Clinical Sports Medicine Update

The Responsiveness of Patient-Reported Outcome Tools in Shoulder Surgery Is Dependent on the Underlying Pathological Condition

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Background: Given the high number of available patient-reported outcome (PRO) tools for patients undergoing shoulder surgery, comparative information is necessary to determine the most relevant forms to incorporate into clinical practice.

Purpose: To determine the utilization and responsiveness of common PRO tools in studies involving patients undergoing arthroscopic rotator cuff repair or operative management of glenohumeral instability.

Study Design: Systematic review.

Methods: A systematic review of rotator cuff and instability studies from multiple databases was performed according to PRISMA guidelines. Means and SDs of each PRO tool utilized, study sample sizes, and follow-up durations were collected. The responsiveness of each PRO tool compared with other PRO tools was determined by calculating the effect size and relative efficiency (RE).

Results: After a full-text review of 238 rotator cuff articles and 110 instability articles, 81 studies and 29 studies met the criteria for final inclusion, respectively. In the rotator cuff studies, 25 different PRO tools were utilized. The most commonly utilized PRO tools were the Constant (50 studies), visual analog scale (VAS) for pain (44 studies), American Shoulder and Elbow Surgeons (ASES; 39 studies), University of California, Los Angeles (UCLA; 20 studies), and Disabilities of the Arm, Shoulder and Hand (DASH; 13 studies) scores. The ASES score was found to be more responsive than all scores including the Constant (RE, 1.94), VAS for pain (RE, 1.54), UCLA (RE, 1.46), and DASH (RE, 1.35) scores. In the instability studies, 16 different PRO tools were utilized. The most commonly used PRO tools were the ASES (13 studies), Rowe (10 studies), Western Ontario Shoulder Instability Index (WOSI; 8 studies), VAS for pain (7 studies), UCLA (7 studies), and Constant (6 studies) scores. The Rowe score was much more responsive than both the ASES (RE, 22.84) and the Constant (RE, 33.17) scores; however, the ASES score remained more responsive than the Constant (RE, 1.93), VAS for pain (RE, 1.75), and WOSI (RE, 0.97) scores.

Conclusion: Despite being frequently used in the research community, the Constant score may be less clinically useful as it was less responsive. Additionally, it is a greater burden on the provider because it requires objective strength and range of motion data to be gathered by the clinician. In contrast, the ASES score was highly responsive after rotator cuff repair and requires only subjective patient input. Furthermore, separate PRO scoring methods appear to be necessary for patients undergoing rotator cuff repair and surgery for instability as the instability-specific Rowe score was much more responsive than the ASES score.

Keywords: patient-reported outcomes; shoulder; instability; rotator cuff repair

Patient-reported outcome (PRO) tools are increasingly used in orthopaedics as instruments to objectively assess patients' perception of their improvement after surgery and responsiveness to treatment. Prior studies have assessed the utilization and psychometric properties of various PRO tools after rotator cuff repair and operative correction of shoulder instability.[10,16] While information has been aggregated for the available PRO tools, little is known about the comparative responsiveness between different tools and whether responsiveness for a given PRO tool varies based on the underlying pathological condition.

The responsiveness of a PRO tool reflects the ability of the instrument to accurately detect change over time.[6] Responsiveness has been suggested to be one of the most important measurement properties of a PRO tool[2] and also allows for direct head-to-head comparisons between the performance of multiple PRO tools when utilized within the same patient population(s).[6,19] As public

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outcome reporting and pay-for-performance measures become more and more likely, comparative data are crucial in knowing which PRO tools to use in practice. Therefore, understanding the responsiveness of common PRO tools as well as the correlation with the underlying pathological condition will help the incorporation of these tools into clinical practice. Thus, the purpose of this systematic review was to evaluate the utilization and responsiveness of PRO tools after either arthroscopic rotator cuff repair or operative management of glenohumeral instability.

