

Effectiveness of Operative and Nonoperative Care for Adult Spinal Deformity: Systematic Review of the Literature

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Abstract

Study Design: Systematic review.

Objective: There is a need for synthesizing data on effectiveness of treatments for patients with adult spinal deformity (ASD) due to its increasing prevalence and health care costs for these patients. The objective of this review was to estimate the effectiveness of surgery versus nonoperative care in patients with ASD.

Methods: A systematic review of articles in published in English using PubMed between 2005 and 2015. Surgical and nonsurgical series that reported baseline and follow-up health-related quality of life measures of patients with ASD with a minimum 2 years of follow-up were selected. Independent extraction of articles by 2 authors using predefined data fields, including risk of bias assessment.

Results: Surgery significantly reduces disability, pain, and improves patients' quality of life. The average postoperative improvement in Oswestry Disability Index was -19.1 (± 9.0), Numerical Rating Scale back pain -4.14 (± 1.38), Numerical Rating Scale leg pain -3.36 (\pm 1.33), Short-Form Health Survey 36-SF36-Physical Component score 11.2 (\pm 5.07), and Short-Form Health Survey 36-Mental Component score 9.93 (\pm 4.96). The complication rate ranged from 9.52% to 81.52% (mean = 39.62%), and the need for revision surgery ranged from 1.72% to 40.0% (mean = 15.71%). The best existing evidence about nonoperative care of ASD is provided from observational studies with very high risk of bias. Quantitative analyses of nonsurgical cohorts did not demonstrate significant changes in quality of life of patients after 2 years of observation.

Conclusions: This data may assist clinicians to counsel patients, as well as to inform health care providers and policymakers about what to expect from the treatment for ASD.

Keywords

scoliosis, adult, surgery, quality of life, systematic review

Introduction

Adult spinal deformity (ASD) is defined as an angular value more than 10° in the coronal plane present after skeletal maturity.¹ Its prevalence varies from 29% to 68%,² considering the population older than 60 years.³

The past decade has witnessed a substantial increase in costs of spinal deformity care. Even in patients with low disability related to the spinal deformity, resource utilization of nonoperative treatments is high.⁴ In a period of 2 years, the estimated costs of nonoperative treatments ranged from \$9704 in low symptomatic patients to \$14022 in disabled patients.⁵ On the other hand, studies have demonstrated a 4-fold increase in the number of spine deformity surgeries and an average

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increase in charge per inpatient stay of more than 230% in Medicare patients from 2000 to 2010 in the United States.⁶

The objective of this review was to evaluate the effectiveness of surgery and nonoperative treatments for patients with ASD. We assessed responsiveness and effect sizes in relation to pain, disability, and quality of life. In addition, complication and revision rates of large modern surgical series were also critically reviewed and summarized.

Methods

Electronic Literature Database

A systematic literature review was undertaken by conducting a PubMed search of articles published between January 2005 and April 2015 using the keywords "adult scoliosis" OR "adult spinal deformity" OR "degenerative scoliosis" NOT "adolescent" NOT "neuromuscular" NOT "syndrome" NOT "ankylosing spondylitis" NOT "congenital" NOT "chiari" NOT "spina bifida" NOT "vascular" NOT "tumor" NOT "infection" NOT "trauma." We limited the results to human studies, articles published in English language, and those with available abstracts. Reference lists of key articles were also checked.

Only articles that reported baseline and follow-up scores of Oswestry Disability Index (ODI) were included for further analysis. Exclusion criteria were the following: no report of ODI, follow-up of less than 2 years, sample size smaller than 20 patients, surgical series containing more than 20% of previously operated patients, majority of sample with age less than 40 years, effectiveness of nonoperative treatment reported after surgical deformity correction, other etiological diagnoses for spinal deformity such as ankylosing spondylitis, trauma, and congenital, as well as narrative reviews, editorials, case reports, and articles written in non-English language.

