



Outcome measures reported for the management of proximal humeral fractures: a systematic review

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Background: The American Shoulder and Elbow Surgeons multicenter taskforce studying proximal humerus fractures reached no consensus on which outcome measures to include in future studies, and currently no gold standard exists. Knowledge of commonly used outcome measures will allow standardization, enabling more consistent proximal humerus fracture treatment comparison. This study identifies the most commonly reported outcome measures for proximal humerus fracture management in recent literature.

Methods: A systematic review identified all English-language articles assessing proximal humerus fractures from 2008 to 2018 using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Review articles, meta-analyses, revision surgery, chronic injuries, studies with <15 patients, studies with <12 month follow-up, anatomic/biomechanical studies, and technique articles were excluded. Included studies were assessed for patient demographics and outcome scores, patient satisfaction, complications, range of motion, and strength.

Results: Of 655 articles, 74 met inclusion criteria. The number of proximal humerus fractures averaged 74.2 per study (mean patient age, 65.6 years). Mean follow-up was 30.7 months. Neer type 1, 2, 3, and 4 fractures were included in 8%, 51%, 81%, and 88% of

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studies, respectively. Twenty-two patient-reported outcome instruments were used including the Constant-Murley score (65%), Disabilities of the Arm, Shoulder, and Hand score (31%), visual analog scale pain (27%), and American Shoulder and Elbow Surgeons score (18%). An average of 2.2 measures per study were reported.

Conclusion: Considerable variability exists in the use of outcome measures across the proximal humerus fracture literature, making treatment comparison challenging. We recommend that future literature on proximal humerus fractures use at least 3 outcomes measures and 1 general health score until the optimal scores are determined.

Level of evidence: Level IV; Systematic Review

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Proximal humerus fractures are the second-most common upper extremity fracture and the third overall most common fracture in the elderly,¹⁶ as well as becoming more common worldwide due to aging populations.²¹ Most fractures are amenable to nonsurgical management; however, surgical intervention using a variety of methods is often recommended in complex fracture patterns. There is great variability and controversy amongst orthopedic surgeons regarding the management of complex proximal humerus fractures.^{10,13} A standardized treatment protocol does not exist to guide the management of these fractures. Surgeons often choose treatment based on a variety of factors including patient characteristics (ie, age, preoperative function, comorbidities, and vocational activities), bone quality, fracture pattern, and experience. A wide variation in outcomes and complications has been reported in the literature, further confounding the decision-making process.

Outcome measures have become important tools for the orthopedic surgeon to assess clinical outcomes after interventions. In the realm of general shoulder pathology, there are a multitude of clinician-measured and patient-reported outcome measures.^{26,44} Many of these metrics have undetermined validities and poor inter- and intra-observer reliabilities. There is no gold standard outcome measure for treatment of proximal humerus fractures. The lack of a gold standard outcome measure has created significant heterogeneity between studies and has made cross-study comparisons problematic in the proximal humerus fracture literature.^{1,8,9,11,14,15,17,18,25,26,29,32,34,43,46-48} Standardization of outcome measures is important, and improves the surgeon's ability to interpret the evidence and evaluate treatment objectives.^{18,32,45}

The purpose of this study conducted by the American Shoulder and Elbow Surgeons (ASES) multicenter taskforce on proximal humerus fractures was to report on which outcome measures were most frequently used in the proximal humerus fracture literature to make an educated recommendation for future research, thereby reducing heterogeneous reporting in future studies.

Methods

A systematic review was performed to include all published studies in the English literature evaluating proximal humerus fractures between January 1, 2008, and October 31, 2018. A targeted search on both November 1, 2018, and January 20, 2019, was performed using the following: In TITLE only: (“proximal” or “upper” or “head” or “neck”) AND (“humerus” or “humeral”) AND “fracture”, limit ENGLISH language. The publication databases searched were PubMed, Cochrane, and Web of Science using PRISMA guidelines.

