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ORIGINAL ARTICLE

Quantifying success after total shoulder arthroplasty: the substantial clinical benefit

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Background: An understanding of the substantial clinical benefit (SCB) after total shoulder arthroplasty (TSA) may help to gauge a minimum threshold beyond which a patient perceives his or her outcome as being substantially better. This study quantifies SCB for 7 outcome metrics and active motion measurements after shoulder arthroplasty and determines how these values vary based on prosthesis type, patient age at surgery, sex, and length of follow-up.

Methods: A total of 1,568 shoulder arthroplasties with 2-year minimum follow-up were performed by 13 shoulder surgeons and enrolled in a multicenter registry. The SCB for the American Shoulder and Elbow Surgeons Shoulder Assessment, Constant Score, University of California Los Angeles Shoulder Rating Scale, Simple Shoulder Test, Shoulder Pain and Disability Index, global shoulder function, and visual analog scale pain scores, as well as active abduction, flexion, and external rotation were calculated for different patient cohorts using an anchor-based method.

Results: The anchor-based SCB results were American Shoulder and Elbow Surgeons score, 31.5 ± 2.0; Constant Score, 19.1 ± 1.7; University of California Los Angeles Shoulder Rating Scale score, 12.6 ± 0.5; Simple Shoulder Test score, 3.4 ± 0.3; Shoulder Pain and Disability Index score, 45.4 ± 2.2; global shoulder function, 3.1 ± 0.2; visual analog scale, 3.2 ± 0.3; active abduction, 28.5° ± 3.1°; active forward flexion, 35.4° ± 3.5°; and active external rotation, 11.7° ± 1.9°. Anatomic TSA patients, male patients, and patients of longer follow-up duration were associated with higher SCB values than female patients, reverse TSA patients, and patients of shorter follow-up duration.

Conclusion: Our analysis demonstrated two-thirds of patients achieved the SCB threshold after TSA. Generally, a change of 30% of the total possible score for each outcome metric approximates or exceeds this SCB threshold.

Level of evidence: Basic Science Study; Validation of Outcome Instruments

Data acquisition and analysis was performed with approval from the Western Institutional Review Board (protocol # WIRB 20091701).

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Use of total shoulder arthroplasty (TSA) has steadily increased over time and has found broad indications for degenerative joint disease and rotator cuff insufficiency. The outcomes associated with TSA, including anatomic TSA (aTSA) and reverse TSA (rTSA) have been demonstrated to be reliably favorable and durable.[3-8,13-15,17,19,20,24,25,27] Most clinical studies have examined patient-reported and objective measures in the context of statistical significance. However, assessment of outcome based only on statistical evaluation can be prone to statistical error because the determination is heavily influenced by sample size and other study power-related variables.[11] Furthermore, statistical significance does not necessarily correlate with clinical relevance or what is perceived to be important or satisfactory to the patient.

To evaluate outcomes in the context of what is clinically relevant to the patient, the concept of minimal clinically important difference (MCID) was introduced by Jaeschke et al[10] in 1989. MCID defines the minimum threshold over which a patient has determined his or her clinical outcome to be beneficial and meaningful. This has been applied to the study of clinical metric outcomes for the nonoperative management of rotator cuff tears and after TSA.[18,21-23,26]

MCID describes the minimum value for meaningful improvement, whereas substantial clinical benefit (SCB) describes the value for substantial improvement.[9,12] SCB was first described by Glassman et al[9] as the value where patients exceed the minimum threshold of improvement. Their premise was that orthopedic surgeons do not seek results that meet a minimum threshold but instead seek results that exceed that minimal threshold. Werner et al[26] has described SCB values after shoulder arthroplasty for the American Shoulder and Elbow Surgeons (ASES) Shoulder Assessment score. To date, this is the only study that has examined SCB values for clinical outcome metrics after shoulder arthroplasty, although SCB has also been defined for the Disabilities of the Arm, Shoulder and Hand (DASH) and Pennsylvania Shoulder Score after rehabilitation for shoulder impingement.[12]

The ability to differentiate MCID and SCB metric values after shoulder arthroplasty is useful, because it helps identify the denominator of a cost-to-benefit ratio for the appropriateness of performing a shoulder arthroplasty, aids counseling patients preoperatively, and also helps interpret clinical outcome studies at various follow-up intervals. We previously reported the MCID values for the ASES, Constant, Simple Shoulder Test (SST), Shoulder Pain and Disability Index (SPADI), University of California Los Angeles (UCLA) Shoulder Rating Scale, visual analog scale (VAS), and global shoulder function scores as well as active range of motion after shoulder arthroplasty.[18] The purpose of this study, however, was to determine the SCB values for those same metrics and quantify the effect of prosthesis type, patient age at the time of surgery, sex, and length of follow-up on the SCB for each of the mentioned outcome metrics.

Materials and methods

This retrospective outcome study focused on patients treated with aTSA and rTSA who were enrolled in a multicenter international registry by 13 fellowship-trained shoulder surgeons. There were 2,057 patients who underwent TSA enrolled between February 2001 and February 2015. The inclusion criteria for this study were any aTSA performed for osteoarthritis (OA) or rheumatoid arthritis (RA) or any rTSA performed for cuff tear arthropathy (CTA) or OA with a rotator cuff tear with greater than 2 years of follow-up. Exclusion criteria were all operations performed for fracture or revisions. The application of all inclusion and exclusion criteria yielded a study population of 1856 patients (average age, 69.6 ± 8.8 years), of which 911 were aTSA (488 women, 423 men; average age, 66.5 ± 9.1 years) and 945 were rTSA (610 women, 335 men; average age, 72.5 ± 7.5 years). The average follow-up was 44.9 ± 23.8 months (range, 24-157 months), with an average follow-up of 49.7 ± 27.5 months for aTSA patients and 40.2 ± 18.6 months for rTSA patients.

Each patient was evaluated preoperatively and at the latest follow-up with 7 metrics: ASES, Constant, SST, SPADI, UCLA, VAS pain, and global shoulder function scores. In addition, the procedural surgeon, physical therapist, or research coordinator measured active range of motion (flexion, abduction, external rotation) and strength preoperatively and at the latest follow-up. Substantial effort was made to standardize the method of data collection. A goniometer was used to assess range of motion with the patient standing. The difference between each preoperative and latest follow-up metric score and range of motion measurement was recorded as improvement.

At the latest follow-up, a global anchor question was also asked: each patient rated their shoulder as "worse," "unchanged," "better," or "much better" relative to his or her preoperative condition. We quantified the SCB as the minimum difference in preoperative-to-postoperative outcome that resulted in a patient describing his or her treatment as "much better" compared with "worse" or "unchanged." As a result, patients who responded as being "better" were excluded because their treatment did not meet this minimum threshold for SCB. The mean outcome metrics at the latest follow-up for the unchanged group ("worse" + "unchanged") and the changed group ("much better") were compared with the mean preoperative metrics for each group to quantify the improvement associated with each group for a given metric. The SCB for each metric was then calculated as the difference in mean improvement between groups. Finally, the study cohort was stratified according to 4 different variables: prosthesis type, patient age, sex, and follow-up duration to determine their effect on SCB. To compare the SCB of 5 metric scores with different ranges (ASES, Constant, UCLA, SST, SPADI), those without a 100-point scale