Measuring Outcomes in Spinal Deformity Surgery

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KEYWORDS

• Spinal deformity outcomes • Patient-reported outcomes • Surgery

KEY POINTS

- The SRS-22 classification system is a highly reliable and well-validated system for ASD.
- The importance of the sagittal plane in adult spinal deformity is a well-established cause of pain and disability. T1 spinopelvic inclination strongly correlates with health-related quality-of-life.
- Wearable technologies such as accelerometers are a promising, objective method to measure outcomes, but remain in development.

INTRODUCTION

Adult spinal deformity (ASD) causes severe functional disability, reduces a patient's quality of life, and imposes a substantial financial and societal burden.[1] ASD surgery can improve these outcomes, but there is no consensus on what defines a successful surgical outcome for deformity surgery. The goal of this narrative review is to provide a summary of spinal deformity outcomes research and relevant outcome measurements including clinical, radiographic, and functional outcomes.

Historically, ASD surgery outcomes have been measured using physician-based assessments such as curve correction with a focus on the achievement of spinal alignment. Outcome assessment in ASD has evolved from these physician-based assessments, to include a patient-centered perception of improvement and health-related quality-of-life (HRQOL) and patient-reported outcome measures (PROMs).[2] From 2004 to 2013 there was an increase in the frequency of studies using PROMs in ASD research, yet quality studies and standardization are lacking.[3,4] Other outcome metrics have been introduced into clinical practice including self-image questionnaires, functional mobility tests, and accelerometers. Financial instruments including cost/quality-adjusted life years (QALYs) are also important metrics that assess cost-effectiveness of ASD surgery for patients. In this narrative review, we outline the major developments in assessing outcomes in ASD surgery, with a particular focus on evolving assessment tools.

METHODS

This narrative literature review was conducted to provide the synthesis of the available literature regarding ASD outcomes. Relevant studies and reviews published between January 1, 2012, and August 1, 2022, were identified using a PubMed search using the keywords "adult spinal deformity surgery" and "outcomes." From the 236 publications identified during this period, titles and abstracts were reviewed. The narrative review was then synthesized from selected full texts identified in this search. Additional references were identified through backward citations of obtained articles.

DISCUSSION

Patient-Reported Outcomes

The U.S. Food and Drug Administration defines a patient-reported outcome (PRO) as "any report of the status of a patient's health condition that comes directly from the patient, without the

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interpretation of the patient's response by a clinician or anyone else."[5] PROs include information about the physical, psychological, and social factors that define a health-related quality of life (HRQOL). Along with the increasing demand for evidence-based medicine, the emphasis on PROs to guide decision-making for ASD treatment is increasing.[3] Therefore, a more relevant discussion of "outcomes" measures involves evaluating the quality of an outcome instrument, which depends on several features including content validity, construct validity, reliability, responsiveness, and ability to detect clinically important differences.[6] Content validity refers to the degree by which the assessment measures the intended outcome it is designed to measure. Construct validity refers to the expectation that HRQOL questionnaires will evaluate the domains considered significant in ASD. Reliability refers to an outcome measurement's stability over time and the accuracy with which it estimates the true effect of a treatment. Responsiveness refers to the sensitivity and ability to detect change, which allows the determination of the effect of a therapeutic intervention such as surgery. The concept of a minimum clinically important difference (MCID) helps researchers and clinicians to understand the context of PROMs scores by establishing clinically relevant thresholds for changes in PROMs values.[7] The MCID quantifies the smallest measurable change in an outcome score that will make a relevant difference to the patient.

