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Patient Factors That Influence Decision Making: Randomization versus Observational Nonoperative versus Observational Operative Treatment for Adult Symptomatic Lumbar Scoliosis (ASLS)

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Abstract

Study Design—Prospective randomized and observational study

Objective—Determine baseline variables affecting adult symptomatic lumbar scoliosis (ASLS) decision making to participate in randomization (RAND), observational nonsurgical (OBS-NS) or observational surgical (OBS-S) cohorts.

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Summary of Background Data—Multiple factors play a key role in a patient's decision to be randomized or to choose an OBS-NS or OBS-S course for ASLS. Studies evaluating these factors are limited.

Methods—Eligible candidates (patients with ASLS and no prior spinal fusion deformity surgery) from 9 centers participated in a RAND, OBS-NS or OBS-S cohort study. Baseline variables (demographics, socioeconomics, patient-reported outcomes [PROs], Functional Treadmill Test, radiographs) were analyzed.

Results—295 patients were enrolled: 67 RAND, 115 OBS-NS, 113 OBS-S. Subanalysis of older patients (60–80 years) found 54% of OBS-NS had college degrees compared to 82% of RAND and 71% of OBS-S ($p=0.010$). Patients deciding to be part of a RAND cohort have similar clinical characteristics to the OBS-S cohort. OBS-S had more symptomatic spinal stenosis (57% vs 39%, $p\text{-value}=0.029$) and worse scores than OBS-NS based on PROs (Back Pain Numerical Rating Scale [NRS 6.3 vs 5.5, $p=0.007$]; Scoliosis Research Society [SRS] Pain [2.8 vs 3.0, $p=0.018$], Function [3.1 vs 3.4, $p=0.019$] and Self-Image [2.7 vs 3.1, $p=0.002$]; Oswestry Disability Index [ODI] [36.9 vs 31.8, $p=0.029$]; post Treadmill back [5.8 vs 4.4, $p=0.002$] and leg [4.3 vs 3.1, $p=0.037$] pain NRS and larger lumbar coronal Cobb angles (56.5° vs 48.8°, $p<0.001$). RAND had more baseline motor deficits (10.4% vs 1.7%, $p=0.036$) and worse scores than OBS-NS based on ODI (38.8 vs 31.8, $p=0.006$), SRS Function [3.1 vs 3.4, $p=0.034$] and Self-Image [2.7 vs 3.1, $p=0.007$].

Conclusion—Patients with worse PROs, more back pain, more back and leg pain with ambulation and larger lumbar Cobb angles are more inclined to select surgical over nonsurgical management.

Keywords

Randomized trial; adult lumbar scoliosis; surgical treatment; nonsurgical treatment; Patient-Reported Outcomes

Introduction

Adult symptomatic lumbar scoliosis (ASLS) patients seek treatment due to increasing deformity, pain, neurological deficits and functional limitations. Factors such as patient's age, co-morbidities, severity of the deformity and extent of symptoms make clinical management and decision making, be it surgical or nonsurgical, challenging.^{1,2} Regardless of the severity of symptoms, nonsurgical resources are highly utilized for the management of adult spinal deformity with minimal complications.³ Decision making for how to manage adult spinal deformity becomes complicated when determining if the benefit of surgical treatment outweighs the risks. The complication rate for adult deformity surgery can be as high as 80% and have a greater than 50% reoperation rate.^{4,5} These factors are important to consider when determining management.

Several retrospective studies have compared surgical and nonsurgical management for ASLS. These studies demonstrate that a patient's decision to undergo surgery is primarily influenced by his/her functional limitations and surgical outcomes are influenced by patient factors, such as body mass index (BMI), smoking, pain severity and psychiatric disorders.^{6,7}

However, there are limited prospective, observational and randomized trials to evaluate the outcomes after adult lumbar scoliosis treatment. Therefore, an NIH-funded clinical randomized trial (R01 AR055176-01A2: A Multi-Centered Prospective Study of Quality of Life in Adult Scoliosis) with a concurrent observational cohort was conducted to evaluate the effectiveness of nonsurgical and surgical interventions in patients with ASLS. The purpose of this study is to determine which baseline variables collected during the NIH study affect the decision to participate in either a randomized or observational nonsurgical or surgical cohort.