Studies were included if they reported on clinical treatment of any type of acute proximal humerus fracture (both surgical and nonsurgical). Exclusion criteria included biomechanical studies, studies with patients less than 16 years old, pathologic fractures, studies with <12-month follow-up, studies with fewer than 15 patients, studies in which the primary injuries did not involve the proximal humerus, animal studies, pure radiographic studies, anatomic studies, review articles (systematic review/meta-analysis), publications not available in English, surgical technique articles, editorials, studies focusing on revision surgery, studies focusing on chronic fractures (>8 weeks old), and articles focusing on only a single complication (without inclusion of other outcomes).

All included study data were collected on a web-based platform (Google Documents). No attempt was made to contact individual study authors, as the goal of this study was to evaluate the current published literature. Duplicate studies were removed. All articles were screened via title and abstract review initially. The remaining articles that met the inclusion criteria then underwent a full-text review.

All included studies were reviewed by a minimum of 2 authors, with one being a senior author. Demographic article data recorded included the following: impact factor, level of evidence, country of study, study design (retrospective or prospective), number of proximal humerus fractures, sex distribution, age at the time of fracture, mean length of follow-up, minimum length of follow-up, smoking status, and worker-compensation status. Fracture-specific data included in each study were recorded including open vs. closed injuries, associated dislocations, fracture classifications used (Neer and/or Arbeitsgemeinschaft für Osteosynthesefragen), and treatment types. Any outcome measure that was reported in each study was recorded. Objective range of motion (flexion, abduction, external rotation, and internal rotation) and objective strength outcomes were also recorded if mentioned in each study.

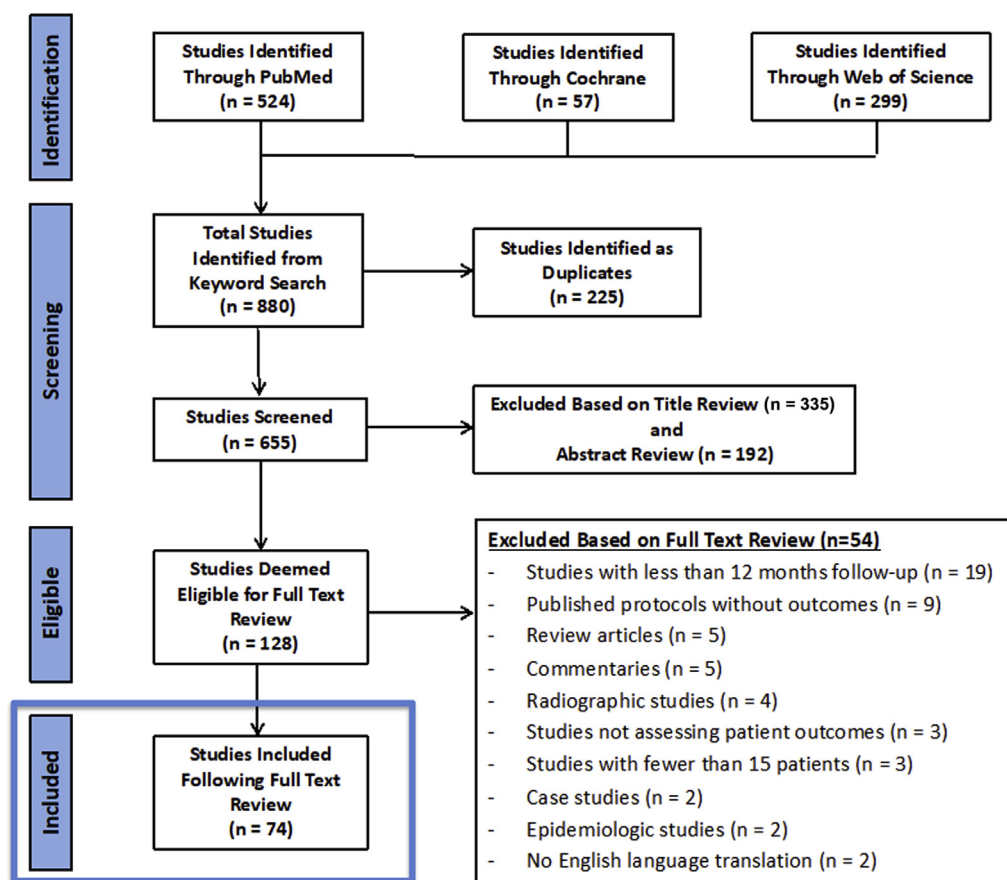


Figure 1 Flowsheet for the determination of included studies.

