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ONLINE ARTICLES

Establishing clinically significant outcome thresholds for the Single Assessment Numeric Evaluation 2 years following total shoulder arthroplasty

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Background: Single Assessment Numerical Evaluation (SANE) is a simple, time-efficient patient-reported outcome measure (PROM) used to assess postoperative shoulder function. Clinically significant outcome values and ability to correlate with longer legacy PROM scores at 2 years following shoulder arthroplasty are unknown.
Methods: A retrospective analysis was performed using SANE, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), and Constant scores that were collected at a minimum 2-year follow-up. A total of 153 patients who underwent anatomic total shoulder arthroplasty (TSA) or reverse total shoulder arthroplasty (RTSA) were included. A distribution-based method was used to determine the minimal clinically important difference (MCID). An anchor-based method was used to determine substantial clinical benefit (SCB). The following anchor question was collected alongside the PROMs and graded on a 15-point Likert-type scale to establish the SCB: ‘‘Since your surgery, has there been any change in the pain in your shoulder?’’ Linear regression was used to assess correlations between PROMs.
Results: SANE showed moderate correlation with ASES ($R^2 = 0.493$) and Constant ($R^2 = 0.586$) scores ($P < .001$). The MCID value was 14.9, and the SCB absolute value was 80.4 (area under the curve = 0.663) for SANE. Multivariate logistic regression demonstrated that patients undergoing RTSA were less likely to achieve SCB on all 3 outcome measures ($P < .02$).
Conclusions: This study establishes concurrent construct validity for SANE and suggests that it is a valid metric to assess the MCID and SCB at 2 years following anatomic TSA and RTSA. SANE demonstrated moderate correlations with ASES and Constant scores. Patients undergoing RTSA demonstrated a lower propensity to achieve SCB at 2 years postoperatively compared with anatomic TSA.
Level of evidence: Basic Science Study; Validation of Outcome Instruments

Keywords: Clinical outcomes; Single Assessment Numeric Evaluation (SANE); total shoulder arthroplasty; minimal clinically important difference (MCID); substantial clinical benefit (SCB); patient-reported outcome instrument validation

Rush University Medical Center Institutional Review Board approved this study (ORA# 20010205).

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Total shoulder arthroplasty (TSA) is an increasingly common procedure in the United States. Demand for TSA in patients older than 55 years is growing at a rate of 12.1% per year and is expected to increase by 755.4% by the year 2030.[27] As the United States health care system moves toward value-based care,[31] it will become imperative to better capture and quantify patient-specific improvement following anatomic TSA and reverse TSA (RTSA) using commonly administered patient-reported outcome measures (PROMs). Furthermore, as payment models are expected to shift from fee-for-service to performance-based reimbursement,[15] PROMs may have financial implications in the future.[37]

There are approximately 25 shoulder-specific scoring systems that may be used in the setting of TSA.[15] Although most of these scoring systems have proven valid and reliable,[32] many require a substantial amount of time to complete and therefore may be subject to task-induced fatigue and poor patient compliance.[3,28] In contrast, the Single Assessment Numeric Evaluation (SANE) score assesses the perception of the affected shoulder by simply asking "What percentage of normal is your shoulder?" on a rating scale from 0% to 100%. This PROM is time-efficient, and there is evidence that it can correlate to more complex legacy PROMs following several types of arthroscopic and open shoulder surgeries.[5,11,26,29,30,39] Provencher et al[29] demonstrated that SANE correlated highly with more laborious questionnaires across multiple shoulder conditions such as rotator cuff tears, instability, and glenohumeral osteoarthritis. SANE is amenable to psychometric interpretation similar to legacy PROMs in that researchers can derive the minimal clinically important difference (MCID) and substantial clinical benefit (SCB) from patient responses to assess if changes in functional scores reflect meaningful changes for the patient. Thigpen and colleagues[36] validated SANE across a sample of patients undergoing operative and nonoperative management of rotator cuff tears, adhesive capsulitis, subacromial impingement, and glenohumeral arthritis and found MCID achievement to be comparable to American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) scores. However, these studies included heterogenous samples and a limited number of TSA cases. Patients who undergo TSA and RTSA tend to be older and less active than those undergoing arthroscopic shoulder surgery, and the utility of SANE in this specific population is less clear.

