Functional Outcome After Nonoperative Treatment of a Proximal Humeral Fracture in Adults

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Background: The functional outcome following nonoperative treatment of a proximal humeral fracture and the factors that influence it are poorly defined. We aimed to prospectively assess patient-reported outcome measures (PROMs) in a patient cohort at 1 year after the injury.

Methods: In this study, 774 adult patients sustaining a proximal humeral fracture completed PROM assessments, including the Oxford Shoulder Score (OSS), the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L), and visual analog scale (VAS) assessments of pain, health, and overall treatment satisfaction at 1 year. The mean patient age was 65.6 years, and 73.8% of patients were female. The influences of demographic and fracture measurements and complications on the OSS and EQ-5D-3L were assessed.

Results: The 1-year mean scores were 33.2 points (95% confidence interval [CI], 32.1 to 34.2 points) for the OSS and 0.58 (95% CI, 0.55 to 0.61) for the EQ-5D-3L. There was considerable heterogeneity in the reported scores, and the 3 demographic variables of higher levels of dependency, higher levels of social deprivation, and a history of affective (mood) disorder were most consistently associated with poorer outcomes, accounting for between 37% and 43% of the score variation. The initial fracture translation potentially leading to nonunion accounted for 9% to 15% of the variation, and a displaced tuberosity fracture was also predictive of 1% to 4% of the outcome variation. There was evidence of a ceiling effect for the OSS, with 238 patients (30.8%) having a score of ≥47 points but a mean outcome satisfaction of only 72.9 points, and this effect was more pronounced in younger, active individuals. At the other end of the spectrum, 239 patients (30.9%) reported an OSS of ≤24 points, and 120 patients (15.5%) had a "worse-than-death" EQ-5D-3L score.

Conclusions: Nonoperative treatment of proximal humeral fractures produces considerable variation in shoulder-specific and general health outcomes at 1 year, and a substantial proportion of patients have poor perceived functional outcomes. The outcome for the majority of less-displaced fractures is mainly influenced by preexisting patient-related psychosocial factors, although the fracture-related factors of displacement, nonunion, and tuberosity displacement account for a small but measurable proportion of the variation and the poorer outcomes in the minority with more severe injuries.

Level of Evidence: Prognostic Level I. See Instructions for Authors for a complete description of levels of evidence.

Nonoperative treatment is widely adopted for patients with proximal humeral fractures, and the role of surgical procedures remains controversial, even for severely displaced or multipart fractures[1]. Authors of observational studies have suggested that nonoperative treatment produces satisfactory overall functional outcomes[2-4], although few studies have examined patient-reported outcomes in large cohorts. Demographic, fracture, and treatment factors, together with a wide range of health and socioeconomic factors, have been shown to affect the functional outcome, but their relative importance remains unclear[2-4]. More information about the functional outcome and the factors that affect it is needed for patient counseling and to develop enhanced strategies to improve outcomes after treatment.

We aimed to prospectively perform assessments of patient-reported outcome measures (PROMs), including visual analog scale (VAS), in nonoperatively treated patients and to examine the relative influence of demographic characteristics, fracture-related factors, and complications on the PROM scores.

Materials and Methods

Recruitment and Treatment Protocol

Between January 2014 and September 2015, all adult patients (≥18 years of age) treated in a single regional

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/G798).

TABLE I Details of Data Gathering and Statistical Analysis Methodology Used in the Study

Aspect of the Multivariate Analysis	Description
Inclusion and exclusion criteria and identification and definition of outcome and predictor variables	
Inclusion criteria for study	(1) Isolated, nonpathologic proximal humeral fracture (between head and shaft) defined by the method of squares, with or without tuberosity involvement; (2) local resident; (3) able to converse in written or spoken English; (4) cognition sufficient to provide written consent; (5) presentation within 2 weeks of the injury; (6) no shoulder degenerative condition or previous surgical procedure; (7) not treated by primary operative intervention; (8) no skin or clinical evidence of neurovascular injury; and (9) adult patients (≥18 years of age).
Exclusion criteria	Initial exclusion of all fracture-dislocations (treated operatively) and all isolated greater and lesser tuberosity fractures. Other patients who were unsuitable for inclusion, those excluded due to a primary surgical procedure, and those excluded after initial enrollment are described in Table II.
Primary outcome variables	OSS: A 12-item PROM assessing shoulder pain, function, and activities of daily living in the previous 4 weeks; scores range from 0 (worst function) to 48 (best possible function). EQ-5D-3L: Assessment of 5 health domains (mobility, self-care, usual activities, pain, and anxiety/depression). Scores then converted to a value score based on normative U.K. population assessment using time trade-off methodology. Scores range from −0.543 to 1, with higher scores representing better overall health and negative scores considered to be worse than death.
Sample size determination	A minimum sample size of 620 was required with a Type-I error set at 0.05 and a Type-II error set at 0.8, with a final model using up to 15 predictors with a minimum effect size of 1%. To allow for potential attrition during follow-up, we over-recruited by 20%.
Secondary outcome measures	VAS assessment from 0 to 100 of residual pain (0 = no pain to 100 = worst pain imaginable), overall satisfaction with treatment outcome (0 = complete dissatisfaction to 100 = complete satisfaction), and current general health (0 = worst to 100 = best health). UCLA scoring of activity ranging from 1 (wholly inactive) to 10 (wholly active and participates in contact sports). Scores were assessed at 1 year after the injury.
Independent (predictor) variables	A priori selected candidate variables assessing patients' demographic characteristics, radiographic fracture measurements, and adverse events or secondary surgical procedure.
Adverse events definition	Nonunion: no radiographic consolidation, fracture gap widening, scalloping, or progressive varus deformity on computed tomography or conventional radiographs. Segmental collapse and osteonecrosis: radiographic evidence of humeral-head segmental collapse or sclerosis with loss of joint space. Other complications were recorded but with no fixed protocol for diagnosis.
Details of multivariate analysis	
Analysis of predictor variables	Bivariate analysis to assess the effect of variables on the 2 primary outcome scores, using the unpaired Student t test for the binary categorical data, and the Pearson correlation for continuous variables. Significant or nearly significant variables ($p < 0.1$) on bivariate analysis included in multivariate linear regression analysis, using enter methodology, to determine independently predictive factors.
Missing data analysis	Patients were excluded if >3 data points were missing. Multiple imputation techniques were used for missing values in the remainder. Radiographic measurements were a complete data set, as all patients had an initial trauma series radiograph.
Assessment of multicollinearity of predictor variables	Assessment of correlation matrices for continuous variables (correlation coefficient of >0.8 indicative of multicollinearity) and variation inflation factor.
Assessment of contribution of predictor variables	Overall adjusted R^2 value to assess proportion of variation in outcome predicted by model. Partial R^2 values used to assess relative contribution of independent predictors in the final model. Constants and regression coefficients (with 95% CIs) reported for each variable; $p < 0.05$ was considered significant in multivariate analysis.
Analysis of residuals and influential cases	Assessment of outliers (>2.5 standard deviations), influential cases, and leverage values.

trauma center for a proximal humeral fracture (as defined in Table I) were referred to specialist trauma clinics and were enrolled in a 1-year prospective cohort study. These patients were included in a previous study to assess the external validity of a model to predict nonunion risk after proximal humeral fracture[5]. The inclusion and exclusion criteria are shown in detail in Tables I and II. Our emergency room provided the only trauma service for the urban adult (97% Caucasian) population.

