



REVIEW ARTICLE

Outcomes assessment in rotator cuff pathology: what are we measuring?



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Background: Assessments used to measure outcomes associated with rotator cuff pathology and after repair are varied. This lack of standardization leads to difficulty drawing comparisons across studies. We hypothesize that this variability in patient-reported outcome measures and objective metrics used in rotator cuff studies persists even in high-impact, peer reviewed journals.

Methods: All studies assessing rotator cuff tear and repair outcomes in 6 orthopedic journals with a high impact factor from January 2010 to December 2014 were reviewed. Cadaveric and animal studies and those without outcomes were excluded. Outcome measures included range of motion (forward elevation, abduction, external rotation, and internal rotation), strength (in the same 4 planes), tendon integrity imaging, patient satisfaction, and functional assessment scores.

Results: Of the 156 included studies, 63% documented range of motion measurements, with 18% reporting range of motion in all 4 planes. Only 38% of studies reported quantitative strength measurements. In 65% of studies, tendon integrity was documented with imaging (38% magnetic resonance imaging/magnetic resonance arthrogram, 31% ultrasound, and 8% computed tomography arthrogram). Finally, functional score reporting varied significantly, with the 5 most frequently reported scores ranging from 16% to 61% in studies, and 15 of the least reported outcomes were each reported in $\leq 6\%$ of studies.

Conclusions: Significant variability exists in outcomes reporting after rotator cuff tear and repair, making comparisons between clinical studies difficult. Creating a uniformly accepted, validated outcomes tool that assesses pain, function, patient satisfaction, and anatomic integrity would enable consistent outcomes assessment after operative and nonoperative management and allow comparisons across the literature.

Level of Evidence: Level IV, Systematic Review.

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Keywords: Rotator cuff tear; outcomes; rotator cuff repair; patient-reported outcomes

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During the past several years, patient-reported outcomes (PRO) have become increasingly important in orthopedic management and literature, such that multiple different outcomes are routinely reported in patient encounters and clinical studies. This increased use, however, causes challenges due to

the variable nature of administration²⁶ and reporting of these outcomes tools. In addition, there is a lack of consensus when considering the collection and reporting of conventional metrics such as range of motion, strength, and imaging findings. This lack of standardization creates challenges when attempting to compare results across multiple studies.

The goal of this study was to quantify the variability in outcomes reporting of a common orthopedic condition—rotator cuff tear—across articles published in high-impact orthopedic journals. We hypothesize that there will be significant variability across the types of metric reported (ie, range of motion, strength, imaging, functional scores, and satisfaction) as well as across individual metrics (ie, among the available validated outcomes scores). Understanding this variability is crucial in taking the first steps toward standardizing reporting of outcomes for patients with any given disease.

Materials and methods

A comprehensive literature review was performed across 6 orthopedic journals with high impact factors during a 5-year period (January 2010 through December 2014) to identify all literature pertaining to clinical trials of rotator cuff pathology and repair. These journals were intentionally chosen to extract the highest quality studies from publications that include literature on shoulder surgery.^{1,3,4,6,16,17} The journals selected were *Journal of Shoulder and Elbow Surgery*, *The Journal of Bone & Joint Surgery (American volume)*, *The Journal of Bone & Joint Surgery (British volume)/The Bone & Joint Journal*, *Clinical Orthopaedics and Related Research*, *The American Journal of Sports Medicine*, and *Arthroscopy*. All articles with keywords of “rotator cuff,” “rotator cuff tear,” and “rotator cuff repair” were selected for review. This methodology has been used previously^{12,21} in similar studies.

Inclusionary criteria consisted of any study reporting clinical outcomes for patients with any type of rotator cuff pathology at baseline or after a nonoperative or operative intervention. Exclusionary criteria included any study that predominately focused on screening or diagnostic outcomes, such as studies documenting imaging findings without any clinical correlations, cadaveric, animal, or basic science studies, and review articles/meta-analyses, case reports, and registry studies.

