

TABLE E-1 Patient Baseline Demographic Characteristics, Comorbid Conditions, Clinical Findings, and Health Status Measures

	No-ESI* (N = 453)	ESI*† (N = 154)	P Value
Patient demographics			
Mean age (stand. dev.) (yr)	41.9 (11.4)	43.1 (12.6)	0.28
Female	186 (41%)	66 (43%)	0.77
Ethnicity: not Hispanic‡	428 (94%)	147 (95%)	0.80
Race: white‡	392 (87%)	122 (79%)	0.041
Education: at least some college	344 (76%)	114 (74%)	0.71
Income: <\$50,000	195 (43%)	65 (42%)	0.93
Marital status: married	324 (72%)	106 (69%)	0.59
Work status			0.031
Full or part-time	274 (60%)	100 (65%)	
Disabled	62 (14%)	9 (6%)	
Other	116 (26%)	45 (29%)	
Compensation§	74 (16%)	22 (14%)	0.64
Mean body mass index (stand. dev.) (kg/m ²)	27.7 (5.5)	28.4 (5.9)	0.22
Smoker	107 (24%)	28 (18%)	0.20
Comorbidities			
Depression	41 (9%)	24 (16%)	0.034
Joint problem	78 (17%)	28 (18%)	0.88
Diabetes	26 (6%)	4 (3%)	0.18
Other#	193 (43%)	81 (53%)	0.039
Time since recent episode <6 mo	371 (82%)	132 (86%)	0.34
Mean baseline outcome scores** (stand. dev.)			
Short Form-36			
Bodily pain	28.5 (21.1)	25.3 (19.10)	0.096

Physical function	39.2 (27)	38.2 (24.20)	0.69
Mental component summary	46.5 (10.8)	43.9 (12)	0.012
Physical component summary	30.7 (8.8)	30.7 (8.20)	0.99
Oswestry Disability Index	49.1 (21.6)	49.1 (21.20)	1
Sciatica frequency index	15.9 (5.30)	15.5 (5.50)	0.34
Sciatica bothersome index	15.6 (5.4)	15 (5.2)	0.22
Low back pain bothersomeness scale	4 (1.9)	4 (1.9)	0.92
Satisfaction with symptoms: very dissatisfied	349 (77%)	125 (81%)	0.34
Patient self-assessed health trend			0.31
Getting better	81 (18%)	23 (15%)	
Staying about the same	185 (41%)	74 (48%)	
Getting worse	184 (41%)	57 (37%)	
Treatment preference at baseline			<0.001
Preference for nonsurgical treatment	139 (31%)	86 (56%)	
Not sure	58 (13%)	38 (25%)	
Preference for surgery	255 (56%)	30 (19%)	
Clinical characteristics			
Pain radiation	437 (96%)	150 (97%)	0.76
Straight leg raise test: ipsilateral	286 (63%)	98 (64%)	0.99
Straight leg raise test: contralateral/both	78 (17%)	21 (14%)	0.36
Any neurological deficit	359 (79%)	108 (70%)	0.027
Reflexes: asymmetrically depressed	194 (43%)	58 (38%)	0.30

Sensory: asymmetric decrease	242 (53%)	66 (43%)	0.03
Motor: asymmetric weakness	198 (44%)	60 (39%)	0.35
Herniation level			0.42
L2-L3/L3-L4	34 (8%)	7 (5%)	
L4-L5	172 (38%)	57 (37%)	
L5-S1	247 (55%)	89 (58%)	
Herniation type			0.12
Protruding	108 (24%)	42 (27%)	
Extruded	301 (66%)	104 (68%)	
Sequestered	44 (10%)	7 (5%)	
Posterolateral herniation	363 (80%)	126 (82%)	0.73
Received surgery††	312 (69%)	74 (48%)	<0.001

*The values are given as the number of patients with the percentage in parentheses unless otherwise indicated. †Defined as receipt of an epidural steroid injection at six weeks or three months during the treatment period. ‡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. #Other indicates problems related to stroke, diabetes, osteoporosis, cancer, fibromyalgia, chronic fatigue syndrome, posttraumatic stress disorder, alcohol abuse, drug abuse, hypertension, migraine, anxiety, or comorbidities involving the heart, lung, liver, kidney, blood vessel, nervous system, stomach, or bowel. **The Short Form-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 sciatica frequency index and sciatica bothersomeness index range 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. ††Patients were classified as having received surgery if they received surgical treatment during the first four years of enrollment.