Gowd et al[12] defined the MCID and SCB for the ASES, Constant, and SANE scores and reported good correlation among the 3 at 1 year following TSA and RTSA. However, the MCID and SCB for the SANE and its correlation to other legacy PROMs has not been established at the 2-year follow-up, which is a benchmark commonly used in clinical outcomes studies in joint arthroplasty[14,16] as patients often continue to have clinical improvement for up to 2 years postoperatively.[34] As such, the primary aims of this study were (1) to determine if SANE correlates with ASES and/or Constant scores at a minimum 2-year follow-up, (2) to define the MCID and SCB, and (3) to identify predictors of achievement of the MCID and SCB at 2 years postoperatively following TSA and RTSA. The authors hypothesized that SANE would correlate with ASES and Constant scores and would be a valid metric to assess MCID and SCB.

Methods

Patient selection

The current study received institutional board approval for the retrospective query and analysis of a secure clinical repository containing prospectively collected shoulder arthroplasty data. A query between September 2016 and October 2017 for consecutive patients who underwent a primary TSA or RTSA by 4 fellowship-trained surgeons (B.F., G.P.N., B.J.C., N.N.V.) was performed. Inclusion criteria consisted of completion of study outcomes and anchor questionnaires at a minimum of 2-year follow-up. Exclusion criteria consisted of revision shoulder arthroplasty, hemiarthroplasty procedures, and arthroplasty performed for traumatic etiology (ie, proximal humerus fractures) because outcomes and complication rates tend to differ compared to primary TSA for osteoarthritis or cuff tear arthropathy.[6,22] The application of inclusion and exclusion criteria for final patient selection is displayed in Figure 1.

Clinical and functional outcomes

All patients were administered the SANE,[40,41] ASES,[23] and Constant[4] questionnaires in-person preoperatively by trained research staff during the day of surgery. Patients again completed these questionnaires at a minimum of 2 years postoperatively using an electronic data collection service (Outcome Based Electronic Research Database; Universal Research Solutions, Columbia, MO, USA). Questionnaires expired 1 month after the anniversary of the patients' surgery in order to mitigate the potential for recall bias.

Preoperative and intraoperative variables were recorded prospectively in an institutional registry by trained research assistants. This database was then retrospectively queried for preoperative variables including patient demographics such as age, body mass index, smoking status, preoperative symptom duration, surgery to dominant arm, preoperative exercise, comorbidities, and worker's compensation status. Intraoperative variables included TSA vs. RTSA. These variables were integrated into multivariate logistic regression analysis to determine their association with clinically significant outcome improvement.[2,12]

Establishment of clinically significant outcome thresholds

Thresholds for clinically meaningful outcome improvement were quantified for the ASES, SANE, and Constant outcomes. In accordance with previous literature, the MCID was defined as the