For each study that met final inclusionary criteria, several metrics were collected. These included country of origin (corresponding to the origin of the senior author), level of evidence, number of patients, mean patient age, predominate size of the tear (partial, small, or medium vs large or massive vs not specified or all inclusive), and outcomes assessed. Outcomes were grouped into 5 categories: range of motion, quantitative strength testing, imaging assessing tendon integrity or healing, patient satisfaction, and PRO scores. When appropriate (eg, comparison of number of PRO used across journal types), analysis of variance testing was used to analyze continuous data.

Range of motion

Range of motion outcomes for each study were reported in any of the following planes: forward elevation/flexion, abduction, external rotation (at the side or in abduction), and internal rotation (at the side

or in abduction). Range of motion noted in any of these planes was recorded (ie, a study did not need to report motion in all of these planes), and was only documented as being reported in a given study if it was clearly included or referenced in the results section. This includes reporting of actual values for given range of motion parameters or conclusions based on relative values (eg, with regards to change in value preoperatively and postoperatively). Reporting of patient position (eg, supine, standing) and the measuring tool (eg, goniometer) was varied, and only quantitative values of range of motion were considered valid for reporting.

Strength

Strength was documented as being reported in a given study if a quantitative measurement of strength was performed and reported. The following planes of strength measurement were considered: forward elevation/flexion, abduction, external rotation, and internal rotation. Strength noted in any of these planes was recorded (ie, a study did not need to report strength in all of these planes). Any reporting of “supraspinatus” strength was defined as being measured in abduction. For this study, only quantitative strength measurements, such as those obtained with the use of a dynamometer, were considered. Testing through manual muscle testing, which usually was on a 0 to 5 rating system, was not included because it was not a quantitative outcome measurement. Strength that was reported as a subset of a functional score (eg, Constant score) was included for the appropriate plane of motion, provided it was a quantitative measurement.

Imaging for tendon integrity

Imaging for the purpose of assessing tendon integrity was noted for each study. This included any use of imaging to assess the status of tendon repair or incidence of repeat tear after an intervention. Baseline radiography was not considered. Moreover, only methodologic use of follow-up imaging was considered, as opposed to its use in only a subset of study patients such as those with complications. These modalities included ultrasound, computed tomography with contrast, or magnetic resonance imaging (MRI)/magnetic resonance arthrogram (MRA) (with or without contrast).

Patient satisfaction

Any reporting of patient satisfaction was noted. This included questions related to satisfaction of treatment, willingness to recommend a surgery or treatment to another person, or whether the patient would undergo the treatment if offered it again. Any study that specifically documented patient satisfaction in any of these parameters was noted. Satisfaction that was reported as a subset of a validated patient-reported outcome measure, such as the University of California, Los Angeles (UCLA) Shoulder Rating Scale, was not included in this calculation because these measures are reported elsewhere.

Clinician and Patient Derived Outcomes

All validated outcomes—both clinician-derived and patient-derived—were documented (complete listing in [Table I](#)). With regards to validated functional outcomes, any reporting of the

Table I Reported outcomes measures

Objective metrics	Imaging/diagnostic	Outcome tools
Range of motion (deg)	X-ray	American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) Simple Shoulder Test (SST)
Forward elevation	Progression of glenohumeral arthritis	Constant score
Abduction	Acromiohumeral interval	Adjusted Constant score
External rotation	Joint kinematics	University of California, Los Angeles (UCLA) Shoulder Score
Internal rotation	CT scan	Western Ontario Rotator Cuff Index (WORC)
Impingement signs	Tendon integrity assessment	Disabilities of the Arm, Shoulder, and Hand Score (DASH)
Strength (quantitative; kg/lb)	Ultrasound	Short Form Health Survey (SF)
Forward elevation	MRI/MRA	Penn Shoulder Score
Abduction	CTA	Rotator Cuff Quality of Life (RC-QoL)
External rotation	Electromyelogram	L'Insalata Shoulder Questionnaire/Shoulder Rating Questionnaire (SRQ)
Internal rotation		Single Assessment Numeric Evaluation (SANE)/Subjective Shoulder Value (SSV)
		Shoulder Pain and Disability Index (SPADI)
		Japanese Orthopaedic Association Shoulder Score (JOA)
		Korean Shoulder Score (KSS)
		EuroQoL (EQ-5D)
		Shoulder Activity Scale
		Marks Activity Scale
		Rowe
		Visual analog scale
		Pain
		Function
		Satisfaction
		Return to activities of daily living
		Return to work
		Return to activity/sports