TABLE E-2 Operative Treatments, Complications, and Events

	No-ESI* (N = 310)	ESI* (N = 74)	P Value
Discectomy level			
L2-L3	4 (1%)	1 (1%)	0.6
L3-L4	11 (4%)	0 (0%)	0.21
L4-L5	116 (38%)	27 (36%)	0.97
L5-S1	184 (59%)	48 (65%)	0.48
Mean operative time (stand. dev.) (<i>min</i>)	72.9 (36.10)	77.6 (54.70)	0.38
Mean blood loss (stand. dev.) (<i>mL</i>)	64.1 (128.50)	66.7 (120.60)	0.88
Blood replacement			0.82
Intraoperative replacement	1 (0%)	1 (1%)	
Postoperative transfusion	0 (0%)	0 (0%)	
Mean length of hospital stay (stand. dev.) (<i>days</i>)	1 (0.9)	1.1 (1.10)	0.51
Intraoperative complications†			
Dural tear/spinal fluid leak	13 (4%)	2 (3%)	0.79
Nerve root injury	1 (0%)	1 (1%)	0.84
Other	1 (0%)	0 (0%)	0.44
None	296 (95%)	71 (96%)	0.89
Postoperative complications/events‡			
Nerve root injury	0	0	
Wound hematoma	2 (1%)	0 (0%)	0.83
Wound infection	8 (3%)	1 (1%)	0.86
Other	12 (4%)	1 (1%)	0.49
None	288 (93%)	70 (97%)	0.31
Additional surgery§			
1-year rate	14 (51%)	4 (5%)	0.77

2-year rate	26 (8%)	4 (5%)	0.4
3-year rate	28 (9%)	5 (7%)	0.53
4-year rate	29 (9%)	7 (9%)	1
Reason for additional surgery			
Recurrent disc herniation	20 (6%)	6 (8%)	
Complication (such as pseudomeningocele repair, epidural hematoma, infection, or other complication)	7 (2%)	0	
New condition	1 (0%)	1	

*The values are given as the number of patients unless otherwise indicated. †None of the following were reported: aspiration, operation at the wrong level, or vascular injury. ‡Any reported complications up to eight weeks after the operation. None of the following were reported: bone graft complication, cerebrospinal leak, paralysis, cauda equina injury, wound dehiscence, or pseudarthrosis. §The one, two, three, and four-year postsurgical reoperation rates are Kaplan-Meier estimates and p values are based on the log-rank test. The numbers and percentages are based on the first additional surgery if more than one additional surgical procedure was performed.

