 0.002$; PF: 31.93 versus 23.27 PLF, $P < 0.021$; and versus 25.29 PPS, $P < 0.036$. However, these differences were not maintained at 3- and 4-year follow-up, when there were no statistically significant differences between the 3 fusion groups.

Conclusion. In patients with DS and associated spinal stenosis, no consistent differences in clinical outcomes were seen among fusion groups over 4 years.

Key words: degenerative spondylolisthesis, spinal stenosis, fusion, surgical technique. **Spine 2009;34: 2351–2360**

Lumbar fusion rates increased dramatically during the 1980s, and accelerated further in the 1990s. Medicare spending for back surgery more than doubled over the decade, with lumbar fusion spending increasing more than 500% to \$482 million. In 1992, lumbar fusion represented 14% of total spending for back surgery; by 2003, lumbar fusion accounted for 47% of spending.¹ While overall rates and cost of spine fusion have increased, there remains little evidence of substantial improvement in patient functional outcomes.

Degenerative spondylolisthesis (DS) is one of the most common conditions for which surgery is performed in the United States. In the Spine Patient Outcomes Research Trial (SPORT),^{2,3} as-treated comparisons with careful control for potentially confounding baseline factors showed that patients with spinal stenosis and associated DS treated surgically had substantially greater improvement in pain and function during a period of 4 years than did patients treated nonoperatively. Despite the evidence that surgically treated patients fare better, questions remain about which surgical fusion treatment is best.^{4–22}

In 1991, Herkowitz and Kurz evaluated 50 patients and concluded that posterolateral fusion provided a significant improvement in relief of back and lower limb pain, and that pseudarthrosis did not preclude a successful result.¹² In a follow-up study, higher radiographic fusion rates were seen with pedicle screw instrumentation but clinical outcomes were not different.⁸ Long-term follow-up of patients with uninstrumented fusions showed that patients with pseudarthrosis had worse outcomes than those with solid fusion¹⁶; however, there was no control group and so the role of instrumentation in improving clinical outcomes remains unclear.

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Despite increasing efforts to establish a solid fusion, the Cochrane review on fusion for a variety of degenerative conditions of the lumbar spine determined that no conclusions are possible about the relative effectiveness of various fusion procedures (anterior, posterior, or circumferential).¹⁰ A review of treatment for DS specifically suggested that spinal fusion may lead to better clinical outcomes, though conclusions about the benefits of instrumentation could not be made.¹⁸

In SPORT, whether and how to fuse patients with DS was optional, based on surgeon/patient preferences. This article explores the relative outcomes of 3 different fusion techniques used in SPORT DS patients.

■ Materials and Methods

Study Design

SPORT was conducted in 11 US states at 13 medical centers, and included both a randomized (RCT) and a concurrent observational (OBS) cohort with identical selection criteria and outcomes assessment. Additional background information is available in previous publications.^{2,3,23,24} This report is a subgroup analysis of fusion methods using the combined RCT and OBS cohorts with DS.

Patient Population

All patients had the following: neurogenic claudication or radicular leg pain with associated neurologic signs; cross-sectional imaging showing spinal stenosis; DS on standing lateral radiographs; persistent symptoms for at least 12 weeks; and physician confirmation as a surgical candidate. Patients with adjacent levels of stenosis were eligible; patients with spondylolysis and isthmic spondylolisthesis were not. Enrollment began in March 2000 and ended in February 2005.

Study Interventions

Patients were either treated nonoperatively or with surgery. The surgeries were classified into the following groups: (1) decompressive laminectomy only; (2) decompression with posterolateral *in situ* fusion (PLF); (3) decompression with instrumented posterolateral fusion with pedicle screws (PPS); and (4) decompression with interbody fusion plus instrumented posterolateral fusion with pedicle screws (360°).

Study Measures

Main endpoints were the SF-36 bodily pain (BP) and physical function (PF) scales,^{25–27} and the AAOS/Modems version of the Oswestry Disability Index (ODI)²⁹ measured at 6 weeks, 3 months, 6 months, and yearly out to 4 years. Additional outcomes included patient self-reported improvement; satisfaction with current symptoms and care³⁰; and the Stenosis Bothersomeness Index.^{26,31} Treatment effect was defined as the difference in the mean changes from baseline between the 3 fusion groups.

SF-36 scores were scaled to range from 0 to 100, with higher scores indicating less severe symptoms; the standard scoring for the ODI was also scaled to range from 0 to 100, but 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.^{26,31} For measures with higher values indicating better outcomes (*i.e.*, BP, PF), a posi-

tive change in score reflects improvement, while for those measures for which lower values indicate better outcomes (*i.e.*, ODI and the Bothersomeness Scales), negative changes in scores reflect improvement.

Radiographic Assessment. As part of routine clinical care the majority of patients undergoing surgery had imaging studies done at 1- and 2-year follow-up. The treating surgeons were asked to evaluate the patients' fusion status based on all available information. Fusion status was rated as solid fusion, pseudarthrosis, or unclear based on the surgeons' overall impression; no specific radiographic protocol was used. Surgeons were also asked to record whether any additional testing was used in addition to plain radiographs to assess fusion status.

Statistical Methods

Statistical methods for the analysis of this trial have been reported in previous publications,^{2,32–34} and are summarized here. Initial analyses compared the baseline characteristics of 3 fusion groups. 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 time until surgical treatment were determined through a stepwise proportional-hazards regression model with 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 evaluated 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.

Repeated measures of outcomes were used as dependent variables, and treatment received was included as a time-varying covariate. Adjustments were made for postsurgical visit times with respect to time of surgery to better approximate the designated follow-up times.

