



Substantial Clinical Benefit Values Demonstrate a High Degree of Variability When Stratified by Time and Geographic Region

Presenter: Cory Hewitt, MD

Wellington IJ, Davey AP, Cote MP, Hawthorne BC, Dorsey CG, Garvin PM, Messina JC, Hewitt CR,
Mazzocca AD

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Disclosures

- Augustus D. Mazzocca serves as a paid consultant for Arthrex inc.
 - The database used for this study was provided by Arthrex inc.
 - Arthrex inc. was not involved with the design of this study.

Background/Purpose

- Substantial Clinical Benefit (SCB) is a value derived from patient reported outcome measures (PROM) which indicates the amount of improvement in the outcome measure needed for a patient to feel they benefited from the intervention.
- SCB values are composed of two things: The outcome measure and **expectation.**
- There is a trend in current literature to publish SCBs for various PROMs for a procedure, and consequently, having these values cited by other researchers to determine efficacy of a treatment.
- *The purpose of this study is to determine the generalizability of SCB values for different PROMs following either anatomic (TSA) or reverse (rTSA) total shoulder arthroplasty.*

Methods

- Database with PROMs from surgeons from 3 different regions of the United States (South, Midwest, West)
- Inclusions:
 - rTSA or TSA
 - Complete data at 1 year for state-based analysis, complete data at 2 years for time-based analysis
 - >All-comers regardless of age or medical comorbidities
 - Anchor Question: “How well did the treatment meet your expectations with regard to reducing your pain level?”
 - Included anyone reporting “did not meet expectations” or “exceeded expectations”
- SCBs were calculated using Receiver Operative Characteristics (ROC) analysis stratified by time or by region for Visual Analogue Scale (VAS) of Pain, Single Assessment Numeric Evaluation (SANE), American Shoulder and Elbow Surgeons score (ASES), and Western Ontario Osteoarthritis of the Shoulder score (WOOS)

Table1. SCB values at 1 y and 2 y postoperatively stratified by region.

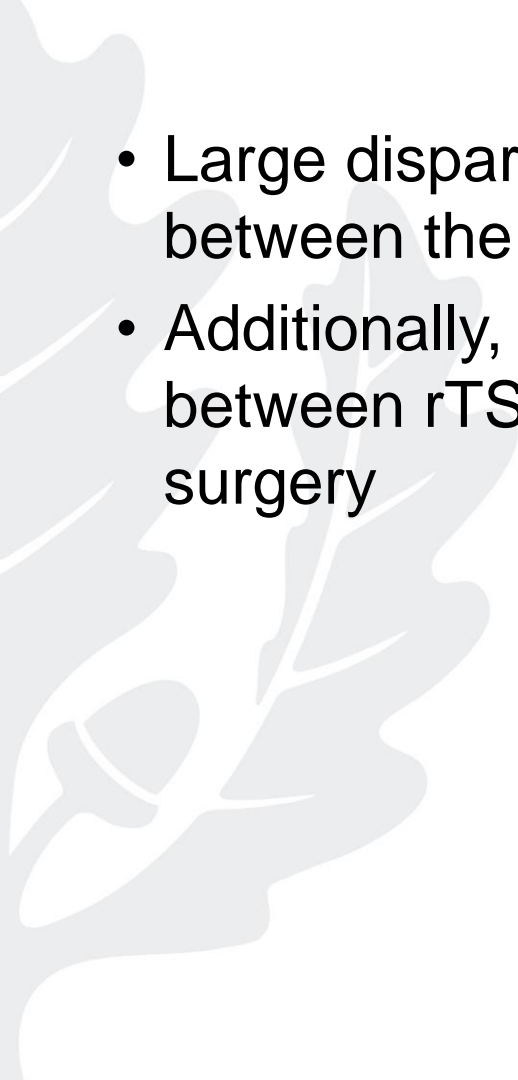
		Postoperative time	aTSA			
			South (n=51)	Midwest (n=70)	West (n=259)	Combined (n=380)
SANE	1 y	30	46	40	40	
SANE	2 y	31	40	50	33	
ASES	1 y	33	30	38	38	
ASES	2 y	30	40	33	33	
VAS	1 y	-4.00	-4.90	-3.69	-3.63	
VAS	2 y	-1.76	-4.00	-3.36	-3.50	
WOOS	1 y	-813	-6.73	-671	-674	
WOOS	2 y	-977	-532	-1035	-1002	

SCB, Substantial Clinical Benefit; aTSA, anatomic total shoulder arthroplasty; SANE, Single Assessment Numeric Evaluation; ASES, American Shoulder Elbow Surgeons; VAS, Visual Analog Scale; WOOS, Western Ontario Osteoarthritis of the Shoulder; rTSA, reverse total shoulder arthroplasty

Table I. SCB values at 1 y and 2 y postoperatively stratified by region.

		rTSA			
		South (n=92)	Midwest (n=141)	West (n=310)	Combined (n=543)
SANE	1 y	1	26	33	38
SANE	2 y	59	51	31	31
ASES	1 y	32	21	28	31
ASES	2 y	24	24	27	27
VAS	1 y	-3.12	-3.02	-3.88	-3.68
VAS	2 y	-2.08	-3.73	-3.40	-3.73
WOOS	1 y	-541	-627	-763	-706
WOOS	2 y	-528	-797	-753	-814