Materials and Methods

A prospective randomized (RAND) cohort study with concurrent observational surgical (OBS-S) and observational nonsurgical (OBS-NS) cohorts was conducted at 9 medical centers in North America. Patients with ASLS between the ages of 40–80 years who had a lumbar curve with a coronal Cobb measurement $\geq 30^\circ$ and had either an Oswestry Disability Index (ODI) score ≥ 20 or a Scoliosis Research Society (SRS) score ≤ 4 in the domains of Pain, Function, and/or Self-Image were offered enrollment in either the randomized or observational cohort. Randomization was strongly recommended to patients by the treating team. If patients refused, they were offered either OBS-S or OBS-NS treatment. Treatment assignments for the participants in the randomized cohort were assigned through a computer-generated randomization. Participants in the observational cohort were able to choose their treatment, nonsurgical or surgical intervention. All patients had to be considered a surgical candidate by the site investigator at the time of consent.

Randomization

Patients consenting to randomization were randomized 1:1 to the nonsurgical or surgical intervention arms. A permuted randomized block approach with blocks of size 4, 6 and 8 and stratified by site, age group (2 levels: 40–59 years of age, 60–80 years of age), gender and Cobb angle-based severity (2 levels: $30\text{--}54^\circ$, $55\text{--}100^\circ$) were used to ensure representative treatment assignment across these demographic and disease-specific categories with approximately balanced assignment totals.

Nonsurgical Intervention

One physician from each center with experience in nonsurgical management determined the nonsurgical care. The nonsurgical treatment included a combination of physical therapy, interventional procedures (i.e., epidural steroid injections, selective nerve root blocks), medications and/or alternative modalities.

Surgical Intervention

Surgical treatment included instrumented arthrodesis with decompressions and correction of the spinal deformity.

Baseline Variables

Within six months prior to intervention implementation, baseline variables were collected. These variables include patient demographics, socioeconomic status, educational level,

Patient-Reported Outcomes (PROs: ODI, SRS-22 domains and Subscore [subtotal of Pain, Function, Mental Health and Self-Image], Short Form [SF]-12 Mental and Physical Component Scores [MCS and PCS], back and leg pain on Numerical Rating Scale [NRS]), radiographic parameters (coronal and sagittal balance, Cobb angles and spinopelvic measures). A baseline clinical assessment (physical exam, length of current symptoms, prior treatments) was completed. Patients also completed a standardized Functional Treadmill Test, evaluating the patient's ability to walk at a pace they selected and felt was sustainable as long as possible up to 30 minutes. Pre- and post- back and leg NRS scores were captured.

Statistical analysis

Pearson Chi-squared was used for categorical variables and Kruskal Wallis for ordinal and continuous variables. Pairwise comparisons were performed with Bonferroni correction for multiple comparisons to determine if differences between any two of the three participation groups were significant. Significance was set at 0.05 for all tests. Statistical analysis was completed using SPSS Statistics for Windows, Version 22.0 (IBM Corp, Armonk, NY).

Results

Two hundred ninety five patients (265 female, 30 male) were enrolled in the study with 67 patients consenting to RAND and 228 patients choosing to be part of the observational cohort. Of those 228 observational patients, 115 chose OBS-NS and 113 chose OBS-S. Enrollment occurred between 2010 and 2014.

Patient Demographics

There were no differences in the mean age or body mass index (BMI). There were differences in the duration of symptoms reported by patients (Table 1). Pairwise comparisons found the RAND group reported longer history of back pain (median 99 vs 48 months, $p=0.023$) and leg pain (48 vs 12 months, $p=0.041$) than the OBS-S group. There were no significant differences (based on PROs) between RAND and OBS-S; the OBS-S group had worse scores than OBS-NS. The OBS-NS patients had a lower percentage of participants with college education (62%) compared to the RAND (72%) and OBS-S (76%) groups, but this was not significant ($p=0.057$). However, a subanalysis of older patients (60–80 years) found 54% of OBS-NS had college degrees compared to 82% of RAND and 71% of OBS-S ($p=0.010$) (Table 2). There were no differences in reported annual household income (Table 3).