Although the focus of this study was to evaluate for differences in outcomes across the 3 fusion surgical groups, the nature of the experimental design and analysis approach dictated that the overall analysis include all patients, both operative and nonoperative, to ensure the best possible estimates of outcome scores across the follow-up interval. Therefore, the fundamental questions of interest regarding differences in outcomes among the 3 surgical fusion protocols were evaluated by constructing preplanned contrasts that tested the overall differences in change from baseline between the 3 fusion groups both overall and at each time of assessment.

We evaluated 2 basic research questions: (1) Do the studied treatments result in improvement over pretreatment health status? (2) Do different fusion approaches result in different patterns of change across the follow-up interval? With regard to question 1, tests for significant change from baseline were evaluated for all outcomes at each follow-up point. With regard to question 2, tests for differences in change from baseline across follow-up intervals were evaluated for each treatment group; and then tests for differences between treatment groups were evaluated at each follow-up time. This was done in a hierarchical fashion. At each assessment interval, the first step was to test for any differences among the 3 fusion groups. In order to increase power (since this study was not designed to compare differences in fusion technique), the tolerance for making a type I error was re-

laxed by setting the threshold at 0.10. If the null hypothesis (H_0 : PLF = PPS = 360°) was rejected at $P < 0.10$, then the next step was to evaluate for differences between the 3 groups based on pair-wise comparisons. For these comparisons, type I error was set at 0.05. Since these comparisons represent the most basic approach for evaluating for treatment differences, they were considered planned comparisons and, as such, no adjustments were made to control for inflated type I error rates due to multiple comparisons.

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, Cary, NC). Data for these analyses were collected through May 1, 2008.

■ Results

A total of 607 participants enrolled in the DS SPORT trial (304 in the randomized cohort and 303 in the observational cohort). Of these, 34.9% (212) were nonoperative patients and 395 were treated surgically. Of the 395 surgical cases, 380 (96%) had surgical descriptive data and at least 1 follow-up; 21% (N = 80/380) had a PLF; 56% (N = 213/380) had a PPS; 17% (N = 63/380) had a 360°; and 6% (N = 23/380) had a decompressive laminectomy only. In the 360° fusion group, 35% underwent an anterior-posterior procedure while 65% underwent a posterior procedure including posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF). These were not independently analyzed due to the small size of these subgroups. Given the small size of the decompression-only group, they are not considered in this analysis. The proportion of enrollees who supplied data at each follow-up interval ranged from 70% to 99% with losses due to dropouts, missed visits, or deaths (Figure 1).

Patient Characteristics

Table 1 summarizes baseline characteristics of the 3 fusion groups. Statistically significant differences were seen between the groups in age, race, work status, osteoporosis, neurologic deficits, and stenosis level, location, and severity (Table 1). Several significant baseline differences appear to be driven by the 360° group. Compared to the other fusion groups, the 360° group was younger; more likely to be working; less likely to report osteoporosis; had lower rates of stenosis at L3–L4; less severe stenosis; less central stenosis; and had lower scores on the SF-36 mental component summary scale. There were no other significant differences in baseline characteristics or functional health status between groups.

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 covariates: age, gender, BMI, compensation status, depression, joint problems, hypertension, current symptom duration, number of moderate/severe stenotic levels, baseline Stenosis

Bothersomeness, enrollment center, and baseline score for each outcome.

Surgical Treatment and Complications

The mean surgical times for the 3 fusion groups ranged from 157 to 274 minutes, PLF having the shortest time and 360° the longest (Table 2). Mean estimated blood loss ranged from 499 mL to 666 mL and was lowest for PLF and highest for PPS. Intraoperative blood replacement was lowest in PLF but did not reach statistical significance ($P = 0.098$); however, there was a difference in the postoperative transfusion rates (14% for PLF *vs.* 26% for PPS and 17% for 360°, $P = 0.05$). The most common surgical complication was dural tear, which was highest for PPS (12% *vs.* 9% PLF and 2% 360°, $P = 0.047$). This may reflect the lower number of operative levels and severity of stenosis in the 360° group. The 4-year reoperation rate did not significantly differ across the 3 groups ($P = 0.27$).

Over 4 years, there were 16 documented deaths across the 3 fusion groups (Figure 1); 8 PLF, 8 PPS, and zero 360° compared to expected numbers based on age-specific mortality rates of 7, 16, and 3, respectively,⁶ for the general population. A Cox model comparing the 3 fusion treatment mortality rates adjusting for patient age, gender, and wait time for surgery was not statistically significant (Wald $\chi^2 = 2.71$, $P = 0.259$). However, the hazard ratio for PLF referenced to PPS was 2.30 (95% CI, 0.85–6.17), which would be clinically significant; this result approached statistical significance at $P < 0.10$ with a 90% CI of 1.001 to 5.265. All 16 deaths were independently reviewed and 12 were judged not to be treatment-related; 2 deaths were of unknown cause; and 2 were judged as potentially related to treatment. For these 2 potentially related deaths, one was in the PLF group and occurred 32 days after surgery due to respiratory distress; and the other, in the PPS group, occurred 82 days after surgery due to sepsis.

Main Treatment Effects

All 3 fusion groups demonstrated significant changes compared to baseline in all primary outcomes (BP, PF, and ODI) out to 4 years (Table 3). The patterns of change are depicted in Figure 2. Overall, there were some varying differences between groups during the early time periods and no significant differences between any of the groups in later time periods.