A study was considered as having a strength measurement only when a quantitative force assessment was reported. Total complication rates, nonunion, osteonecrosis or tuberosity healing, hardware prominence, need for revision surgery, return to work, return to sport, return to activities of daily living, and overall patient satisfaction were also recorded.

Weighted means were used to report the demographic information, which was calculated based on the number of patients included in each study. Bias was not assessed in the individual studies based on the limited scope of the research question.

Results

The search identified 655 articles after removal of duplicates. Five hundred and twenty-seven articles were removed based on title and abstract review. Fifty-four were excluded based on full-text review. This left 74 articles that reported on outcomes of proximal humerus fractures with a mean of 74 patients per study. A flowsheet for the determination of included studies is presented in Fig. 1. Of these articles, the mean weighted patient age was 65.6 years. Weighted mean follow-up was 30.7 months. Weighted minimum follow-up was 20.5 months. Included article demographics are presented in Table I.

There were more retrospective studies (41) compared with prospective studies (35), with 2 studies having both a retrospective and prospective arm. Level 4 was the most common level of evidence (45% of included studies). Neer type 3-part and 4-part fractures were more commonly included in these studies (81% and 99%, respectively). Open reduction and internal fixation was the most common treatment option reported (66% of studies), with arthroplasty treatment included in only 35% of studies. Smoking status was only reported in 16% of studies. Studies were most commonly performed in Europe (53% of studies) compared with other continents. Complete study details are listed in Table II.

Range of motion was assessed in 40 studies (54%), with flexion reported in 51%, external rotation in 42%, abduction in 35%, and internal rotation in 30%. Objective strength measurements were only independently reported outside of the Constant score in 12% of studies (nine studies), with abduction strength being the most common one reported in 8% of studies.

Overall, 22 different outcome measures were used, with an average of 2.2 outcome measures used per study. The most common outcome measures used in the proximal humerus fracture literature were the Constant score (65%),

Table I Demographics of included studies

Study demographics and follow-up	Mean	Range
Number of patients per study	74.2 (median 61)	18-411
Weighted patient age (yr)	65.6	35-80.4
Weighted follow-up length (mo)	30.7	12-90
Weighted minimum follow-up (mo)	20.5	12-60
Number of outcome scores reported per study	2.2 (median 2)	1-5

Disabilities of the Arm, Shoulder, and Hand (DASH) score (31%), visual analog scale pain (VAS, 27%), and ASES score (18%). [Table III](#) lists all outcome measures and their frequency. A health or quality-of-life score was reported in 15 studies (20%).

Patient-satisfaction rate was only reported in 16 studies (22%) and return to activities of daily living was only reported in 9 studies (12%). Complications were reported in 91% of studies (67 studies) and revision surgery rate was reported in 73% of studies (54 studies). Osteonecrosis was reported in 66% of appropriate studies. Nonunion or tuberosity healing rate was reported in 70% of appropriate studies.

Articles with a level of evidence of 3 or better were associated with publication in journals with a higher impact factor (1.59 vs. 1.10, $P = .046$). Higher level of evidence articles used a higher number of outcome scores (2.7 vs. 1.7, $P < .001$). There was a higher percentage use of the ASES score in higher level of evidence articles, with

similar rates of Constant score use seen regardless of level of evidence. See [Table IV](#) for study details and level of evidence.

Proximal humerus fracture studies that included outcomes of patients with arthroplasty procedures had a longer mean follow-up and demonstrated an older patient population. A similar number of outcome scores, type of scores used, and number of fractures were seen between studies including arthroplasty as a treatment option and studies that did not include shoulder arthroplasty. Complete details are outlined in [Table V](#).