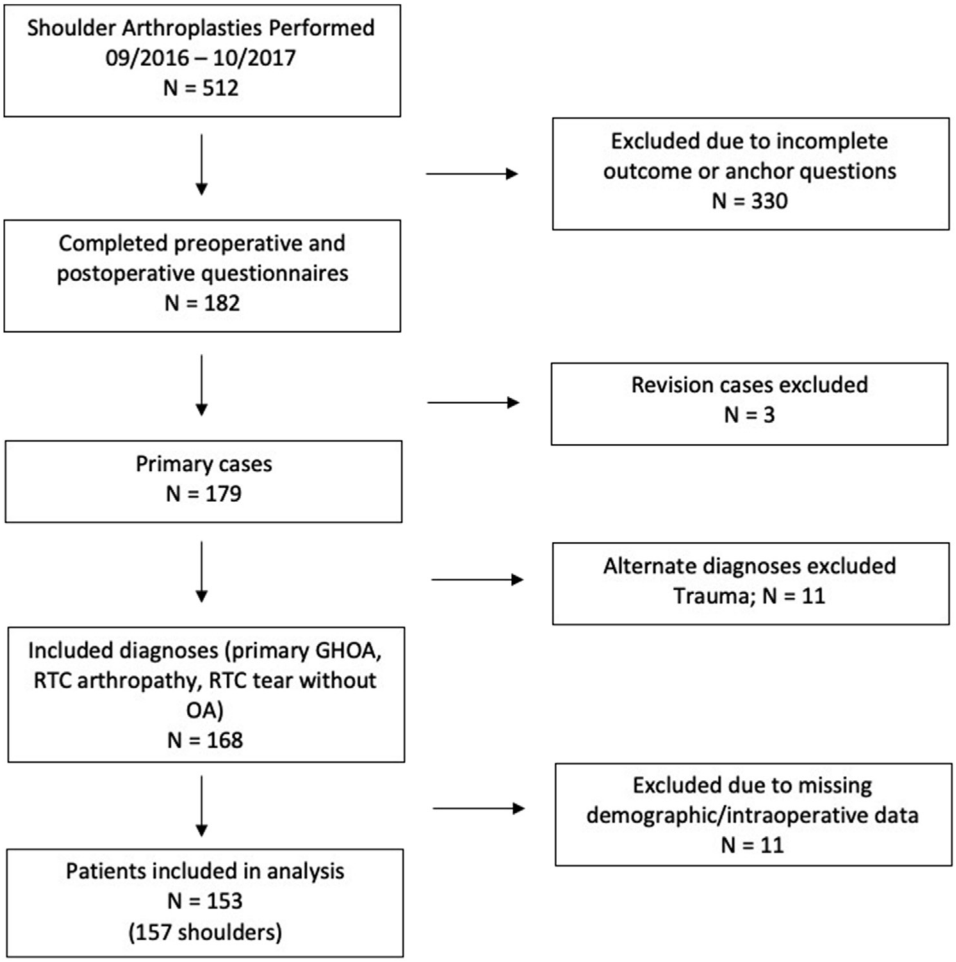

Figure 1 Patient selection flow chart diagram.

minimum change in an outcome measure from baseline that patients perceive as meaningful. The MCID can be calculated using both anchor- and distribution-based methodologies, with the anchor-based method coupling changes in PROMs to an anchor question assessing patients' perceptions of their symptom improvement. However, in the absence of the necessary anchor responses, previous research has demonstrated that one-half of the standard deviation across various health-related questionnaires reliably corresponds to the MCID.[24] As such, the MCID was calculated using a distribution-based method and was derived from the value equal to one-half of the standard deviation of the mean for the overall cohort for each outcome tool.[2,19,25]

The SCB was derived using anchor questions, which were administered along with outcome questionnaires at 2 years postoperatively. The anchor question was structured as follows: "Since your surgery, has there been any change in the pain in your shoulder?" This anchor question was graded on a previously reported 15-point scale.[17,18] Patients who experienced substantial improvement were classified as those who responded "A good deal better" or "A great deal better" or "A very great deal better." Patients who experienced no change were classified as those who responded "Almost the same, hardly any worse" or "No change" or "Almost the same, hardly any better." Differences in delta and absolute 2-year PROM scores between the no-change group (n = 13) and substantial improvement group (n = 118) were used to calculate the SCB.[12] The SCB threshold was calculated using a nonparametric receiver operating characteristic curve with area under the curve (AUC) analysis and subsequently Youden index as this criterion optimizes the sensitivity and specificity of the threshold value (Fig. 2).[2] The MCID and SCB thresholds were calculated for the total (ie, TSA and RTSA patients combined) study cohort in accordance with previous literature.[12]

Statistical analysis

All data were screened to determine whether they met parametric assumptions prior to conducting the statistical analyses. Continuous variables were described as means with standard deviations, whereas categorical variables were reported as frequencies with percentages. The proportion of patients achieving the MCID and SCB for each outcome was also reported as frequencies with percentages. A series of linear regression analyses were constructed to determine the correlation between the SANE score and the Constant and ASES outcomes while normalizing for each respective scale. Normalization was performed by subtracting the mean from each score and dividing the result by the standard deviation.[26,33] Multivariate logistic regression models were