For SF-36 BP, the groups were similar at the early time points, though at 1-year there was a trend toward a difference between the 3 groups overall ($P < 0.10$) with the 360° fusion demonstrating a slightly larger improvement than PLF (38.99 *vs.* 30.7; $P = 0.04$) and PPS (38.99 *vs.* 32.32; $P = 0.06$) in pair-wise comparisons. At 2-years, the groups were significantly different ($P < 0.008$), with 360° having significantly better outcomes than PLF (39.08 *vs.* 29.17; $P = 0.01$) and PPS (39.08 *vs.* 29.13; $P = 0.003$); however, no significant differences were seen between fusion types at 3 years

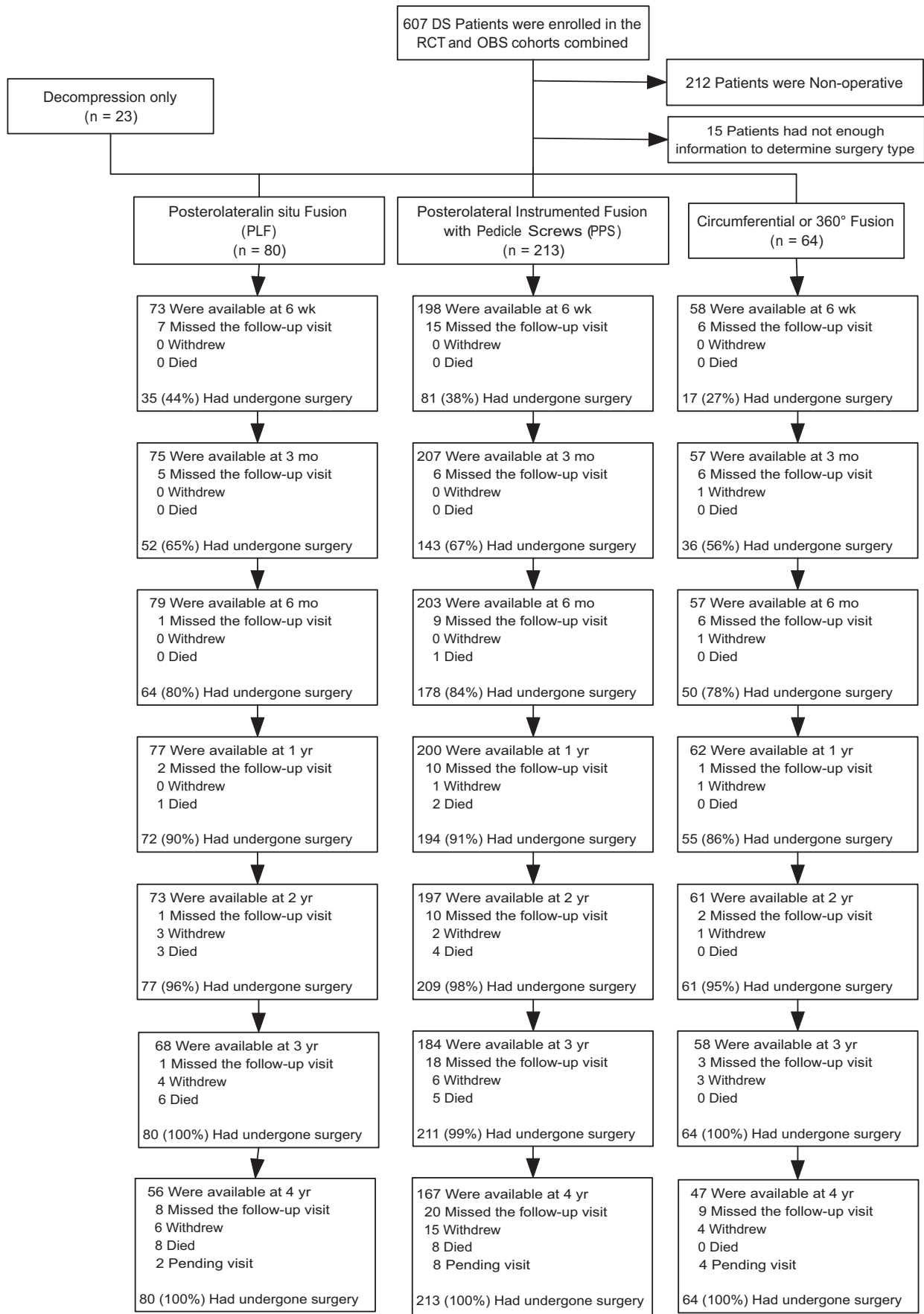


Figure 1. Exclusion, enrollment, randomization, and follow-up of trial participants. The values for surgery, withdrawal, and death are cumulative over 4 years. For example, a total of 3 patients in the group assigned to surgery died during the 4-year follow-up period (Dataset 05/01/2008).

Table 1. Baseline Demographic Characteristics and Comorbidities According to Treatment Received