Standardized PROMs questionnaires used in ASD studies include the 12-Item Short Form Health Survey (SF-12) and the longer 36-Item Short Form Health Survey (SF-36), Oswestry Disability Index (ODI), and the Scoliosis Research Society-22 Patient Questionnaire (SRS-22).[3] SF-12 and SF-36 are not disease-specific, whereas the ODI and SRS-22 are specific to spinal conditions. In general, based on a bibliometric analysis of usage, the ODI and SRS instruments have emerged as standards in ASD surgery.[3]

The ODI is a questionnaire that was developed to measure the degree of disability caused by spine-related pain.[8,9] The ODI questions focus on function; intensity of pain; lifting; ability to care for oneself; ability to walk, sit, and stand; sexual function; social life; sleep quality; and ability to travel. It correlates with the SF-36 score and is a widely used marker of overall health.[10] The ODI has been validated as a responsive measurement tool.[11] In one study of patients with ASD who underwent surgery, the ODI domains in which the greatest functional improvement occurred were those of lifting, walking, standing, and traveling.[12]

The SRS-22 was developed in 1999 by the Scoliosis Research Society as a disease-specific measure of clinical outcomes for idiopathic scoliosis.[13,14] The SRS-22 questionnaire contains 20 questions distributed in 4 domains (function/activity, pain, self-perceived image, and mental health) and 2 additional questions about the patient's satisfaction with the received treatment. Each dimension has five items, except for "satisfaction," which has 2 items. Each item is scored from 1 (worst possible) to 5 (best possible). Each dimension has a total sum score ranging from 5 to 25, except *satisfaction*, whose sum score ranges from 2 to 10. A subtotal sum score of the 4 scales with a range of 20 to 100 can be obtained, but the usual practice is to calculate the mean of each dimension. With the addition of the 2 questions on satisfaction, the overall score ranges from 22 to 110.[15]. The SRS-22 has been modified with standardized methods to include a revised (SRS-22r) questionnaire and an extended version, the SRS-30, which includes questions about the patient's self-image as well as the perceived effect of treatment on the disease. The SRS-22 and SRS-22R are valid and reliable instruments for assessing patients with idiopathic scoliosis, and it is sensitive to changes following surgery.[16] In an analysis of 1321 patients with ASD undergoing surgery, the MCID was identified to be 0.4 for the SRS-22R pain domain, activity domain, subscore, and total.[17] Unlike the SRS-22, the SRS-30 has not been specifically validated, and it is unclear whether these additional questions correlate with the true treatment score changes on the main scale (SRS-22).

Other outcome measurements have been employed for spinal deformity surgery including The Core Outcome Measures Index for the back (COMI-back),[18] EuroQoL 5-dimension 5-level,[19] and Patient-Reported Outcomes Measurement Information System (PROMIS). The COMI-back and PROMIS scores correlate strongly with SRS-22 and show good construct validity and responsiveness to surgery.[18,20]

Numerical rating scale (NRS) and visual analog score (VAS) are quantifiable PROs that are used in ASD to define a patient's back and leg pain and may help to better predict patient outcome. For instance, one study found that after deformity surgery, patients with radiculopathy exhibited increased pain and disability when compared to patients without leg pain.[21] Another study demonstrated a higher correlation with HRQOL scores for back pain and a higher correlation with sagittal parameters for leg pain.[22]

The aforementioned PROMs have been extensively used in ASD research (**Table 1**). Overall

Table 1
Selected patient-reported outcome measures

Outcome Measurement	Scope
ODI	Identifies the disruption of activities of daily living due to chronic low back pain
SRS-22, SRS-22R, SRS-24	Disease-specific health-related quality of life questionnaire for spinal deformity patients. SRS-30 includes additional evaluation of self-image and perception of one's treatment.
SF-12, SF-36,	Generic health status to measure the quality of life
NRS -back, -leg	11-point scale that measures pain sensation and intensity
VAS	100mm horizontal line that measures "no pain" to "most severe pain imaginable"
COMI -back	Identifies the disruption of activities of daily living due to chronic back pain

Abbreviations: COMI, Core Outcome Measures IndexNRS; numeric rating scale, ODI; oswestry disability index, SF; short form, SRS; scoliosis research society, VAS; visual analog scale.