index												
No-ESI	−11.8 (0.40)	−8.5 (0.50)	−3.4 (−4.6, −2.1)	−11.1 (0.30)	−8.6 (0.50)	−2.5 (−3.8, −1.3)	−11 (0.4)	−8.9 (0.50)	−2.1 (−3.4, −0.9)	−11.9 (0.40)	−8.9 (0.50)	−2.9 (−4.3, −1.6)
ESI	−10.9 (0.70)	−8.1 (0.60)	−2.8 (−4.4, −1.2)	−11.1 (0.70)	−8.2 (0.60)	−2.9 (−4.5, −1.3)	−11 (0.7)	−8.2 (0.60)	−2.8 (−4.5, −1.1)	−11 (0.7)	−7.8 (0.70)	−3.1 (−4.9, −1.3)
P value	0.25	0.64	0.58		0.6	0.72	0.94	0.34	0.52	0.26	0.18	0.87
Low back pain bothersomeness scale												
No-ESI	−2.4 (0.10)	−1.5 (0.10)	−0.9 (−1.3, −0.5)	−2.4 (0.10)	−1.5 (0.10)	−0.9 (−1.3, −0.5)	−2.3 (0.10)	−1.5 (0.20)	−0.8 (−1.2, −0.4)	−2.5 (0.10)	−1.7 (0.20)	−0.8 (−1.2, −0.4)
ESI	−2.1 (0.20)	−1.4 (0.20)	−0.7 (−1.2, −0.2)	−2.2 (0.20)	−1.5 (0.20)	−0.7 (−1.2, −0.2)	−2.1 (0.20)	−1.6 (0.20)	−0.5 (−1, 0)	−2.2 (0.20)	−1.4 (0.20)	−0.7 (−1.3, −0.1)
P value	0.25	0.74	0.56		0.93	0.57	0.57	0.71	0.50	0.2	0.18	0.89
Very/somewhat satisfied with symptoms (%)												
No-ESI	80.6	40.7	40 (28.8, 51.1)	82.6	49.3	33.3 (21.9, 44.7)	78.3	49.8	28.6 (16.3, 40.8)	83.5	47	36.6 (24.5, 48.7)
ESI	64.5	48.7	15.8 (−1.5, 33.2)	77.3	43.6	33.7 (17.8, 49.6)	77.9	43.5	34.4 (17.8, 51)	73.7	34.8	38.9 (21.7, 56.1)
P value	0.02	0.29	0.012		0.47	0.83	0.95	0.42	0.66	0.12	0.13	0.86
Work status: working (%)												
No-ESI	88.9	78.2	10.7 (0.2, 21.1)		82.3	4.5 (−5.3, 14.4)	83.1	80.3	2.8 (−8.3, 14)	86.2	74.7	11.6 (−0.9, 24.1)
ESI	78.3	89.9	−11.6 (−25.5, 2.3)		90.7	−5.2 (−16.9, 6.4)	86.9	83.3	3.7 (−10.6, 17.9)	87.5	86.1	1.4 (−12.8, 15.6)
P value	0.079	0.049	0.005		0.11	0.21	0.64	0.68	0.90	0.87	0.13	0.42

*Adjusted for age, sex, marital status, smoking status, race, compensation, herniation location, working status, depression, other comorbidity, self-rated health trend, duration of most recent episode, treatment preference, baseline score (for Short Form-36, Oswestry Disability Index, and sciatica bothersomeness index), and center. Other indicates problems related to stroke, diabetes, osteoporosis, cancer, fibromyalgia, chronic fatigue syndrome, posttraumatic stress disorder, alcohol abuse, drug abuse, hypertension, migraine, anxiety, or comorbidities involving the heart, lung, liver, kidney, blood vessel, nervous system, stomach, or bowel. †The Short Form-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 sciatica bothersomeness index ranges from 0 to 24, with lower scores indicating less severe symptoms. The low back pain bothersomeness scale ranges from 0 to 6, with lower scores indicating less severe symptoms. ‡The values are given as the mean with the standard error in parentheses unless otherwise indicated. §Treatment effect is the difference between the surgical and nonoperative mean change from baseline. Analysis is done with use of a mixed model with a random subject intercept term. Treatment is a time-varying covariate where a patient’s experience prior to surgery is attributed to the nonoperative arm and time is measured from enrollment. His/her postsurgery outcomes are attributed to the surgical arm and time is measured from the time of surgery. The 95% confidence interval is given in parentheses.

TABLE E-4 Average Area-Under-the-Curve Results (Per Year) Over Four Years from Adjusted As-Treated Outcome Analysis by ESI/No-ESI Group