Data Extraction

Each retrieved citation was independently reviewed by 2 authors (ART, AF) using predefined data fields. Most articles were excluded on the basis of the information provided by the abstract. Citations that seemed to be appropriate or those that could not be excluded unequivocally from the abstract were identified, and the corresponding full-text reports were reviewed by both authors. Any disagreement between them was resolved by consensus. From the included articles the following data was extracted: study design, sample size, treatment strategy, complication rates, revision rates, and risk of study bias. As data on Scoliosis Research Society scale was not uniformly reported, we opted to include only series in which ODI was assessed as a patient-reported outcome measure. Numerical Rating Scale (NRS) of back and leg pain, and Short-Form Health Survey 36 (SF36) reported as Physical Component score (SF36-PC) and Mental Component score (SF36-MC) were also analyzed as outcome measures.

Risk of Bias Assessment

Risk of bias was assigned to each article independently by 2 reviewers (ART, AF). Any disagreement was resolved by consensus. Risk of bias assessment was evaluated with the Methodological Index for Non-Randomized Studies (MIN-ORS) tool.⁷ MINORS contains 12 methodological points, with the first 8 points applying to both comparative and noncomparative studies and the remaining 4 points relating only to studies with 2 or more groups. The maximum score is 24 for comparative studies and 16 for noncomparative studies. Higher scores are associated with better quality studies. This instrument has already been demonstrated to possess adequate validity and reliability in the evaluation of nonrandomized studies.⁸

Analysis

All analyses were performed on a study level. From series that reported outcomes of primary and revision surgery, only data from primary cases was analyzed.

Articles that reported both surgical and nonsurgical patients presented high risk of selection bias; thus, we opted to include series without control group in this review and to present changes in health-related quality of life (HRQOL) separately for each series. No series with a specific nonoperative regimen was identified.

Weighted means of age, length of follow-up, ODI, NRS of axial and leg pain, SF36-PC, and SF36-MC were calculated with SPSS (version 20 for Mac). Data on HRQOL was presented as a range in the measures from baseline to the last follow-up when they were assessed. To compare responsive-ness of pain, disability, and quality of life scores after surgery or nonoperative care, we calculated effect sizes by dividing change scores by the standard deviation of the baseline scores. According to previously published methodology,⁹ effect size around 0.3 was considered small, effect size around 0.5 was considered medium, effect size greater or equal to 0.8 was considered large, and effect size greater than 1.3 was considered very large. Graphs were built using templates proposed by Weissgerber et al.¹⁰

Definitions of major and minor complications were not uniform among studies. Complication rates were calculated as the percentage of patients who presented at least one complication during the follow-up period as reported by the authors. Series that did not report the number of patients with complications were excluded from this analysis. The same calculations were performed for revision rates in surgical series, defined as the number of patients who required surgical re-intervention during the follow-up period divided by the number of patients in the series.

Results

A total of 943 articles were identified after PubMed/Medline search (Figure 1). Most of these articles were primarily excluded on the basis of the information provided in the

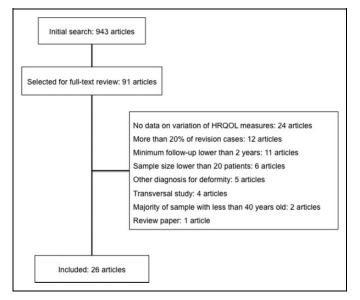


Figure 1. Flow chart of article selection. Table 1. Characteristics and Risk of Bias of Studies. abstracts. A total of 91 articles underwent full-text review. After full-text review, 65 articles were excluded for the following reasons: sample size less than 20 patients (n = 6), minimum follow-up less than 2 years (n = 11), more than 20% of revision cases (n = 12), no data on variation of HRQOL measures (n = 24), majority of sample less than 40 years (n = 2), other diagnosis for deformity (n = 5), review article (n = 1), and transversal study (n = 4).

After exclusions, 26 articles were analyzed by the authors^{5,11-35} (Table 1). Most of them were retrospective in nature (n = 22; 84.6%). No randomized clinical trial comparing surgery versus any type of nonoperative care was identified. The methodological quality of the selected studies demonstrated a range in MINORS between 5 and 11 in noncomparative studies and between 13 and 20 in comparative studies, demonstrating a high risk of bias in the majority of articles.