the ODI, SRS-22, SF-12, and SF-36 are the most widely used PROMs and have been translated and validated in more than 10 different languages, making them suitable for international use.[4] Three studies have evaluated the clinimetric properties of the SRS-22, SF-12, and ODI in the ASD population, and Pearson's correlations of 0.70 were found between the SRS-22, SF-12, and ODI, reflecting good criterion validity.[23–25]

Bridwell and colleagues[23] compared the SRS-22 with the ODI and SF-12. They found that the SRS-22 did as well or better in score distribution compared with the other instruments. Looking at the domains of pain, function, and mental health, the concurrent validity was high between the SRS-22 and the SF-12. Reliability was excellent in all domains, and internal consistencies were high in all domains except pain, where it was 0.67, which is still acceptable. Berven and colleagues analyzed the SRS-22 alongside the SF-36 to evaluate validity, reliability, and discrimination in an adult population.[24] They found the SRS-22 to have excellent psychometric properties, which is in line with other studies.[23,26] For function, the SRS function scale has better characteristics (based on the floor/ceiling response distribution) than the SF-12, and similar characteristics as the ODI with fewer questions.[23] A limitation of the SRS-22R includes that domain scores are found to be affected by demographic and socioeconomic factors.[27]

Radiographic

The association between spinopelvic parameters and HRQOL has been studied extensively, and HRQOL scores are associated with improvement in radiographic alignment.[28] Positive sagittal balance strongly correlates with poor clinical outcomes[29]; proper restoration of sagittal alignment is critical to improving clinical outcome and reducing pain.[30,31] The sagittal vertical axis (SVA) is the most used measurement to evaluate global sagittal alignment, but the T1 spinopelvic inclination (T1-SPi) and T1 pelvic angle (T1PA) also measure sagittal alignment and correlate with HRQOL.[30,32] T1PA was developed to account for postural compensation and pelvic retroversion, and is less affected by variations in standing compensation. T1PA correlates with ODI, SF-36, and SRS, and the MCID was found to be 4.1° on the ODI.[32] High values of pelvic tilt (PT), which represents compensatory pelvic retroversion for sagittal spinal malalignment, also strongly correlated to the HRQOL of patients.[33]

A general consensus has not been reached on which radiographic parameters best correlate with outcomes,[34,35] possibly due to the various subtypes of ASD.[36] One study reported that the most strongly correlated radiographic parameters for the ODI were PT, SVA, and pelvic incidence-lumbar lordosis (PI-LL).[37] In contrast, Chapman *and colleagues* reported only weak correlations between sagittal modifiers and SRS function in patients with lumbar scoliosis.[38] Takemoto and colleagues found no significant association between preoperative HRQOL and radiographic parameters but found a significant correlation with postoperative HRQOL and sagittal parameters.[34] The lack of association between spinopelvic parameters and HRQOL in these studies was thought to be due to the broad spectrum of scoliosis subtypes that were included. Faraj and colleagues performed a study composed of 74 patients with degenerative lumbar scoliosis to evaluate the impact of the surgical correction on

scoliosis outcomes and found only weak correlations were found between SVA with ODI, NRS-back, and SRS pain domain.[35] Similarly, weak correlations between the ODI with T1PA (r = 0.137) and PI-LL (r = 0.137) were demonstrated in another study.[39] A Japanese study found a weak correlation between LL with lumbar function (r = 0.285), and moderate correlation between LL with VAS score for leg pain (r = 0.328).[40] The aforementioned studies suggest that at least a weak correlation between HRQOL and radiographic parameters is found in the degenerative scoliosis population.