Discussion

Our study has confirmed a lack of homogeneity in the use of outcome measures across the proximal humerus fracture literature where 22 different outcome measures were used

Table II Data included in studies on proximal humerus fractures

Data	Details	Number	Percentage
Type of study	Retrospective	39	52.7
	Prospective	33	44.6
	Combination of retrospective and prospective arms	2	2.7
Level of evidence	1	6	8.1
	2	10	13.5
	3	25	33.8
	4	33	44.6
Neer type included	1-part	6	8
	2-part	38	51
	3-part	60	81
	4-part	65	88
Treatment type included	Nonoperative	10	14
	ORIF	49	66
	CRPP	4	5
	Hemi/TSA	20	27
	RSA	12	16
	Any arthroplasty	26	35
Smoking status included	Yes	12	16
	No	62	84
Continent of study	Africa	3	4
	Asia	20	27
	Europe	39	53
	North America	11	15
	South America	1	1

ORIF, Open Reduction Internal Fixation; CRPP, Closed Reduction Percutaneous Pinning; TSA, Total Shoulder Arthroplasty; RSA, Reverse Total Shoulder Arthroplasty.

Table III Outcome scores reported in the proximal humerus fracture literature

Outcome score	Number of studies reporting	Percentage of all studies
Any Constant score	48	65
Standard Constant score	47	64
Normalized Constant score	8	11
Individual Relative Constant score	1	1
DASH score	23	31
Pain visual analog score (VAS)	20	27
ASES score	13	18
SST, UCLA	7	9
EQ-5D, Short Form-36, Neer score	6	8
QuickDASH	5	7
Oxford Shoulder score, SF-12	4	5
Other pain scores (not VAS pain)	3	4
SANE/SSV, HRQoL, SMFA	2	3
WOOS Index, 15D QoL, CESD Scale, VASSF	1	1

DASH, Disabilities of the Arm, Shoulder, and Hand; *ASES*, American Shoulder and Elbow Surgeons; *SST*, Simple Shoulder Test; *UCLA*, University of California, Los Angeles Shoulder Score; *EQ-5D*, EuroQoL-5 Dimension; *SF-12*, Short Form-12 Dimension; *SANE*, Single Assessment Numeric Evaluation; *SSV*, Subjective Shoulder Value; *HRQoL*, Health-related Quality of Life; *SMFA*, Short Musculoskeletal Functional Assessment; *WOOS*, Western Ontario Osteoarthritis of the Shoulder; *15D QoL*, 15 Dimension Quality of Life; *CESD*, Center for Epidemiologic Studies Depression; *VASSF*, Visual Analog Scale for Shoulder Function.

in the 74 studies identified. This inconsistency has negative consequences for future meta-analyses and systematic reviews due to the difficulty in comparing studies and pooling regarding outcomes of proximal humerus fractures.

Heterogeneity in reported outcome measures is not unique to the proximal humerus fracture literature. The inconsistent use of outcome measures has been noted in other shoulder pathologies such as rotator cuff disease,¹⁹ superior labral tears,⁴⁰ and acromioclavicular joint injuries.⁴ This problem underscores the need for increased standardization among musculoskeletal researchers.

Several proximal humerus fracture review studies have noted that problems with cross-study comparisons have made interpreting the literature difficult.^{1,3,8,9,11,14,15,17,18,25,26,29,32,34,43,46,48} In a meta-analysis of reverse shoulder arthroplasty for fracture, Longo et al¹⁷ discussed the lack of uniformity in both clinical and functional outcomes as a limitation to their

statistical analysis. In a systematic review analyzing the results for intramedullary nailing of proximal humerus fractures, Wong et al⁴⁸ mentioned lack of uniformity in reported outcomes as a significant limitation.