CT, computed tomography; CTA, computed tomography arthrogram; MRA, magnetic resonance arthrogram; MRI, magnetic resonance imaging.

outcome, whether an aggregate score or a subscore only, was noted. Pain scores were noted if reported after administration of a visual analog scale (VAS) only (as opposed to scaled scores from any of the validated PROs). Additional outcomes reported included that of patient satisfaction, return to activities of daily living (ADL), return to work, and return to activity/sports. Finally, any reporting of age-matched or sex-matched Constant scores was also recorded.

All studies were screened for inclusion by the principal investigator (E.C.M.), who was a chief resident in orthopedic surgery at the time of data collection. All studies were then reviewed by 2 different investigators (E.C.M, M.E.S.), with any discrepancy of reporting resolved through mutual agreement.

Results

Study inclusion

A total of 156 studies were included from the literature review regarding rotator cuff tears from the 5 study journals during a 5-year period (January 2010 through December 2014). Included were 44 references from *The American Journal of Sports Medicine*, 39 from the *Journal of*

Shoulder and Elbow Surgery, 31 from *Arthroscopy*, 24 from *The Journal of Bone & Joint Surgery (American volume)*, 11 from *Clinical Orthopaedics and Related Research*, and 7 from *The Journal of Bone & Joint Surgery (British volume)/The Bone & Joint Journal* (Table II). The average number of shoulders in each study was 83 (range, 8-400), with an average age of 60.2 years. Of the 144 studies in which a level of evidence was designated, there were 19 Level I studies (13%), 25 Level II studies (17%), 38 Level III studies (26%), and 62 Level IV studies (43%).

Range of motion

Forward elevation was reported in 63% (99 of 156) of all studies, compared with 30% (47 of 156) of studies for abduction, 53% (82 of 156) for external rotation, and 35% (54 of 156) for internal rotation. When considering number of parameters reported, 37% (57 of 156) of all studies failed to report any range of motion parameters, 6% (9 of 156) reported 1 measurement, 16% (25 of 156) reported two measurements, 24% (37 of 156) reported 3 measurements, and 18% (28 of 156) reported 4 measurements.

Table II Impact factor and included references by journal

Journal	2014 impact factor	Included references (No.)
<i>Journal of Shoulder and Elbow Surgery</i>	2.289	39
<i>The Journal of Bone & Joint Surgery, American volume</i>	5.280	24
<i>The American Journal of Sports Medicine</i>	4.362	44
<i>Arthroscopy</i>	3.206	31
<i>The Journal of Bone & Joint Surgery, British volume/The Bone & Joint Journal</i>	2.801	7
<i>Clinical Orthopaedics and Related Research</i>	2.765	11