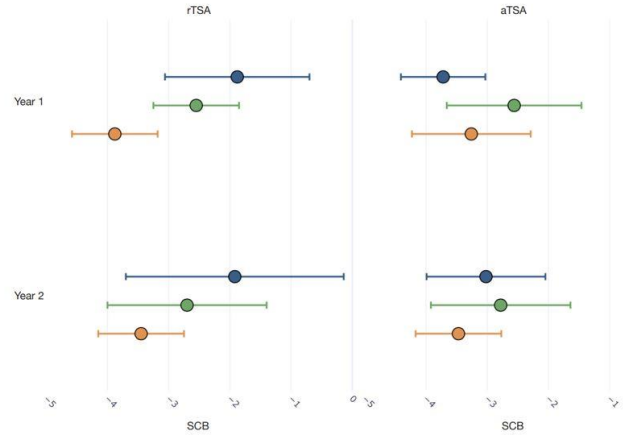
SCB, Substantial Clinical Benefit; *aTSA*, anatomic total shoulder arthroplasty; *SANE*, Single Assessment Numeric Evaluation; *ASES*, American Shoulder Elbow Surgeons; *VAS*, Visual Analog Scale; *WOOS*, Western Ontario Osteoarthritis of the Shoulder; *rTSA*, reverse total shoulder arthroplasty

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- Large disparities in the SCB values for all 4 PROMs exist between the three studied regions
 - Additionally, there were large differences in these values between rTSA and TSA at 1 year and 2 years from surgery

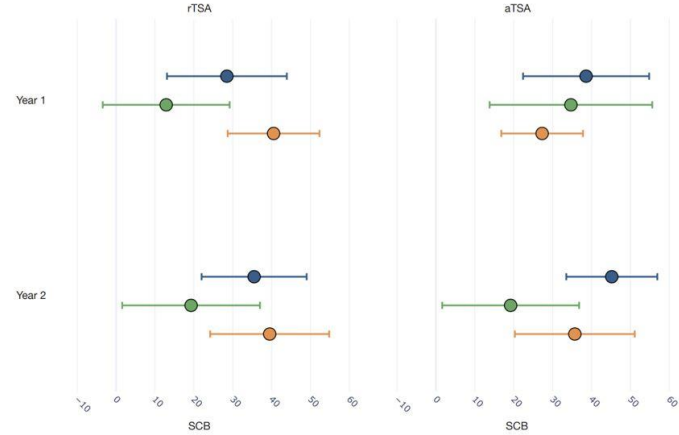
Methods Continued.

- To determine the variability of potential SCBs within each region, simulated datasets were created to determine a distribution of possible SCBs
- Data was simulated using sample size, mean, and standard deviation of the different scores for each procedure, timepoint, and region, and an SCB was calculated for this simulated data.
- This process was repeated 1000 times resulting in a distribution of 1000 simulated SCB values for each of the groupings.

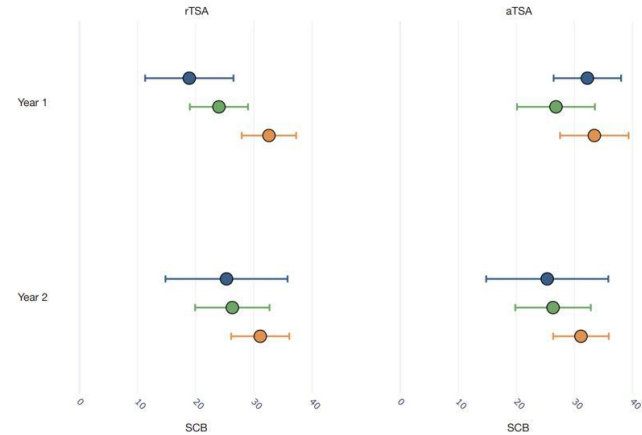
VAS Pain SCB



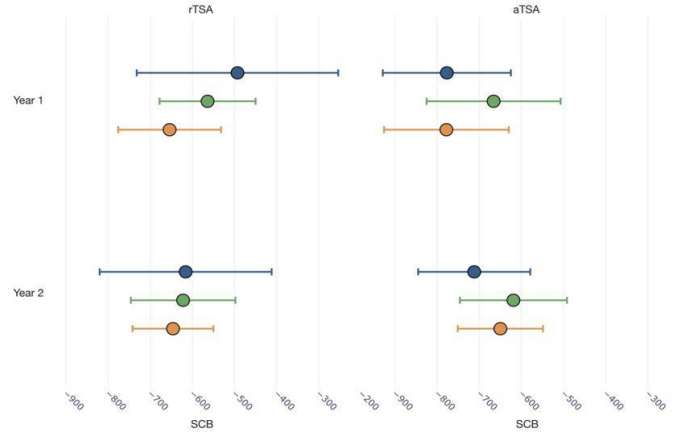
SANE SCB



ASES SCB



WOOS SCB



Mean SCB values for VAS Pain, SANE, ASES, and WOOS scores calculated at one y and two y postoperatively from 1000 simulated datasets. The error lines indicate the range of potential SCB values calculated from these datasets.

Conclusions

- There is a significant heterogeneity in SCB values for ASES, SANE, VAS, and WOOS following both TSA and rTSA based on both time and state.
 - This calls into question the current trend in outcomes research to cite previously reported SCBs.
 - Applying a previously published SCB value to a new dataset may not be a sound research methodology.
- Future outcomes research should calculate SCBs for the individual dataset being analyzed.
 - Studies could alternatively include an anchor question in their surveys to parse out who significantly improved following surgery, and use the answers to this question to stratify groups, rather than using established SCB values
 - i.e. directly asking patients “Did you significantly benefit from the procedure
- Future studies are needed to see if this trend maintains for Minimal Clinically Important Difference (MCID) or Patient Acceptable Symptom State (PASS) values.

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