Self-Image Outcome Measurements

In addition to PROMs and radiographic outcomes, a patient's perception of his or her own self-image has been recognized as negatively impacts preoperative health and life satisfaction for many patients with ASD.[13,41] A low degree of life satisfaction associated with physical disorders such as spinal deformity can have a serious psychological impact, leading to the deterioration of physical health and self-perceived quality of life. Importantly self-image consistently demonstrates improvement following surgery.[13,41] The SRS-22r scale recognizes the importance of the impact of self-image and includes a self-image domain,[42] but specific surveys for assessing appearance have also been developed including the Spinal Appearance Questionnaire (SAQ) and the Trunk Appearance Perception Scale (TAPS) (**Table 2**). TAPS uses drawings of the torso to evaluate patients' perceptions of their trunk deformity in addition to self-image, but it has not been extensively studied.[43] SAQ was developed from the Walter Reed Visual Assessment Scale (WRVAS) to assess patients' perceptions of several aspects of their spinal deformity and their expectations regarding treatment.[44] The SAQ questions include body curve, rib and flank prominence, thoracic deformity, head position, shoulder, and scapular asymmetry. The SAQ has been validated, and one study found that the SAQ measured self-image with greater correlation to curve magnitude than SRS Appearance and Total Score. It also discriminated between patients who required surgery from those who did not.[44]

Functional Mobility Tests

The main evaluation of patients with ASD is based on PROMs or radiographic parameters derived from X-rays. However, due to their static nature, X-rays can be deficient in assessing dynamic functionalities including balance, gait, and the risk of falling.[38] Several assessment tools that evaluate the dynamic properties of patients with ASD include the Berg balance scale,[45] The Dubousset

Table 2
Selected self-image outcome measurements

Self-Image Outcome Measurements	Description
SRS-22R	Five questions scored from 1 to 5. Questions include • How do you look in clothes? • Which of the following best describes the appearance of your trunk? • Do you feel attractive with your current back condition? • If you had to spend the rest of your life with your back shape as it is right now, how would you feel about it? • Do you feel that your back condition affects your personal relationships?
Spinal Appearance Questionnaire	A 33-questions assessment that include body curve, rib and flank prominence, thoracic deformity, head position, shoulder, and scapular asymmetry. There are also 11 pictorial questions that the patient identifies what most looks like him or herself.
Trunk Appearance Perception Scale	Uses three sets of figures that depict the trunk from three viewpoints. Each drawing is scored from 1 (greatest deformity) to 5 (smallest deformity) and a mean score is obtained from the three drawings. Scores range from 1 to 15 with higher scores indicating a smaller self-perception of deformity
Walter Reed Visual Assessment Scale	A visual test including seven items that deal with various aspects of the deformity including spinal deformity, rib prominence, lumbar prominence, thoracic deformity, trunk imbalance, shoulder asymmetry, and scapular asymmetry. Each question has a set of five figures that represent the degrees of severity of the deformity.

Abbreviation: SRS, scoliosis research society.

Functional Test,[46] and kinetic models to measure dynamic spinal parameters.[47] Functional mobility tests (FMTs) have also been validated for the assessment of physical function, trunk and lower limb muscle integrity, and body balance.[48] FMTs should be simple, easy to perform, reproducible and not require special equipment. Therefore, FMTs may be useful in preoperatively assessing the functionalities of patients with ASD and anticipating their surgical outcomes. In one study of patients with either ASD or lumbar spinal stenosis, four FMTs including alternate step test (AST), six-m walk test (SMT), sit-to-stand test (STS), and timed up and go test (TUGT) were found to be significantly correlated with the ODI scores postoperatively in the ASD group, but not the lumbar spinal stenosis group.[48] Patients with ASD are at high risk of falls, and postural balance measurements have been shown to significantly differ between fallers and non-fallers.[49] Overall, FMTs are appropriate tools for assessing the dynamic functionalities of patients with ASD and might play a bridging role between static radiographic parameters and subjective PROs when assessing patients with ASD.

Accelerometers

Emerging technological advances provide an opportunity to objectively measure activity and disability.[50] Wearable technologies, including continuous physical activity monitors, or accelerometers, present an opportunity for the objective measurement of physical activity, as patient questionnaires have been shown to exaggerate physical activity levels compared to device-based measurements.[51] Accelerometers also provide real-time and longitudinal information about patient mobility and return of function. In a spinal surgery study that included of 17 of 22 patients who had undergone deformity surgery, a moderate preoperative correlation was found between greater mean total daily steps and lower ODI ($r = -0.61$) and higher SF-36 physical component ($r = 0.60$).[52] A small body of literature regarding the portable assessment of spine motion has found that wearable systems represent valid tools to track spine movement.[53] However, the use of these technologies is still confined to research studies and is in a preliminary stage of development, but represent a promising adjunct to measuring outcomes after scoliosis surgery.