From the 26 articles, a total of 42 series were analyzed separately (total number of patients = 2469), including 6 series of nonoperative care (n = 545). As reported in nonoperative

Author (Year)	Type of Study	Treatment	Total Sample	MINORS
Scheer et al (2015)	RP	Open surgery (n = 235) versus nonoperative care (n = 186)	421	17/24
Hsieh et al $(2015)^{12}$	Retrospective	Comparison between anterior-posterior $(n = 56)$ versus only posterior $(n = 54)$ approaches	110	7/16
Zhu et al (2014) ¹³	Retrospective	TLIF series	95	10/16
Anand et al (2014) ¹⁴	Retrospective	DLIF or ALIF and percutaneous pedicle screws	50	8/16
Castro et al (2014) ¹⁵		XLIF stand-alone series	35	9/16
Ha et al (2014) ¹⁶	Retrospective	Comparison between short-fusion ($n = 29$) and long-fusion ($n = 30$)	59	16/24
Fu et al (2014) ¹⁷	RP	Open surgery, mix procedures	53	19/24
Kim et al (2014) ¹⁸	RP	Comparison between upper thoracic $(n = 91)$ versus lower thoracic $(n = 107)$ fusion	198	17/24
Phillips et al (2013) ¹⁹	Prospective	XLIF series	67	9/16
Daubs et al (2013) ²⁰	RP	Open surgery, mix procedures	85	11/16
Hassanzadeh et al (2013) ²¹	RP	Open/exclusion of patients previously operated	59	19/24
Kasliwal et al (2012) ²²	RP	Matched-cohort analysis/excluded patients previously operated	30	20/24
O'Shaughnessy et al (2012) ²³	RP	Comparison between T3 (n = 20) and T10 (n = 38) as proximal level fused	58	19/24
Smith et al (2011) ²⁴	RP	Open surgery, mix procedures (3 series separated by age)	206	11/16
Tsai et al (2011) ²⁵	Retrospective		58	6/16
Zimmerman et al (2010) ²⁶	Prospective	Open surgery, mix procedures	35	11/16
Transfeldt et al (2010) ²⁷	Retrospective	Comparison of decompression only $(n = 21)$, limited fusion $(n = 44)$, and long fusion $(n = 20)$	85	6/16
Di Silvestre et al (2010) ²⁸	Retrospective	Decompression and dynamic stabilization series $(n = 29)$	29	5/16
Glassman et al (2010) ⁵	Prospective	Series of nonoperative care (n $=$ 68) and no treatment (n $=$ 55)	123	7/16
Li et al (2009) ²⁹	Retrospective	Open surgery $(n = 34)$ versus nonoperative care $(n = 49)$	83	15/24
Smith et al (2009) ³⁰	RP	Open surgery $(n = 96)$ versus nonoperative care $(n = 112)$	208	15/24
Bridwell et al (2009) ³¹	Retrospective	Open surgery $(n = 85)$ versus nonoperative care $(n = 75)$	160	15/24
Cho et al (2009) ³²	Retrospective	Comparison between fusion to L5 $(n = 24)$ and SI $(n = 21)$	45	13/24
Crandall et al (2009) ³³	Prospective	Comparison between ALIF (n = 20) versus TLIF (n = 20) plus posterior pedicle screws	40	16/24
Cho et al (2008) ³⁴	Retrospective	Comparison between long short (n $=$ 28) versus long (n $=$ 22) fusion	50	13/24
Wu et al (2008) ^{′35}	Retrospective		27	7/16

Abbreviations: MINORS, Methodological Index for Non-randomized Studies; RP, retrospective review of prospective collected data; TLIF, transforaminal lumbar interbody fusion; DLIF, direct lumbar interbody fusion; PLIF, posterior lumbar interbody fusion; XLIF, extreme lateral interbody fusion.