METHODS

A search was performed of the PubMed, SportDiscus, Cochrane, and CINAHL databases according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[15] Inclusion criteria included human studies that directly assessed PROs of the surgical repair of rotator cuff tears or shoulder instability between the dates of April 18, 2006, and April 17, 2016. Review articles and case studies were excluded, as were studies that were not available in English or did not include a full-text article such as an abstract or poster. The specific PRO tools utilized, number of patients, mean follow-up time, and preoperative and postoperative means and SDs were recorded for each article, when available.

A subanalysis was performed for those studies that utilized multiple PRO tools within the same study population to directly compare the responsiveness of different PRO tools in a "head-to-head" fashion. To do so, only articles that employed $\geq$2 PRO tools, both before surgery and at a minimum 1 year after surgery, were included. Also, the calculations required that both means and SDs be reported at both the preoperative and postoperative time points, and we excluded from our responsiveness analysis any articles that did not meet these criteria.

To directly compare responsiveness between PRO tools, the effect size and relative efficiency (RE) were calculated to establish the responsiveness of each PRO tool.[13,14,19] The effect size, which is a measure of the magnitude of the preoperative to postoperative change in relation to the amount of variability in the scores, was calculated by dividing the mean change score for each PRO tool by the SD of the preoperative score for that PRO tool. Effect sizes (d) between 0.20 and 0.49 are considered small, between 0.50 and 0.79 are considered moderate, and $\geq$0.80 are considered large,[3,8] and we calculated the preoperative to postoperative effect size for each PRO tool individually. To compare the responsiveness between 2 different PRO tools, the RE was calculated from articles that utilized more than 1 PRO tool within the same patient population. The RE was derived from the resultant t score as provided by paired t tests, which compared the preoperative score for a PRO tool with the postoperative score. The RE was calculated by dividing the t score for one PRO tool by the t score of another PRO tool and then squaring the resultant value.[14,19] If a given PRO tool had an RE value <1 when being directly compared with a second PRO tool administered to the same patient population, the first PRO tool would be considered to be "less responsive" than its comparator. Conversely, if a PRO tool had an RE value >1 when compared with a different PRO tool, it would be considered "more responsive" than its comparator.[14,19]

To determine if the responsiveness of the different PRO tools varies based on the underlying pathological condition, calculations were made of the effect size and RE of the different PRO tools used before and after rotator cuff repair; separately compared were the effect size and RE of the different PRO tools in articles that assessed preoperative to postoperative changes after surgical correction of shoulder instability.

RESULTS

Rotator Cuff Repair

Overall, 25 different PRO tools were utilized in the 81 articles that met the inclusion criteria (Figure 1). Multiple PRO tools were used in 61 of 81 studies. The most commonly used PRO tools were the Constant-Murley (n = 50 studies, 82.0%), visual analog scale (VAS) for pain (n = 44, 72.1%), American Shoulder and Elbow Surgeons (ASES; n = 39, 63.9%), University of California, Los Angeles (UCLA; n = 20, 32.8%), Simple Shoulder Test (SST; n = 16, 26.2%), Disabilities of the Arm, Shoulder and Hand (DASH; n = 13, 21.3%), and Western Ontario Rotator Cuff Index (WORC; n = 5, 8.2%). There were a number of other PRO tools used, but those had appeared in fewer than 5 studies. The effect size and responsiveness of the most common PRO tools were evaluated with a subset of 28 articles that reported means and SDs both preoperatively and at a minimum of 1 year postoperatively (Table 1). While large effect sizes were demonstrated by all the commonly used PRO tools, the ASES and WORC scores appeared to be the most responsive, whereas the Constant and DASH scores were the least responsive of the shoulder-specific tools (Table 2). The single-question VAS for pain score was less responsive than the ASES and SST scores but was actually more responsive than both the UCLA and Constant scores.

Shoulder Instability

After a full-text review of 110 instability articles, 29 studies met the criteria for final inclusion (Figure 2).