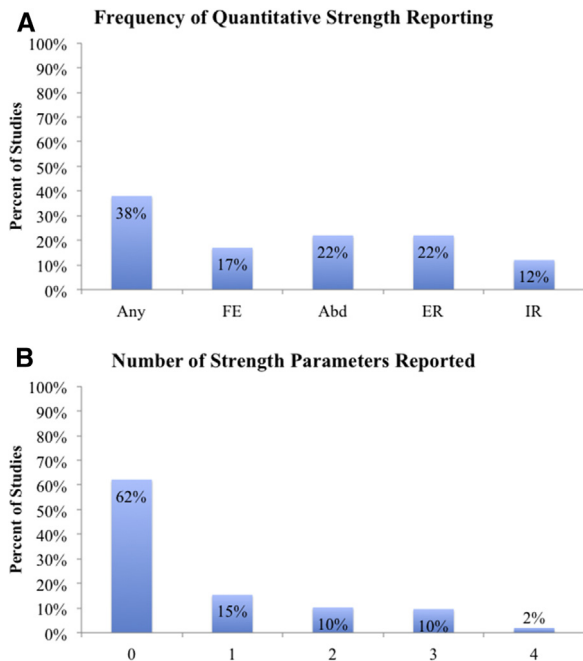


Figure 1 (A) Quantitative strength outcomes were reported in 38% of all studies. (B) Only 2% of studies reported strength in all planes of motion. *Abd*, abduction; *ER*, external rotation; *FE*, forward elevation; *IR*, internal rotation.

Strength

Of the 156 studies, only 59 studies (38%) reported any quantitative strength measurement, and 27 (17%) reported forward elevation strength compared with 34 (22%) for abduction, 34 (22%) for external rotation, and 18 (12%) for internal rotation (Fig. 1, A). With regard to number of parameters reported, 24 studies (15%) reported 1 measurement, 16 (10%) reported 2, 15 (10%) reported 3, and 3 (2%) reported measurements in all 4 planes of motion (Fig. 1, B).

Imaging of tendon integrity

This outcome measure was used in 65% (101 of 156) of studies (Fig. 2). When considering individual imaging modalities, ultrasound was used in 31% (49 of 156) of

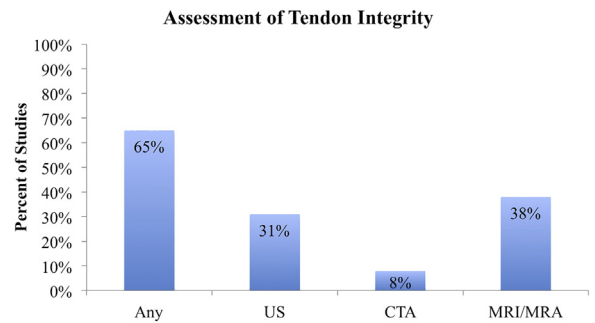


Figure 2 Among the 65% of studies that used advanced imaging to report tendon integrity, the most commonly used means were ultrasound (*US*) and magnetic resonance imaging (*MRI*). *CTA*, computed tomography arthrogram.

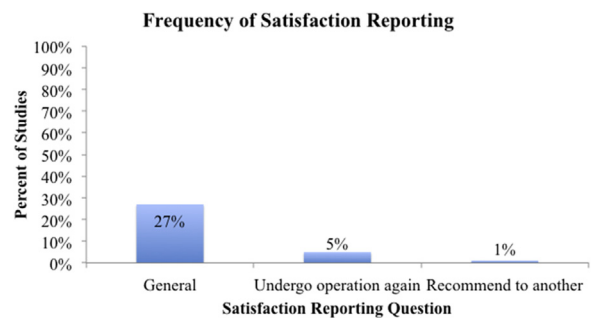


Figure 3 Among the 27% of studies that reported patient satisfaction scores, the most commonly reported response was a general question of satisfaction.

studies, whereas computed tomography arthrogram (*CTA*) was used in 8% (13 of 156) and *MRI/MRA* in 38% (60 of 156) of studies.

Patient satisfaction

Among the 156 included studies, 42 (27%) specifically documented patient satisfaction scores (Fig. 3) and 42 (27%) reported a response to a general question of patient satisfaction. Eight studies (5%) reported whether the patient would undergo the surgery if given the chance again, and 2 (1%) reported whether the patient would recommend this surgery to another patient.