Clinical assessment

There were significant differences in baseline PROs (Table 4), Functional Treadmill Test (Table 5) and coronal and sagittal plane radiographic parameters (Tables 6 and 7). Subsequent pairwise comparisons (Table 8) revealed patients in the OBS-S group were more symptomatic and reported worse baseline scores than the OBS-NS group for the following variables: back pain NRS (6.3 vs 5.5, $p=0.007$); SRS domains of Pain (2.8 vs 3.0, $p=0.018$), Function (3.1 vs 3.4, $p=0.019$), Self-Image (2.7 vs 3.1, $p=0.002$) and Subscore (3.1 vs 3.3, $p=0.007$); ODI (36.9 vs 31.8, $p=0.029$); post Treadmill back (5.8 vs 4.4, $p=0.002$) and leg (4.3 vs 3.1, $p=0.037$) pain NRS, as well as larger lumbar Cobb angle (56.6° vs 48.8°),

$p < 0.001$). The RAND group was also more symptomatic than the OBS-NS group at baseline based on the following variables: ODI (38.8 vs 31.8, $p = 0.006$) and the SRS domains of Function (3.1 vs 3.4, $p = 0.034$), Self-Image (2.7 vs 3.1, $p = 0.007$) and Subscore (3.1 vs 3.3, $p = 0.016$). Post-hoc analysis found no differences in PROs, radiographic or Functional Treadmill parameters between the RAND and OBS-S groups. OBS-NS patients were less likely to have a motor deficit on presentation (1.7%) compared to the RAND (10.4%; $p = 0.036$) (Table 9) whereas OBS-S patients were more likely to have symptomatic spinal stenosis/claudeication (56.6%) compared to the OBS-NS (39.1%) group ($p = 0.029$) (Table 10). The OBS-S group had more motor deficits at presentation than the OBS-NS group, but the difference was not significant.

There were no differences among groups in reporting the types of nonsurgical treatments utilized prior to enrollment or current medication use (Table 11). When asking patients in the observational cohort why they decided not to randomize, the majority of patients who chose OBS-S felt they had exhausted nonsurgical treatment and the majority of patients who chose OBS-NS were not interested in surgery at this time (Table 12).

Discussion

This study evaluates multiple baseline parameters to determine which variables might influence a patient's decision to participate in a randomized or observational cohort (surgical or nonsurgical treatment). In this study, older patients (60–80 years) with a lower educational level are more likely to decide to be part of an OBS-NS cohort than the OBS-S or RAND cohorts. With that said, multiple studies have shown that socioeconomic status and educational level do not affect a patient's decision to participate in a study. However, these prior studies evaluate a patient's willingness to participate in the study, not their decision of which cohort to join.^{8,9}

Multiple retrospective studies demonstrate that pain and functional limitations influence an adult scoliosis patient's decision to undergo surgical management.^{2,4,7,10,11} Weinstein et al's randomized and observational Spine Patient Outcomes Research Trial (SPORT) for degenerative spondylolisthesis demonstrated that patients who decided to join the observational surgical cohort had worse PROs (pain, function and disability) than patients in the observational nonsurgical group.¹² Our prospective study evaluating ASLS patients concluded similar results in that SRS and ODI scores were worse in patients who chose to be part of an OBS-S instead of an OBS-NS treatment group. The RAND and OBS-S groups had similar PROs at baseline. This current study demonstrates that not only back pain, but increased back and leg pain after ambulation, is a strong driving force for patients to decide to undergo surgery for ASLS. Interestingly, the OBS-S group did not report more leg pain at presentation than the OBS-NS group. Glassman et al demonstrated similar results in regard to back pain. However, they found more surgical patients complained of leg pain than patients treated nonsurgically.¹ The possible reason our study results differ in regard to leg pain is that we compared the intensity of leg pain (NRS) while Glassman et al analyzed the presence of leg pain (yes or no). Pekmezci et al demonstrated similar results to our study in regard to intensity of leg pain being similar between groups.⁶ This current study also demonstrates that patients with increased back and leg pain after ambulation, potential

presence of a motor deficit and clinically significant spinal stenosis are more likely to choose surgery over nonsurgical management.