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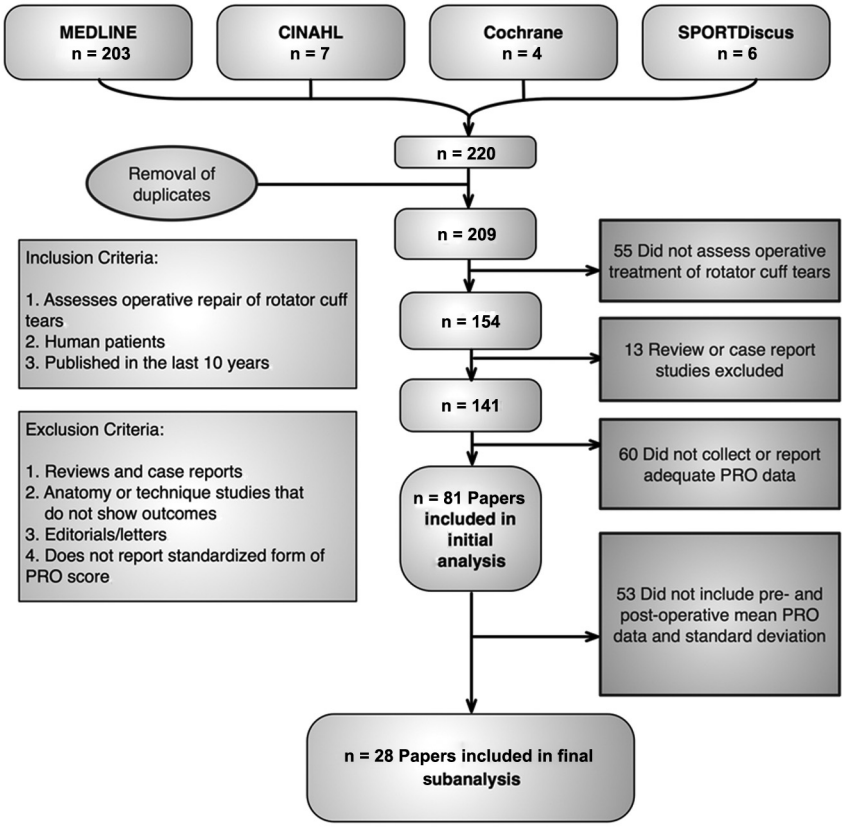

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) article selection flow diagram for rotator cuff studies. Article selection flowchart as recommended by PRISMA guidelines.[15] PRO, patient-reported outcome.

TABLE 1
Pooled Preoperative and Postoperative Scores and Effect Sizes for the Most Frequently Used PRO Tools After Rotator Cuff Repair[a]

PRO Tool	No. of Studies	No. of Patients	Mean Preoperative Score	Mean Postoperative Score	Effect Size (*d*)
Constant-Murley	24	1730	51.5	84.9	1.9
ASES	19	1245	47.6	88.7	2.5
VAS for pain	15	1070	5.5	1.3	1.9
UCLA	10	678	16.1	29.2	2.5
SST	6	400	4.7	10.4	2.2
DASH	6	395	50.2	19.0	1.5
WORC	2	103	42.4	81.3	2.1

[a]ASES, American Shoulder and Elbow Surgeons; DASH, Disabilities of the Arm, Shoulder and Hand; PRO, patient-reported outcome; SST, Simple Shoulder Test; UCLA, University of California, Los Angeles; VAS, visual analog scale; WORC, Western Ontario Rotator Cuff Index.

Sixteen different PRO tools were reported in various combinations in the included studies. The majority of studies (72.4%) utilized more than 1 PRO tool. The most commonly used PRO tools were the ASES (n = 13 studies, 44.8%), Rowe (n = 10, 34.5%), Western Ontario Shoulder Instability Index (WOSI; n = 8, 27.6%), VAS for pain (n = 7, 24.1%), UCLA (n = 7, 24.1%), and Constant-Murley (n = 6, 20.7%) scores. The remaining PRO tools appeared in $\leq$3 studies. The responsiveness of the different PRO tools was assessed in articles that included complete data of the sample size, preoperative and postoperative means, and preoperative and postoperative SDs (Table 3). The Rowe score was much more responsive than both the ASES (RE, 22.84) and Constant (RE, 33.17) scores. On the contrary, the VAS for pain score was the least responsive, with an RE of 0.57 when compared with the ASES score and an RE of 0.32 when compared with the WOSI score (Table 4). The ASES score remained more responsive than