Characteristics	PLF (n = 80)	PPS (n = 213)	360° (n = 63)	P
Mean age (SD)	67.2 (10.1)	64.8 (9.5)	59.7 (10.5)	<0.001
Female—no. (%)	50 (62%)	144 (68%)	50 (79%)	0.088
Ethnicity: not Hispanic—no. (%)*	80 (100%)	204 (96%)	63 (100%)	0.045
Race: white—no. (%)*	76 (95%)	174 (82%)	54 (86%)	0.016
Education: at least some college—no. (%)	53 (66%)	148 (69%)	37 (59%)	0.28
Married—no. (%)	56 (70%)	142 (67%)	41 (65%)	0.80
Work status—no. (%)				0.028
Full or part time	31 (39%)	69 (32%)	34 (54%)	
Disabled	6 (8%)	22 (10%)	5 (8%)	
Retired	38 (48%)	90 (42%)	19 (30%)	
Other	5 (6%)	32 (15%)	5 (8%)	
Compensation—no. (%)†	5 (6%)	22 (10%)	5 (8%)	0.53
Mean body mass index (BMI), (SD)‡	30.3 (8.7)	29.3 (5.5)	29.1 (6.3)	0.40
Current smoker—no. (%)	6 (8%)	19 (9%)	8 (13%)	0.55
Comorbidities—no. (%)				
Hypertension	31 (39%)	102 (48%)	26 (41%)	0.31
Diabetes	9 (11%)	32 (15%)	6 (10%)	0.44
Osteoporosis	10 (12%)	28 (13%)	0 (0%)	0.01
Heart problem	17 (21%)	36 (17%)	12 (19%)	0.68
Stomach problem	16 (20%)	45 (21%)	17 (27%)	0.55
Bowel or intestinal problem	9 (11%)	14 (7%)	6 (10%)	0.39
Depression	19 (24%)	33 (15%)	8 (13%)	0.15
Joint problem	40 (50%)	122 (57%)	35 (56%)	0.54
Others§	31 (39%)	79 (37%)	28 (44%)	0.57
Symptom duration >6 mo—no. (%)	55 (69%)	127 (60%)	35 (56%)	0.23
Very dissatisfied with symptoms—no. (%)	60 (75%)	167 (78%)	50 (79%)	0.78
Self-assessment of health trend—no. (%)				0.31
Getting better	4 (5%)	8 (4%)	5 (8%)	
Staying about the same	22 (28%)	48 (23%)	20 (32%)	
Getting worse	53 (66%)	155 (73%)	38 (60%)	
Treatment preference at baseline—no. (%)				0.95
Preference for nonsurgery	20 (25%)	46 (22%)	14 (22%)	
Not sure	15 (19%)	48 (23%)	14 (22%)	
Preference for surgery	45 (56%)	119 (56%)	35 (56%)	
Pseudoclaudication—no. (%)	73 (91%)	180 (85%)	52 (83%)	0.25
SLR or femoral tension—no. (%)	13 (16%)	22 (10%)	12 (19%)	0.13
Dermatomal pain radiation—no. (%)	65 (81%)	164 (77%)	47 (75%)	0.61
Any neurological deficit—no. (%)	53 (66%)	104 (49%)	35 (56%)	0.027
Asymmetric reflex depressed	36 (45%)	39 (18%)	18 (29%)	<0.001
Asymmetric sensory decrease	31 (39%)	48 (23%)	21 (33%)	0.013
Asymmetric motor weakness	22 (28%)	49 (23%)	10 (16%)	0.26
Listhesis levels—no. (%)				0.94
L3–L4	7 (9%)	16 (8%)	5 (8%)	
L4–L5	73 (91%)	197 (92%)	58 (92%)	

Characteristics	PLF (n = 80)	PPS (n = 213)	360° (n = 63)	P
Stenosis levels—no. (%)				
L2–L3	8 (10%)	19 (9%)	1 (2%)	0.12
L3–L4	34 (42%)	91 (43%)	11 (17%)	<0.001
L4–L5	78 (98%)	206 (97%)	62 (98%)	0.76
L5–S1	4 (5%)	20 (9%)	5 (8%)	0.47
No. moderate or severe stenotic levels—no. (%)				0.006
None	0 (0%)	5 (2%)	5 (8%)	
One	46 (57%)	135 (63%)	47 (75%)	
Two	26 (32%)	61 (29%)	10 (16%)	
Three+	8 (10%)	12 (6%)	1 (2%)	
Stenosis locations—no. (%)				
Central	80 (100%)	197 (92%)	52 (83%)	<0.001
Lateral recess	71 (89%)	194 (91%)	59 (94%)	0.60
Neuroforamen	30 (38%)	86 (40%)	34 (54%)	0.10
Stenosis severity—no. (%)				0.032
Mild	0 (0%)	5 (2%)	5 (8%)	
Moderate	30 (38%)	69 (32%)	25 (40%)	
Severe	50 (62%)	139 (65%)	33 (52%)	
Instability—no. (%)¶	3 (4%)	26 (12%)	4 (6%)	0.057
HRQOL scales				
Bodily pain (BP) score (SD)	33.4 (18.2)	30.4 (19.1)	31.3 (19.2)	0.49
Physical functioning (PF) score (SD)	31.2 (17.2)	30.4 (21.9)	34 (21.7)	0.48
Mental component summary (MCS) score (SD)	53.4 (11)	49.2 (11.3)	46 (11.5)	<0.001
Oswestry disability index (ODI) (SD)	41.2 (15.8)	45.5 (16.9)	46 (17.2)	0.12
Stenosis frequency index (0–24) (SD)	14.5 (5.4)	15.1 (5.6)	14 (5.8)	0.36
Stenosis Bothersome Index (0–24) (SD)	15.5 (5.3)	15.8 (5.6)	14.7 (5.8)	0.43
Back Pain Bothersomeness (0–6) (SD)	4.5 (1.8)	4.4 (1.8)	4.3 (1.7)	0.82

*Race or ethnic group was self-assessed. Whites and blacks could be either Hispanic or not 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 indicates problems related to stroke, cancer, lung, fibromyalgia, chronic fatigue syndrome, post-traumatic stress disorder, alcohol, drug dependency, liver, kidney, blood vessel.
 ¶Instability is defined as a change of more than 10° of angulation or more than 4 mm of translation of the vertebrae between flexion and extension.
 ||HRQOL (health-related quality-of-life) scores:
 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.
 The Stenosis Bothersomeness Index ranges from 0 to 24, with lower scores indicating less severe.
 The Low Back Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less.

($P < 0.79$) or 4 years ($P < 0.74$). The outcomes of PLF and PPS were similar in all pair-wise comparisons.