Reviewing pre-treatment radiographs demonstrated similar lumbar coronal Cobb angles between the RAND and OBS-S groups. Both of these groups had larger lumbar curves than patients in the OBS-NS group. This suggests that the patient's deformity is an important driver for surgery.¹³ Also in this study there was no difference among the three groups in regard to sagittal parameters (C7 plumb, sagittal Cobb, pelvic incidence [PI], pelvic tilt [PT], sacral slope [SS] and PI-Lumbar Lordosis [LL] mismatch). Interestingly though, multiple retrospective studies have demonstrated no correlation between curve magnitude and pain, but have shown that increased sagittal imbalance is associated with pain.^{14,15} This differs from our results and could be explained by the fact that the majority of these retrospective studies included a combination of primary and revision surgeries. Our patient population consisted only of primary patients who had not undergone prior spinal fusion surgery and therein the prevalence of sagittal imbalance or mismatch between pelvic incidence and lumbar lordosis was far smaller than typically seen in revision patients.

Even though our study showed that the type of prior treatment modality had no effect on which group a patient chose, the majority of patients who decided not to be randomized and to be part of the OBS-S group felt they had exhausted all nonsurgical treatments. This demonstrates that failure of prior nonsurgical treatment has some influence on a patient's decision of treatment.

A limitation to this study is while some of the PROs were statistically different between groups (i.e., SRS Subscore 3.1 vs 3.3 $p=0.003$), one could question if these findings are clinically important as the minimal clinically important difference (MCID) for the SRS-22 domains in adult spinal deformity is 0.4.¹³ MCID thresholds have been suggested for NRS back and leg pain and ODI outcomes measures, but these have never been studied for an adult spinal deformity population. Further, an MCID is an effort to establish the clinically important difference for a patient comparing baseline to post-treatment. Therein, it is unclear whether these clinically important difference parameters can be applied to groups of patients being studied at baseline, as is the case in our study. Nonetheless, we realize the numerical differences between the groups, although statistically significant, do not represent large numbers. We believe the paradoxical conclusion is that the three groups are distinctly different, but similar in many regards. If we were to present VENN diagrams of the three groups, substantial overlap would be observed. Also, although patients were the decision makers in this study, by design, it is intuitive that surgeon influence remains a potential factor that is very difficult to measure.

A strength of this paper is that most p-values are highly significant and likely do represent a difference between the groups (i.e., OBS-S vs OBS-NS post-treadmill NRS back pain; 5.8 vs 4.4, $p=0.002$). Other strengths of this study are its prospective and highly controlled and monitored structure, which ensures data integrity.

In conclusion, patients who elect to be part of a randomization cohort have similar clinical characteristics to patients deciding to be part of an observational surgical cohort. However,

patients in the randomized cohort had worse SRS Function and Self-Image domain scores and ODI scores than patients who decided to be treated surgically. In addition, patients deciding to be treated nonsurgically have statistically worse baseline PRO scores (SRS Pain, Function, Self-Image domains; back pain NRS; and ODI), less post-ambulation back and leg pain and smaller lumbar and fractional coronal curves than patients deciding to undergo surgery.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Baseline Demographics (Descriptives and ANOVA).

		N	Mean	sd	Median	Min	Max	KW p value
Age at Enrollment (years)	RAND	67	60.7	9.5	62.8	63.0	40.8	.082
	OBS-S	113	58.8	8.6	59.0	60.4	40.0	
	OBS-NS	115	61.1	9.9	61.7	63.0	40.0	
	Total	295	60.2	9.4	61.1	61.2	40.0	
BMI	RAND	67	27.3	5.4	25.8	28.6	19.2	.582
	OBS-S	113	26.7	4.9	26.2	27.6	18.4	
	OBS-NS	115	26.7	6.2	25.3	27.9	17.1	
	Total	295	26.8	5.5	25.7	27.5	17.1	
Femoral Neck t-score	RAND	54	-1.1	0.9	-1.3	-0.9	-2.6	.907
	OBS-S	83	-1.2	0.9	-1.3	-1.0	-2.8	
	OBS-NS	83	-1.2	1.1	-1.4	-0.9	-3.1	
	Total	220	-1.2	1.0	-1.3	-1.0	-3.1	

RAND=randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical

There were no significant differences between groups in these parameters.