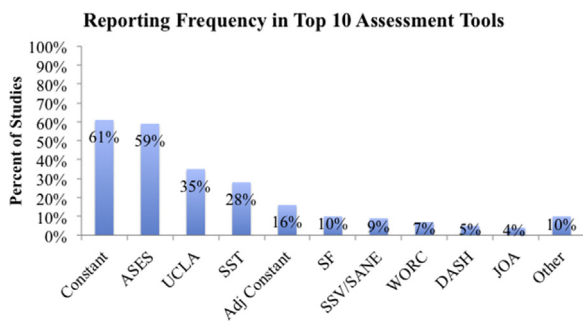


Figure 4 Among patient-reported outcomes, the most frequently reported outcomes were the Constant (61%), American Shoulder and Elbow Surgeons (ASES; 59%), University of California, Los Angeles Shoulder Rating Scale (UCLA; 35%), and the Simple Shoulder Test (SST; 28%) scores. The more esoteric outcomes (Penn, L'Insalata/Shoulder Rating Questionnaire, Shoulder Pain and Disability Index, Rotator Cuff-Quality of Life, EuroQol-5D, Shoulder Activity Scale, Marks Activity Scale, Korean Shoulder Score, and Rowe) were reported in 10% of studies, combined. DASH, Disabilities of the Arm, Shoulder and Hand; JOA, Japanese Orthopaedic Association Shoulder Score; SANE, Single Assessment Numeric Evaluation; SF, Short Form Health Survey; SSV, Subjective Shoulder Value; WORC, Western Ontario Rotator Cuff Index.

Validated outcomes assessments

Each study was assessed for inclusion of functional outcomes scores with respect to frequency of reporting from Table I. The 10 most frequently used scores are reported in Figure 4. Of the validated functional outcomes, the Constant score was used most often, reported in 61% (95 of 156) of all studies. The American Shoulder and Elbow Surgeons (ASES) score was the second-most used validated outcomes assessment, reported in 59% (92 of 156) of all studies. The adjusted Constant score (for age or gender, or both) was only explicitly reported in 16% of all studies. The third-most used validated outcome (the UCLA Shoulder Rating Scale) was used in less than 40% of all studies.

Several validated functional outcomes appeared in less than 4% of all studies ("Other" in Fig. 4). These included the Penn Shoulder Score, L'Insalata/Shoulder Rating Questionnaire, Shoulder Pain and Disability Index, Rotator Cuff-Quality of Life, EuroQol-5D, Shoulder Activity Scale, Marks Activity Scale, Korean Shoulder Score, and Rowe, which were reported in 10% of studies, combined.

Comprehensive reporting frequency

In addition to reporting of frequency of use of individual metrics (range of motion, strength, tendon imaging, and functional scores), each study was assessed for comprehensiveness of reporting of these outcomes (Fig. 5). Only 21% (32 of 156) of all studies reported at least 1 outcome

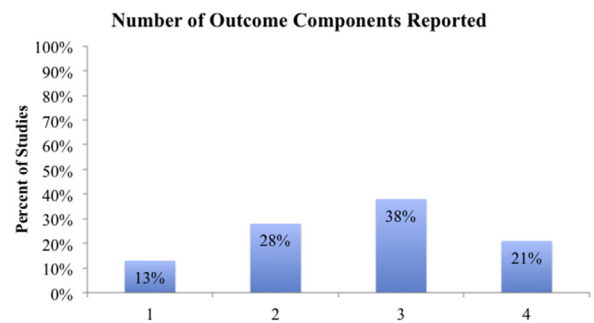


Figure 5 Only 21% of studies reported outcomes involving each of range of motion, strength, imaging for tendon integrity, and patient-reported outcomes.

Table III Patient-reported outcomes by journal

Journal	Studies (No.)	Mean PROs* (No.)	Standard deviation
AJSM	44	2.66	1.18
JSES	39	2.21	1.10
Arthroscopy	31	2.45	1.06
JBJS (Am)	24	2.19	0.75
CORR	11	1.55	0.69
BJJ/JBJS (Br)	7	1.29	0.95

AJSM, *The American Journal of Sports Medicine*; BJJ/JBJS (Br), *The Journal of Bone & Joint Surgery, British volume/The Bone & Joint Journal*; CORR, *Clinical Orthopaedics and Related Research*; JBJS (Am), *The Journal of Bone & Joint Surgery, American volume*; JSES, *Journal of Shoulder and Elbow Surgery*; PRO, patient-reported outcomes.

