

**Cost-effectiveness Improves for Operative vs Nonoperative Treatment of Adult
Symptomatic Lumbar Scoliosis at Eight-Year Follow-up**

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ABSTRACT

Study Design: Secondary data analysis of the NIH sponsored study on Adult Symptomatic Lumbar Scoliosis (ASLS).

Objectives: The purpose of this study is to perform a cost-effectiveness analysis comparing operative versus non-operative care for ASLS eight years after enrollment.

Summary of Background Data: A prior cost-effectiveness analysis of the current cohort comparing operative to non-operative care at five years after enrollment showed an ICER of \$44,033 in the As-Treated analysis and a ICER of \$27,480 in the Intent-to-treat analysis.

Methods Data was collected every three months for the first two years, then every six months for the remainder of the study. Data included use of non-operative modalities, medications and employment status. Costs for index and revision surgeries and non-operative modalities were determined using Medicare Allowable rates. Medication costs were determined using the RedBook and indirect costs were calculated based on reported employment status and income. Quality Adjusted Life Years (QALY) was determined using the SF6D.

Results: There were 101 cases in the Operative (Op) and 103 in the Non-operative (Non-Op) group with complete eight year data. Thirty-eight patients (37%) in the Non-Op group had surgery from 3 to 72 months after enrollment. An As-Treated analysis including only cases who never had surgery (N=65) or cases with complete eight-year post-operative data (N=101) showed that operative treatment was favored with an ICER of \$20,569 per QALY gained which is within Willingness-to-Pay (WTP) thresholds. An Intent-to-Treat analysis demonstrated greater QALY gains and lower cost in the Op group (ICER = \$-13,911). However, Intent-to-Treat analysis is influenced by Non-Op patients who crossed over to operative treatment at variable times during follow-up.

Conclusion: Operative treatment was more cost-effective than non-operative treatment for ASLS at eight-year follow-up. The ICER continued to improve as compared to the five-year values (\$20,569 vs. \$44,033).

KEYPOINTS

- A cost-effectiveness study including an As-Treated and Intent-to-Treat analysis comparing operative versus non-operative care on patients with eight-year follow-up data from the Adult Symptomatic Lumbar Scoliosis that included randomized and observational arms was performed.
- There were 101 cases in the Operative (Op) and 103 in the Non-operative (Non-Op) group with complete eight year data. Thirty-eight patients (37%) in the Non-Op group had surgery from 3 to 72 months after enrollment.
- An As-Treated analysis including only cases who never had surgery (N=65) or cases with complete eight-year post-operative data (N=101) showed that operative treatment was favored with an ICER of \$20,569 per QALY gained which is within Willingness-to-Pay (WTP) thresholds.
- An Intent-to-Treat analysis demonstrated greater QALY gains and lower cost in the Op group (ICER = \$-13,911). However, Intent-to-Treat analysis is influenced by Non-Op patients who crossed over to operative treatment at variable times during follow-up.
- Operative treatment was more cost-effective than non-operative treatment for ASLS at eight-year follow-up. The ICER continued to improve as compared to the five-year values (\$20,569 vs. \$44,033).

INTRODUCTION

With an aging population, adult spinal deformity is becoming a relatively prevalent condition [1-3] for which there continues to be uncertainty regarding the appropriate treatment approach [4-7]. Several studies have shown favorable outcomes after surgery in well-selected patients [6, 8, 9], but concerns with complications and revision rates remain [10-13]. For non-operative care, a systematic review found only level II evidence for the use of injections and level IV evidence for physical therapy and bracing [14]. Another study showed that non-operative care does not improve a patient's quality of life [15], but it is unknown if these patients would have worsened without treatment [4, 15]. Thus there is need for a robust cost-effectiveness analysis comparing operative versus operative care for adult spinal deformity.