Outcome*	Surgical†	Nonsurgical†	Treatment Effect‡
Short Form-36			
Bodily pain			
No-ESI	47.4 (1.10)	31.9 (1.40)	15.5 (11.9, 19.1)
ESI	44 (1.8)	31.3 (1.80)	12.7 (8.6, 16.8)
P value	0.12	0.77	0.30
Physical function			
No-ESI	43.8 (1)	28.9 (1.30)	14.9 (11.6, 18.3)
ESI	41.7 (1.80)	25.2 (1.70)	16.4 (12.8, 20.1)
P value	0.32	0.081	0.54
Oswestry Disability Index			
No-ESI	−38.5 (0.90)	−25 (1.1)	−13.5 (−16.2, −10.8)
ESI	−36.2 (1.50)	−22.2 (1.40)	−14 (−16.9, −11.1)
P value	0.2	0.11	0.78
Sciatica bothersomeness index			
No-ESI	−10.4 (0.30)	−7.8 (0.40)	−2.5 (−3.5, −1.6)
ESI	−9.9 (0.50)	−7.2 (0.40)	−2.7 (−3.7, −1.7)
P value	0.37	0.19	0.79

* The Short Form-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 sciatica bothersomeness index ranges from 0 to 24, with lower scores indicating less severe symptoms. †The values are given as the mean with the standard error in parentheses unless otherwise indicated. ‡Treatment effect is the difference between the surgical and nonoperative mean change from baseline. Analysis is done with use of a mixed model with a random subject intercept term. Treatment is a time-varying covariate where a patient’s experience prior to surgery is attributed to the nonoperative arm and time is measured from enrollment. His/her postsurgery outcomes are attributed to the surgical arm and time is measured from the time of surgery. The 95% confidence interval is given in parentheses.

TABLE E-5 Crossover of Assigned/Chosen Treatment Groups at Four Years

	No-ESI (N = 453)	ESI (N = 154)	P Value*
Assigned/chose surgery, crossed over to nonoperative (%)	37/304 (12%)	24/59 (41%)	<0.001
Assigned/chose nonoperative, crossed over to surgery (%)	45/149 (30%)	40/95 (42%)	0.057

*P values are from the chi-square test for a significant difference in crossover between the ESI and No-ESI patients in the surgical and nonoperative groups.

TABLE E-6 Percentage of Patients Who Underwent Surgery at Each Time Point

	No-ESI				ESI			
Time Point	Total No. of Patients Who Were Assigned/Chose Surgery	Cumulative % Having Surgery (Among Enrolled)	Total No. of Patients Who Were Assigned/Chose Nonsurgical Treatment	Cumulative % Having Nonsurgical Treatment (Among Enrolled)	Total No. of Patients Who Were Assigned/Chose Surgery	Cumulative % Having Surgery (Among Enrolled)	Total No. of Patients Who Were Assigned/Chose Nonsurgical Treatment	Cumulative % Having Nonsurgical Treatment (Among Enrolled)
6 weeks	252	83%	13	9%	11	19%	5	5%
3 months	265	87%	25	17%	24	41%	18	19%
6 months	266	88%	35	23%	30	51%	26	27%
1 year	267	88%	41	28%	33	56%	32	34%
2 years	267	88%	42	28%	35	59%	35	37%
3 years	267	88%	44	30%	35	59%	37	39%
4 years	267	88%	45	30%	35	59%	40	42%
Total number	304		149		59		95	

TABLE E-7 Crossover of Assigned/Chosen Treatment Groups at Four Years for the Patients Who Had Baseline Preference for Surgery

	No-ESI (N = 255)	ESI (N = 30)	P Value*
Assigned/chose surgery, crossed over to nonoperative (%)	2/236 (1%)	2/15 (13%)	0.0436
Assigned/chose nonoperative, crossed over to surgery (%)	15/19 (79%)	9/15 (60%)	0.2764

*P values are from the chi-square test for a significant difference in crossover between the ESI and No-ESI patients in the surgical and nonoperative groups.

TABLE E-8 Crossover of Assigned/Chosen Treatment Groups at Four Years Follow-up for the Patients Who Had Baseline Preference for Nonoperative Treatment

	No-ESI (N = 139)	ESI (N = 86)	P Value*
Assigned/chose surgery, crossed over to nonoperative (%)	19/34 (56%)	15/31 (48%)	0.6229
Assigned/chose nonoperative, crossed over to surgery (%)	21/105 (20%)	18/55 (33%)	0.0838

* P values are from the chi-square test for a significant difference in crossover between the ESI and No-ESI patients in the surgical and nonoperative groups.