* The average number of PROs reported per study was 1.29 to 2.66, with a statistically significant difference across this range ($P = .003$).

from each of these 4 categories. Thirty-eight percent (60 of 156) of studies reported 3 different metrics, 28% (43 of 156) reported 2 different metrics, and 13% (21 of 156) reported only 1 type of metric.

Finally, a comparison across journals with respect to average number of PROs used per study was also performed (Table III). The average number of PROs used per study ranged from 1.29 to 2.66, and there was a statistically significant difference in reporting frequency across this range ($P = .003$).

Discussion

The results from this study indicate that even in high-impact orthopedic journals, reporting of outcomes after rotator cuff tear are highly variable. Such variability diminishes the comparative strength of these studies, enabling only assessment of relative changes within individual studies but without the ability to compare outcomes across different studies.

We documented low reporting adherence for objective measures among the studies included in this review. Of the literature reviewed, 63% reported range of motion measurements, 38% documented quantitative strength measurements, and 65% noted tendon integrity. Although outcomes measured objectively should allow cross-study comparisons, such low rates of reporting make these evaluations difficult. Nevertheless, focusing on these objective metrics may be misguided because they might not capture functional changes experienced by patients postoperatively. A study by Roddey et al²⁴ analyzed the relationship between objective measures of strength and mobility and self-reported outcomes scores. They found that such objective, or “impairment,” outcomes do not correlate with patient self-reported function. Other studies have corroborated these findings, indicating that changes in objective metrics do not reliably explain variations in functional outcomes.^{10,13,22}

During the past several years, there has been an increasing emphasis on the importance of using PROs²⁵ as tools in assessing the health of patients. Within shoulder surgery, and specifically rotator cuff disease, a number of these metrics have been proposed as a way to measure the true outcomes in patients after an intervention. Some of these scores are specific to shoulder function (ASES,²³ Constant,^{7,8} UCLA²) and upper extremity function (Disabilities of Arm, Shoulder, and Hand¹⁵), whereas others are specific to rotator cuff pathology (Western Ontario Rotator Cuff Index,²⁰ Rotator Cuff-Quality of Life¹⁴). However, many of these tools have not been properly validated and have instead simply been used because of historical merit.²⁶

Evidence suggests that no single tool may be adequately indicative of patient function and satisfaction after rotator cuff repair.¹⁸ In fact, patient satisfaction may need to be assessed outside of these validated outcomes. In our investigation, 27% of studies reported patient satisfaction without using validated outcomes scores. Therefore, incorporation of this metric should be considered for any comprehensive validated outcome tool. In addition, some instruments incorporate scores that include both patient-reported and clinician-reported components, leading to possible bias and subjectivity of responses.²⁶ There is further evidence that suggests outcomes tools are appropriately used only 64% of the time in shoulder literature.²⁵ Finally, it is important to note that many of these instruments were created by clinicians and therefore may not have had significant input from patients in their creation. Further research is needed in determining the outcomes and metrics that are truly important to patients with rotator cuff tears.

Harvie et al¹² recently performed a literature review of shoulder surgery to identify the various outcomes measures reported. The study team reported 44 different outcome scores spanning all types of shoulder literature. These studies were recruited from a series of 3 high-impact orthopedic journals over a 10-year period. Similarly, a

study by Gartsman et al¹¹ investigated clinical shoulder research published in *The Journal of Bone & Joint Surgery* during the period 2004 to 2014 and found 39 different validated and nonvalidated outcomes tools. Although these investigators report substantial variability in outcomes reporting, their inclusion of shoulder studies in general, as opposed to focusing on a specific diagnosis, makes it difficult to draw substantive conclusions.

Outcomes variability across a range of pathologies (ie, instability, arthritis, and rotator cuff pathologies) is expected, and the reader is therefore uncertain whether the variability reported by Harvie et al¹² and Gartsman et al¹¹ is due to true inconsistencies or simply a result of the inclusion of heterogeneous pathologies. Because many shoulder scores are disease-specific,²⁶ it is important to analyze reporting variability within the confines of a single diagnosis. While using similar inclusionary criteria with respect to types of journals surveyed, we focused on the rotator cuff literature to minimize such variability and reported fewer than 30 scores. Despite the variability of inclusionary criteria, both studies report similar rates of use of range of motion and pain scores.