Table 2

Educational Level

Age Group		Cohort			Total	Chi Square p value
		RAND	OBS-S	OBS-NS		
All Patients	High School, GED or Less	Count	19	27	44	0.057
		Percent	28	24	38	
	College degree	Count	48	86	71	
		Percent	72	76	62	
	Total	Count	67	113	115	
40–59 years	High School, GED or Less	Count	12	12	15	0.074
		Percent	43	20	29	
	College degree	Count	16	49	37	
		Percent	57	80	71	
	Total	Count	28	61	52	
60–80 years	High School, GED or Less	Count	7	15	29	0.010
		Percent	18	29	46	
	College degree	Count	32	37	34	
		Percent	82	71	54	
	Total	Count	39	52	63	

RAND=randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical

There were no differences in the educational level attained among study participation groups ($p=0.061$). Subanalysis of older patients (60–80 years), found 54% of OBS-NS had college degrees compared to 80% of RAND and 71% of OBS-S.

Table 3

Annual Household Income

		Cohort			Total	Chi Square p value
		RAND	OBS-S	OBS-NS		
Less than \$20,000/year	Count	4	6	8	18	0.183
	Percent	22.2	33.3	44.4	100.0	
\$20,000 to 39,999/year	Count	6	11	16	33	
	Percent	18.2	33.3	48.5	100.0	
\$40,000 to 74,999/year	Count	20	15	26	61	
	Percent	32.8	24.6	42.6	100.0	
More than \$75,000/year	Count	26	62	52	140	
	Percent	18.6	44.3	37.1	100.0	
No response	Count	11	19	13	43	
	Percent	25.6	44.2	30.2	100.0	
Total	Count	67	113	115	295	
	Percent	22.7	38.3	39.0	100.0	

RAND=randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical
There were no differences in the annual reported incomes by participation group.

Table 4

Baseline PROs: Descriptives and Kruskal-Wallis results.

		N	Mean	sd	Median	Mtn	Max	KW p value
Back Pain past 4 weeks (NRS)	RAND	67	6.0	2.3	7.0	6.6	0.0	0.008
	OBS-S	113	6.3	2.3	7.0	6.7	0.0	
	OBS-NS	115	5.5	2.2	5.0	5.9	0.0	
	Total	295	6.0	2.2	6.0	6.2	0.0	
Leg Pain past 4 weeks (NRS)	RAND	67	4.2	3.2	5.0	5.0	0.0	0.047
	OBS-S	113	3.8	2.9	4.0	4.3	0.0	
	OBS-NS	115	3.1	3.0	3.0	3.7	0.0	
	Total	295	3.6	3.0	4.0	4.0	0.0	
SRS Pain Domain Score	RAND	67	2.9	0.8	2.8	3.1	1.2	0.019
	OBS-S	113	2.8	0.8	2.8	2.9	1.0	
	OBS-NS	115	3.0	0.7	3.0	3.2	1.6	
	Total	295	2.9	0.7	3.0	3.0	1.0	
SRS Function Domain Score	RAND	67	3.1	0.7	3.2	3.3	1.6	0.008
	OBS-S	113	3.1	0.7	3.2	3.3	1.4	
	OBS-NS	115	3.4	0.6	3.4	3.5	1.8	
	Total	295	3.3	0.7	3.4	3.3	1.4	
SRS Self-Image Domain Score	RAND	67	2.7	0.7	2.8	2.9	1.2	0.001
	OBS-S	113	2.7	0.7	2.8	2.9	1.3	
	OBS-NS	115	3.1	0.7	3.0	3.2	1.3	
	Total	295	2.9	0.7	2.8	3.0	1.2	
SRS Mental Health Domain Score	RAND	67	3.6	0.7	3.8	3.8	2.2	0.620
	OBS-S	113	3.7	0.8	3.8	3.8	1.2	
	OBS-NS	115	3.7	0.8	3.8	3.8	2.0	
	Total	295	3.7	0.8	3.8	3.8	1.2	
SRS Subscore	RAND	67	3.1	0.5	3.1	3.2	2.0	0.003
	OBS-S	113	3.1	0.6	3.1	3.2	1.4	
	OBS-NS	115	3.3	0.5	3.4	3.4	1.8	

