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SPORT: Does incidental durotomy affect long-term outcomes in cases of Spinal Stenosis?

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Abstract

Background—Incidental durotomy is a familiar encounter during surgery for lumbar spinal stenosis. The impact of durotomy on long-term outcomes remains a matter of debate.

Objective—To determine the impact of durotomy on the long-term outcomes of patients in the Spine Patient Outcomes Research Trial (SPORT).

Methods—SPORT cohort participants with a confirmed diagnosis of spinal stenosis (SPS), without associated spondylolisthesis, undergoing standard, first-time, open decompressive laminectomy, with or without fusion, were followed from baseline at 6 weeks, and 3, 6, 12 months and yearly thereafter, at 13 spine clinics in 11 US states. Patient data from this prospectively gathered database was reviewed. As of May 2009, the mean follow-up among all analyzed patients was 43.8 months.

Results—409 patients underwent first-time open laminectomy with or without fusion. 37 (9%) of these patients had an incidental durotomy. No significant differences were observed with or without durotomy in age, sex, race, body mass index, the prevalence of smoking, diabetes and hypertension, decompression level, number of levels decompressed, or whether or not an additional fusion was performed. The durotomy group had significantly increased operative duration, operative blood loss and inpatient stay. There were however, no differences in incidence of nerve root injury, mortality, additional surgeries, primary outcomes (SF-36 scores of body pain or physical function, or Oswestry disability index) at yearly follow ups to 4 years.

Conclusions—Incidental durotomy during first time lumbar laminectomy for spinal stenosis did not impact long-term outcomes in affected patients.

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Keywords

durotomy; spinal stenosis; lumbar spine; outcomes; complications

INTRODUCTION

Lumbar laminectomy for spinal stenosis is one of the most common spinal procedures performed. A frequent complication associated with laminectomy is incidental durotomy. Various series have estimated the incidence of an unintentional durotomy during lumbar spine surgery to be between 1 and 17%,[1–20] with higher incidences associated with repeat surgery, increased patient age, and reduced surgeon experience.[1, 3, 7, 8, 20–22]

Dural tears have been associated with significant morbidity, most notably with spinal headaches, meningeal pseudocyst formation, and dural-cutaneous cerebrospinal fluid fistulas.[8, 10] To avoid these sequelae, several interventions have been used once a dural tear is recognized. These include primary repair, lumbar drain placement and post-operative bed rest.[1, 4, 6, 7, 23] Even when such precautions are taken, the effect of unintentional durotomy on long-term outcomes remains controversial.[6, 10] In addition, the incidence and subsequent outcomes of dural tears during specific lumbar spine procedures (such as discectomy, or laminectomy for spinal stenosis) have not previously been studied.

The Spine Patient Outcomes Research Trial provides a significant opportunity to examine long-term outcomes after incidental durotomy during lumbar laminectomy for spinal stenosis given its large cohort size,[24, 25] long-term follow-up and the multiple standardized outcome measures recorded in the trial. Furthermore, all laminectomies were performed using an open approach (i.e. without the use of a tubular retractor system) and all were performed in patients without previous history of lumbar spine surgery.

This study was undertaken in order to investigate whether incidental durotomy during first-time surgery for spinal stenosis across the 13 multidisciplinary spine clinics participating in the SPORT trial had any effects on long-term outcomes.

METHODS

Study Design

SPORT was conducted at 13 medical centers with multidisciplinary spine practices in 11 states in the United States. Institutional review board approval was obtained at each center. The trial was registered with ClinicalTrials.gov (NCT00000411). Additional background information is available in previous publications.[24, 25]

Patient Population

All patients had neurogenic claudication or radicular leg pain with associated neurological signs, spinal stenosis seen on cross-sectional imaging, symptoms that had persisted for at least twelve weeks, and surgeon (Orthopedic and/or Neurosurgeon) confirmation that they were surgical candidates. Pre-enrollment non-operative care included physical therapy, anti-

inflammatory medications, opioid analgesics, epidural injections, and chiropractic care. Enrollment began in March 2000 and ended in February 2005.

Surgery Performed

The protocol surgery consisted of a standard open laminectomy at the affected level or levels with or without fusion. The use of a microscope was at the surgeon's discretion but was not recorded as a SPORT data element.

Study Measures

The short-term outcome measures were operative duration, operative blood loss, inpatient length of stay, perioperative nerve root injury, requirement for blood transfusion, wound complications (e.g. infection) and post-operative mortality up to 3 months.