The majority of published cost-effectiveness analysis (CEA) on operative compared to non-operative treatment in patients with adult spinal deformity are mathematically modelled based on published data [16-18]. These studies may over-estimate the value of operative compared to non-operative treatment. Two CEA studies evaluating the cost-effectiveness of operative versus non-operative treatment for Adult Symptomatic Lumbar Scoliosis (ASLS) from an NIH sponsored trial at 5 year follow-up reported an Incremental Cost effectiveness Ratio (ICER) of \$44,033 per QALY gained in the As-Treated analysis [19] and an ICER of \$27,480 per QALY gained in the Intent-to treat analysis [20]. Given the high upfront costs of surgery and revision rates in patients with adult spinal deformity [10-12], it is important to determine the

durability of the procedure with longer term follow-up. The purpose of this study is to perform a cost-effectiveness analysis comparing operative versus non-operative care for ASLS eight years after enrollment.

METHODS

The primary study evaluated operative and non-operative treatments in patients with ASLS and included randomized and observational arms. Inclusion criteria were age between 40 and 80 years old with lumbar scoliosis with coronal Cobb $\geq 30^\circ$, and either an Oswestry Disability Score (ODI) [21, 22] score of 20 or greater, or an Scoliosis Research Society-22 (SRS-22) [23] Pain, Function or Appearance score less than 4.0, and no prior fusion surgery. Exclusion criteria were the presence of medical comorbidities that precluded surgery, high-grade (≥ 3) spondylolisthesis, prior thoracic or lumbar fusion, prior multilevel (≥ 3) thoracolumbar decompression, severe osteoporosis (femoral neck t-score ≥ -3.0), neuromuscular scoliosis or presence of congenital lumbar spine anomalies. Subjects were enrolled from April 2010 to July 2014 and follow-up ended in February 2023. Initial funding was provided by the National Institutes of Health through an RO1 grant: A Multi-Center Prospective Study of Quality of Life in Adult Scoliosis (R01AR055176-01A2) followed by a grant from the Scoliosis Research Society. Institutional review board approval was obtained at each participating center prior to subject enrollment. Institutional review board approval was also obtained for this secondary analysis.

Patients undergoing Operative (Op) or non-operative (Non-Op) treatment with at least eight year follow-up data were identified. Surgical approach, technique and levels fused in the

Op cohort were under the discretion of the treating surgeon. Data was collected every three months the first two years then every six months for the duration of the study. Data included frequency of use of non-operative modalities (physical therapy, chiropractor, pain management visits and epidural steroid injections), medication use (non-steroidal anti-inflammatory drugs, opioids, muscle relaxants) and employment status. Health-related quality-of-life scores (HRQOLs) collected included the Oswestry Disability Index (ODI) [21, 22], the SRS-22 [23] and the SF-12 [24].

The incremental cost-effectiveness ratio (ICER) at eight years was determined. ICER determines whether an intervention produces sufficient improvements in health status to justify its cost [25]. ICER summarizes the additional cost per unit of health state improvement in switching from one medical treatment to another (Non-operative to Operative). ICER is the difference in cost between two possible interventions, in this case Non-operative versus Operative treatment for ASLS, divided by the difference in their effect. Total costs included all surgical and nonsurgical costs in both cohorts. Surgical costs for the index and revision surgeries within eight years and direct costs for non-operative care were determined using Medicare Allowable rates [26]. Medication costs were determined using the lowest price quoted [27] and indirect costs were determined based on reported employment status and income. Treatment effectiveness in terms of Quality Adjusted Life Years (QALY) was determined using the Short Form – 6 Dimensions (SF6D) [28] derived from the SF-12. For a patient who crossed over, all costs and benefits prior to the cross-over were included in the analysis.

Baseline characteristics of the Op and Non-Op cohorts were compared using unpaired independent t-tests for continuous variables and Fisher's exact test for categorical variables. A p-value threshold of 0.05 was used to determine statistical significance.