TABLE II Exclusions from Analysis in the Study

Timing of Exclusion	Reason for Exclusion	No. of Patients Excluded
Patients seen in clinics during the trial period who were unsuitable for inclusion	Not able to give consent due to cognitive impairment	70
	Non-English-speaking	11
	Fracture-dislocation (2, 3, or 4 parts)	22 (all treated operatively)
	Isolated 2-part tuberosity fracture with or without dislocation	141 (11 treated operatively)
	Not a local resident	25
	Presentation >2 weeks after injury	4
	Preexisting shoulder condition, pathologic fracture, or previous surgery to shoulder	34
	Other injuries	12
	Subtotal	319
Patients excluded due to primary operative treatment	Surgeon protocol-based decision	18
	Patient preference for operative treatment	14
	Skin compromise	4
	Neurovascular compromise	3
	Fracture extending to diaphysis	15
	Subtotal	54
Patients excluded after initial enrollment	Missing >3 of the 10 demographic data points studied	15
	Subsequent fracture or reinjury in the first year after injury	4
	Loss to follow-up in the year after injury	39
	Died during the year after injury	84
	Subtotal	142

Patients had a consultation within 2 weeks of the injury with clinical and radiographic (scapular-plane anteroposterior and Velpeau views) assessment, then at 6, 12, and 24 weeks, and at 1 year, when PROM assessment was made. Management was protocol-driven, with a minority of patients excluded because they were primarily treated operatively because of substantial tuberosity involvement with >1 cm of displacement in a 3-part or 4-part fracture configuration, because of complete separation of the humeral head from the shaft, or because of a humeral-head angular deformity resulting in a head-shaft inclination angle of <90° or >160° (Table II). For the remaining patients, treatment comprised wearing a sling for 3 weeks, followed by physiotherapy for 3 to 6 months.

Measurement of Predictor Variables

Demographic data were collected by a research worker at the first research clinic visit, using a deidentified standardized booklet. The details recorded are shown in Table III. Adverse events and secondary operative procedures were prospectively coded at each clinic visit.

Blinded radiographic measurements of radiographs were made retrospectively using ImageJ software (National Institutes of Health) by the senior author (Table III, Fig. 1). The measurements were selected because either they were components of fracture classifications[6-9] or they had been previously associated with poorer functional outcomes[1-4,10-12]. Nonunion or humeral-head collapse and osteonecrosis were diagnosed according to fixed criteria (Table I).

Outcome Measures

PROMs were completed at the 1-year follow-up and the final follow-up concluded in September 2016. The primary outcomes (Table I) were the shoulder-specific Oxford Shoulder Score (OSS), a 12-item assessment of shoulder pain, function, and activities of daily living[13]; and the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L) general health assessment, a 5-health-domain assessment of mobility, self-care, activities, pain, and anxiety/depression that is converted to a score based on assessment of a normative population using time trade-off methodology[14]. The OSS can range from 0 to 48 points, with the latter being the best possible function. The EQ-5D-3L score can range from −0.543 to 1, with higher scores representing better overall health and negative scores considered to be "worse than death." The secondary outcome measures were VAS assessments of residual pain, health, and overall satisfaction with treatment outcome (100-mm scale) and University of California Los Angeles (UCLA) activity score[15] at 1 year (Table I).

Statistical Analysis

The coding methodology, sample size determination, and missing data management are described in Table I. We assessed 29 candidate predictor variables and used bivariate analysis to assess their effect on the 2 primary outcome scores assessed,

TABLE III Details of the Demographic Variables, Fracture-Related Variables, and Complications within the First Year After the Injury and the Bivariate Analysis of Their Effect on Functional Outcomes

Variable	Measurement or Coding*	Value†	OSS†	P Value	EQ-5D-3L†	P Value
Demographic variables						
Age at time of injury§	Continuous data (years)	65.6 (64.6 to 66.6 [18 to 98])	−0.26	<0.001	−0.250	<0.001
Sex§	Female (0)	571 (73.8%)	32.6 (31.4 to 33.8)	0.090	0.55 (0.52 to 0.59)	0.01
	Male (1)	203 (26.2%)	34.7 (32.6 to 36.8)		0.64 (0.58 to 0.70)	
Injury to dominant side§	Injury to nondominant side (0)	379 (49%)	33.5 (32.0 to 35.0)	0.500	0.59 (0.54 to 0.63)	0.6
	Injury to dominant side (1)	395 (51%)	32.8 (32.0 to 35.0)		0.57 (0.53 to 0.61)	
Mode of injury§	Simple fall (0)	632 (81.7%)	32.9 (31.7 to 34.0)	0.300	0.57 (0.54 to 0.60)	0.4
	Other mode of injury (1)	142 (18.3%)	34.5 (32.0 to 36.9)		0.61 (0.53 to 0.68)	
Tobacco usage§#	Non-smoker or smokes ≤5 cigarettes or equivalent per day (0)	606 (78.3%)	35.6 (34.5 to 36.7)	<0.001	0.64 (0.60 to 0.67)	<0.001
	Current smoker (>5 cigarettes or equivalent per day) (1)	168 (21.7%)	24.2 (21.8 to 26.6)		0.36 (0.30 to 0.42)	
Alcohol consumption§#	≤20 units of alcohol per week (0)	599 (77.4%)	34.6 (33.4 to 35.7)	<0.001	0.61 (0.58 to 0.65)	<0.001
	>20 units of alcohol per week (1)	175 (22.6%)	28.3 (26.0 to 30.6)		0.45 (0.38 to 0.51)	
History of affective disorder§#	No history of anxiety or depression (0)	540 (69.8%)	36.9 (35.8 to 38.0)	<0.001	0.69 (0.66 to 0.72)	<0.001
	History of anxiety or depression (requiring either medical anxiolytic or antidepressant treatment, or psychological or psychiatric counseling) (1)	234 (30.2%)	24.5 (22.6 to 26.4)		0.31 (0.26 to 0.36)	
Social deprivation: Scottish Index of Multiple Deprivation§#	Score from 0 to 6,976 converted to score from 0 (most deprived) to 100 (least deprived)	54.4 (52.5 to 56.3 [0.7 to 93.2])	0.44	<0.001	0.480	<0.001
Medicolegal claim for personal injury§#	No medicolegal claim (0)	698 (90.2%)	34.5 (33.4 to 35.5)	<0.001	0.61 (0.58 to 0.64)	<0.001
	Active medicolegal claim (1)	76 (9.8%)	21.2 (17.9 to 24.5)		0.31 (0.21 to 0.40)	
Charlson Comorbidity Index#	Continuous score to evaluate medical conditions, used to assess medical comorbidity	1.1 (1.0 to 1.2 [0 to 9])	−0.36	<0.001	−0.340	<0.001
Employment status§	Retired or employed (0)	674 (87.1%)	35.3 (34.3 to 36.3)	<0.001	0.63 (0.60 to 0.66)	<0.001
	Unemployed (1)	100 (12.9%)	18.8 (15.8 to 21.7)		0.21 (0.13 to 0.29)	
Previous shoulder problem§	No previous shoulder problem (0)	710 (91.7%)	33.8 (32.7 to 34.8)	<0.001	0.60 (0.57 to 0.62)	<0.001
	Problem requiring medical treatment (1)	64 (8.3%)	26.4 (22.6 to 30.2)		0.36 (0.25 to 0.47)	
Independence§	Self-caring and independent (0)	628 (81.1%)	36.4 (35.4 to 37.4)	<0.001	0.66 (0.64 to 0.69)	<0.001
	Requiring assistance or full-time care (1)	146 (18.9%)	19.3 (16.9 to 21.6)		0.20 (0.13 to 0.26)	
Mobility§	Fully ambulant without walking aids (0)	621 (80.2%)	36.4 (35.3 to 37.4)	<0.001	0.66 (0.63 to 0.69)	<0.001
	Non-ambulant or using walking aids (1)	153 (19.8%)	20.1 (17.9 to 22.4)		0.24 (0.18 to 0.31)	
Residence§	Living in own home (0)	658 (85%)	35.4 (34.4 to 36.5)	<0.001	0.64 (0.61 to 0.67)	<0.001
	Living with relatives, supported accommodation, nursing home (1)	116 (15%)	20.2 (17.5 to 22.9)		0.22 (0.15 to 0.29)	

continued

TABLE III (*continued*)