FINANCIAL OUTCOMES

As the cost of spine care is high, surgery costs and return to work outcomes are important economic metrics for ASD care.[54,55] Cost-effectiveness research is conducted using the outcomes measure *cost/quality-adjusted life years (QALYs)*: the cost of the health intervention divided by the QALYs. A QALY measures the health state of an individual on a scale, with zero the equivalent of death and 1 equal to the optimal state for 1 year of life.[56] Traditionally, $100,000/QALY is accepted as the threshold in the US for cost effectiveness.[57] A data analysis of 541 patients who underwent ASD surgery found that the average cost/QALY at 5-year follow-up was $120,311.73, but that 40.7% of patients fell under the threshold of a cost/QALY of less than $100,000. Cost-effective patients had higher baseline ODI scores, lower baseline total SRS scores, and shorter fusions.[58] Of the most common instruments used to measure outcomes, only SF-36 is routinely used for cost-effectiveness studies,[3] which makes surgical cost-outcome decisions difficult. Overall, the financial impact of ASD surgery is an important outcome measurement.

Accounting for Risk Factors

Many of the PROMs used in clinical practice fail to account for patient-specific risk factors that influence outcomes. To develop a standardized set of PROMs for future clinical trials and registries, it is necessary to correct for patient risk factors to allow fair comparison of outcomes. Without correcting for patient risk factors, surgeons managing patients with more comorbidities would appear to have worse outcomes.[59] Several indices have been developed to risk-stratify and predict patient outcomes in patients, such as the general Charlson Comorbidity Index and scoliosis-specific indices including the Seattle Spine Score,[60] the Adult Spinal Deformity Frailty Index,[61] and the adult spinal deformity (ASD)-comorbidity scale (ASD-CS).[10] The ASD-CS index accounts for patient comorbidities, and this index was associated with PROMs (such as SRS22r) as well as postoperative complications.[10]

An adult spinal deformity-surgical and radiographical (ASD-SR) score has been developed, which predicts EBL and operative time.[62] Although some studies have indicated that complications do not significantly correlate with changes in ODI scores,[63] complications can significantly affect other outcome measurements such as length of hospital stay, 90-day readmission, and reoperation and can have a significant economic impact.[12,64] Despite a substantial complication rate in adult scoliosis surgery,[65] patient satisfaction is high with improved pain scale and ODI scores.[12] Further external validation of these indices with PROs would be beneficial.

SUMMARY

The SRS-22 and ODI are the predominantly used PRO measurements for deformity surgery. Correction of sagittal alignment correlates with improved PRO, and T1-SPI outperforms the SVA. Functional outcomes and accelerometer measurements represent newer methods of measuring outcomes that have not yet been widely adopted or validated. Further adoption of a minimum set of core outcome domains, PROs such as SRS-22, and contributing risk factors will help facilitate international comparisons and benchmarking, and ultimately enhance value-based healthcare.

CLINICS CARE POINTS

- The SRS-22 classification system is a highly reliable and well-validated system for ASD.
- The importance of the sagittal plane in adult spinal deformity is a well-established cause of pain and disability. T1-SPI strongly correlates with HRQOL and outperforms the SVA.

DISCLOSURE

Dr K. Than is a consultant for DePuy Synthes, NuVasive, Accelus, Bioventus, and Cerapedics, and receives honoraria from SI Bone. Dr M.M. Abd-El-Barr is a consultant for Spineology, DePuy Synthes, TrackX. He has received research funding from NIH, United States, Abbvie, United States, Dana and Christopher Reeve Foundation.

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