		N	Mean	sd	Median	Min	Max	KW p value
		Total	3.2	0.6	3.2	3.2	1.4	
ODI score	RAND	67	38.8	17.0	42.0	42.9	2.0	0.003
	OBS-S	113	36.9	15.3	38.0	39.8	4.0	
	OBS-NS	115	31.8	14.2	32.0	34.4	2.0	
	Total	295	35.3	15.5	34.0	37.1	2.0	
SF-12 MCS	RAND	67	50.3	11.9	50.2	53.2	17.3	0.695
	OBS-S	113	50.5	11.2	52.6	52.6	21.0	
	OBS-NS	114	49.8	10.8	50.1	51.8	26.4	
	Total	294	50.2	11.2	50.5	51.5	17.3	
SF-12 PCS	RAND	67	35.9	9.4	35.4	38.2	15.4	.662
	OBS-S	113	34.9	10.2	34.4	36.8	18.1	
	OBS-NS	114	34.8	10.1	34.2	36.7	17.3	
	Total	294	35.1	9.9	34.7	36.2	15.4	

RAND=randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical

There were significant differences between the three groups. Post hoc analysis (Table 8) found the OBS-NS pts reported worse scores than the OBS-S group in all SRS domains except for mental health, ODI and severity of back and leg pain in the past 4 weeks. The OBS-NS also reported significantly worse scores than the RAND group in SRS domains of Function and Self-Image and ODI.

Table 5

Functional Treadmill Test: Descriptives and Kruskal-Wallis

		N	Mean	sd	Median	Min	Max	KW p value
Pre Treadmill Back Pain NRS	RAND	65	3.9	2.8	3.0	1.0	11.0	0.753
	OBS-S	112	3.9	2.6	4.0	1.0	10.0	
	OBS-NS	110	3.6	2.3	3.0	1.0	9.0	
	Total	287	3.8	2.5	3.0	1.0	11.0	
Post Treadmill Back Pain NRS	RAND	65	5.5	3.2	5.0	1.0	11.0	0.002
	OBS-S	112	5.8	3.0	6.0	1.0	11.0	
	OBS-NS	110	4.4	2.7	4.0	1.0	11.0	
	Total	287	5.2	3.0	5.0	1.0	11.0	
Pre Treadmill Leg Pain NRS	RAND	65	2.7	2.7	1.0	1.0	11.0	0.293
	OBS-S	112	2.6	2.4	1.0	1.0	9.0	
	OBS-NS	110	2.1	2.0	1.0	1.0	10.0	
	Total	287	2.4	2.3	1.0	1.0	11.0	
Post Treadmill Leg Pain NRS	RAND	65	4.3	3.3	4.0	1.0	11.0	0.020
	OBS-S	112	4.3	3.4	3.5	1.0	11.0	
	OBS-NS	110	3.1	2.9	1.0	1.0	10.0	
	Total	287	3.9	3.2	2.0	1.0	11.0	

RAND= randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical

There were significant differences between groups after completing a Functional Treadmill Test to evaluate the patient's ability to walk; documenting pre/post treadmill back and leg NRS scores. Post hoc analysis (Table 8) found differences between the OBS-S and OBS-NS groups with the OBS-S group reporting more back and leg pain after ambulation.

Table 6

Coronal Plane Radiographic Parameters: Descriptives and Kruskal-Wallis

		N	Mean	sd	Median	Min	Max	KW p value
Thoracic Cobb (degrees)	RAND	36	51.1	16.5	48	56.6	29.0	0.445
	OBS-S	71	51.1	14.0	48	54.4	30.0	
	OBS-NS	53	47.8	12.6	46	51.3	30.0	
	Total	160	50.0	14.2	48	52.2	29.0	
Lumbar Cobb (degrees)	RAND	67	53.3	15.2	51	57.0	30.0	0.001
	OBS-S	113	56.5	15.0	57	59.3	30.0	
	OBS-NS	115	48.8	11.7	49	51.0	31.0	
	Total	295	52.8	14.2	51	54.4	30.0	
Fractional Cobb (degrees)	RAND	63	23.2	10.6	21	25.9	4.0	0.054
	OBS-S	111	23.8	10.4	24	25.8	3.0	
	OBS-NS	112	20.3	8.6	20	21.9	0.0	
	Total	286	22.3	9.9	22	23.4	0.0	
Coronal Balance (mm)	RAND	66	22.7	19.9	18.5	0	110	.093
	OBS-S	113	27.8	26.8	19	0	149	
	OBS-NS	114	19.3	16.2	13.5	0	79	
	Total	293	23.3	21.9	18	0	149	

RAND= randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical

There were statistical differences in the magnitude (degrees) of lumbar Cobb angles ($p=0.001$). Post hoc analysis (Table 8) found differences between the OBS-NS and OBS-S groups ($p<0.001$).