Variable	Measurement or Coding*	Value†	OSS†	P Value	EQ-5D-3L†	P Value
Hospital admission after fracture§	No requirement for hospital admission (0)	678 (87.6%)	34.3 (33.3 to 35.4)	<0.001	0.61 (0.57 to 0.64)	<0.001
	Hospital admission after fracture (1)	96 (12.4%)	24.8 (21.7 to 27.8)		0.38 (0.30 to 0.46)	
Marital status§	Married or with partner (0)	388 (50.1%)	38.2 (36.8 to 39.5)	<0.001	0.70 (0.66 to 0.74)	<0.001
	Single, widowed, separated, divorced (1)	386 (49.9%)	28.1 (26.6 to 29.6)		0.45 (0.41 to 0.49)	
Fracture-related variables and complications						
Location neck fracture**	Anatomic neck (0)	205 (26.5%)	34.0 (32.1 to 36.0)	0.300	0.60 (0.55 to 0.65)	0.351
	Surgical neck (1)	569 (73.5%)	32.8 (31.6 to 34.1)		0.57 (0.53 to 0.60)	
Tuberosity involvement**	No tuberosity fracture or nondisplaced fracture (0)	536 (69.3%)	35.7 (34.5 to 36.9)	<0.001	0.63 (0.60 to 0.67)	<0.001
	Fracture displaced >1 cm (1)	238 (30.7%)	27.4 (25.7 to 29.2)		0.45 (0.40 to 0.50)	
Head-shaft translation††	Maximal head-shaft translation on anteroposterior or Velpeau view (% of diaphyseal diameter)	16.8 (14.9 to 18.8 [0 to 133])	−0.35	<0.001	−0.350	<0.001
Head-shaft angulation††	Continuous data (degrees)	123.9 (122.5 to 125.2 [75 to 188])	0.14	<0.001	0.103	0.004
Head-shaft impaction or distraction	Nondisplaced, impacted, distracted ≤1 cm (0)	671 (86.7%)	33.1 (31.9 to 34.2)	0.700	0.57 (0.54 to 0.61)	0.74
	Distracted >1 cm (1)	103 (13.3%)	33.7 (30.9 to 36.5)		0.59 (0.51 to 0.67)	
Cortical thickness (predictor of proximal humeral bone quality)	Continuous data (mm)	3.8 (3.7 to 3.9 [1 to 7])	−0.29	0.400	−0.014	0.7
Metaphyseal or calcar comminution	No comminution (0)	569 (73.5%)	32.8 (31.5 to 34.0)	0.200	0.57 (0.54 to 0.60)	0.471
	>2 fragments (excluding tuberosities) (1)	205 (26.5%)	34.3 (32.3 to 36.2)		0.59 (0.54 to 0.65)	
Head-split component to fracture**	Absent (0)	737 (95.2%)	33.0 (31.9 to 34.1)	0.200	0.57 (0.54 to 0.60)	0.508
	Present (1)	37 (4.8%)	36.1 (32.1 to 40.1)		0.62 (0.49 to 0.75)	
Humeral head subluxation without dislocation††	Fully congruent (0)	727 (93.9%)	33.2 (32.1 to 34.3)	0.700	0.58 (0.55 to 0.61)	0.441
	Inferior subluxation (1)	47 (6.1%)	32.2 (27.9 to 36.5)		0.53 (0.40 to 0.66)	
Nonunion at 1 year#	Fracture healed (0)	695 (89.8%)	35.4 (34.4 to 36.4)	<0.001	0.64 (0.61 to 0.67)	<0.001
	Nonunion of fracture (1)	79 (10.2%)	13.4 (11.9 to 15.0)		0.04 (−0.02 to 0.09)	
Segmental collapse or osteonecrosis at 1 year#	No segmental collapse or osteonecrosis (0)	757 (97.8%)	33.5 (32.5 to 34.6)	<0.001	0.59 (0.56 to 0.62)	<0.001
	Segmental collapse or osteonecrosis (1)	17 (2.2%)	16.1 (12.5 to 19.7)		0.07 (−0.09 to 0.23)	
Operative treatment for complications in first year#	No surgical treatment in first year (0)	741 (95.7%)	33.8 (32.7 to 34.8)	<0.001	0.60 (0.57 to 0.63)	<0.001
	Surgical treatment in first year (1)	33 (4.3%)	18.3 (14.9 to 21.6)		0.08 (−0.05 to 0.21)	

*The values are given as the measurement for continuous variables or as the coding, in parentheses, used for categorical variables in all analyses. †The values are given either as the mean, with the 95% CI in parentheses and the range in brackets, or as the number of patients, with the percentage in parentheses. ‡The values are given either as the correlation coefficients for continuous measurements or as the subgroup mean, with the 95% CI in parentheses, for categorical measurements. §This category was included as a general demographic feature. #This category was previously associated with poorer outcome. **This category is a component of the Neer and OTA classifications. ††This category is a component of the Neer classification. ‡‡This category is a component of the Resch classification.

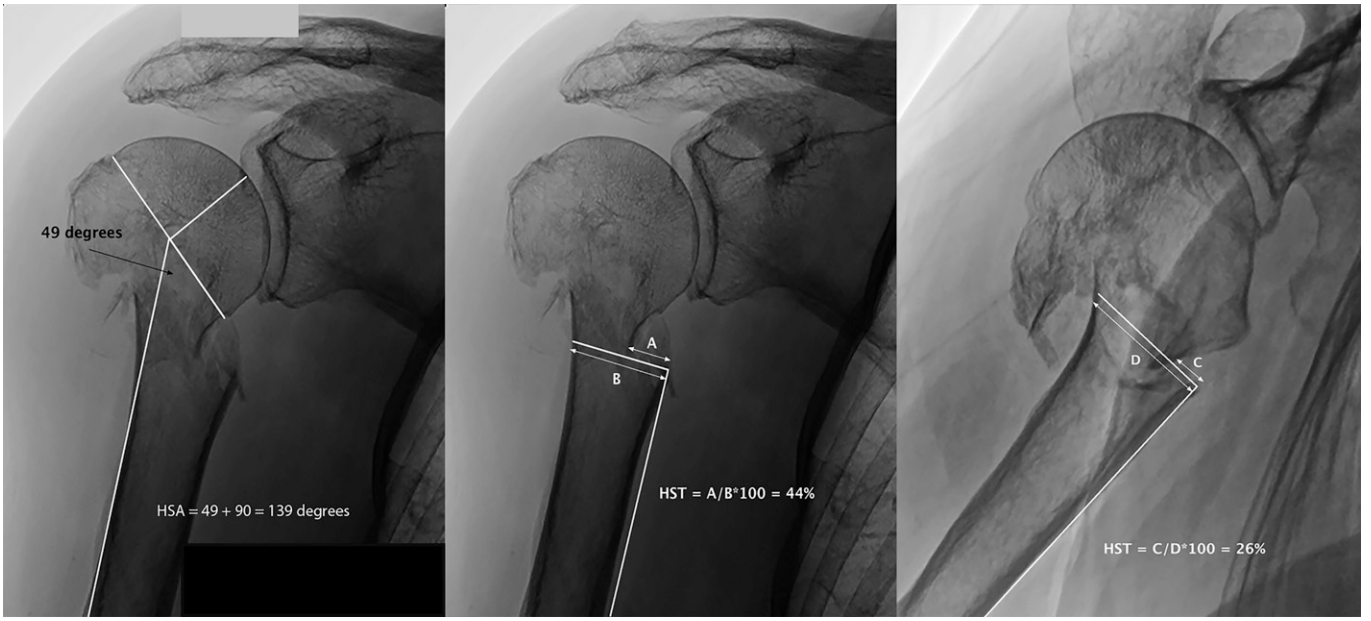

Fig. 1

Measurement of humeral head-shaft angulation (HSA) and humeral head-shaft translation (HST) on conventional anteroposterior and Velpeau-view radiographs. HSA was assessed by measuring the angle subtended by the diaphyseal axis and a line drawn perpendicular to the anatomical neck segment plane (*left panel*). HST was assessed by measuring the medial or lateral displacement of the head relative to the overall diameter of the metaphysis measured at the medial or lateral cortical level (dependent on the direction of displacement) of the fracture on the anteroposterior view (*middle panel*) and the anterior or posterior displacement of the head relative to the overall diameter of the metaphysis measured at the anterior or posterior cortical level (dependent on the direction of displacement) of the fracture on the Velpeau view (*right panel*).

