Establishing Clinically Significant Outcomes of Total Shoulder Arthroplasty at Minimum 5-Year Follow-up

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INTRODUCTION: Reverse and anatomic total shoulder arthroplasty (rTSA and aTSA) are increasingly performed to treat symptoms of glenohumeral arthritis or rotator cuff tears refractory to repair. With an increased emphasis on patient-centered care, patient reported outcome measures (PROMs) are now focused on relevant, meaningful outcomes through the utilization of clinically significant outcomes (CSOs). Thresholds for CSO, namely the minimal clinically important difference (MCID), patient acceptable symptomatic state (PASS), and substantial clinical benefit (SCB), have been previously established at one- and two-year minimum follow-up following shoulder arthroplasty. However, thresholds at mid- and long-term follow up remain unknown. The purpose of this study is to determine CSO thresholds for American Shoulder and Elbow Surgeons (ASES), Single Assessment Numeric Evaluation (SANE), veterans RAND (VR-12), and Patient-Reported Outcomes Measurement Information System (PROMIS) in patients who undergoing rTSA and aTSA at a minimum 5-year follow-up.

METHODS:

A prospectively collected, single-institution database spanning from January 2015 – April 2017 was retrospectively reviewed to identify patients who underwent rTSA or aTSA and completed PROMs at both baseline and at a minimum of 5-year follow-up. Surgeries were performed by one of three fellowship-trained physicians. Patient demographics and surgical characteristics were collected. A distribution-based approach was utilized to calculate MCID, as previously described, while an anchor-based approach was utilized for SCB and PASS. Absolute values were utilized for both SCB and PASS. A receiver operating characteristic curve was created, an area under the curve >0.7 was considered an acceptable predictor, while >0.8 was considered an excellent predictor. Univariate regression analysis was utilized to determine patient variables associated with CSO achievement.

RESULTS: A total of 105 patients meeting inclusion criteria were identified (Table 1). Mean patient age was 65.4 ± 8.7 years. rTSA was performed in 54.3% (n=57/105) of patients. Calculated MCID/SCB/PASS for ASES were 10.8/84.2/78.3 and for SANE were 17.5/78.5/68.5, respectively (Table 2). Due to limited baseline scores, only SCB and PASS were calculated for PROMIS questionnaires. Most AUCs (n = 4/7) for SCB met criteria as an acceptable predictor, while most AUCs (n = 5/7) for PASS met criteria for excellent predictors (Figure 1). Decreased odds of achieving MCID were associated with higher baseline scores. Decreased odds of achieving SCB and PASS for PROMIS depression were associated with male sex (p = 0.02; 95% OR 0.08-0.83), while decreased odds of achieving SCB for PROMIS pain was associated with right-sided procedures (p = 0.04; 95% OR 0.09-0.89). Increased odds of achieving PASS were associated with higher baseline scores.

DISCUSSION AND CONCLUSION: This study defines CSOs thresholds for ASES, SANE, VR-12, and PROMIS questionnaires following shoulder arthroplasty at a minimum of 5-year follow-up. Higher baseline scores were associated with decreased odds of achieving MCID and increased odds for PASS achievement. Due to inherent differences in outcomes and indications for reverse and anatomic shoulder replacement, establishing separate CSOs for each procedure may be warranted.

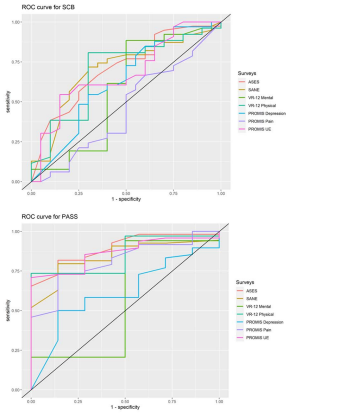

Figure 1: Receiver operating characteristic (ROC) analysis for American Shoulder and Elbow Surgeons (ASES), Single Assessment Numeric Evaluation (SANE), Veterans RAND (VR-12) Mental and Physical, and Patient-Reported Outcomes Measurement Information System (PROMIS) depression, pain, and upper extremity (UE) subscales thresholds for 5-year for substantial clinic benefit (SCB) and patient acceptable symptomatic state (PASS).

Table 1: Patient Characteristics (N = 105)

Age at surgery, years	65.4 ± 8.7
Male sex	62 (59.0)
Body mass index	30.1 ± 5.2
Current or former smoker	27 (25.7)
Shoulder laterality (right)	64 (61.0)
Symptom duration, y	3.2 ± 2.8
Arthroplasty	
Reverse	57 (54.3)
Anatomic	48 (45.7)
Preop diagnosis	
Primary glenohumeral osteoarthritis	73 (69.5)
Rotator cuff arthropathy	28 (26.7)
Rotator cuff tear without osteoarthritis	4 (3.8)

Legend: Binomial variables are presented as frequency (proportion). Continuous variables are listed as mean ± SD.

Table 2: Clinically Significant Outcomes

Variable	Threshold	AUC	SN	SP	Percent achieved, %
MCID					
ASES	10.8	-	-	-	91.4
SANE	17.5	-	-	-	76.9
VR-12 mental	3.9	-	-	-	30.7
VR-12 physical	4.2	-	-	-	74.3
SCB					
ASES	84.2	**0.709**	74.4	60.0	66.2
SANE	78.5	**0.705**	71.8	70.0	63.8
VR-12 mental	65.7	0.575	88.5	50.0	20.5
VR-12 physical	43.9	**0.709**	80.8	70.0	64.1
PROMIS - Depression	49.9	0.631	84.8	40	31.2
PROMIS - UE	43.5	**0.711**	54.5	85	58.3
PROMIS - Pain	49.4	0.456	66.7	40	42.6
PASS					
ASES	78.3	**0.896**	81.8	85.7	74.3
SANE	68.5	**0.841**	79.6	85.7	75.4
VR-12 mental	52.0	0.574	94.1	50.0	89.7
VR-12 physical	41.4	**0.853**	73.5	100.0	71.8
PROMIS - Depression	41.5	0.616	50.0	85.7	56.7
PROMIS - UE	41.6	**0.866**	70.8	100.0	60.6
PROMIS - Pain	53.5	**0.811**	72.9	85.7	33.3

Legend: ASES, American Shoulder and Elbow Surgeons; AUC, area under the curve; PROMIS, Patient-Reported Outcomes Measurement Information System; SANE, Single Assessment Numeric Evaluation; SN, sensitivity; SP, specificity; UE, upper extremity; VR-12, Veterans RAND.