Table 7

Sagittal Plane Radiographic Parameters: Descriptives and Kruskal-Wallis

		N	Mean	sd	Median	Min	Max	KW p value
T2–T12 (degrees)	RAND	61	35.0	18.7	32	39.8	–15.0	0.408
	OBS-S	111	32.6	16.6	32	35.7	–2.0	
	OBS-NS	111	35.5	15.6	35	38.4	4.0	
	Total	283	34.2	16.7	33	36.2	–15.0	
T5–T12 (degrees)	RAND	65	29.5	18.1	26	34.0	–7.0	0.600
	OBS-S	113	26.5	15.6	26	29.5	–6.0	
	OBS-NS	115	28.1	15.2	29	30.9	–2.0	
	Total	293	27.8	16.0	26	29.6	–7.0	
T10–L2 (degrees)	RAND	67	14.3	15.4	11	18.1	–21.0	0.102
	OBS-S	113	17.1	15.6	17	20.0	–19.0	
	OBS-NS	115	12.9	17.4	13	16.2	–31.0	
	Total	295	14.8	16.3	14	16.7	–31.0	
T12–Sacrum (degrees)	RAND	67	–36.7	19.3	–36	–32.0	–83.0	0.041
	OBS-S	113	–37.7	19.2	–37	–34.1	–81.0	
	OBS-NS	115	–42.2	18.6	–45	–38.7	–77.0	
	Total	295	–39.2	19.1	–40	–37.0	–83.0	
Sagittal Balance (mm)	RAND	66	39.1	40.1	33	49.0	–26.0	0.108
	OBS-S	113	33.0	47.6	21	41.8	–42.0	
	OBS-NS	114	25.2	43.4	21	33.3	–80.0	
	Total	293	31.3	44.6	25	36.5	–80.0	
Pelvic Incidence (degrees)	RAND	62	56.1	12.1	55	59.1	21.0	0.924
	OBS-S	106	55.6	10.0	54	57.5	37.0	
	OBS-NS	108	55.7	13.9	55	58.4	31.0	
	Total	276	55.8	12.1	55	57.2	21.0	
Sacral Slope (degrees)	RAND	62	30.7	11.0	31	33.5	3.0	0.412
	OBS-S	106	32.2	9.7	32	34.0	7.0	
	OBS-NS	108	32.8	11.5	33	35.0	5.0	

		N	Mean	sd	Median	Min	Max	KW p value
Pelvic Tilt (degrees)	Total	276	32.1	10.7	32	33.4	3.0	
	RAND	62	25.6	8.9	24	27.9	6.0	0.282
	OBS-S	106	23.7	9.4	24	25.5	2.0	
	OBS-NS	108	23.2	10.1	23	25.1	3.0	
	Total	276	23.9	9.5	23	25.1	2.0	
PL-L Mismatch (degrees)	RAND	62	20.0	18.9	19.0	24.8	-15.0	0.094
	OBS-S	106	18.7	18.4	15.5	22.3	-19.0	
	OBS-NS	108	14.1	18.1	12.5	17.6	-19.0	
	Total	276	17.2	18.5	16.0	19.4	-19.0	

RAND=randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical

There were statistical differences in the degrees of lumbar lordosis (T12-Sacrum) among the three cohorts (p=0.041) but post hoc pairwise comparisons were not significant.

Table 8

Post Hoc Pairwise Comparison of Significant Cohort Differences

Dependent Variable	Significantly Different Cohorts		Post Hoc Sig.
	OBS-S	Rand	
Duration of Back Symptoms (months)	OBS-S	Rand	.023
Duration of Leg Symptoms (months)	OBS-S	Rand	.041
Back Pain NRS Past 4 weeks	OBS-NS	OBS-S	.007
SRS Pain Domain	OBS-NS	OBS-S	.018
SRS Function Domain	OBS-NS	OBS-S	.019
SRS Self Image Domain	OBS-NS	OBS-S	.002
SRS Subscore	OBS-NS	OBS-S	.007
ODI	OBS-NS	OBS-S	.029
Post Treadmill Back Pain NRS	OBS-NS	OBS-S	.002
Post Treadmill Leg Pain NRS	OBS-NS	OBS-S	.037
Lumbar Cobb	OBS-NS	OBS-S	<0.001
SRS Function Domain	OBS-NS	RAND	.034
SRS Self Image Domain	OBS-NS	RAND	.007
SRS Subscore	OBS-NS	RAND	.016
ODI	OBS-NS	RAND	.006