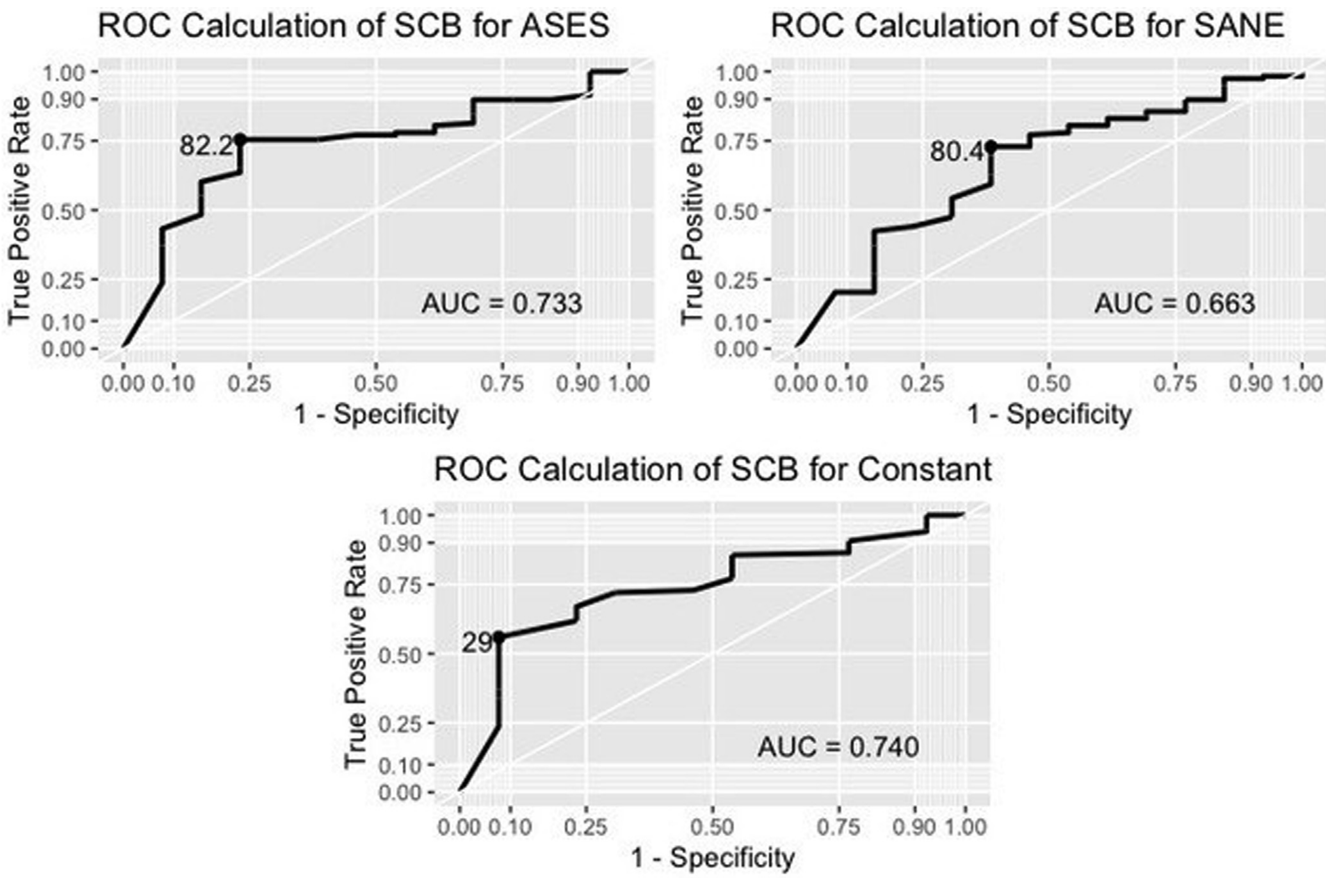

Figure 2 Receiver operating characteristic curves displaying calculation of the SCB cutoff values using Youden index for ASES, SANE, and Constant. *SCB*, substantial clinical benefit; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *SANE*, Single Assessment Numeric Evaluation.

constructed to determine the associations of preoperative and intraoperative characteristics with achieving clinically significant outcome improvement (MCID and SCB) for the SANE, ASES, and Constant scores. Regression models were only created for absolute SCB achievement because the predictive value (ie, AUC) was greater in all PROs assessed relative to the delta SCB thresholds. An a priori power analysis indicated that the sample size necessary to achieve an AUC value of 0.7 for calculation of the SCB threshold was 130 (113 cases and 17 controls), with an alpha of 0.05, power of 80%, and kappa of 0.15. The kappa value was determined based on previous literature, with an expected imbalance between the no improvement and substantial improvement groups of 1:6.67.[13] Statistical significance was considered as $P < .05$. All statistical analyses were performed using RStudio software, version 1.0.143 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Patient demographics

A total of 512 patients who underwent a shoulder arthroplasty procedure between September 2016 and October 2017 were evaluated. Following application of inclusion and exclusion criteria, 153 patients (157 shoulders) were included in final analysis. Demographic variables of the included patient population are displayed in Table I.