In a 2015 literature review, Slobogean et al³⁷ mentioned the lack of prospective randomized control trials, focused systematic reviews, and studies evaluating nonoperative treatment as major gaps in the proximal humerus literature. Such inconsistency underscores the importance of standardization of outcome measure for future studies to allow for comparison of treatment options and the ability to perform adequate meta-analyses. One systematic review also discussed that some studies reporting on high complication rates and poor functional outcomes may contribute to the wide variety of treatment decisions based more on surgeon experience and less on evidence-based medicine.¹² Given the plethora of treatment modalities and varied outcomes, the ability to perform high-level

Table IV Comparison of studies with level of evidence <4 vs. 4

Level of evidence	1, 2, or 3	4	P value
Number of studies	41	33	n/a
Number of outcome scores (mean)	2.7	1.7	<.001
Impact factor (mean)	1.59	1.10	.046
Mean follow-up (mo)	25.2	36.6	.008
Mean age (yr)	67.6	62.5	.005
Number of fractures per study	80.0	68.8	.46
Studies including arthroplasty (%)	37	33	.81
Studies reporting on ASES score (%)	29	3	.004
Studies reporting on VAS pain score (%)	32	21	.43
Studies reporting on Constant or Normalized Constant score (%)	66	61	.79

ASES, American Shoulder and Elbow Surgeons; *VAS*, visual analog score.

Table V Comparison of studies including shoulder arthroplasty patients vs. those that did not include shoulder arthroplasty patients

Studies including arthroplasty	No	Yes	P value
Number of studies	48	26	n/a
Number of outcome scores (mean)	2.21	2.31	.73
Level of evidence	3.21	3.04	.46
Impact factor (mean)	1.26	1.59	.20
Mean follow-up (mo)	26.5	37.8	.01
Mean age (yr)	62.5	70.9	<.001
Number of fractures per study	82.3	62.0	.19
Studies reporting on ASES score (%)	15	23	.53
Studies reporting on VAS pain score (%)	27	27	.98
Studies reporting on Constant or Normalized Constant score (%)	63	65	.84

ASES, American Shoulder and Elbow Surgeons; VAS, visual analog score.

systematic reviews would facilitate an appropriate treatment algorithm for these complex injuries.

The Constant-Murley score (CMS) was the most frequently used outcomes measure, having been included in 65% of studies. Several proximal humerus fracture review articles have noted that the Constant score was the most common score used among included studies.^{1,3,5,20,29,34,43,45,47} One reason for the high utilization may be due to the European Society for Surgery of the Shoulder and Elbow adopting CMS as the preferred functional outcome tool and over half of the studies in this review being European. This outcome measure takes into consideration pain, function, strength, and range of motion, including both patient-reported and clinician-measured outcomes.⁶ The CMS is used for many different shoulder pathologies, and is considered an appropriate test for assessing outcomes for proximal humerus fractures. However, this appears to be based only on face validity and imitation, and has not been validated for proximal humerus fractures.^{2,45} Van de Water et al⁴⁴ reported on the minimal clinically important difference (MCID) for the CMS in a population of proximal humerus fracture patients, but noted a concern regarding the test-retest reliability in this population as well. Criticisms of the CMS arise from the strength measurement portion, which has high point-weighting and lacks standardization across studies regarding positioning, length of testing, and measurement device.^{6,45,49} The CMS also has a strong focus on body function and physician-measured outcomes, which lack the subjective measures of health and disability²⁷ that are important to patients with proximal humerus fractures.

The DASH score was the second-most used outcome measure at 31%. It takes into account daily activities, symptoms, and social/role function over the past week. The DASH score has been shown to have strong reliability and moderately strong validity for assessing patients with proximal humerus fractures.³⁹ The MCID for the DASH score in proximal humerus fractures has been reported in 1 study.⁴⁴ In addition, it was found to have high psychometric properties, theoretically making it a good test to use between populations.³⁹

The ASES score was the fourth-most used (18%) and, like the DASH score, has been extensively studied and found to have good reliability and validity^{22,31} but not specifically for proximal humerus fractures. However, the ASES score has known MCID and has specifically been recommended for patients after shoulder arthroplasty.^{7,31,36} In addition, it has a known MCID for proximal humerus fractures,⁴⁴ making it a reasonable option for outcome measures assessing proximal humerus fractures. One study found that the ASES score correlated the most with physical examination findings of all of the patient-reported outcome scores evaluated (DASH, Simple Shoulder Test, and Oxford Shoulder score) in the management of proximal humerus fractures, suggesting a benefit in its use.³⁸