	Weighted N	Mean	
	Surgery	Conservative	Difference
Mean age	60.7 (6.90)	56.36 (6.47)	4.35
Follow-up	3.18 (1.48)	2.04 (0.14)	1.14
Baseline ODI	45.1 (9.73)	27.2 (4.21)	17.9
Follow-up ODI	25.9 (7.93)	28.0 (4.40)	-2.11
Difference in ODI	-19.1 (9.00)	0.84 (1.06)	<u> </u>
Baseline NRS axial	7.10 (1.02)	4.52 (0.51)	2.57
Follow-up NRS axial	2.95 (0.69)	4.85 (0.55)	-1.89
Difference in NRS axial	-4.14 (1.38)	0.32 (0.03)	-4.47
Baseline NRS radicular	5.40 (1.34)	4.21 (0.31)	1.18
Follow-up NRS radicular	2.03 (0.69)	3.18 (0.49)	-1.15
Difference in NRS radicular	-3.36 (1.33)	-1.02 (0.76)	-2.33
Baseline SF36-PC	39.3 (9.03)	42.3 (3.61)	-2.96
Follow-up SF36-PC	50.7 (14.4)	, ,	8.57
Difference in SF36-PC	11.2 (5.07)	-0.15 (1.17)	11.36
Baseline SF36-MC	48.8 (19.2)	51.4 (0.89)	-2.54
Follow-up SF36-MC	59.7 (15.6)	51.1 (1.04)	8.61
Difference in SF36-MC	9.93 (4.96)	-0.26 (0.14)	10.19

Table 2. Summary of Pooled Data on Patients With Adult Spinal Deformity (n = 2469).

Abbreviations: ODI, Oswestry Disability Index; NRS, Numerical Rating Scale of Pain; SF36-PC, Physical Component Short Form-36 Physical Outcomes; SF36-MC, Mental Component Short Form 36 Medical Outcomes.

studies, the decision to manage the patients surgically or not was based on individual discussions between surgeons and patients, taking into account the patient's goal of care. As a general rule, most authors reported that patients showing symptoms of progressive neurological deficit, myelopathy, or bowel/ bladder incontinence were advised to pursue operative treatment. Nonoperative care was generally assessed in terms of resource utilization of nonsurgical treatments (ie, medications, physical therapy, injections, etc) during the time of observation. No study reporting any specific nonoperative treatment regimen was selected in our search. For analysis purpose, patients who received no treatment were also included in the category of nonoperative care. In surgical series (n = 1924), there were 1751 patients treated by open surgery (32 series), 152 by minimally invasive surgery (MIS) approaches (3) series), and 21 patients treated only by simple decompression procedures (1 series).

All 42 series included ODI scores before and after treatment. Variations of back and leg NRS of pain were identified in 16 (2 nonsurgical) and 14 (3 nonsurgical) series, respectively. SF36-PC was reported in 3 surgical and 3 nonsurgical series, while SF36-MC was reported in 2 surgical and 2 nonsurgical series.

Table 2 presents the weighted means of baseline, follow-up, and range in HRQOL measures according to each group. The mean follow-up time was 3.18 (\pm 1.48) years in the surgical group and 2.04 (\pm 0.14) years in the nonsurgical group. Mean age was 60.7 (\pm 6.90) years in the surgical group and 56.3 (\pm 6.47) in the nonsurgical group.

The mean improvement in disability (as measured by ODI) after surgery was 19.1. The mean reduction in back and leg pain after surgery was 4.14 and 3.36, respectively.

The mean improvement in quality of life after surgery was 11.2 for the SF36-PC and 9.93 for the SF36-MC. Figures 2 to 6 show the values of both treatment modalities (surgery vs nonoperative care) presented in each series. Surgery presented a very large effect size in reducing disability, back and leg pain, and a medium effect size in increasing physical and mental components of quality of life (Figure 7). No effects on pain, disability, and quality of life were observed in nonoperative series (Figure 7).

Complications were recorded in 25 surgical series (n = 1196). The complication rates ranged from 9.52% to 81.52% (weighted mean = 39.62 \pm 16.62%). The mean rate of complication was 39.5% (\pm 17.5) in the open surgery group and 40.1% (\pm 1.58) in the MIS group. No complications were reported in nonsurgical series. Revision rates were reported in 25 surgical series (n = 1101). The need for revision surgery ranged from 1.72% to 40.0% (weighted mean = 15.71 \pm 8.99%). The mean revision rate was 14.9% (\pm 8.93) in the open surgery group and 20.3% (\pm 7.96) in the MIS group.