Establishing threshold scores for MCID and SCB

A total of 13 patients reported "no improvement," 14 reported "minimal improvement," 118 reported "substantial improvement," and 12 categorized their shoulder condition as "worse" at 2 years following surgery (n = 157). The MCID threshold values determined using the distribution-based method were 11.8, 14.9, and 4.2 for ASES, SANE, and Constant, respectively. The absolute SCB thresholds calculated using anchor-based methodology were 82.3 for ASES (AUC = 0.733, 95% confidence interval [CI] 0.611-0.838), 80.4 for SANE (AUC = 0.663, 95% CI 0.518-0.791), and 29.0 for Constant (AUC = 0.740, 95% CI 0.616-0.843). The delta SCB thresholds were 33.3 for ASES (AUC = 0.669, 95% CI 0.519-0.804), 52.4 for SANE (AUC = 0.579, 95% CI 0.446-0.710), and 15.0 (AUC = 0.653, 95% CI 0.492-0.794) for Constant. The percentage of MCID and SCB achievement for the total

Table I Demographic variables of included patients receiving total shoulder arthroplasty and reverse total shoulder arthroplasty

	TSA (n = 76)	RTSA (n = 81)
Demographics		
Age, yr	61.0 ± 8.4	70.2 ± 7.5
Body mass index	31.5 ± 6.5	28.8 ± 5.9
Female sex	25 (32.9)	43 (53.1)
Preoperative symptom duration, mo*	65.0 (27.0-149.0)	26.0 (14.5-84.8)
Workers' compensation status	4 (5.3)	6 (7.4)
Dominant-sided surgery	35 (46.1)	44 (54.3)
Preoperative diagnosis		
Primary glenohumeral osteoarthritis	74 (97.4)	45 (55.6)
Rotator cuff arthropathy	2 (2.6)	28 (34.6)
Rotator cuff tear without osteoarthritis	0	8 (9.9)

TSA, total shoulder arthroplasty; *RTSA*, reverse total shoulder arthroplasty.
Values are mean ± standard deviation or n (%).
* Presented as median (interquartile range) because of non-normal distribution.

study population as well as TSA and RTSA cohorts individually is displayed in Table II.

Comparison of MCID/SCB achievement by patient-reported outcome score

A series of linear regressions comparing normalized change scores demonstrated significant, moderate correlations between ASES and SANE ($R^2 = 0.493$, $P < .001$), Constant and SANE ($R^2 = 0.586$, $P < .001$), and Constant and ASES ($R^2 = 0.686$, $P < .001$) (Fig. 3). Of the patients achieving MCID for SANE, 97.1% (134/138) additionally achieved the MCID for either the ASES or Constant, and 84.8% (117/138) achieved the MCID for all 3 outcomes. Of those achieving SCB for SANE, 87.4% (83/95) additionally achieved the SCB for either the ASES or Constant, and 54.7% (52/95) achieved the SCB for all 3 outcomes.

Multivariate analysis of patient factors associated with MCID/SCB achievement

The association between patient factors and achievement of the MCID and SCB was analyzed using stepwise multivariate logistic regression. A greater preoperative PRO score was found to be associated with a reduced likelihood of achieving the MCID for ASES, SANE, and Constant. Longer duration of symptoms preoperatively was associated with a decreased likelihood of achieving the MCID for ASES and Constant, although the magnitude of association was extremely low (odds ratio of 0.999 for both). Female sex and workers' compensation status were both associated with a modest decrease in likelihood of achieving the MCID for Constant. A greater preoperative ASES or Constant score was associated with an increased likelihood of achieving the SCB for ASES and Constant, respectively. However, the magnitude of this association was very low with odds ratios of 1.005 for ASES and 1.022 for Constant. Undergoing an RTSA was associated with a significantly reduced likelihood of achieving the SCB for the ASES, Constant, and SANE scores (Table III).

Discussion

The main finding of the current study was that SANE showed a significant correlation with ASES and Constant scores at minimum 2-year follow-up after TSA and RTSA. The results of this study and previous work on the topic indicate that SANE is a viable alternative to traditional legacy measures based on construct validity, meaningful improvement metrics, and correlation to more comprehensive instruments. Additionally, the MCID and SCB following shoulder arthroplasty were defined for SANE as 14.9 and 80.4, respectively. Lastly, patients undergoing anatomic TSA were slightly more likely to achieve SCB in all 3 outcome measures compared to RTSA on multivariate regression.