Given that activity level, health status, and quality of life are important in influencing the patient's ultimate function after proximal humerus fractures, it is prudent to include an outcome score that evaluates these factors. The importance of accounting for a patient's activity level and comorbidities has been a concern for previous reviews.^{12,29,32} Two activity-level/health status measures, the EuroQol-5 Dimension (EQ-5D) and the Short Form-6 Dimension (SF-6D), have shown strong reliability and moderately strong validity in patients with proximal humerus fractures, with the only limitation of the EQ-5D being that it exhibited a larger ceiling effect compared with the SF-6D.³⁹ The EQ-5D has also shown good responsiveness and has been recommended as an Health-related Quality of Life (HRQoL) tool for patients with proximal humerus fractures.²⁸ The EQ-5D is the only quality-of-life score that has been reported enough to be analyzed in a proximal humerus fracture systematic review article.³⁴

Several meta-analyses and/or systematic reviews noted that outcome-score comparison could only be performed with certain outcome measures: CMS,^{1,5,8,9,11,12,14,15,20,25,33-35,41,46} ASES score,^{1,9,12,20,35,47,48} DASH score,^{1,12,33,35,41} Neer score,^{15,48} and Oxford Shoulder score.²⁰

This study found that higher level of evidence studies (1, 2, or 3) used a higher number of outcome scores (2.7 vs. 1.7 scores), were published in higher impact factor journals (1.6 vs. 1.1), and more commonly used the ASES score

(29% vs. 3%). This suggests that future studies with higher levels of evidence should strive to use at least 3 outcome scores and that the ASES score should be considered as one of them.

Although the CMS was the most widely used outcome measure for proximal humerus fractures in this review, there is little evidence to support its use considering the lack of validity and reliability in the evaluation of proximal humerus fractures. In contrast, the ASES and DASH scores have good validity and reliability for proximal humerus fracture management and demonstrate established MCID for clinical interpretation in this population. One analysis looking at the specific concepts evaluated with reported outcome scores for proximal humerus fractures recommended the use of at least 1 score addressing the restoration of daily activities for which they recommended the DASH score, ASES score, or Oxford Shoulder score.²⁷ One systematic review looking at the quality of available patient-reported outcome scores using the EMPRO tool (evaluating the measurement of patient-reported outcomes) recommended using the shoulder function index, DASH score, and the EQ-5D based on the available evidence for evaluation of patients with proximal humerus fractures.²⁶

A more recent score called the Patient-Reported Outcome Measurement Information System (PROMIS) score uses computer adaptive testing to allow for a lower questionnaire burden and more efficient administration. This score has been tested in a variety of diagnoses in recent studies that involved large populations of patients with upper extremity injuries comparing PROMIS to other outcome scores with good correlation.^{23,30} However, to our knowledge, only 1 study has evaluated the PROMIS score in patients with proximal humerus fractures.²⁴ Morgan et al²⁴ evaluated 47 patients with proximal humerus fractures and found that the PROMIS score correlated well with the DASH score, the CMS, and the Short Musculoskeletal Functional Assessment and was administered in less time. The PROMIS score shows potential as being a viable outcome score for proximal humerus fracture evaluation that can be administered in an efficient manner. Additional

studies are needed to confirm the validity and reliability of this outcome measure in this distinct patient population.