Discussion

Following a systematic review of the literature, 26 articles reporting outcomes of surgical or nonsurgical treatment for ASD met the inclusion criteria of this review. No randomized controlled trial was identified. No study using any specific nonoperative treatment regimen such as medications, physical therapy, or injections met the inclusion criteria. All the studies reporting outcomes of surgery versus nonoperative treatment presented a high risk of selection bias, mainly due to the marked diversity in baseline patient characteristics and indications for interventions. Thus, caution should be taken when analyzing these 2 types of treatment regarding comparative effectiveness.

In fact, generating accurate and meaningful evidence from medically managed cohorts that may allow a satisfactory comparison with surgically treated patients has already been recognized to be a significant challenge in the literature.³⁶ In nonrandomized studies, nonsurgical cohorts tend to present patients responsive to nonoperative care, whereas surgical cohorts tend to focus on patients less satisfied with their initial trial with conservative therapy. In spite of these weaknesses and potential for bias in nonrandomized studies, the evaluated data represents the best existing evidence about the value of surgical versus nonsurgical care in patients with ASD.^{37,38}

The use of patient-reported outcomes has become a standard in comparative effectiveness research.^{39,40} Since the validation of ODI in 1980,⁴¹ this instrument has been extensively reported as a valuable tool for assessing disability and its evolution after different types of treatment modalities for spinal disorders.⁴² It has been suggested that the minimal clinically important difference (MCID) for ODI is -12.8, the MCID for SF36-PC is +4.9, and the MCID for back and leg NRS scores are -1.2 and -1.6, respectively.⁴³ Our pooled analyses demonstrated a significant improvement in pain (back: -4.14; leg: -3.36),

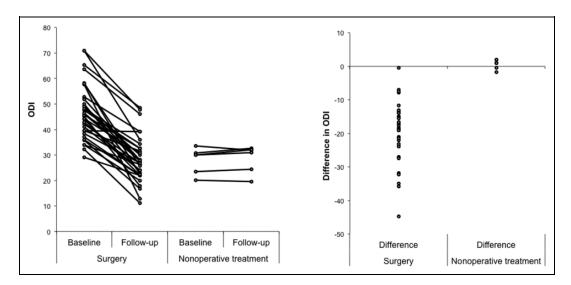


Figure 2. Scatterplot demonstrating the effect of surgery and nonoperative care for adult spinal deformity patients in Oswestry Disability Index.

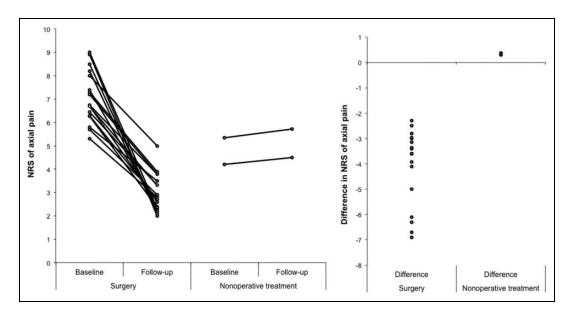


Figure 3. Scatterplot demonstrating the effect of surgery and nonoperative care for adult spinal deformity patients in back pain.

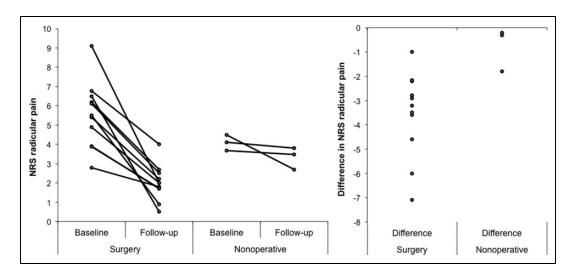


Figure 4. Scatterplot demonstrating the effect of surgery and nonoperative care for adult spinal deformity patients in leg pain.