SANE showed significant correlations with both ASES and Constant scores ($P < .001$) on linear regression analysis. The strength of this correlation was moderate in relation to both ASES ($R^2 = 0.493$) and Constant ($R^2 = 0.586$) and were stronger than previously reported at 1-year follow-up, which showed weak correlations to both ASES ($R^2 = 0.131$) and Constant ($R^2 = 0.339$).[12] Correlation of SANE to other traditional functional outcome measures has been previously performed following several different shoulder surgeries. Williams et al[40] initially described the SANE score in a study of shoulder function following surgery for shoulder instability. The authors found moderate correlations to both ASES ($R^2 = 0.64$) and Rowe ($R^2 = 0.54$) scores at 2 years. A follow-up study performed by Cunningham et al[5] showed strong correlations ($R^2 = 0.75$ to 0.88) between SANE and ASES scores for primary and

Table II Clinically significant outcome thresholds and achievement rates at 2 years following shoulder arthroplasty

Measure	Outcome			
	MCID	Achieved MCID (%)	SCB	Achieved SCB (%)
ASES	11.8	90.1	82.3	59.6
SANE	14.9	88.4	80.4	60.5
Constant	4.2	89.2	29.0	35.0

ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *SANE*, Single Assessment Numeric Evaluation; *MCID*, minimal clinically important difference; *SCB*, substantial clinical benefit.