ASES Proximal Humerus Taskforce recommendations of outcome measures

The total number of proximal humerus fractures is expected to rise due to an aging osteoporotic population worldwide. The combination of analyses regarding the different techniques may allow for improved treatment algorithms in managing proximal humerus fractures. Ideally, all proximal humeral fracture studies would report the same outcome measures for uniform comparison. The chosen measures should be easy to obtain, cost effective, and reproducible. Our recommendation is to use the ASES score, VAS pain score, and Single Assessment Numeric Evaluation score to measure functional outcome and the EQ5D for the evaluation of general health. The ASES score is reliable, as noted previously, freely available, and does not require objective measurement. It is also important to note that the VAS pain score is imbedded within the ASES questionnaire; therefore, utilization of the ASES includes the VAS pain score. Inclusion of the Single Assessment Numeric Evaluation score is based on the fact that it is only a single question and is therefore not associated with significant burden, and has shown good validity and responsiveness for shoulder pathology.⁴² The addition of the DASH score may be a consideration given its validity in proximal humerus fractures, but it is a longer questionnaire, making compliance a challenge. An alternative to the DASH or ASES score is the Constant score. However, although it was the most reported score in this study, the Constant score has obvious limitations, namely, length of testing and the need for strength testing with a dynamometer, which are not easily consistently obtained. In addition, the PROMIS score may be considered in future studies to evaluate burden reduction and validity. Finally, all outcome studies on proximal humerus fractures should include a range-of-motion assessment (minimum of forward flexion, external rotation at the side, and internal rotation to the nearest

Table VI ASES Multicenter Taskforce on proximal humerus fracture minimum recommendations for future studies

Type of outcome measure	Range of motion	General health/pain measures	Other
Shoulder-specific measures			
ASES score	Forward elevation	VAS pain	Complication fate
SANE/SSV	External rotation at side	EQ-5D	Reoperation rate
DASH score (exclude if concerned about large question burden) (Constant-Murley score as alternative)	Internal rotation (spinal level)	(SF-6D as alternative)	

ASES, American Shoulder and Elbow Surgeons; VAS, visual analog score; SANE, Single Assessment Numeric Evaluation; SSV, Subjective Shoulder Value; EQ-5D, EuroQol-5 Dimension; DASH, Disabilities of the Arm, Shoulder, and Hand; SF-6D, Short Form-6 Dimension.

spinal level). Our recommendations for minimum reporting requirements are reported in Table VI. We recognize that further literature is needed to confirm the validity of these scores and to evaluate other scoring systems that may be more sensitive for evaluating the myriad treatment options for proximal humerus fractures.^{26,45}

The strengths of this study include its descriptive qualities to identify the most frequently used outcome measures and its systematic approach. This is the first study, to our knowledge, to describe the most frequently used outcome measures along with the number of measures used in studies reporting on the management of proximal humerus fractures. Although identification of the most commonly used outcome measures in this patient population is an important step moving forward, it does not mean that these measures are the best measures to assess proximal humerus fractures. Future researchers should consider including these measures to aid in cross-study comparison, validity assessment, and outcome evaluation.

The limitations of this study are consistent with other systematic reviews. It is possible that some proximal humerus fracture studies were missed, despite using broad terms across 3 large publication databases. This study is also subject to data-extraction error due to the large number of studies being evaluated and the number of authors. Of note, the VAS for pain has significant limitations and is sensitive to the patient's pain tolerance and perceptions of care; however, it is commonly used in multiple shoulder pathologies, highly reported in the proximal humerus fracture literature, and easy to obtain. Another limitation of this study is the susceptibility to publication bias based on this study's reliance on only published data to make conclusions.

Conclusions

This study further delineates the problematic heterogeneity of outcome measure reporting in the proximal humerus fracture literature. The most commonly reported outcome measures were the Constant score (65%), DASH score (31%), VAS pain (27%), and ASES score (18%). We recommend that future studies include at least 3 outcome measures and preferentially include these commonly reported outcome measures to improve cross-study comparison and test the validity of other outcome measures included. In addition, inclusion of a quality-of-life score (the EQ-5D or the SF-6D) will likely aid in future treatment comparisons for proximal humeral fractures. This recommendation takes into account survey burden, frequency of use in prior studies, and the current evidence supporting their use in this patient population. At this time there is no overwhelming evidence to advocate for the use of a single outcome measure. Although much knowledge is

lacking in the best treatment strategies for proximal humerus fractures, future studies should focus on the feasibility of adding the same validated outcome measures to allow for cross-study comparison.

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