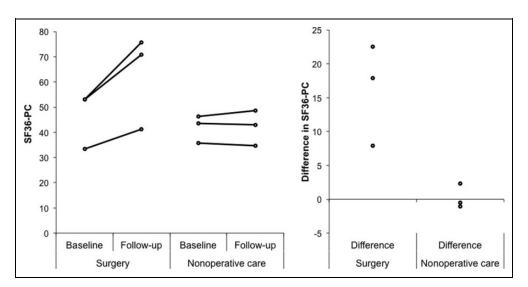


Figure 5. Scatterplot demonstrating the effect of surgery and nonoperative care for adult spinal deformity patients in Physical Component of SF36.

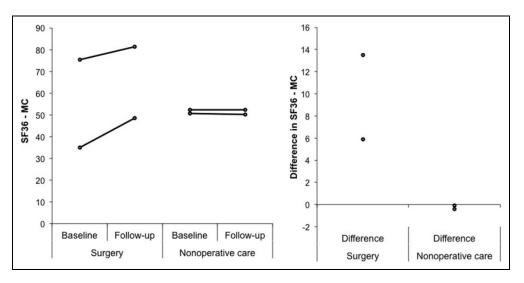


Figure 6. Scatterplot demonstrating the effect of surgery and nonoperative care for adult spinal deformity patients in Mental Component of SF36.

disability (ODI: -19.1), and quality of life (SF36-PC: 11.2; SF36-MC: 9.93) after surgical treatment for patients with ASD.

In this review, the overall postoperative complication rate was 39.62% (range = 9.52% to 81.52%). One may logically expect that higher levels of complications would have a negative impact on clinical outcomes after surgery.⁴⁴ In fact, a recent study by Smith et al⁴⁵ found that higher complication rates were associated with worse clinical outcomes in patients undergoing surgery for ASD (odds ratio = 9.012; 95% confidence interval = 1.16-69.62; P = .035). However, in the study of Zimmerman et al,²⁶ no differences in HRQOL were identified between patients with and without complications. Despite the high rate of postoperative complication and revision in this subset of patients, the clinical benefit of surgery was still very significant and sustained in a minimum follow-up of 2 years (Figure 7).

Some concerns about nonoperative series included in our analyses must be taken into consideration. Conservative treatment was not straightforward in terms of indications nor standard in terms of regimen or protocol in any of the evaluated studies. For example, Glassman et al⁵ used a resource utilization questionnaire to evaluate the utility of nonoperative care in patients with ASD. From 123 patients, 68 received at least one type of nonoperative treatment, whereas 55 patients did not receive any treatment. Nonoperative resource utilization was monitored for a broad array of treatment alternatives including medications, exercise modality, physical therapy, injections, chiropractic care, bed rest, and bracing. However, in such study, the resource utilization survey was administered only in a yearly basis, raising the issue of recall bias. In the studies of Li et al²⁹ and Smith et al,³⁰ no data on nonoperative care utilization was available. In the study of Bridwell et al,³¹ 21%

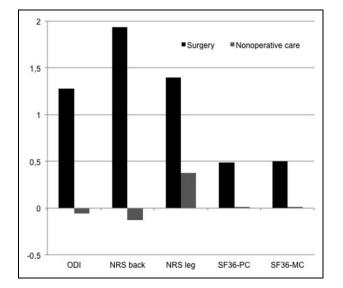


Figure 7. Effect size of surgery and nonoperative care in different health-related quality of life measures for adult spinal deformity.

of patients were only observed (ie, no conservative treatment modality was employed), 26% received medications, 40% received medications and associated physical therapy and/or injections, and 13% received alternative treatment other than medications. This lack of uniformity leads to a deep uncertainty if some subset of patients with ASD could effectively benefit from any specific nonoperative regimen. Moreover, loss of follow-up in nonoperative cohort was 56% in Scheer et al's study¹¹ and 55% in Bridwell et al's study.³¹ This high loss of follow-up should be taken into account, as it may have underestimated the benefits of nonoperative care.