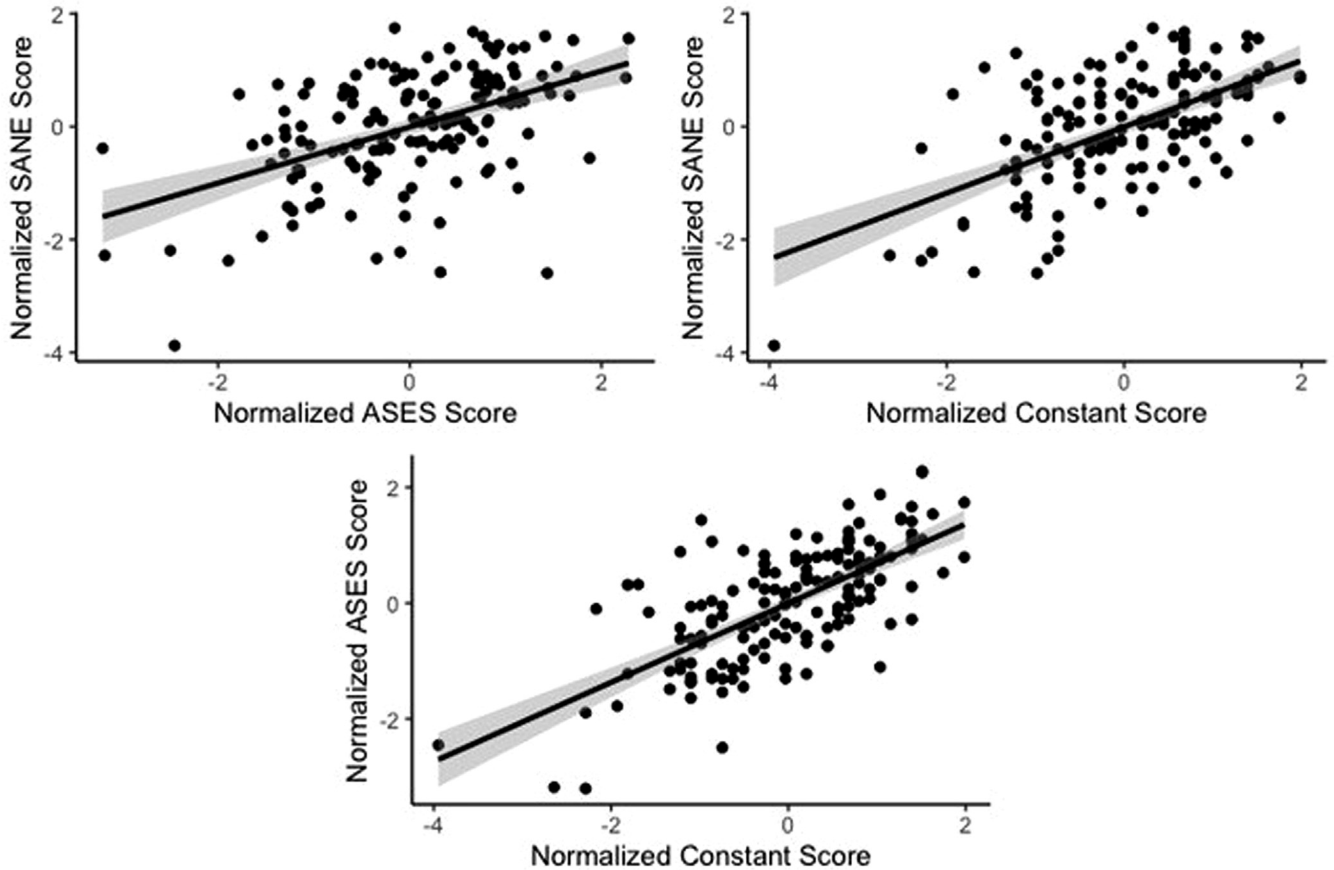

Figure 3 Scatterplots and linear regressions comparing the correlation of change in normalized scores between ASES, SANE, and Constant. Gray shading indicates the 95% confidence interval. *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *SANE*, Single Assessment Numeric Evaluation.

revision rotator cuff repair as well as SLAP repair. These findings were also replicated in a study performed by Retzky et al,[30] which demonstrated a strong correlation between SANE and ASES in a small subset of 33 patients undergoing shoulder arthroplasty ($R^2 = 0.78$); however, the authors were unable to make conclusions regarding this cohort given the limited sample size. The current study corroborates the latter correlation in a larger sample size at minimum 2 years postoperatively with a more modest correlation coefficient. As such, these findings further suggest that SANE is a practical alternative to multiple-item shoulder outcome scores, such as ASES and Constant following shoulder arthroplasty at a minimum of 2 years.

Although moderate correlations were seen in this study, variance still exists between measures for a number of reasons. SANE is a self-reported global assessment of the condition of a patient's shoulder compared with their definition of normal. Therefore, the score is subjective and largely depends on the patient's definition of a "normal" shoulder. In contrast, the Constant score relies on objective measures such as range of motion, strength, and activity

Table III Stepwise multivariate logistic regression for predictors of clinically significant outcome achievement

	Odds ratio (95% CI)	*P* value
Minimal clinically important difference		
ASES		
RTSA	0.915 (0.823, 1.017)	.102
Greater BMI	1.007 (0.998, 1.015)	.150
Longer symptom duration	**0.999 (0.999, 1.000)**	**.041**
Exercise	1.087 (0.982, 1.203)	.112
Preoperative ASES	**0.995 (0.996, 1.000)**	**<.001**
Constant		
Female sex	**0.898 (0.810, 0.997)**	**.045**
Greater BMI	0.992 (0.983, 1.001)	.088
Longer symptom duration	**0.999 (0.999, 1.000)**	**.037**
WC	**0.792 (0.647, 0.969)**	**.025**
Preoperative Constant	**0.984 (0.975, 0.993)**	**.001**
SANE		
Preoperative SANE	**0.997 (0.995, 1.000)**	**.036**
Substantial clinical benefit		
ASES		
Age >65 yr	1.158 (0.968, 1.385)	.110
Current smoker	0.468 (0.178, 1.235)	.127
RTSA	**0.725 (0.609, 0.864)**	**<.001**
Preoperative ASES	**1.005 (1.001, 1.010)**	**.018**
Constant		
Age >65 yr	1.167 (0.980, 1.388)	.085
Greater BMI	1.008 (0.994, 1.023)	.247
DM	0.816 (0.643, 1.034)	.095
RTSA	**0.813 (0.685, 0.963)**	**.018**
Preoperative Constant	**1.022 (1.008, 1.037)**	**.003**
SANE		
Age >65 yr	1.179 (0.986, 1.409)	.073
WC	0.755 (0.548, 1.041)	.151
RTSA	**0.779 (0.654, 0.928)**	**.009**
Preoperative SANE	1.002 (0.999, 1.006)	.188

ASES, American Shoulder and Elbow Surgeons; *RTSA*, reverse total shoulder arthroplasty; *BMI*, body mass index; *WC*, workers' compensation; *SANE*, Single Assessment Numeric Evaluation; *DM*, diabetes mellitus; CI, confidence interval.
Bold values indicate statistical significance ($P < .05$).