Decision tree analysis based on expected utility was used to perform the cost-effectiveness analysis as this takes into account the continuing use of non-operative modalities and the incidence of index and revision surgeries in both groups, as patients were allowed to cross-over to either arm during the study. Using mean costs and mean QALY gains for each cohort does not take into account the difference in the number of patients continuing to use non-operative care and the number of patients undergoing primary as well as revision surgeries in each cohort. [29, 30]. Both an As-Treated and an Intent-to-Treat analyses were performed. The As-Treated analysis compared patients who had surgery to those who did not have surgery regardless of treatment assignment at study inclusion. Patients assigned to the Non-Op group at the time of enrollment and crossed-over to surgery were considered to be in the Op group. The Intent-to-Treat analysis compared patients as they were assigned at study inclusion. Patients assigned to the Non-Op group at the time of enrollment remained in the Non-Op group even after they crossed over and had surgery.

RESULTS

Of 286 subjects enrolled in the study, 205 had data available at the eight-year follow-up period. There were 101 cases in the Operative (Op) and 103 in the Non-operative (Non-Op) group with complete eight year data (Figure 1). The proportion of patients from the Observational arm was similar between the Op (79, 78%) and Non-Op groups (79, 77%, $p=0.867$). The Op and Non-Op groups were similar in age, sex distribution and body mass index (Table 1). There was 1 (1%) smoker in the Op group and 4 (4%) in the Non-Op group ($p=0.155$). All baseline HRQOL scores were not statistically different for Op vs. Non-op including the Short Form 6D ($p=0.538$), ODI ($p=0.697$), SRS-22 Pain ($p=0.829$), Function

($p=0.093$), Mental Health ($p=0.872$) and Subscore ($p=0.168$), with the exception that the SRS22 Self Image score was worse for Op compared to the Non-Op ($p=0.004$). The major scoliosis Cobb angle, and the coronal and sagittal alignment parameters were not statistically different for Op and Non-Op (Table 1).

The majority of the costs (64%) for the non-operative care was from medication, including narcotics, non-steroidal anti-inflammatory drugs, muscle relaxants, neuroleptics and over-the-counter medications, followed by physical therapy visits (21%), pain management (11%) and injections (2%). All of the 101 cases in the Op group had posterior instrumentation and fusion, 54 of which included an osteotomy (Table 2). Fifty-eight had a transforaminal lumbar interbody fusion, and 4 had an anterior lumbar interbody fusion as part of a two stage procedure. Thirty-eight patients (37%) in the Non-Op group had surgery from 3 to 72 months after enrollment, 22 of which included an osteotomy. Twenty-two patients had an osteotomy with one patient having a PSO at one level and a VCR at another level.

In the Op group 61 patients did not require a revision after their index surgery, 29 had one revision, seven had two revision surgeries, three had three revision surgeries and one had four revision surgeries. Thirty-eight patients (37%) in the Non-Op group had surgery from 3 to 72 months after enrollment, with seven undergoing one revision, seven had two revisions and one patient had three revisions. The most common indication for a revision was non-union followed by proximal junctional kyphosis or failure (Table 3).

The cumulative cost for the Non-Op group ($N=65$) who never had surgery over the eight year follow-up period was \$31,819 with a cumulative QALY gain of 0.32 for a cost per QALY gained of \$97,907. The cumulative cost for the patients in the Op group with complete eight-year post-operative data ($N=101$) was \$66,970 with a QALY gain of 2.03 for a cost per QALY

gain of \$33,007 (Figure 2). For patients who had surgery and did not have any revision during the follow-up period, the cost per QALY gained was \$18,241 in the Op group and \$55,986 in the Non-op group who crossed-over and had surgery. For patients who had surgery and underwent one revision surgery the cost per QALY gained was \$36,048 in the Op group and \$91,282 in the Non-op group who crossed-over and had surgery.