The long-term outcome measures were the need for repeat surgery at 3 months, and 1, 2, 3 and 4 years, the Short Form-36 (SF-36) bodily pain, physical function and mental component scores, Stenosis bothersomeness index (SBI) and the American Academy of Orthopaedic Surgeons MODEMS (Musculoskeletal Outcomes Data Evaluation and Management System) version of the Oswestry Disability Index, measured at 3 months, and yearly up to 4 years. The effect of the incidental durotomy on long-term outcome was defined as the difference in the mean changes, as compared with baseline, between the durotomy and no-durotomy groups (the difference in the difference).

SF-36 scores range from 0 to 100 points, with higher scores indicating less severe symptoms; the Oswestry Disability Index ranges from 0 to 100 points, with lower scores indicating less severe symptoms; the Stenosis Bothersomeness Index ranges from 0 to 24 points, with lower scores indicating less severe symptoms.

Statistical Methods

The baseline characteristics and short- and long-term outcome measures were compared between the patients in the durotomy cohort and those in the no-durotomy cohort. The analyses consisted of comparisons of both groups. The baseline characteristics were only analyzed for patients in both groups that had at least one year of follow-up. Computations were performed with the use of the PROC MIXED procedure for continuous data and the PROC GENMOD procedure for binary and non-normal outcomes from the SAS software package (version 9.1; SAS Institute, Cary, North Carolina). Significance was defined as $p < 0.05$ on the basis of a two-sided hypothesis test with no adjustments made for multiple comparisons. The data for these analyses were collected through May 1, 2009.

RESULTS

Incidence of durotomy

A total of 409 patients underwent standard lumbar laminectomy with or without fusion. Of these, durotomy occurred in 37, for an incidence of 9%.

Follow-up

As of May 2009, the mean (SD) follow-up among all analyzed patients undergoing surgery for spinal stenosis was 43.8 (14) months (No durotomy: 43.2 vs. durotomy: 46, p-value=0.25). The median (range) follow-up time among all analyzed SPS patients was 47 (1, 95.6) months.

Baseline characteristics (Table 1)

Out of 409 patients that underwent surgery, 404 patients had greater than one-year follow-up and their baseline characteristics were reviewed. No significant differences were seen between the durotomy and no-durotomy groups in baseline clinical characteristics. These included age, sex, race, body mass index, the prevalence of smoking, diabetes and hypertension, pre-operative neurological symptoms or deficits, and pre-operative SF-36 and Oswestry disability index scores. There were also no differences in the stenosis level or number of levels, the location (central, lateral recess or neural foraminal) or severity (mild, moderate, severe) of the stenosis, or whether or not the patients had previous lumbar epidural steroid injections.

Operative events (Table 2)

There were no differences between the two groups in decompression levels, number of levels, or the addition of instrumented or non-instrumented fusion to the decompression. There was a significantly increased operative duration (161.7 minutes versus 125.2 minutes, p=0.001) and operative blood loss (534.4ml versus 288.9ml, p<0.001) in the durotomy group. This amounted to an approximately 29% and 85% increase respectively. However, these patients did not have significantly increased needs for intra-operative or post-operative blood transfusion.

Short-term outcomes (Table 3)

There was a significantly increased length of hospital stay among the durotomy group (4.3 versus 3.1 days, p=0.003). This amounted to an approximately 39% increase in hospital stay. There were no increases in the incidence of wound hematoma or infection and post-operative nerve root injury. No occurrences of CSF fistula formation, wound dehiscence, bone graft complication, paralysis or cauda equina injury, pseudoarthrosis, or other complications attributable to surgery were observed. One patient (in the no durotomy group) died 9 days after surgery from a myocardial infarction.

Long-term outcomes (Table 3, Table 4, Figure 1)

There were no significant differences between the durotomy and no-durotomy groups in the incidence of recurrent stenosis or development of listhesis. One-, two-, three- and four-year post-surgical re-operation rates were calculated from Kaplan-Meier plots and no significant difference was observed between the two groups. (Table 3).

There were no differences between the durotomy and no-durotomy groups in mean difference from baseline for SF-36 bodily pain, physical function and mental component summary scores, at 3 months, 1 year, 2 years, 3 years and 4 years. Similarly there were no

difference in Oswestry disability index and Stenosis bothersomeness index at 3 months, and 1, 2, 3 and 4 years (Table 4, Figure 1).