using unpaired Student t tests for binary categorical data and Pearson correlations for continuous variables. Checks for potential interactions and collinearity and model diagnostics were performed (Table I). Significant or nearly significant variables ($p < 0.1$) on bivariate analysis were included in a multivariate linear regression analysis, using enter methodology (all variables entered into the analysis at the same time), to determine independently predictive factors. Two multivariate analyses were performed for each primary outcome measure: the first included only those variables assessed at the initial

TABLE IV Outcome Scores and Partial Correlations Between Scores*

		Pearson Correlation Coefficients Between Scores							
Outcome Measure	Value at 1 Year†	OSS	EQ-5D-3L	Pain VAS	Health VAS	Treatment Satisfaction VAS	UCLA Activity Score at Time of Injury	UCLA Activity Score at 1 Year	Change in UCLA Activity Score
Primary outcome measures at 1 year									
OSS	33.2 (32.1 to 34.2)	1	0.86	−0.81	0.65	0.53	0.48	0.65	0.38
EQ-5D-3L	0.58 (0.55 to 0.61)		1	−0.82	0.7	0.58	0.47	0.61	0.35
Secondary outcome measures at 1 year									
Pain VAS	31.7 (29.4 to 34.0)			1	−0.65	−0.62	−0.42	−0.55	−0.31
Health VAS	67.8 (65.8 to 69.7)				1	0.59	0.47	0.56	0.24
Treatment satisfaction VAS	59.7 (57.7 to 61.8)					1	0.2	0.31	0.26
UCLA activity score	4.4 (4.3 to 4.6)							1	0.37

*All correlations were significant ($p < 0.05$). †The values are given as the mean, with the 95% CI in parentheses.

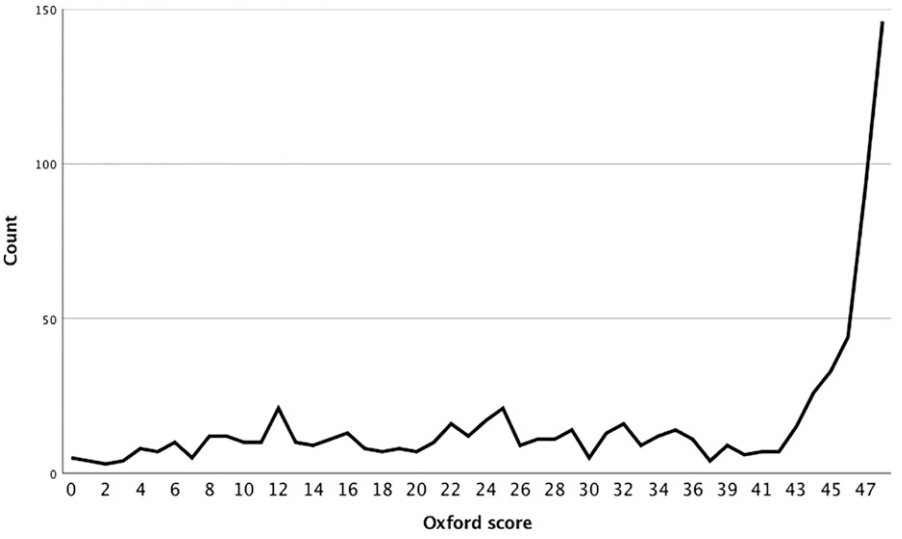

Fig. 2-A

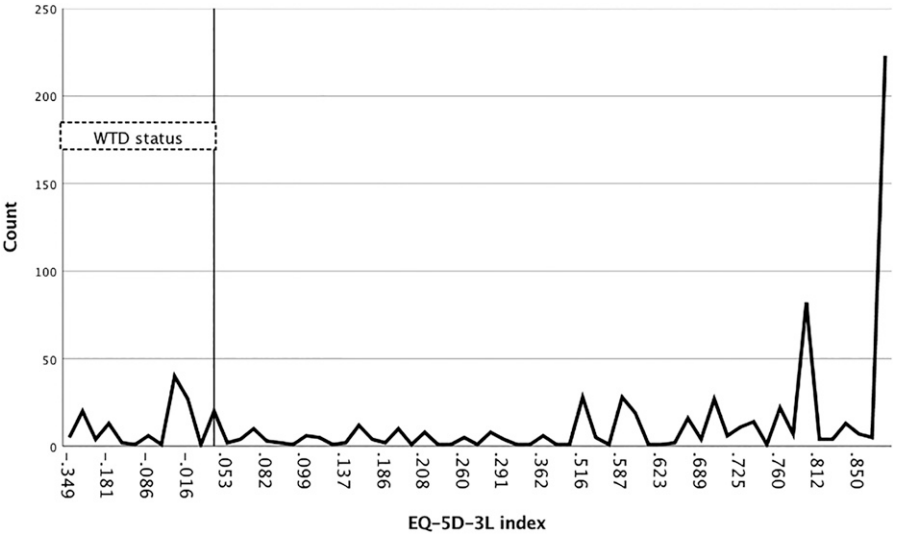

Fig. 2-B

Fig. 2-A and 2-B Line graphs depicting the distribution of OSSs (**Fig. 2-A**) and EQ-5D-3L scores (**Fig. 2-B**). WTD = worse than death.

presentation (primary multivariate analysis), and the second included adverse events and surgical procedure during the first year (secondary multivariate analysis). A p value of 0.05 was considered significant for a Type-I error.

Source of Funding
No external funding source was used for this study.

Results

A 1-year follow-up assessment was completed in 774 patients with a mean age of 65.6 years (range, 18 to 98 years), with 571 female patients (73.8%), and low-energy fall causation in 632 patients (81.7%) (Table III). Injuries caused by low-energy falls tended to occur in an older population of patients (mean age, 68.9 years) compared with falls due to other, higher-energy mechanisms (mean age, 59.3 years).

The 1-year mean scores were 33.2 points (95% confidence interval [CI], 32.1 to 34.2 points) for the OSS and 0.58 (95% CI, 0.55 to 0.61) for the EQ-5D-3L (Table IV, Figs. 2-A and 2-B). The secondary outcome measures correlated with the primary outcomes (Table IV), but were less favorable, with mean treatment outcome scores of 31.7 (95% CI, 29.4 to 34.0) for VAS pain and 59.7 (95% CI, 57.7 to 61.8) for VAS satisfaction. The mean 1-year VAS health score was 67.8 (95% CI, 65.8 to 69.7), and the UCLA activity score was a mean of −0.74 (95% CI, −0.82 to −0.67) lower than before the injury.