An As-Treated analysis comparing all patients who had surgery (38 patients in the Non-Op cohort who crossed over plus the 101 patients in the Op group) to those who never had surgery (65 patients in the Non-Op group) results in an ICER of \$20,569 per QALY gained favoring Op versus Non-Op treatment. In the Intent-to-Treat analysis comparing all 103 patients assigned to Non-Op, whether they crossed over or not, to the 101 patients in the Op group, the cumulative cost for the Non-Op group was \$82,177 with a cumulative QALY gain of 0.94 resulting in an ICER of -13,911 favoring surgical over non-surgical treatment.

DISCUSSION

Appropriate treatment of patients with adult lumbar scoliosis continues to be actively debated [4, 5]. Some studies directly compare outcomes of operative to non-operative treatment [4, 31-34] without the consideration of cost. While other studies evaluate costs or cost per QALY gained for surgical treatment only [12, 16-18] without consideration of non-operative treatment. Only one study has reported on costs of non-operative treatment for this patient population [15]. All of these studies used data that were collected retrospectively over a two-year time horizon.

Our previous analyses on the current study cohort at the five year follow-up time point showed an ICER of \$44,033 per QALY gained in the As-Treated analysis with the economic

benefit of surgical versus nonsurgical treatment becoming favorable at three years after surgery [19]. In comparison, the Intent-to-Treat analysis favored surgical over nonsurgical treatment at four years after patient enrollment but had smaller ICER of \$27,480 at five years [20]. The current study, with longer follow-, showed that the As-Treated analysis results in an ICER of \$20,569 while the Intent-to-Treat analysis results in an ICER of -13,911, both favoring surgical over non-surgical treatment.

The negative ICER in the Intent-to-Treat analysis indicates that the greater QALY gains for operative treatment came at a lower cost. While greater improvement at a lower cost is ideal, this Intent-to-Treat analysis should be interpreted with caution. Intent-to-Treat analysis can be distorted by high crossover rates. Costs from the surgical intervention in the substantial number of patients who crossed over from the Non-Op to the Op group are attributed to the Non-Op intervention in an Intent-to-Treat analysis. In addition, some patients in the Non-Op group had surgery later in the study, and would therefore have fewer years of QALY gains as compared to the primary Op group.

The current study, as in prior studies on this cohort, demonstrated some QALY improvement with nonsurgical treatment [9, 19, 20]. This is in marked contrast to a maintenance or loss of QALYs that had been predicted in previous studies using statistical modeling [17]. In the current study cost per QALY gained in patients who stayed in the non-surgical arm for the entire eight year period was \$97,907. Taken in isolation, this value is above the widely accepted willingness-to-pay threshold of \$50,000 [35, 36] or World Health Organization (WHO) United States Gross Domestic Product (US GDP) based lower threshold of \$83,000 [37]. It is unclear if these patients would have worsened without any treatment.

The smaller ICERs at the eight year follow-up time point compared to the five year time point, may indicate durability of the clinical improvement with surgical treatment, despite the high incidence of revisions. The revision rate was 40% in both the Op group and the Non-Op group who crossed over to surgery. Although this may seem high compared to previously published studies, this may be due to complexity of the deformity or the longer follow-up period available. Database studies report a cumulative revision rate of 30% at two years in a Danish cohort [10] and 16% at four years in a US cohort [11].

In the current study, surgical treatment remained cost effective for patients undergoing one revision surgery compared to nonsurgical treatment, with a cost per QALY gained of \$36,048 in the Op group and \$91,282 in the Non-op group who had surgery. Only when patients undergo more than one revision surgery does the cost per QALY gain become less favorable compared to non-surgical treatment or go above the Willingness-to-Pay thresholds.