TABLE 2
Relative Efficiency (ie, Comparative Responsiveness) Results
Between the Most Commonly Used PRO Tools After Rotator Cuff Repair[a]

	Constant	ASES	VAS for Pain	UCLA	SST	DASH	WORC
Constant		0.52	0.72	1.06	0.68	0.91	—
ASES	1.94		1.54	1.46	1.22	1.35	0.83
VAS for pain	1.40	0.65		1.35	0.83	—	—
UCLA	0.94	0.68	0.74		0.81	2.31	—
SST	1.47	0.82	1.67	1.24		1.21	—
DASH	1.10	0.74	—	0.43	0.83		—
WORC	—	1.21	—	—	—	—	

[a]Values <1 suggest that the PRO tool in the left column is less responsive than the corresponding PRO tool in the top row. Conversely, values >1 suggest that the PRO tool in the left column is more responsive than the corresponding PRO tool in the top row. A dash indicates that no studies were available to compare the 2 PRO tools. ASES, American Shoulder and Elbow Surgeons; DASH, Disabilities of the Arm, Shoulder and Hand; PRO, patient-reported outcome; SST, Simple Shoulder Test; UCLA, University of California, Los Angeles; VAS, visual analog scale; WORC, Western Ontario Rotator Cuff Index.

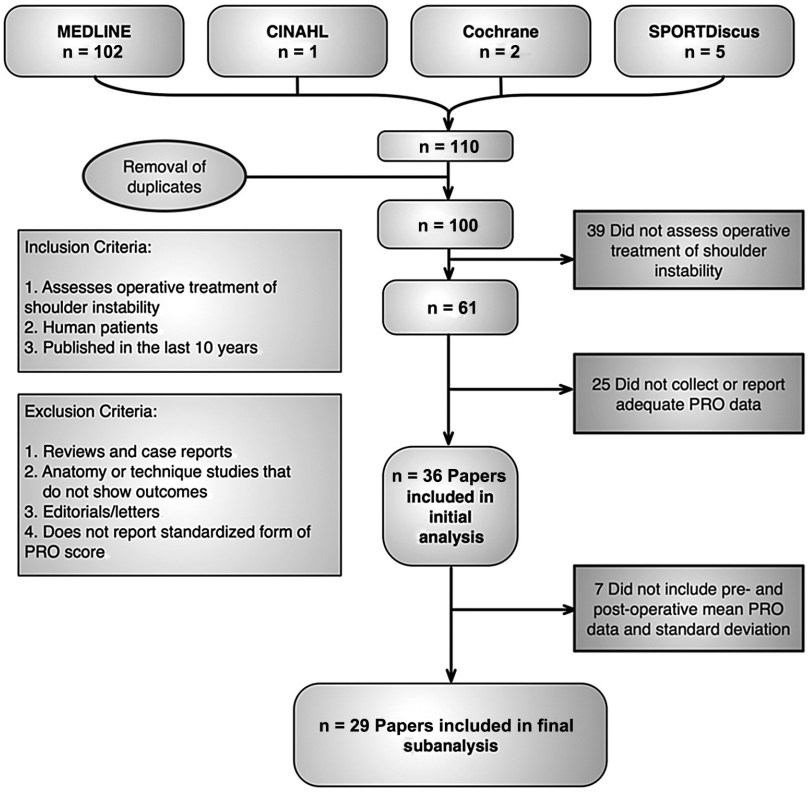

Figure 2. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) article selection flow diagram for shoulder instability studies. Article selection flowchart as recommended by PRISMA guidelines.[15] PRO, patient-reported outcome.

the Constant (RE, 1.93), VAS for pain (RE, 1.75), and WOSI (RE, 0.97) scores.