DISCUSSION

Incidental durotomy occurred in less than 10% of SPORT cases of spinal stenosis during lumbar spine surgery. Although durotomy has been associated with a number of medical malpractice lawsuits,[26] the effects of this complication in patient outcomes has remained controversial, at best. In addition, there has to date been limited information on the incidence of dural tears and their outcomes in patients undergoing specific spinal procedures.

Several studies attempting to analyze effects on outcome after durotomy have yielded inconsistent results. Wang et al[7] demonstrated that dural tears do not have any deleterious effects on outcomes in the largest series of incidental durotomies (88 patients) presented to date. Jones et al[1] did not identify any difference in outcome between their 17 patients with incidental durotomies and appropriately matched controls. Cammisa et al[8] reached similar conclusions in their study group of 66 incidental durotomies. In agreement with these results, the current study has demonstrated that in patients undergoing lumbar laminectomies for spinal stenosis, incidental durotomies – while affecting intraoperative blood loss and hospital length of stay – do not increase the risk of other perioperative morbidities or adversely affect patient outcome at 6 weeks, 3 months or at 1, 2, 3 or 4 years. However, all the previous studies were retrospective in nature and took into account all lumbar spine procedures, including lumbar discectomy and surgery for spondylolisthesis, in addition to revision surgeries. These confounding variables have been addressed in the current study, where prospectively collected data from patients with a single pathology and operation (open lumbar laminectomy), that were part of a multi-institution study, are analyzed.

Saxler et al[10] had contrasting results after retrospectively analyzing their group of 41 lumbar discectomy patients in whom durotomy occurred intraoperatively, and comparing them with appropriately matched controls. Patients with incidental durotomy had a poorer outcome after surgery, with a decreased Tenger Score, more re-operations, more postoperative headaches, a longer inability to work, more back pain and functional limitations related to it. Although these data contradict most of the literature on durotomies, they are not in conflict with the present study on laminectomy for spinal stenosis patients, since they deal exclusively with discectomy patients. However, several methodological pitfalls raise concerns about the applicability of these data. Recall bias can hinder the validity of these results, while the retrospective nature of the study makes it possible that patients with good postoperative results were lost at follow up further confounding the outcomes. The current study overcomes several of these limitations by describing standardized outcomes in a multi-center cohort of prospectively collected data of patients undergoing first time surgery.

The rate of incidental durotomy in the present study was 9%, comparable to that reported for lumbar spine surgery in previous series.[1, 4, 7, 8, 10] The reported incidence of dural tears ranges from 1–17% and varies according to the patient characteristics, surgeon experience and the surgical procedure performed.[11] Our rate in this series may be partially attributable to the nature of the surgery analyzed; previous studies have suggested a higher rate of

durotomy in patients undergoing surgery for longstanding spinal stenosis.[12] Deyo et al[21] evaluated operative complications, including dural tears, in a large series of spinal procedures. The morbidity was lower for younger patients and for discectomies, while worst outcomes were associated with increased age, spinal stenosis, and re-operations. Several other authors have confirmed these results[1, 3, 7, 8, 11, 22]. Although several of these studies have supported the finding that fusion is also associated with an increased risk of durotomy, our two groups (durotomy versus no-durotomy) did not demonstrate any significant difference in the incidence of fusion. However, as expected in stenosis without listhesis, the overall rate of fusion was very low, limiting our ability to assess any potential difference, but rates were similar in the SPORT degenerative spondylolisthesis cohort (9% in the observational group and 11% in the randomized group) wherein fusion was performed in most cases.

The complications associated with dural tears are varied. They include postoperative headache, pseudomeningocele, nerve root entrapment with resultant neurological damage, wound infection, meningitis, and arachnoiditis.[1, 20, 26] In addition, several rarer complications have been reported, including symptomatic pneumorachis[27], spinal subdural empyema[28], bilateral subdural hematomas[29], and cerebral vasospasm[30]. While in the present study a significantly increased length of hospital stay among the durotomy group was observed, we did not observe an increase in the incidence of post-operative nerve root injury or wound infection. There were no occurrences of CSF fistula formation, wound dehiscence, neurological complications, or other complications attributable to surgery. The observed increased length of stay among patients with dural tears may be attributed to the tendency for increased post-operative bed rest and slower mobilization of these patients.

Several outcome measures have been used in the literature to quantify long-term outcomes in patients with incidental durotomies[10]. In the current study, there were no significant differences between the durotomy and no-durotomy groups in the incidence of recurrent stenosis, development of listhesis, or re-operations (Table 3). There were no differences between the durotomy and no-durotomy groups in mean difference from baseline for SF-36 bodily pain, physical function and mental component summary scores, and in Oswestry Disability Index and stenosis bothersome index scores over time. (Table 4).