For SF-36 PF, there were trends toward early differences at 6 weeks ($P < 0.07$) and 3 months ($P < 0.08$), slightly favoring PLF over PPS (6 weeks 12.73 vs. 6.22; $P = 0.02$ and 3 months 25.24 vs. 18.95; $P = 0.03$). Pair-wise differences between PLF and 360°, or PPS and 360° were not significant at these early time points. No differences between the groups were seen at 1 year but the 360° group had better outcomes at 2 years compared to both PLF (31.93 vs. 23.27; $P =$

Table 2. Operative Treatments, Complications, and Events for DS 4-Year Fusion

	PLF (n = 80)	PPS (n = 213)	360° (n = 63)	P
Multilevel fusion—no. (%)	14 (18%)	50 (23%)	24 (38%)	0.018
Decompression level—no. (%)				
L2–L3	15 (19%)	24 (11%)	1 (2%)	0.008
L3–L4	47 (59%)	107 (51%)	15 (25%)	<0.001
L4–L5	78 (98%)	208 (98%)	58 (95%)	0.55
L5–S1	30 (38%)	56 (27%)	17 (28%)	0.18
No. levels decompressed —no. patients (%)				<0.001
1	27 (34%)	84 (39%)	38 (62%)	
2	25 (31%)	86 (40%)	16 (26%)	
3+	28 (35%)	43 (20%)	7 (11%)	
Operation time, min (SD)	156.7 (58.5)	212.2 (74)	274.4 (89.8)	<0.001
Blood loss, mL (SD)	498.7 (370.5)	666.4 (519.2)	576.1 (408.6)	0.021
Blood replacement— no. (%)				
Intraoperative replacement	21 (26%)	83 (39%)	25 (40%)	0.098
Postoperative transfusion	11 (14%)	55 (26%)	11 (17%)	0.05
Length of stay, d (SD)	4.2 (3.5)	4.8 (2.7)	5.6 (3.7)	0.67
Postoperative immobilization: Brace/Corset— no. (%)	43 (54%)	99 (47%)	45 (71%)	0.003
Intraoperative complications — no. (%)*				
Dural tear or cerebrospinal fluid leak	7 (9%)	25 (12%)	1 (2%)	0.047
Vascular injury	0 (0%)	1 (0%)	0 (0%)	0.71
Other	3 (4%)	4 (2%)	1 (2%)	0.58
None	70 (88%)	184 (86%)	62 (97%)	0.066
Postoperative complications and events—no. (%)†				
Nerve root injury	0 (0%)	1 (0%)	0 (0%)	0.71
Wound dehiscence	0 (0%)	0 (0%)	1 (2%)	0.099
Wound hematoma	0 (0%)	0 (0%)	1 (2%)	0.099
Wound infection	5 (6%)	5 (2%)	1 (2%)	0.17
Other	4 (5%)	26 (12%)	4 (6%)	0.10
None‡	62 (78%)	133 (63%)	47 (75%)	0.03
Death within 3 mo after surgery—no. (%)	1 (1.3%)	1 (0.5%)	0 (0%)	0.58
Additional spine surgeries within 1 yr—no. (%)§	5 (6%)	12 (6%)	5 (8%)	0.804
Additional spine surgeries within 2 yr	11 (14%)	23 (11%)	6 (9%)	0.719
Additional spine surgeries within 3 yr	13 (16%)	26 (12%)	7 (11%)	0.614
Additional spine surgeries within 4 yr	14 (18%)	29 (14%)	7 (11%)	0.272
Recurrent stenosis/progressive listhesis	4 (5%)	11 (5%),	0	
Pseudarthrosis/fusion exploration	1 (1.3%)	2 (1.1%)	1 (2%)	
Complication	7 (8.7%)	12 (5.8%)	5 (7.8%)	
New condition¶	3 (4%)	4 (1.9%)	1 (2%)	

One PPS patient had a length of stay of 372 days—not counting that case the average LDS for PPS would be 4.8 (2.7).

*None of the following were reported: aspiration, nerve root injury, operation at wrong level.

†Any reported complications up to 8 wk postoperation. None of the following were reported: bone graft complication, CSF leak, paralysis, *cauda equina* injury, and pseudarthrosis.

‡None indicates no complications and no postoperative transfusion.

§The postsurgical reoperation rates are Kaplan-Meier estimates.

¶One new stenosis occurred in the randomized cohort, 2 herniations and 2 stenoses occurred in the observational cohort.

0.02) and PPS (31.93 *vs.* 25.29; $P = 0.04$). There were no significant differences between the groups at 3 or 4 years but there was a trend toward worse outcomes in PPS at 4 years.

For ODI, differences between the 3 fusion groups were observed at 6 weeks ($P < 0.10$), 3 months ($P < 0.042$), and 1 year ($P < 0.036$). In pair-wise analysis, PPS demonstrated significantly greater improvement than 360° at 6 weeks (-14.46 *vs.* -9.30 , $P < 0.03$) and 3 months (-22.30 *vs.* -16.78 , $P < 0.02$). At 1 year, PLF was worse than PPS (-20.92 *vs.* -26.33 , $P < 0.02$) and 360° (-27.61 , $P < 0.03$). Again, no significant differences were seen between any of the groups at 3 and 4 years.

Additional Outcomes

The Stenosis Bothersomeness Scale revealed no statistically significant differences between PLF and 360°, and slightly worse outcomes in PPS compared to 360° that were statistically significant at 2 years ($P = 0.009$), but not at other time points. Back Pain Bothersomeness showed a similar pattern with somewhat worse outcomes in PPS compared to 360° at 2 and 3 years but not at other time points (Figure 3). There were no significant differences across fusion groups in satisfaction with symptoms or care at any of the 5 follow-up time intervals (data not shown).

Radiographic Assessment

Fusion status classifications were reported for 74% (282/380) of the cases. Of the 282 fusion classifications, 89.7% were classified based on plain radiographs only, 3.9% indicated that classification included CT, and the remaining 6.4% indicated that classification included some “other” method.

As illustrated in Table 4, solid fusion was the predominant classification. However, across the 3 treatment approaches, the solid fusion ratings were significantly different, $\chi^2 = 10.69$, $P < 0.005$. Follow-up tests using logistic regression methods revealed that the PLF group had a significantly lower solid fusion rate (67.24%) compared to both the PPS (85.29%, $P < 0.004$) and the 360° (87.04%, $P < 0.017$) approaches, respectively. The difference in solid fusion rates for the 2 instrumented approaches was not significant (85.29% *vs.* 87.04%, $P < 0.75$).