In an important recent study by Schmidt et al,²⁵ the study team critically assessed 11 different PROs in shoulder surgery and rated each according to the Evaluating Measures of Patient Reported Outcomes (EMPRO) tool. The authors determined that the ASES, Simple Shoulder Test (SST), and Oxford Shoulder Score were the highest rated with respect to validity, reliability, responsiveness, and administrative burden. Despite these high ratings, the results from our study indicate that these measures are not routinely used in studies of rotator cuff tears. In our study, ASES was used in only 59% of studies, the SST was used in 28%, and none of the 156 studies documented use of the Oxford score. Similarly, Gartsman et al¹¹ showed low rates of use of these highest rated outcomes scores, with 31.7% reporting ASES, 18.6% using SST, and 1.2% documenting an Oxford score.¹¹ These low frequencies of the highest rated shoulder scores indicate that not only are we, as a specialty, missing an opportunity to use high-performing outcomes scores but that we are also expending significant energy in reporting suboptimal outcomes scores. Finally, given the importance of documenting patient satisfaction scores, we also recommend consideration of such use (through a formal Single Assessment Numeric Evaluation assessment or other VAS type) for patient encounters and research purposes.

One additional interesting finding in our study was the relative lack of use of age-matched or gender-matched Constant scores. We documented use of the Constant score in 61% (95 of 156) of studies. However, a specifically referenced adjusted Constant score¹⁹ was only used in 16% (25 of 156) of studies. This adjusted score more accurately represents the function of the shoulder with respect to variation in age and gender. Therefore, most of the reporting of Constant scores may be considered invalid.⁵ It

is important that future studies in rotator cuff pathology consider reporting the adjusted Constant score to improve reporting quality.

We note that many studies report multiple patient-reported outcomes measures. For a single disease state, whether multiple tools provide additional or unique information is unclear. Patients may place differing importance on variable outcome parameters such as pain, function, strength, and return to sport. In some cases, the use of multiple scores may be required to address these differing aspects of patient outcomes. However, the addition of multiple PROs results in significant survey burden and may lead to decreasing compliance. Recognizing this challenge, a study by Cook et al⁹ attempted to develop an adaptive strategy that solved this problem. The resulting Flexilevel Scale of Shoulder Function adaptive scale minimized the burden by identifying appropriate items for patients with varying levels of functionality while showing excellent reliability. In the future, adopting this approach to consolidate the most important scores into an adaptive test with generalizability would be useful, enabling outcomes comparisons across a wide range of shoulder disabilities.

Our study does have limitations. Because this was a literature search based on specific keywords, there is a possibility of inadvertent study exclusion if the title did not explicitly mention the designated keywords. However, given that more than 150 studies were extracted across 6 different journals, there is likely wide enough breadth in study inclusion to validate the findings. In addition, tight requirements for inclusion of outcome reporting, such as inclusion of only strength testing via quantitative means with a dynamometer, caused exclusion of studies that relied on manual muscle testing. These inclusion criteria were used to identify the outcomes with the highest likelihood of reproducibility because such outcomes may be most readily compared across researchers and reviewers of the literature.

Finally, all data collection in this study was guided by the clarity of reporting in the individual studies assessed. Therefore, studies with ambiguous data reporting would consequently pose challenges in data entry for purposes of this study. For example, an age-matched or gender-matched Constant score that was collected but not clearly reported was documented as absent according to the methodology of this study. However, a full-text review was conducted for each manuscript assessed, thereby limiting possible data omission due to selective reporting in the abstract or remainder of the text.

Conclusions

Clinical literature regarding rotator cuff tears displays significant variability in the types and nature of outcomes reporting, despite being published in high-impact orthopedic journals. Future efforts to consolidate and

standardize outcomes reporting in rotator cuff tear would facilitate cross-study outcomes comparisons for the treatments and populations of interest.

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