The results from the current study should be interpreted with its limitations in mind. We did not have access to the precise methods of treatment followed in the different centers for the incidental durotomies and therefore their homogeneity cannot be assessed, and a comparison with the treatments of the literature cannot be attempted. Data on the use of microscope were also not collected and therefore we cannot provide an answer as to whether the incidence of durotomy can be altered by its use, nor did we have cases using percutaneous tubular decompressions.

The power of the present study in evaluating differences in outcome should also be considered. While the sample size is relatively large (409 patients, with 37 durotomies) in comparison to previously reported series, the 95% confidence intervals for the differences in the long-term outcome measures (SF-36, Oswestry Disability Index, Stenosis Bothersomeness Index) between the durotomy and no-durotomy groups in this study are

relatively broad, and are in some instances greater than 10 points from zero (Table 4). However, the tendency at all of these data points is for better outcomes in the durotomy group (higher SF-36 scores and lower Oswestry Disability Index and Stenosis Bothersomeness Index scores), although this is not statistically significant. Hence, while the broad confidence intervals suggest that a difference in outcome cannot be excluded, this difference, if it exists, appears to be the direction of improved outcomes after durotomy. While improved outcomes cannot be easily explained, the broad confidence intervals that raise this possibility highlight the limited power of this study for detecting differences in outcome and suggest a need for larger observational studies to confirm equivalence in outcome after durotomy.

Conclusions

Incidental durotomy is a relatively uncommon complication during lumbar laminectomy for spinal stenosis (<10%). In the current study, patients in whom durotomy occurred had significantly increased operative duration, operative blood loss and inpatient stays. There were however, no differences in incidence of nerve root injury, post-operative wound complications, additional surgeries, SF-36 scores of body pain or physical function, or Oswestry disability index at 1, 2, 3 and 4 years. Therefore, incidental durotomy during first time lumbar laminectomy for spinal stenosis does not appear to affect long-term outcome in affected patients.

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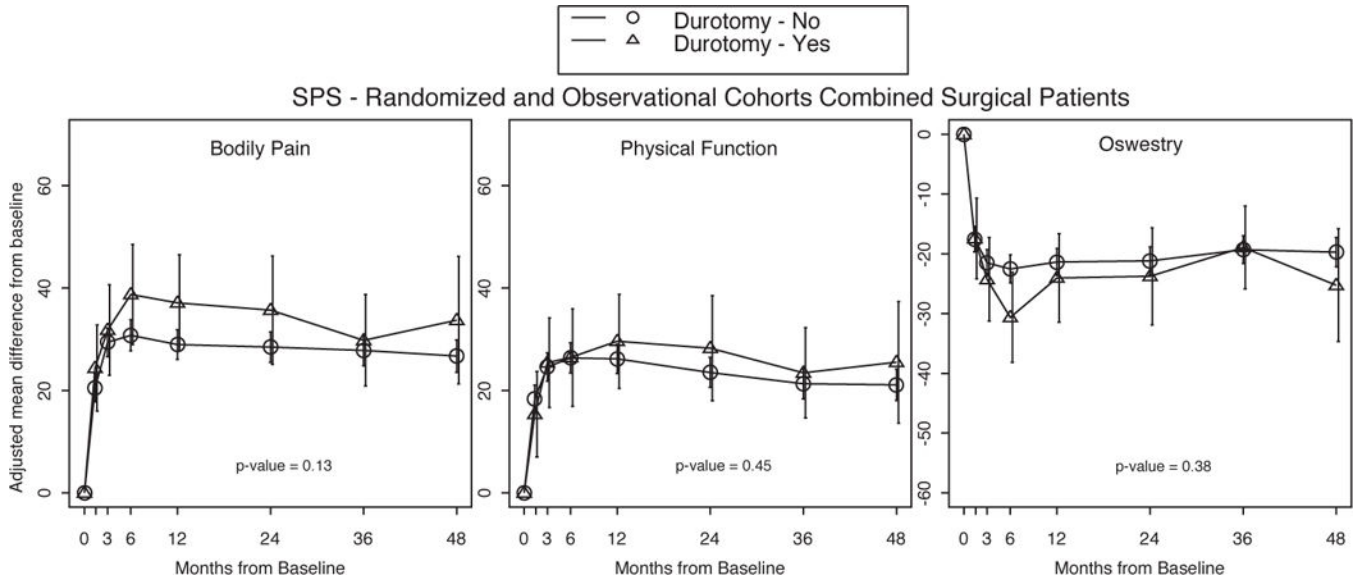

Figure 1.