Discussion

The rationale for surgical treatment of DS is 2-fold. The primary goal is decompression of the neural structures to relieve the symptoms of neurogenic claudication *via* laminectomy. Fusion is performed to prevent potential further slippage of the vertebrae and to stabilize the associated degenerative disc and arthritic facets for improvement in or prevention of back pain and possible instability. Traditional factors favoring fusion include: improved spine stability; minimization of long-term back pain from the operated degenerative levels; and concern for recurrent leg pain from progression of the spondylolisthesis in the absence of fusion. Radiographic

Table 3. Comparison of Fusion Techniques by Primary Outcome Measures

Outcome	Treatment Group	Follow-Up Interval						
		6 wk	3 mo	6 mo	1 yr	2 yr	3 yr	4 yr
Bodily pain	PLF	16.93 (2.53)	32.32 (2.49)	30.94 (3.07)	30.71 (2.67)	29.17 (2.70)	32.13 (2.80)	32.17 (3.02)
	PPS	17.69 (1.49)	28.19 (1.55)	34.47 (1.85)	32.32 (1.67)	29.13 (1.71)	31.24 (1.79)	29.91 (1.87)
	P	0.7952	0.1568	0.3222	0.6075	0.9897	0.7878	0.5226
	PLF	16.93 (2.53)	32.32 (2.49)	30.94 (3.07)	30.71 (2.67)	29.17 (2.70)	32.13 (2.80)	32.17 (3.02)
	360°	12.16 (2.80)	31.96 (2.77)	36.03 (3.49)	38.99 (3.08)	39.08 (2.84)	33.54 (2.91)	32.18 (3.46)
	P	0.2060	0.9233	0.2729	0.0424	0.0115	0.7263	0.9986
	PPS	17.69 (1.49)	28.19 (1.55)	34.47 (1.85)	32.32 (1.67)	29.13 (1.71)	31.24 (1.79)	29.91 (1.87)
	360°	12.16 (2.80)	31.96 (2.77)	36.03 (3.49)	38.99 (3.08)	39.08 (2.84)	33.54 (2.91)	32.18 (3.46)
	P	0.0793	0.2333	0.6906	0.0558	0.0025	0.4973	0.5614
Physical function	PLF	12.73 (2.44)	25.24 (2.41)	28.20 (2.95)	29.87 (2.57)	23.27 (2.60)	26.85 (2.69)	29.93 (2.93)
	PPS	6.22 (1.45)	18.95 (1.51)	26.67 (1.79)	28.13 (1.62)	25.29 (1.67)	24.81 (1.71)	23.55 (1.80)
	P	0.0201	0.0247	0.6555	0.5627	0.5089	0.5183	0.0603
	PLF	12.73 (2.44)	25.24 (2.41)	28.20 (2.95)	29.87 (2.57)	23.27 (2.60)	26.85 (2.69)	29.93 (2.93)
	360°	7.66 (2.69)	21.79 (2.66)	31.87 (3.33)	31.08 (2.95)	31.93 (2.73)	25.83 (2.80)	30.54 (3.26)
	P	0.1605	0.3333	0.4070	0.7560	0.0209	0.7926	0.8886
	PPS	6.22 (1.45)	18.95 (1.51)	26.67 (1.79)	28.13 (1.62)	25.29 (1.67)	24.81 (1.71)	23.55 (1.80)
	360°	7.66 (2.69)	21.79 (2.66)	31.87 (3.33)	31.08 (2.95)	31.93 (2.73)	25.83 (2.80)	30.54 (3.26)
	P	0.6316	0.3473	0.1651	0.3761	0.0356	0.7527	0.0576
Oswestry Disability	PLF	-13.61 (1.89)	-19.10 (1.86)	-20.92 (2.27)	-20.92 (1.98)	-21.21 (2.00)	-20.29 (2.07)	-21.86 (2.21)
	PPS	-14.46 (1.15)	-22.30 (1.17)	-26.46 (1.37)	-26.33 (1.26)	-24.39 (1.28)	-21.17 (1.33)	-23.01 (1.38)
	P	0.6974	0.1401	0.0356	0.0197	0.1765	0.7159	0.6548
	PLF	-13.61 (1.89)	-19.10 (1.86)	-20.92 (2.27)	-20.92 (1.98)	-21.21 (2.00)	-20.29 (2.07)	-21.86 (2.21)
	360°	-9.30 (2.12)	-16.78 (2.07)	-25.80 (2.56)	-27.61 (2.29)	-26.56 (2.11)	-24.42 (2.15)	-22.85 (2.56)
	P	0.1260	0.4022	0.1526	0.0264	0.0643	0.1647	0.7684
	PPS	-14.46 (1.15)	-22.30 (1.17)	-26.46 (1.37)	-26.33 (1.26)	-24.39 (1.28)	-21.17 (1.33)	-23.01 (1.38)
	360°	-9.30 (2.12)	-16.78 (2.07)	-25.80 (2.56)	-27.61 (2.29)	-26.56 (2.11)	-24.42 (2.15)	-22.85 (2.56)
	P	0.0300	0.0188	0.8175	0.6179	0.3702	0.1929	0.9545

rates of solid fusion are improved when instrumentation is used; however, many studies have demonstrated a lack of benefit from instrumentation in terms of patient-oriented outcomes.^{10,18} Concern for adjacent segment

degeneration or facet violation from instrumentation and the potential for increased operative and perioperative complications must be considered with increased surgical complexity.^{35,36}