There are limitations to the study. As with the majority of randomized clinical trials evaluating surgical versus non-surgical treatment for spine pathologies [38], the high uni-directional cross-over rate, makes the Intent-to-Treat analysis difficult. The high up-front cost of the surgical intervention and the differences in the time after enrollment the patients in the Non-Op arm crossed over and had surgery limits the conclusions that can be drawn especially with the Intent-to-Treat analysis. Additionally, costs were assigned to healthcare interventions instead of actual individual costs per patient and indirect costs due to lost wages by the caregiver was not included in the analysis.

Despite the RCT design, selection bias may be present due to loss to follow-up as well as the inclusion of an observational arm. However, the underlying dataset is still much more complete and has a longer follow-up than most of the adult spinal deformity literature [19, 20, 39].

Although there is a statistically significant difference in baseline Self-image scores between the two groups, this may not be clinically relevant as the difference in scores (0.29) is much smaller than the reported minimally clinically important difference for Self-image (1.17) in this cohort [40]. Aside from the SRS22 self-image scores, the Op and Non-Op groups were comparable at baseline in terms of demographics, functional disability and radiographic parameters. These similarities may allow for a more direct comparison of these two interventions.

In conclusion, the current study shows that at the eight year follow-up period, operative treatment is durable as it continues to be more cost-effective than non-operative treatment for adult lumbar symptomatic scoliosis, with no decrement in ICERs compared to the five-year follow-up period. The current study not only shows durability of operative treatment for adult lumbar symptomatic scoliosis but actually demonstrates improvement and increasing cost-effectiveness at the eight year follow-up with a smaller ICER of \$20,569 compared to the five-year ICER of \$44,033.

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Figure 1. Patient Flow chart