There was evidence of a ceiling effect, with 238 patients (30.8% of the cohort) having a near-maximal OSS of 47 or 48 points (Figs. 3-A and 3-B), but a mean VAS score for the level of satisfaction with treatment of only 72.9 (95% CI, 70.1 to 75.8). There was evidence that the ceiling effect was more

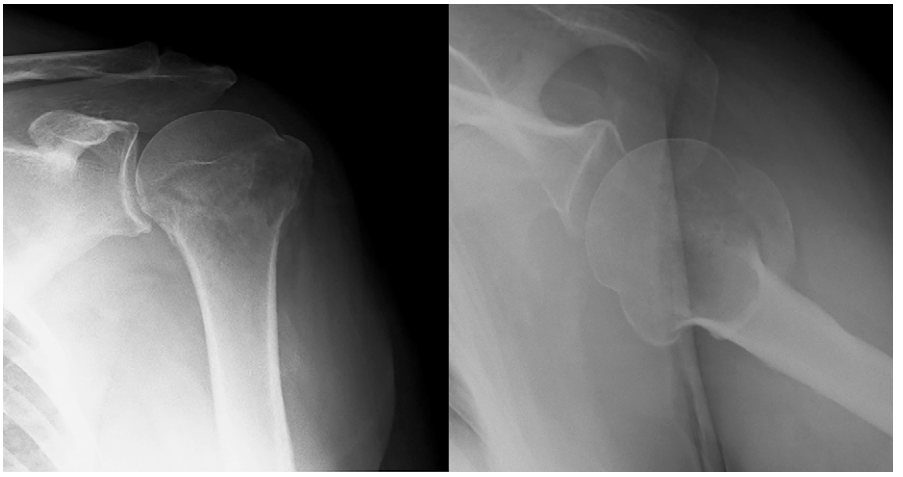

Fig. 3-A

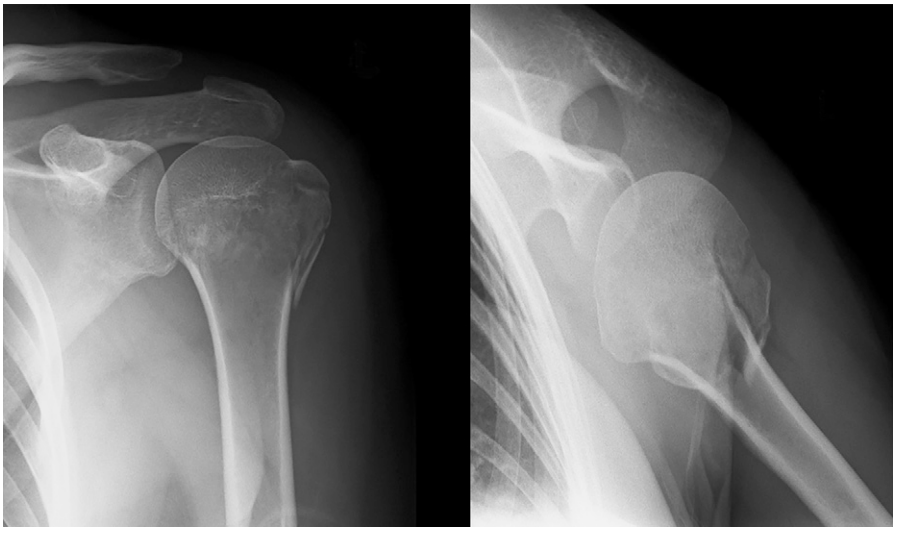

Fig. 3-B

Fig. 3-A and 3-B Radiographs of 2 patients with similar fracture configurations and functional scores but different levels of satisfaction. **Fig. 3-A** Radiographs showing the anteroposterior view (*left panel*) and Velpeau view (*right panel*) for a 42-year-old man who sustained a closed proximal humeral fracture with slight valgus angulation of the humeral head and minimally displaced tuberosity fractures in a fall off his bicycle. The fracture healed and the OSS at 1 year was 48 points, with a full range of shoulder movement, yet the level of satisfaction with the shoulder was only 40%, due to his inability to return to playing racket sports. **Fig. 3-B** Radiographs showing the anteroposterior view (*left panel*) and the Velpeau view (*right panel*) for a 75-year-old woman who sustained a similar closed injury in a domestic fall. Her functional expectations were minimal and the OSS at 1 year was 48 points, with a full range of shoulder movement, and the level of satisfaction was 95%.

pronounced in younger, active individuals, because the level of treatment satisfaction correlated positively with age ($r = 0.48$; $p < 0.001$) and negatively with the UCLA level of activity prior to the injury ($r = -0.36$; $p < 0.001$). In patients with an OSS of 47 or 48 points, the level of satisfaction with the treatment outcome was only 56.5 in the 78 patients who were <55 years of age, compared with 80.9 in the 160 patients who were ≥55 years of age (t test; $p < 0.001$). Satisfaction scores were 59.6 for those with a UCLA activity level of ≥7 and 80.2 for those with a UCLA activity level of <7 (t test; $p < 0.001$).

Poorer OSSs (of ≤24 points) were reported in 239 patients (30.9%), and 120 patients (15.5%) had negative, or worse-than-death, EQ-5D-3L scores (Figs. 2-A and 2-B). Of the 120 patients with EQ-5D-3L outcomes defined as worse than death, 101 (84.2%) reported maximal levels of pain and 34 (28.3%) reported maximal levels of anxiety and depression in the component scores of the EQ-5D-3L assessing these parameters.

Many candidate variables assessed at the time of the first consultation correlated with the OSS and EQ-5D-3L on the bivariate analysis (Table III) and retained significance on the primary multivariate analysis (Table V). These accounted for 61% of the variation in the OSS and 58% of the variation in the EQ-5D-3L. The values increased only modestly to 68% and

TABLE V Multivariate Analysis of Predictive Factors for OSS and EQ-5D-3L Using Variables Assessed within 2 Weeks After the Injury*

Variable	Regression Coefficient†	Partial R^2	Adjusted R^2
OSS			0.61
Intercept (constant)	47.13 (43.3 to 50.97)		
Independence	−5.94 (−7.96 to −3.91)	0.202	
Social deprivation score	0.09 (0.06 to 0.11)	0.114	
Head-shaft translation	−0.13 (−0.16 to −0.11)	0.091	
Affective disorder	−5.67 (−7.24 to −4.1)	0.072	
Employment status	−7.32 (−9.56 to −5.08)	0.034	
Tuberosity involvement	−4.44 (−5.92 to −2.96)	0.028	
Mobility	−5.88 (−7.85 to −3.91)	0.021	
Medicolegal claim for personal injury	−5.74 (−8.1 to −3.38)	0.014	
Age	−0.09 (−0.14 to −0.04)	0.011	
Alcohol consumption	−2.78 (−4.41 to −1.14)	0.008	
Comorbidity score	−0.77 (−1.22 to −0.31)	0.005	
Tobacco usage	−3.18 (−4.98 to −1.38)	0.005	
Marital status	−2.31 (−3.75 to −0.87)	0.005	
Previous shoulder problems	−2.49 (−4.93 to −0.05)	0.002	
EQ-5D-3L			0.58
Intercept (constant)	0.83 (0.72 to 0.94)		
Social deprivation score	0.004 (0.003 to 0.005)	0.226	
Independence	−0.18 (−0.24 to −0.12)	0.111	
Head-shaft translation	−0.004 (−0.005 to −0.003)	0.091	
Affective disorder	−0.22 (−0.27 to −0.18)	0.089	
Employment status	−0.17 (−0.23 to −0.1)	0.018	
Age	−0.004 (−0.007 to −0.001)	0.014	
Mobility	−0.13 (−0.18 to −0.07)	0.010	
Tuberosity involvement	−0.08 (−0.12 to −0.04)	0.008	
Alcohol consumption	−0.078 (−0.125 to −0.032)	0.006	
Medicolegal claim for personal injury	−0.09 (−0.16 to −0.02)	0.005	
Comorbidity score	−0.02 (−0.03 to −0.01)	0.004	
Previous shoulder problems	−0.08 (−0.15 to −0.01)	0.003	

*The coding of categorical variables was described in Table III. †The values are given as the regression coefficient, with the 95% CI in parentheses.