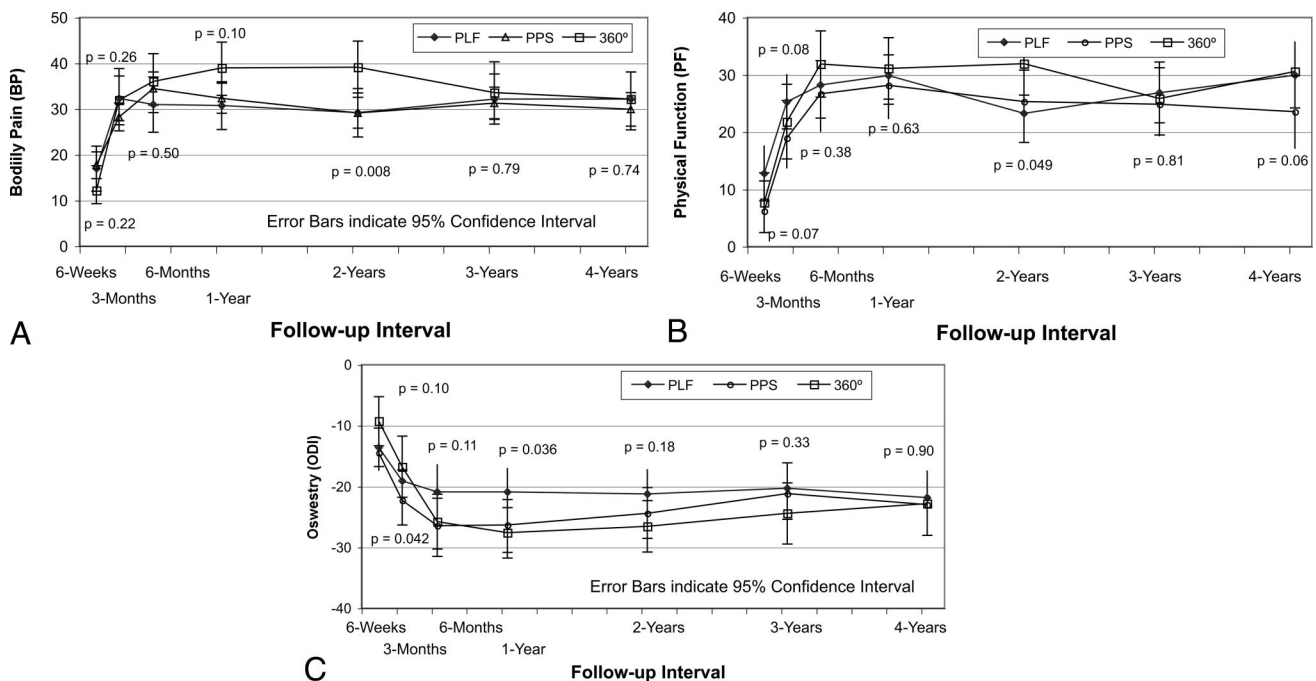


Figure 2. Summary of fusion group pattern of results for the SF-36 bodily pain (BP) and physical function (PF) scales and the Oswestry Disability Index (ODI). PLF = decompression with posterolateral *in situ* fusion; PPS = decompression with instrumented posterolateral fusion with pedicle screws; 360° = decompression with interbody fusion plus instrumented posterolateral fusion with pedicle screws.

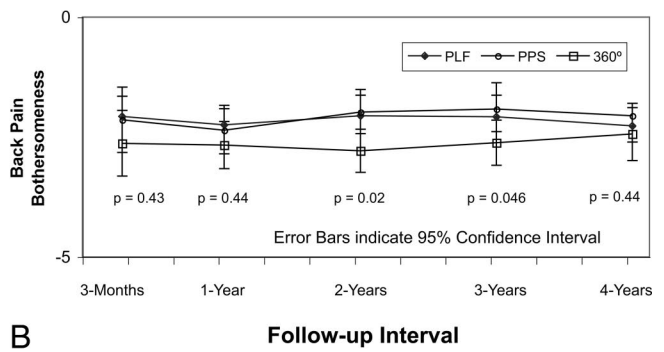
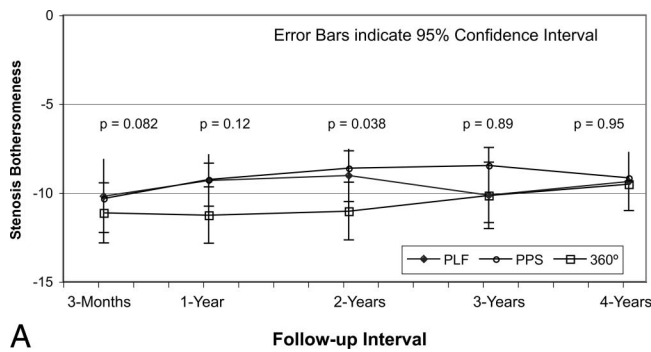


Figure 3. Summary of fusion group pattern of results for Stenosis Bothersomeness and Back Pain Bothersomeness Indexes. PLF = decompression with posterolateral *in situ* fusion; PPS = decompression with instrumented posterolateral fusion with pedicle screws; 360° = decompression with interbody fusion plus instrumented posteriolateral fusion with pedicle screws.

In patients presenting with image-confirmed DS with spinal stenosis, signs and symptoms of which had persisted for at least 12 weeks, the treatment effects did not consistently demonstrate one fusion procedure to be better than any other. On some measures and at some time points, PLF was somewhat better and for others 360° was sometimes better. There was very little to suggest any advantage for PPS based on the outcomes studied here.

As with previous studies we did find a higher rate of solid fusion on imaging in the groups with instrumented procedures. We found a 67% solid fusion rate in the PLF group, similar to the 64% seen by Herkowitz and Kurz¹² and better than the 45% solid fusion rate seen by Fischgrund *et al.*⁸ However, these determinations were largely based on surgeon impressions from plain radiographs and were based on surgeon impression rather than a fixed protocol and, therefore, the reliability and validity of these assessments are unclear. Similar to these prior studies, however, the difference in radiographic fusion rate did not seem to affect the short-term clinical outcomes.