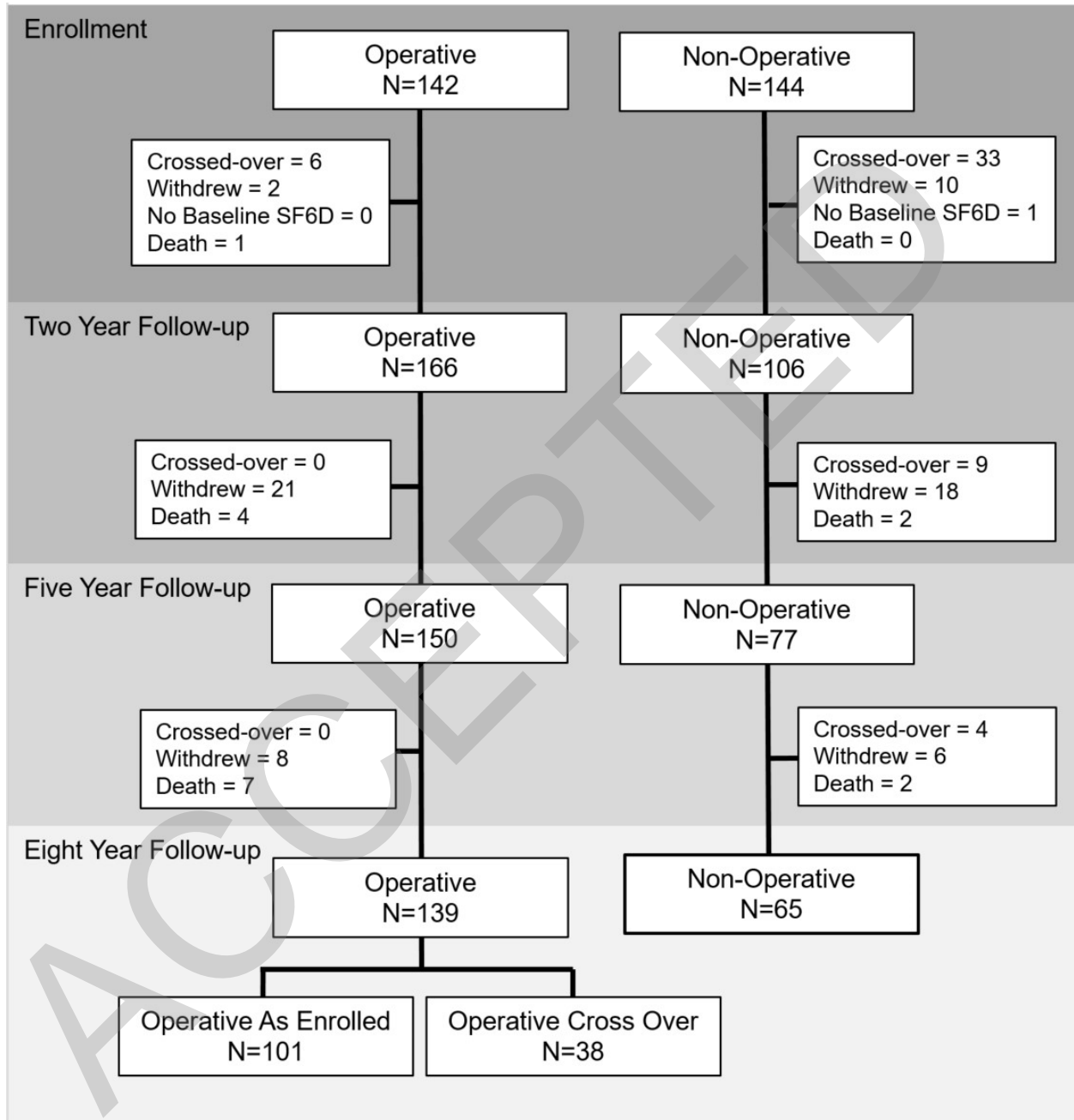


Figure 2. Decision Tree for non-operative versus operative treatment for adult symptomatic lumbar scoliosis. Costs include all non-operative and operative costs for each patient in all cohorts. As-Treated analysis compares all patients who had surgery (38 patients in the Non-Op cohort who crossed over plus the 101 patients in the Op group) to those who never had surgery (65 patients in the Non-Op group). Intent-to-Treat analysis compares all 103 patients assigned to Non-Op, whether they crossed over or not, to the 101 patients in the Op group.