level.[4] The ASES includes data related to pain medications, difficulty level related to various activities, and a number of physical examination findings related to range of motion, strength, instability, and specific signs.[1] In addition, some components of ASES such as scars, biceps tenderness, overhead throwing, and certain aspects of the instability examination are less relevant in the context of TSA or RTSA, which may contribute to variability in scoring. With greater focus on patient satisfaction and patient-based measures in recent years, SANE may be a more relevant measure in the current health care climate.[37]

The current study also established the MCID to be 14.9 and SCB to be 80.4, with an acceptable AUC value for the SANE score at 2 years following TSA and RTSA. Achievement rates of MCID and SCB were similar across all 3 outcome measures in the present study with the exception of lower achievement rate of SCB on the Constant measure (35.0%). Of patients achieving MCID for SANE, 97.1% additionally achieved MCID for ASES or Constant. Similarly, 87.4% of patients achieving SCB for SANE also achieved SCB on ASES or Constant. This indicates that these measures, particularly SANE and ASES, reflect the capability to transform a patient's perception of clinical improvement from a raw score into a translatable measure of outcome, which can be more easily discussed in clinical settings with patients. Of note, lower SCB achievement with Constant has been observed in the literature. Comparable to the current study, Gowd et al[12] noted an SCB achievement rate of 26.9% at 1 year following shoulder arthroplasty. Although Constant demonstrated the highest AUC value on SCB calculation in the present study, it also showed the lowest sensitivity (55.9%) compared to ASES and SANE (75.4% and 72.9%, respectively) and may not be the optimal measure to determine SCB.

As the role of PROMs becomes more prominent in the delivery of health care, it is critical to overcome 2 major barriers: patient compliance and administrative burden in data collection. For example, compliance with completing electronic PROMs at 1 year was recently noted to be 45%, despite reminders to patients from dedicated research staff.[21] Reliable data collection also requires the cost of electronic data collection systems or administrative duties that are necessary to collect paper versions of PROMs. Concise measures such as SANE may be optimal to improve patient compliance while requiring minimal administrative burden. In addition, the simple 1-digit response may make it the most feasible outcome measure to potentially be collected via messaging on a mobile device. Despite these advantages, SANE has a number of limitations compared to legacy measures. SANE does not capture granular data on pain, activity level, or function. Therefore, patients' improvement in specific areas cannot be followed over time, and the instrument cannot be used to identify certain functional deficiencies. Without objective data points and physical examination findings, comparison across populations or interventions is also limited. Other initiatives such as computer adaptive testing with Patient Reported Outcomes Measurement Information System (PROMIS) aim to obtain accurate outcome measures with a limited number of questions. However, validation of PROMIS in shoulder pathology is ongoing.[10]

Consistent with previous research,[33] multivariate analysis in this study indicated patients who underwent anatomic TSA were slightly more likely to achieve SCB on all 3 outcome measures when compared to RTSA. Patients undergoing TSA were 23%-38% more likely to achieve the SCB when controlled for covariates. Previous literature comparing TSA and RTSA in the setting of glenohumeral arthritis or rotator cuff arthropathy have produced varying results. Although some recent studies have shown postoperative PROMs to be comparable,[8,20] others have shown more frequent complications and worse outcome scores with RTSA, possibly related to more limited active motion and arm lengthening.[7,9,35,38] Future research is warranted to determine what factors may contribute to one's likelihood of achieving the MCID and SCB following TSA and RTSA.

Limitations

There are a number of limitations to the current study. A total of 330 patients were excluded from the cohort because of incomplete questionnaires or anchor questions, which may subject the sample to selection bias. The study was performed in a retrospective manner; however, data were collected prospectively by dedicated research assistants. All surgeries were performed at a high-volume academic practice, which may limit generalizability to community settings. Lastly, only a limited number of potential variables and their relationships to clinically significant outcome improvement on the SANE were explored as these are the only variables routinely collected at our institution.

Conclusions

This study establishes concurrent construct validity for SANE and suggests that it is a valid metric to assess the MCID and SCB at 2 years following anatomic TSA and RTSA. SANE demonstrated moderate correlations with ASES and Constant scores, and all 3 outcome measures had similar rates of MCID and SCB achievement with the exception of SCB achievement using the Constant score. However, patients undergoing RTSA demonstrated a lower propensity to achieve SCB at 2 years postoperatively on all 3 outcome measures compared with those undergoing anatomic TSA.

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