Although SPORT was not specifically designed to study these fusion subgroups, they do represent the largest cohort of DS patients studied to date and the only report in DS comparing the 3 common fusion methods. Furthermore, the results of this study are strengthened by use of specific inclusion and exclusion criteria, the overall sample size, and adjustment for potentially confounding baseline factors. However, the current study does have several limitations. It represents a subgroup analysis and not the *a priori* hypothesis for which SPORT was designed. These cases were not randomized to treatment

groups, and radiographic fusion was not formally assessed predominately by CT or fusion exploration. Although these data suggest that fusion method does not influence outcome out to 4 years, further study with appropriate methodologic design is necessary to properly answer the questions of clinical outcome, risk, cost effectiveness, and benefit of each of these fusion techniques. In addition, these results may not extrapolate to clinical outcomes for spine fusions performed for other diagnoses than DS.

Comparisons to Other Studies

We are aware of only one other study specifically comparing different fusion techniques specifically in patients with DS. Fischgrund *et al* randomized 66 patients undergoing decompressive laminectomy to PLF or instrumented posterolateral fusion with pedicle screws, similar to the PLF and PPS groups in this study.⁸ They found a higher pseudarthrosis rate in the PLF group but no difference in clinical outcomes at 2-year follow-up, similar to our findings.

Several comparative studies of these different fusion techniques have been performed in other lumbar conditions. Andersen *et al* randomized patients with a variety of degenerative conditions (but not DS) to posterolateral fusion with or without pedicle screw instrumentation (PLF *vs.* PPS) and found no significant differences in pain outcomes at 5 years, similar to our results in DS.³⁷ Similarly, the Swedish Lumbar Spine Study Group randomized 222 patients with degenerative low back pain (not DS) to PLF, PPS, or 360° fusion and 72 to a nonsurgical group. The clinical outcomes were similar across the 3 fusion groups at 2-years.³⁸ Also, Swan *et al* compared instrumented posterolateral fusion with circumferential fusion in patients with radiographically unstable isthmic spondylolisthesis in a nonrandomized prospective cohort study and found significantly better outcomes with 360° fusion at 6 months and 1 year, but results became similar between the groups at 2 years.³⁹

Our results only go out to 4 years and there is the possibility that differences between the groups could emerge with longer-term follow-up. Kornblum *et al* followed DS patients following PLF and found that at long-

Table 4. Fusion Status for SPORT DS Fusion Subgroups

Treatment	Fusion Status N (PCT)			Total
	Pseudarthrosis	Solid Fusion	Unclear	
PLF	13 (22.41)	39 (67.24)	6 (10.34)	58 (20.57)
PPS	3 (1.76)	145 (85.29)	22 (12.94)	170 (60.28)
360°	3 (5.56)	47 (87.04)	4 (7.41)	54 (19.15)
Total	19 (6.74)	231 (81.91)	32 (11.35)	282

term follow-up (5–14 years; average, 7 years 8 months) patients with pseudarthrosis reported worse clinical outcomes than those with solid arthrodesis.¹⁶ However, this case series of patients with PLF did not have a control group who underwent instrumented fusion and thus does not shed any direct light on the relative outcomes between different fusion approaches. Videbaek *et al* report the long-term follow-up of patients with a variety of degenerative lumbar conditions (although not DS) randomized to PPS or 360° fusion.⁴⁰ Of note, they found no differences between the 2 groups at 2 years but found significantly better results in the 360° group at 5 to 9 years. This highlights the importance of ongoing follow-up in our study.

There was little evidence of harm from any of the fusion treatments. Over 4 years there have not been any cases of paralysis in any of the treatment groups. The 2-year reoperation rates in each of the 3 fusion groups were similar to those seen in the Swedish Lumbar Spine Study for PLF (14% *vs.* 12%) but lower in PPS (11% *vs.* 22%) and 360° (9% *vs.* 17%),³⁸ and somewhat higher than those in the study by Fischgrund *et al* (PLF [14% *vs.* 6%] and PPS [11% *vs.* 8%]).⁸ The overall complication rates were slightly higher than those in the Swedish Study for PLF (22% *vs.* 12%) and PPS (38% *vs.* 22%) but similar for 360° (25% *vs.* 25%).³⁸ Overall perioperative mortality was 0.05%, which is less than the 1.3% seen in Medicare patients after fusion surgery for spondylolisthesis.⁶ The 4-year mortality rate was similar across all fusion groups and was lower than actuarial projections, suggesting the likely selection of healthier than average patients for surgery.

■ Conclusion

Patients with DS and associated spinal stenosis are commonly treated by a combined procedure of decompression and fusion. Results out to 4 years suggest no significant advantage of one fusion technique over another on clinical outcomes, though longer-term follow-up may be needed. The fusion techniques were not randomly assigned and selection bias may have affected these results; a more definitive study would require random allocation into the various surgical approaches.

■ Key Points

- The SPORT trial prospectively investigated and demonstrated the effectiveness of surgical treatment compared with nonsurgical treatment of spinal stenosis with associated DS out to 4 years.
- Three commonly performed fusion methods were non-randomly performed in association with standard lumbar decompression.
- Baseline patient characteristics differed but health-related quality of life characteristics were the same among fusion cohorts.

- Early follow-up demonstrated variable outcomes, with one fusion method inconsistently favored over another, but at 3 and 4 years there were no differences in health-related quality of life outcomes, satisfaction, or Bothersomeness scores.
- Prospective randomized studies are required to determine which fusion method provides the most improved outcomes and the most cost-effective treatment.

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