64% after inclusion of the extra parameters in the secondary multivariate analysis (Table VI).

The 3 patient-related factors of level of independence, social deprivation score, and history of affective (mood) disorder were consistently the strongest independent predictors of PROM scores, accounting for a total of between 37% and 43% of the overall variation in all 4 multivariate analyses (Tables V and VI, Figs. 4-A and 4-B).

Although less influential, fracture translation accounted for 9% of the variation in the primary multivariate analysis and nonunion accounted for approximately 15% in the secondary analysis. There was evidence of collinearity between the initial translation and nonunion ($p < 0.001$), suggesting that the effect of fracture displacement in the primary multivariate analysis was related to nonunion prediction. Of the 79 patients (10.2%) with nonunion, the mean scores were 13.4 points for the OSS and 0.04 for the EQ-5D-3L, compared with mean scores of 35.4 points for the OSS and 0.64 for the EQ-5D-3L in those patients without any complication (Figs. 5-A and 5-B). Of the patients with this complication, 46 (58.2%) reported negative, or worse-than-death, EQ-5D-3L scores. Only 33 patients underwent a secondary operative treatment in the first year (Table III), and the indications were nonunion in 25 patients and humeral-head segmental collapse in 8 patients. Other patients with these complications either were awaiting a surgical procedure or had declined operative treatment. The requirement for surgical intervention within the first year was only weakly predictive of 1-year PROM scores on multivariate analysis. The presence of a displaced tuberosity fracture was consistently predictive of 1% to 4% of the variation in both the primary and secondary analyses (Tables V and VI). Other patient-related and injury-related factors were significantly

TABLE VI Multivariate Analysis of Predictive Factors for OSS and EQ-5D-3L Using All Variables Able to Be Assessed at 1 Year After the Injury*

Variable	Regression Coefficient†	Partial R^2	Adjusted R^2
OSS			0.68
Intercept (constant)	47.33 (43.83 to 50.83)		
Independence	−4.19 (−6.18 to −2.19)	0.202	
Nonunion of fracture	−17.53 (−19.62 to −15.44)	0.152	
Affective disorder	−5.32 (−6.77 to −3.87)	0.113	
Social deprivation score	0.07 (0.05 to 0.10)	0.059	
Tuberosity involvement	−4.73 (−6.10 to −3.37)	0.037	
Medicolegal claim for personal injury	−7.31 (−9.48 to −5.15)	0.027	
Mobility	−4.93 (−6.75 to −3.11)	0.021	
Comorbidity score	−0.85 (−1.26 to −0.43)	0.018	
Employment status	−6.50 (−8.55 to −4.45)	0.016	
Age	−0.09 (−0.14 to −0.04)	0.010	
Alcohol consumption	−2.46 (−3.96 to −0.96)	0.005	
Segmental collapse of humeral head	−8.06 (−12.37 to −3.75)	0.006	
Previous shoulder problems	−3.54 (−5.76 to −1.31)	0.004	
Hospital admission after fracture	−2.83 (−4.77 to −0.90)	0.004	
Marital status	−1.97 (−3.28 to −0.66)	0.003	
Tobacco usage	−2.05 (−3.71 to −0.40)	0.003	
Residence	−2.13 (−4.21 to −0.05)	0.002	
EQ-5D-3L			0.64
Intercept (constant)	0.87 (0.77 to 0.97)		
Social deprivation score	0.003 (0.003 to 0.004)	0.226	
Nonunion of fracture	−0.48 (−0.52 to −0.39)	0.158	
Affective disorder	−0.22 (−0.26 to −0.17)	0.106	
Independence	−0.16 (−0.21 to −0.11)	0.069	
Comorbidity score	−0.03 (−0.04 to −0.01)	0.022	
Tuberosity involvement	−0.08 (−0.12 to −0.04)	0.014	
Mobility	−0.11 (−0.16 to −0.05)	0.011	
Employment status	−0.14 (−0.20 to −0.08)	0.010	
Age	−0.003 (−0.004 to −0.002)	0.008	
Medicolegal claim for personal injury	−0.13 (−0.19 to −0.06)	0.007	
Segmental collapse of humeral head	−0.24 (−0.36 to −0.11)	0.007	
Previous shoulder problems	−0.11 (−0.18 to −0.05)	0.005	
Alcohol consumption	−0.07 (−0.11 to −0.02)	0.004	
Operative treatment for fracture complications	−0.11 (−0.21 to −0.01)	0.002	

*The coding of categorical variables was described in Table III. †The values are given as the regression coefficient, with the 95% CI in parentheses.

predictive of functional outcomes, but either had weaker or inconsistent associations or were binary outcome measures in which the adverse outcome was rarer and less influential in the multivariate analysis (Tables V and VI).

Discussion

This study suggests that nonoperative treatment of proximal humeral fractures is associated with considerable variation in shoulder function and general health perception, when assessed using PROMs at 1 year. Although satisfactory outcomes have been reported by the majority, with many achieving near-normal scores, a substantial minority of patients have only mediocre or poor outcomes.

Most of the variation in the PROM scores at 1 year was predicted by premorbid demographic and psychosocial features: the 3 factors of the level of dependency, social deprivation score, and history of affective disorder were consistently the strongest independent predictors, accounting for between 37% and 43% of the variation in all 4 multivariate analyses. The model's predictive value only improved modestly by inclusion of complication codes and surgical intervention that occurred in the year after the injury, suggesting that most