Outcome results over time by status of durotomy with area under curve p-value that compares the durotomy group to the no-durotomy group

Table 1

Comparison of baseline characteristics between the durotomy and no durotomy groups.

Characteristics	No durotomy (n=367)	Durotomy (n=37)	p-value
Mean Age (SD)	63.9 (12.3)	64 (11.9)	0.96
Female – no. (%)	140 (38%)	16 (43%)	0.67
Mean Body Mass Index (BMI), (SD)	29.5 (5.3)	28.7 (6.1)	0.36
Smoker	34 (9%)	3 (8%)	0.95
Comorbidities – no. (%)			
Hypertension	157 (43%)	15 (41%)	0.93
Diabetes	51 (14%)	5 (14%)	0.85
Osteoporosis	28 (8%)	4 (11%)	0.72
Depression	41 (11%)	3 (8%)	0.77
Joint Problem	194 (53%)	21 (57%)	0.78
SF-36 scores, mean (SD)			
Bodily Pain (BP)	30.5 (18.8)	29.6 (41%)	0.78
Physical Functioning (PF)	31.9 (22)	30.9 (68%)	0.80
Vitality (VT)	41.4 (21.6)	41.6 (41%)	0.96
Physical Component Summary (PCS)	29 (8)	28.5 (68%)	0.71
Mental Component Summary (MCS)	48.6 (12)	48.8 (41%)	0.92
Oswestry Disability Index (ODI)(SD)‡‡	45.9 (18)	45.1 (16.2)	0.80
Stenosis Bothersome Index (0–24)(SD)§§	15.5 (5.3)	14.7 (6.5)	0.37
Any Neurological Deficit	197 (54%)	20 (54%)	0.90
Reflexes-Asymmetric Depressed	97 (26%)	9 (24%)	0.94
Sensory-Asymmetric Decrease	108 (29%)	12 (32%)	0.85
Motor – Asymmetric Weakness	93 (25%)	11 (30%)	0.70
Stenosis Level			
L2–L3	106 (29%)	16 (43%)	0.10
L3–L4	244 (66%)	29 (78%)	0.20
L4–L5	337 (92%)	34 (92%)	0.76
L5–S1	91 (25%)	13 (35%)	0.24
Number of Moderate/Severe Stenotic Levels			
None	6 (2%)	0 (0%)	
One	135 (37%)	8 (22%)	
Two	140 (38%)	19 (51%)	
Three +	86 (23%)	10 (27%)	
Stenosis Locations			
Central	315 (86%)	33 (89%)	0.75
Lateral Recess	297 (81%)	31 (84%)	0.84
Neural foramen	106 (29%)	16 (43%)	0.10

Characteristics	No durotomy (n=367)	Durotomy (n=37)	p-value
Stenosis Severity			
Mild	6 (2%)	0 (0%)	
Moderate	153 (42%)	15 (41%)	
Severe	208 (57%)	22 (59%)	
Instability	0 (0%)	0 (0%)	
Prior lumbar epidural steroid injection	204 (56%)	21 (57%)	0.97

* Patients receiving surgery were classified according to whether they received surgical treatment during the first 4 years of enrollment.

§ 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, nervous system, migraine,

†† 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 range from 0 to 24, with lower scores indicating less severe symptoms.

Table 2

Comparison of perioperative outcomes between the durotomy and no durotomy groups.

Outcome	No durotomy (n=371)	Durotomy (n=38)	p-value
Specific Procedures†			0.54
Decompression Only	321 (88%)	33 (89%)	
Non instrumented Fusion	19 (5%)	3 (8%)	
Instrumented Fusion	23 (6%)	1 (3%)	
Multi-level Fusion	15 (4%)	1 (3%)	0.99
Decompression Level			
L2–L3	129 (36%)	17 (45%)	0.35
L3–L4	251 (69%)	29 (76%)	0.47
L4–L5	335 (92%)	36 (95%)	0.82
L5–S1	134 (37%)	19 (50%)	0.16
Levels Decompressed			0.082
None	8 (2%)	0 (0%)	
1	86 (23%)	7 (18%)	
2	120 (32%)	7 (18%)	
3+	157 (42%)	24 (63%)	
Operation time (min)	125.2 (66.8)	161.7 (44.5)	0.001
Blood loss (ml)	288.9 (396.1)	534.4 (421.8)	<0.001
Blood Replacement			
Intraoperative replacement	33 (9%)	6 (16%)	0.26
Post-operative transfusion	17 (5%)	3 (8%)	0.59
Length of stay (days)	3.1 (2.4)	4.3 (2.1)	0.003
Intraoperative complications§			
Vascular injury	0 (0%)	0 (0%)	
Other	3 (1%)	0 (0%)	0.66
None	368 (99%)	38 (100%)	

* Surgical information was available for 371 non-durotomy and 38 durotomy patients.