DISCUSSION

The data from this study demonstrate that the responsiveness of PRO tools in shoulder surgery is dependent on the underlying pathological condition. Specifically, the ASES score was more responsive for patients undergoing rotator cuff repair, and the Rowe score was the most responsive for the instability population. Consistent with the prior literature, we found that there is significant variability among utilized and reported PRO tools, and the most commonly utilized PRO tools were not necessarily the most responsive.

TABLE 3
Pooled Preoperative and Postoperative Scores and Effect Sizes
for the Most Frequently Used PRO Tools After Surgical Correction of Shoulder Instability[a]

PRO Tool	No. of Studies	No. of Patients	Mean Preoperative Score	Mean Postoperative Score	Effect Size (*d*)
ASES	4	169	67.3	91.5	1.1
VAS for pain	3	115	5.5	2.0	1.1
Constant-Murley	2	104	80.5	90.5	0.6
WOSI	2	87	43.0	78.9	1.6
Rowe	1	50	41.1	91.4	9.7

[a]ASES, American Shoulder and Elbow Surgeons; PRO, patient-reported outcome; VAS, visual analog scale; WOSI, Western Ontario Shoulder Instability Index.

TABLE 4
Relative Efficiency (ie, Comparative Responsiveness) Results
Between the Most Commonly Used PRO Tools After Surgical Correction of Shoulder Instability[a]

	ASES	VAS for Pain	Constant	WOSI	Rowe
ASES		1.75	1.93	0.97	0.04
VAS for pain	0.57		—	0.32	—
Constant	0.52	—		1.19	0.03
WOSI	1.03	3.09	0.84		—
Rowe	22.84	—	33.17	—	

[a]Values <1 suggest that the PRO tool in the left column is less responsive than the corresponding PRO tool in the top row. Conversely, values >1 suggest that the PRO tool in the left column is more responsive than the corresponding PRO tool in the top row. A dash indicates that no studies were available to compare the 2 PRO tools. ASES, American Shoulder and Elbow Surgeons; PRO, patient-reported outcome; VAS, visual analog scale; WOSI, Western Ontario Shoulder Instability Index.

Variability among studies focusing on rotator cuff tears was evident by the 25 different PRO tools reported in this group of 81 studies. Furthermore, 20 studies utilized only 1 PRO tool, 20 utilized 2 PRO tools, 24 utilized 3 PRO tools, and 18 utilized ≥4 PRO tools. There were 42 different combinations of PRO tools utilized, and the most common combination (ASES, Constant, VAS for pain) was utilized in only 9 studies. While there were fewer instability studies included in our analysis, there was still substantial variability. For instance, there were 26 different combinations of PRO tools utilized among only 29 studies, and the most that one combination was reported was twice. In the prior literature, Makhni et al[17] and Lukenchuk et al[16] discussed the variability in outcome reporting after rotator cuff repair and instability, respectively, demonstrating the need for a uniformly accepted and validated outcome tool to aid in interpretation of the literature and guide clinical management. Similarly, Steinhaus et al[25] discussed the variability in reporting of patient outcomes in patients with SLAP tears. They also addressed the need for consistency in research tools to more accurately assess patient outcomes. Ideally, standardizing outcome reporting in terms of consistently collecting data and using the same tool would allow better comparisons when assessing the literature and provide insight into patient outcomes and prognoses.

As further evidence to the need for a uniform outcome measure in specific patient populations, this study demonstrated that the most commonly utilized PRO tool was not the most responsive PRO tool for either rotator cuff tears or instability. In the rotator cuff repair population, the Constant score was the most utilized tool, while the ASES score proved to be the most responsive. Similarly, the Rowe score was found to be the most responsive in patients with instability, despite the ASES score being more frequently utilized.