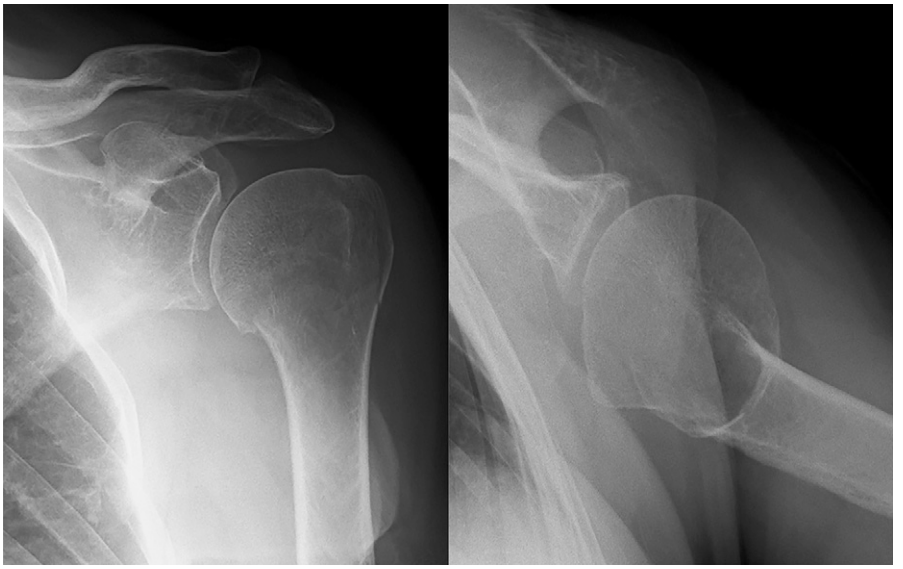

Fig. 4-A

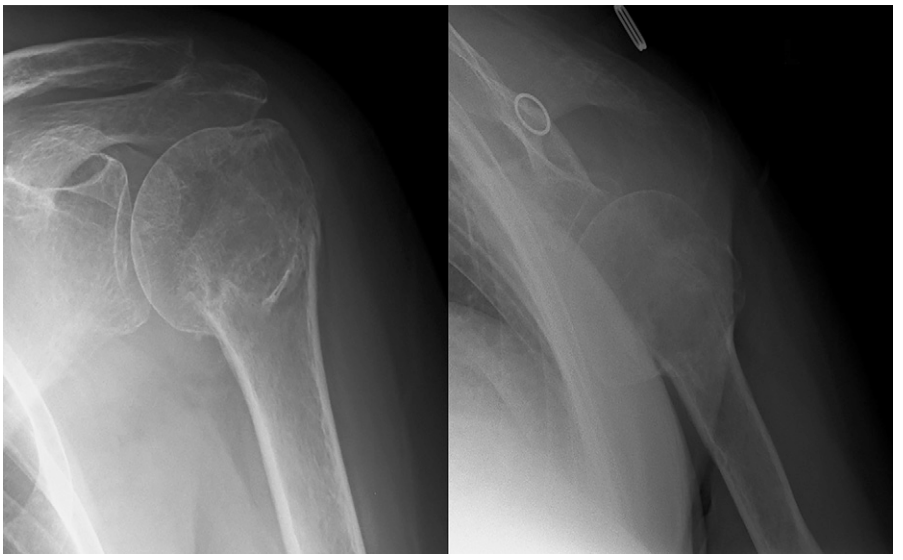

Fig. 4-B

Fig. 4-A and 4-B Radiographs of 2 patients with similar fracture configurations but different outcomes. **Fig. 4-A** Shoulder radiographs showing the anteroposterior view (*left panel*) and Velpeau view (*right panel*) for a 56-year-old unemployed man from the 10th social deprivation percentile, with a history of affective disorder requiring antidepressant medication. The fracture had slight varus angulation and was minimally displaced. The fracture had united at 1 year and the patient had full range of shoulder movement at this time, yet the OSS was 15 points, the EQ-5D-3L was −0.181 (worse-than-death status), and the level of satisfaction with treatment was 15%. **Fig. 4-B** Shoulder radiographs showing the anteroposterior view (*left panel*) and Velpeau view (*right panel*) for a 81-year-old retired man from the 85th social deprivation percentile with medical comorbidities but no history of affective disorder. The fracture had a similar degree of slight varus angulation and minimal displacement. The fracture had united at 1 year and the patient had full range of shoulder movement at this time, with an OSS of 47 points, an EQ-5D-3L of 0.848, and a level of satisfaction with treatment of 98%.

of the outcome variation can be predicted immediately after the injury.

Fracture-related factors were less influential than psychosocial factors in predicting outcome, although the initial fracture displacement potentially leading to subsequent nonunion was associated with between 9% and 15% of the variation in the measured PROMs and worse overall outcomes in the 79 patients (10.2%) who developed this complication, 58.2% of whom reported worse-than-death general health scores. However, by 1 year, only a minority of patients had undergone a surgical procedure to treat this complication, and some of those who were treated may have had incomplete functional recovery.

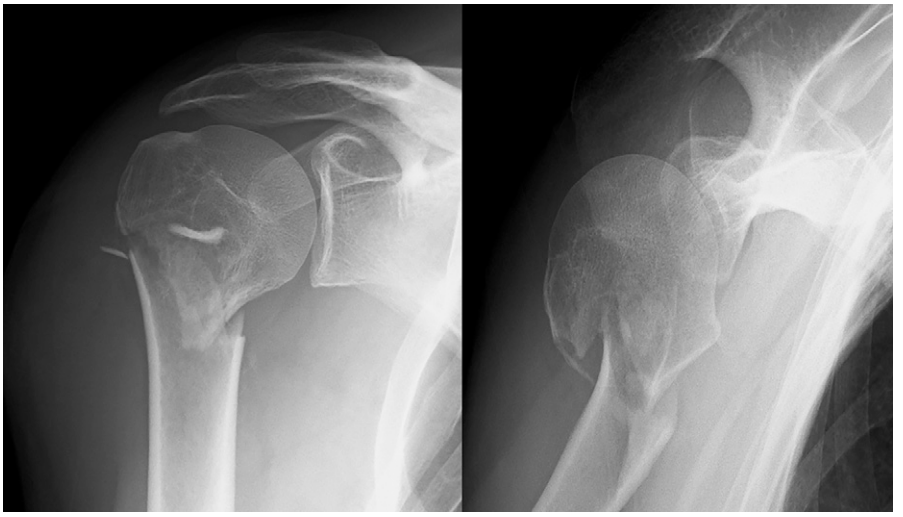

Fig. 5-A

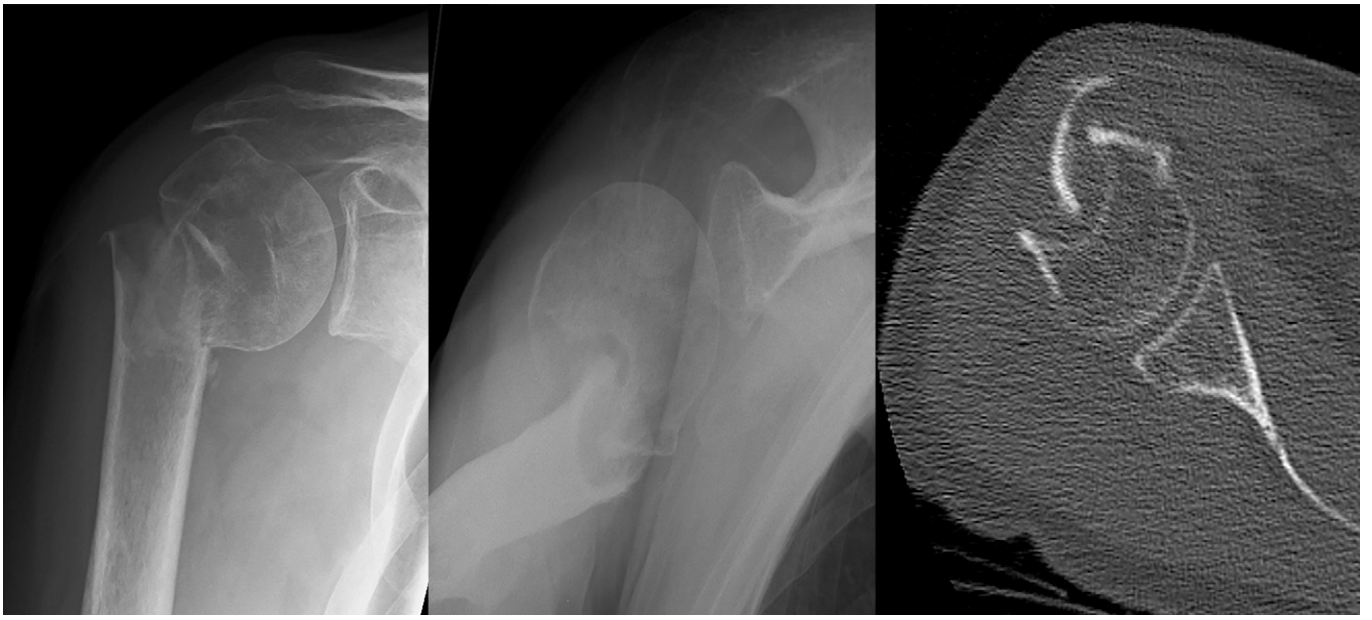

Fig. 5-B

Fig. 5-A and 5-B A 68-year-old woman with a translated Neer 2-part fracture sustained in a simple fall. **Fig. 5-A** Conventional shoulder radiographs showing the anteroposterior view (*left panel*) and Velpeau view (*right panel*). The patient had a number of medial comorbidities and initially elected to be treated nonoperatively. **Fig. 5-B** Conventional shoulder radiographs at the 6-month follow-up showing the anteroposterior view (*left panel*) and the Velpeau view (*center panel*) of the fracture revealing progressive varus deformity and suspected nonunion, which was confirmed on computed tomography (*right panel*). The patient's general health had declined and she was not a candidate for operative treatment at this stage. At 1 year, the OSS was 16 points, the EQ-5D-3L was −0.349 (worse-than-death status), the VAS pain score was 90%, and the VAS level of satisfaction was 10%.