RAND=randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical

After Kruskal-Wallis test was completed to determine if there were differences in the variables (Tables 4, 5, 6 and 7) between groups, subsequent pairwise comparisons were performed. A Bonferroni correction for multiple comparisons was made. This post hoc analysis revealed significant differences between groups for the variables listed above. There were no significant group-to-group differences for lumbar lordosis on the post hoc analysis.

Table 9

Motor Deficits

		Cohort			Total	Chi Square p value
		RAND	OBS-S	OBS-NS		
No Motor Deficit	Count	60	107	113	280	0.036
	Percent	89.6	94.7	98.3	94.9	
Motor Deficit	Count	7	6	2	15	
	Percent	10.4	5.3	1.7	5.1	
Total	Count	67	113	115	295	
	Percent	100.0	100.0	100.0	100.0	

RAND=randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical
OBS-NS presented with significantly fewer motor deficits at baseline than the RAND group. OBS-NS presented with fewer motor deficits than OBS-S, but this was not significant.

Table 10

Symptomatic Spinal stenosis

		Cohort			Total	Chi Square p value
		RAND	OBS-S	OBS-NS		0.029
No Symptomatic Stenosis	Count	36	49	70	155	
	Percent	53.7	43.4	60.9	52.5	
Symptomatic Stenosis	Count	31	64	45	140	
	Percent	46.3	56.6	39.1	47.5	
Total	Count	67	113	115	295	
	Percent	100.0	100.0	100.0	100.0	

RAND=randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical
Symptomatic Spinal stenosis was more prevalent in the OBS-S patients compared to the OBS-NS patients.

Spine Treatments

Table 11

		Cohort			Total	Chi Square p value
		RAND	OBS-S	OBS-NS		
Past Treatment: Interventional	No	Count	33	53	62	148
		Percent	49.3	46.9	53.9	50.2
	Yes	Count	34	60	53	147
		Percent	50.7	53.1	46.1	49.8
Past Treatment: Physical Therapy	No	Count	13	25	29	67
		Percent	19.4	22.1	25.2	22.7
	Yes	Count	54	88	86	228
		Percent	80.6	77.9	74.8	77.3
Past Treatment: Alternative Treatments	No	Count	21	45	46	112
		Percent	31.3	39.8	40.0	38.0
	Yes	Count	46	68	69	183
		Percent	68.7	60.2	60.0	62.0
Currently using Medications for Back/Leg symptoms	No	Count	9	14	14	37
		Percent	13.4	12.4	12.3	12.6
	Yes	Count	58	99	100	257
		Percent	86.6	87.6	87.7	87.4
Currently using Narcotics for Back/Leg symptoms	No	Count	45	63	79	187
		Percent	67.2	55.8	68.7	63.4
	Yes	Count	22	50	36	108
		Percent	32.8	44.2	31.3	36.6

RAND=randomization; OBS-S=observational surgery; OBS-NS=observational nonsurgical

There were no differences in the treatments reported by patients.

Table 12

Reasons for Declining Randomization

Reason for Declining Randomization Participation	OBS-NS		OBS-S		Total	
	n	%	n	%	n	%
Participant is not interested in surgical intervention at this time	92	80	0	0	92	40
Participant feels they have exhausted non-surgical treatment options	0	0	50	44	50	22
Participant feels now is the time to proceed with surgical intervention from a family/social standpoint	0	0	40	36	40	17.5
Participant prefers to select treatment options	20	17	18	16	38	17
Surgeon feels patient is not appropriate for randomization cohort	3	3	5	4	8	3.5
Total	115	100	113	100	228	100

OBS-S=observational surgery; OBS-NS=observational nonsurgical
96.5% of the participants electively selected their treatment; 3.5% were directed by the surgeon's influence.