Multiple factors contribute to the utilization rates of different PRO tools in the literature. This is largely dependent on the preferences of the principal investigator and likely relate to the implementation of registries that employ certain PRO tools. However, given the results of this study, it is reasonable to question this historical preference to the utilization of certain PRO tools. When deciding which tools to incorporate into practice, clinicians must not only consider the psychometric properties of the tool, such as responsiveness, but also the ease and time required to complete it, ability to be completed solely by the patient, cost, method of deployment, comparability and widespread use in the scientific literature, and potential for the patient to complete the assessment remotely.[1,7,9,18,22,24]

In today's high-tech world, remote completion of completely subjective tools is possible via the Internet and simple online forms.[20] This allows for not only the ease of completion and data collection but also eliminates the need for a visit with a provider to assess functional outcomes. In this study, the most responsive tools were the ASES and Rowe scores in the rotator cuff repair and instability populations, respectively; both measures could be

assessed remotely. The ASES score has 1 pain item and 10 function/disability items with a scale of 0 to 100, with a lower score meaning greater pain and higher disability.[21] Similarly, the Rowe score, proposed by Rowe et al[23] in 1978 to assess patients after Bankart repair, assesses stability, motion, and function of a total of 100 points, with a higher score correlating with higher function and stability. In contrast, the Constant score, although used frequently in the shoulder research community, requires 65 of 100 points of objective provider-gathered information.[4] Based on the results of this study, it appears that the additional strength and range of motion testing that places additional burden on the provider may not be necessary in the rotator cuff repair population because pain is the primary factor in terms of patient outcomes. Keeping in mind that these traditional objective measures remain important, the results of this study suggest that after rotator cuff repair, the inability of patients to complete outcome assessments themselves and/or remotely is a major downfall of the Constant score. Furthermore, it appears that general shoulder PRO instruments do not adequately assess outcomes for those with instability. This is similar to what has been previously shown in the patellofemoral literature. General knee instruments such as the International Knee Documentation Committee score did not adequately assess outcomes for those with patellar instability, which ultimately led to the creation of the Kujala score for this subset of patients.[12]

This systematic review provided insight into the variability of reporting among patients with rotator cuff repair and shoulder instability while demonstrating the potential need for a standardized PRO tool to be used in each cohort of patients. Based on the review, the ASES score was more responsive in patients undergoing rotator cuff repair, and the Rowe score appears to be the optimal tool in the instability population as it was much more responsive than the other scores. Further evidence for using the Rowe score in the instability population was provided by Cunningham et al.[5] In a prospective study, they used functional magnetic resonance imaging (fMRI) to assess brain activation patterns in patients with apprehension related to shoulder instability.[5] They assessed 5 common PRO scores (VAS, Rowe, SST, Subjective Shoulder Value, and WOSI) in 28 patients with a positive shoulder apprehension test finding and 10 control patients without apprehension. The Rowe score provided the strongest link between shoulder apprehension and brain level alterations on fMRI.

There were limitations with this systematic review. First, there were a limited number of shoulder instability articles that utilized multiple PRO tools within the same patient population. Furthermore, among both the rotator cuff and instability literature, there were many articles with incomplete data, making it impossible to include in our analysis. This further adds to the already mentioned aspirations to provide complete and consistent outcome reporting in the future literature to allow more accurate conclusions to be drawn and help guide treatment. Also notable, according to the literature, there are at least 4 versions of the Rowe score with varying reliability[11]; thus, one must consider that our data provide evidence of the responsiveness of the 1978 score only. Similarly, there are modified versions of the Constant score, and it was unclear which versions of the Constant score were used in some of the articles analyzed. Last, not all tools were analyzed because they were not adequately represented in the articles meeting our inclusion criteria.

CONCLUSION

There are many important factors to consider when deciding which PRO tools to incorporate into clinical practice, but it appears that different tools are required depending on the pathological condition. The ASES score appears to be the optimal tool for patients undergoing rotator cuff repair, despite the Constant score being frequently used historically. Furthermore, the instability-specific Rowe score appears to be the ideal tool in patients undergoing instability surgery.

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