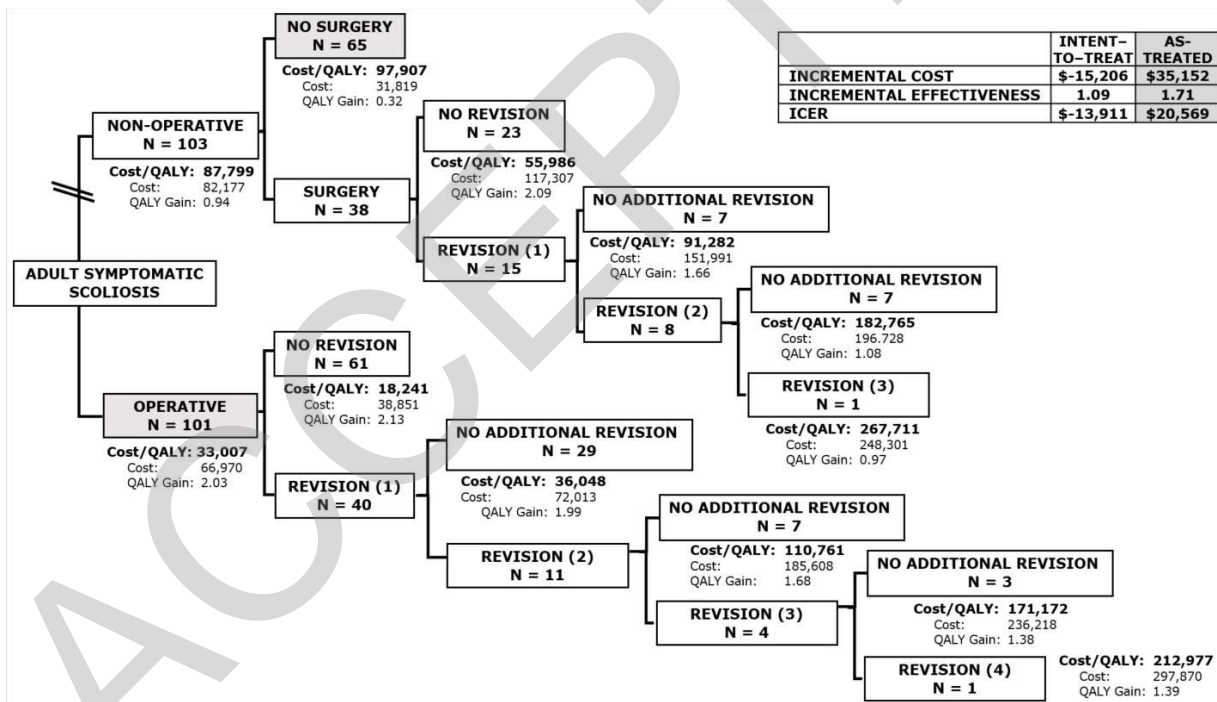


Table 1. Summary of Baseline Characteristics of Subjects in the Operative and Non-Operative Cohorts			
	Operative	Non-Operative	p-value
Total	101	103	
Arm, N (%)			0.867
Observational	79 (78%)	79 (77%)	
Randomized	22 (22%)	24 (23%)	
Female, N (%)	93 (92%)	92 (89%)	0.631
Smoking Status, N (%)			0.155
Never	70 (69%)	60 (58%)	
Former	30 (30%)	39 (38%)	
Current	1 (1%)	4 (4%)	
Age, years, Mean (SD)	58.15 (8.35)	60.42 (9.79)	0.076
Short Form – 6D, Mean (SD)	0.65 (0.13)	0.66 (0.14)	0.538
Oswestry Disability Index, Mean (SD)	33.79 (15.23)	32.95 (15.57)	0.697
Scoliosis Research Society 22, Mean (SD)			
Pain	2.96 (0.74)	2.94 (0.73)	0.829
Function	3.26 (0.7)	3.42 (0.65)	0.093
Self-Image	2.79 (0.71)	3.08 (0.71)	0.004
Mental Health	3.77 (0.77)	3.75 (0.73)	0.872
Subscore	3.20 (0.54)	3.30 (0.51)	0.168
Coronal Cobb Magnitude, °, Mean (SD)	51.34 (15.41)	50.53 (13.81)	0.762
Coronal Balance, mm, Mean (SD)	-0.61 (28.05)	-1.25 (25.98)	0.866
Sagittal Balance, mm, Mean (SD)	21.81 (33.78)	28.94 (42.11)	0.183

Table 2. Summary of Surgical Parameters of Subjects who had Surgery			
	Operative	Non-Operative	p-value
Total	101	38	
Number of Posterior Surgical Levels	11.30 (3.77)	10.19 (3.65)	0.170
Posterior Osteotomies			0.458
Smith-Petersen	50	21	
Posterior Subtraction	3	1*	
Vertebral Column Resection	1	2	
Interbody Fusion			0.546
None	39	16	
Transforaminal Lumbar	58	19	
Anterior Lumbar	4	3	

Table 3. Summary of the indications for revision surgeries				
Operative	Revision Number			
	First	Second	Third	Fourth
Nonunion	25	3	2	1
Proximal Junctional Kyphosis/Failure	4	2	2	
Iliac Screw removal	2	1		
Implant removal	2	2		
Proximal Junctional Kyphosis with Nonunion	2	1		
Delayed Wound Infection	1	1		
Neuro deficits	1			
CSF leak	1			
Other	2	1		
Total	40	11	4	1
Non-Operative				
Nonunion	5	4	1	
Proximal Junctional Kyphosis/Failure	5			
Iliac Screw removal	1			
Implant removal	2	3		
Delayed Wound Infection	1			
Neuro deficits	1			
Other		1		
Total	15	8	1	