† Specific procedure data was available for 363 non-durotomy and 37 durotomy patients.

§ No cases were reported of aspiration into the respiratory tract or operation at wrong level.

Table 3

Comparison of post-operative outcomes between the durotomy and no durotomy groups.

Outcome	No durotomy (n=371)	Durotomy (n=38)	p-value
Postoperative complications¶			
Nerve root injury	0 (0%)	0 (0%)	
Wound hematoma	4 (1%)	0 (0%)	0.81
Wound Infection	7 (2%)	2 (5%)	0.43
Other	20 (5%)	4 (11%)	0.34
None	325 (88%)	29 (78%)	0.15
Post-operative mortality (death within 6 weeks of surgery)	1 (0.2%)	0 (0%)	
Post-operative mortality (death within 3 months of surgery)	1 (0.2%)	0 (0%)	
Additional surgeries (1-year rate)//	20 (5%)	1 (3%)	0.461
Additional surgeries (2-year rate)//	28 (8%)	3 (8%)	0.959
Additional surgeries (3-year rate)//	41 (11%)	3 (8%)	0.554
Additional surgeries (4-year rate)//	49 (13%)	3 (8%)	0.363
Recurrent stenosis/progressive lesthesis	22 (6%)	1 (3%)	
Pseudoarthrosis/fusion exploration	0 (0%)	0 (0%)	
Complication or Other	15 (4.1%)	2 (5.3%)	
New Condition	7 (1.9%)	1	

*Surgical information was available for 371 non-durotomy and 38 durotomy patients.

¶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.

//Rates of repeated surgery at 1, 2, 3, and 4 years are Kaplan-Meier estimates. P values were calculated with the use of the log-rank test. Numbers and percentages are based on the first additional surgery if more than one additional surgery.

Table 4

Change scores and their differences (“No durotomy” minus “durotomy”) for SF- 36 scores, Oswestry disability index scores and Stenosis bothersome index scores, according to status of durotomy.

	3-month		1-year		2-year		3-year		4-year		
	Difference[†] (95% CI)	p-value	Difference[†] (95% CI)	p-value	Difference[†] (95% CI)	p-value	Difference[†] (95% CI)	p-value	Difference[†] (95% CI)	p-value	AUC p-value
SF-36 Bodily Pain (SE)[‡]	−2.4 (−11.7, 6.9)	0.61	−8.2 (−18, 1.7)	0.10	−7.2 (−18.2, 3.8)	0.20	−2 (−11.4, 7.4)	0.68	−7 (−19.8, 5.8)	0.28	0.13
SF-36 Physical Function (SE)[‡]	−0.9 (−10, 8.3)	0.86	−6.3 (−13.1, 6.2)	0.49	−4.7 (−15.4, 5.9)	0.38	−2.2 (−11.4, 7.1)	0.65	−4.4 (−16.7, 7.9)	0.48	0.45
SF-36 Mental Component Summary (SE)[‡]	−2.7 (−6.6, 1.1)	0.16	−1.8 (−5.9, 2.2)	0.38	−2.7 (−7.3, 1.8)	0.24	0.2 (−3.7, 4.1)	0.92	0.5 (−4.8, 5.8)	0.86	0.40
Oswestry Disability Index (SE)[§]	2.8 (−4.5, 10.1)	0.46	2.7 (−5.1, 10.4)	0.50	2.6 (−5.9, 11)	0.55	−0.4 (−7.7, 7)	0.92	5.5 (−4.2, 15.3)	0.27	0.38
Stenosis Bothersomeness Index (SE)[¶]	1 (−2, 3.9)	0.53	0.7 (−1.8, 3.2)	0.58	1.5 (−1.4, 4.3)	0.31	1.2 (−1.3, 3.6)	0.36	2.5 (−0.7, 5.7)	0.12	0.22

[*] Adjusted for age, gender, BMI and baseline score.

[†] Difference is the difference between no durotomy group mean change from baseline and had durotomy group 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