Also, in nonoperative series, the study population consisted mainly of patients referred to a tertiary spine center for evaluation of their scoliosis, so that the entire cohort comprised both symptomatic and asymptomatic patients. In fact, baseline scores of HRQOL measures were significantly lower in the nonoperative as compared to operative series. As demonstrated by Carreon et al,⁴⁶ worse preoperative ODI correlate with greater improvements in ODI postoperatively. Scheer et al¹¹ also demonstrated that patients with worse scores in back and leg pain presented greater improvements in HRQOL scores postoperatively. Such findings have also been observed in nonsurgical cohorts. For example, Slobodyanyuk et al⁴⁷ demonstrated that the likelihood of achieving MCID is higher in patients with poorer baseline HROOL who received nonoperative care after 1 year of follow-up. Moreover, most patients in surgical series received nonoperative care previously to surgical treatment.

Our analyses demonstrated no significant deterioration in HRQOL measures in nonoperative series during a minimum of 2-year observation. One could argue that some patients treated conservatively might have deteriorated during the follow-up if it were not for the benefit derived from their conservative treatment. However, in the Glassman study,⁵ untreated patients did not demonstrate deterioration during

2-year observation similarly to what has been observed in patients who received some type of nonoperative treatment. The study of Scheer et al,¹¹ however, provides a different perspective on the occurrence of deterioration in nonsurgical patients. In their study, approximately 30% of patients reported deterioration in pain after 2 years of nonoperative care. Also, 50% of patients who did not report back pain at enrollment reported some back pain after 2 years, whereas 27% of patients presented new-onset leg pain during the same period. The likelihood of achieving MCID during 2 years of nonoperative care was 24%, 18%, and 4% in NRS back, NRS leg, and ODI, respectively.¹¹

Conclusions and Implications for Future Research

Analyses of HRQOL outcomes after surgery clearly demonstrate the high effectiveness of such therapeutic modality for patients with ASD. Surgery has been demonstrated to significantly reduce disability and pain and to improve patients' quality of life (Figures 2–7). In our review, the average postoperative improvement in ODI was $-19.1 (\pm 9.0)$, in NRS back pain $-4.14 (\pm 1.38)$, in NRS leg pain $-3.36 (\pm 1.33)$, in SF36-PC $+11.2 (\pm 5.07)$, and in SF36-MC $+9.93 (\pm 4.96)$. The complication rates of surgical series ranged from 9.52%to 81.52% (weighted mean = $39.62 \pm 16.62\%$) and the need for revision surgery ranged from 1.72% to 40.0% (weighted mean = $15.71 \pm 8.99\%$). Such data may assist clinicians to counsel patients, as well as to inform health care providers and policymakers about what to expect from the surgical treatment for ASD.

Although several recent series have highlighted the correlation between sagittal balance and spinopelvic parameters and self-reported outcomes, both before⁴⁸⁻⁵⁰ and after surgical treatment for patients with ASD,^{50,51} due to the novelty of such concepts, the incorporation of the preoperative evaluation of such parameters is still not reflected in the reported outcomes available in the literature as a whole. In objective terms, the largest prospective multicenter study involving both operative and nonoperative treatment of patients with ASD has demonstrated that a pelvic tilt (PT) of 22° or more, an sagittal vertical axis of 47 mm or more, and pelvic incidence minus lumbar lordosis (PI – LL) of 11° or more can be used as key threshold values for identifying patients with severe disability (ODI > 40).⁵⁰

In terms of future research on the field, a prospective comparison between the predictive value of standard methods for evaluating sagittal balance (such as the C7-sacrum plumb line) and newly proposed techniques (such as the T1 pelvic angle⁵²) are still warranted. Similarly, a comprehensive analysis of the reliability of new methods for evaluating coronal balance (such as the recently proposed axis-line angle technique)⁵³ in relationship to the classic method of the central sacral vertical line, as well as their possible predictive value in terms of clinical outcomes is also necessary. Unfortunately, at the present moment, the best existing evidence on nonoperative care of ASD is derived from observational studies with a high risk of bias. No randomized controlled trial was identified in our search to support the long-term value of current nonsurgical therapeutic options such as injections, physical therapy, or medications. Similarly, quantitative analyses of nonsurgical cohorts was not able to demonstrate sustained changes in the quality of life of patients. Ultimately, well-designed prospective studies are required to generate high-quality evidence concerning the nonoperative treatment in these patients.

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Declaration of Conflicting Interests

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