At the time of this writing, other patients were still awaiting a surgical procedure, and it was possible that their PROM scores would have subsequently improved.

A displaced tuberosity fracture was the other fracture variable that was consistently associated with worse PROM scores, predicting between 1% and 4% of the variation in both the primary and secondary analyses. Humeral-head osteonecrosis was also associated with worse outcome, but was less influential overall, due to its rarity.

There was evidence of a ceiling effect, with 30.8% of patients having a near-maximal OSS (≥47 points). This effect was more marked in younger, active individuals who, despite experiencing pain relief in a functional shoulder, were less satisfied with their treatment outcome. At the other end of the spectrum, 30.9% of patients had much poorer PROM scores with residual pain and functional incapacity, and 120 patients (15.5%) had negative, worse-than-death, EQ-5D-3L scores.

TABLE VII Summary of Results After Nonoperative Treatment for Proximal Humeral Fractures in English-Language Observational Studies and Clinical Trials That Showed Functional Outcome*

Study	Fractures Studied	No. of Patients	Age† *(yr)*	Follow-up† *(mo)*	Outcome Assessment	Functional Outcome Score§
Observational studies						
Koval[2] (1997)	Mixed	104	63 (24 to 94)	41 (12 to 117)	Unvalidated scoring system	94% (40% to 100%)
Zyto[21] (1998)	Complex	14	70 (26 to 65)	120	Constant	Mean, poor
Serin[28] (1999)	Complex	29	54 (18 to 81)	42	Neer	76% good or excellent
Court-Brown[10] (2001)	AO A3.2 translated 2-part	97	72	12	Neer	78.9
Court-Brown[22] (2002)	AO B1.1 impacted valgus	125	71 (44 to 88)	12	Constant	71.8
					Neer	87.1
Gaebler[11] (2003)	Neer 1-part	376	63 (13 to 87)	12	Neer	90
Court-Brown[26] (2004)	AO A2.2 impacted varus	99	68 (23 to 94)	12	Neer	87
Keser[29] (2004)	Minimally displaced	27	25 (12 to 34)	25 (12 to 34)	Constant	74% good or excellent
Fjalestad[23] (2005)	Mixed	55	71 (25 to 94)	12 to 14	Modified Rowe	Minimally displaced, 56.7
						Simple displaced, 53.2
						Complex displaced, 48
Olsson[30] (2005)	Mixed	47	59 (24 to 79)	12 to 156	Constant	83% good or excellent
Platzer[31] (2005)	Minimally displaced	135	56 (18 to 88)	44 (24 to 120)	Constant	97% good or excellent
Lefevre-Colau[32] (2007)	Mixed	64	63.3	6	Constant	Good (mean)
Baker[25] (2008)	Mixed	103	61.4 (15 to 85)	12	Oxford	22.72 (12 to 56)
					Constant	66.23 (6 to 100)
Hanson[12] (2009)	Mixed	124	63.3 ± 14.8	12	Constant	74.3 (95% CI, 72.0 to 76.5)
Foruria[27] (2011)	Mixed	93	71 (26 to 93)	12	Neer	75.2% good or excellent
					DASH	23 (0 to 70)
					ASES	78 (18 to 100)
					SF-36 Physical	46 (18 to 64)
					SF-36 Mental	51 (21 to 68)
Clement[24] (2014)	Mixed	587	76.9 (65 to 98)	12	Constant	64.2 ± 16.4
Clement[3] (2014)	Mixed	711	NR	12	Constant	69.1 ± 16.3
Kruithof[33] (2017)	Mixed	410	70 ± 12.0	90 ± 48	DASH	6.67 (0.83 to 22.50)
Jayakumar[4] (2019)	Mixed	173	66 (18 to 95)	6 to 9	QuickDASH	31.9 (0 to 79.5)
					Oxford	34.8 (14 to 48)
					EQ-5D-3L	40.5 (26.2 to 56.4)
Clinical trials						
Kristiansen[19] (1989)	Mixed	73	NR	6	Neer	62% good or excellent
Rangan[16] (2015)	Mixed	109	65.79 ± 11.97	24	Oxford	40.40 (95% CI, 38.59 to 42.13)
					SF-12 Physical	44.20 (95% CI, 41.87 to 46.54)
					SF-12 Mental	50.69 (95% CI, 48.40 to 52.97)
Çaliskan[17] (2019)	Mixed	47	58.4 (25 to 89)	25	ASES	2-part fractures: 82.3, 3-part fractures: 85.9, 4-part fractures: 70.3

continued

TABLE VII (*continued*)

Study	Fractures Studied	No. of Patients	Age† *(yr)*	Follow-up‡ *(mo)*	Outcome Assessment	Functional Outcome Score§
Launonen[20] (2019)	Displaced 2-part	39	73 (60 to 86)	24	DASH	17.4 ± 2.8#
					Constant	66.0 ± 3.3#
					Oxford	41.5 ± 1.4#
Lopiz[18] (2019)	Mixed	30	85 ± 4.8	12	Constant	79.6
					DASH	28.8 ±19.6

*NR = not reported, DASH = Disabilities of the Arm, Shoulder and Hand questionnaire, ASES = American Shoulder and Elbow Surgeons score, SF = Short Form, and QuickDASH = the abbreviated version of the DASH questionnaire. †The values are given as the mean, with or without the range in parentheses or the standard deviation. ‡The values are given as the mean, with or without the range in parentheses or the standard deviation, or as the range. §The values are given as the mean, with or without the range in parentheses or the standard deviation, unless otherwise stated, or as the percentage with poor, good, or excellent results. #The values are given as the mean and the standard error.

Clinical trials of nonoperative treatment have shown generally favorable results that are equivalent to those of operative treatment, but with a lower rate of a revision surgical procedure (Table VII)[16-20]. Observational cohort studies have also demonstrated favorable overall results, but with up to 25% having poorer outcomes (Table VII)[2-4,10-12,21-33]. As in this current study, most studies find that a variety of psychosocial factors and social dependency have more influence on functional outcome than fracture severity has[3,4,12,20]. However, there is considerable disparity in the relative importance of the factors linked to poorer outcomes. Some have found that psychosocial measures, such as overcoming fears of movement, reinjury, and greater self-efficacy, are the strongest predictors of outcome[4], whereas others have attached greater importance to markers of dependency and social deprivation[3,12,20]. The outcome measures assessed vary from generic scoring systems[3,20] to PROM assessments[4], and this may account for the variation in the relative importance of the factors reported.

Although some studies have highlighted the importance of fracture displacement and nonunion in predicting a poorer outcome[27,34], others have not found this association[12]. The less influential association of tuberosity fracture and humeral-head osteonecrosis with poorer outcomes has not previously been demonstrated[3,4,12,20]. In cohort studies, most fractures are minimally displaced and tuberosity involvement, nonunion, and humeral-head osteonecrosis are uncommon; it is possible that studies with smaller sample sizes were inadequately powered to detect the effect of these factors on the PROM scores[3,11,12,20].

Most studies have focused on the outcomes in the elderly[3,4,12,20], in whom lesser functional demands dictate that a satisfactory outcome may be achieved with a mobile shoulder that had experienced pain relief, resulting in a high OSS. Our study suggests that such scores in younger, more active individuals may be associated with a degree of loss of function and dissatisfaction with treatment. Further studies examining the outcomes in younger patients would be worthwhile, incorporating scoring systems that can detect more subtle functional deficits. In high-functioning patients, the inability to return to physically demanding activities may be contributory to their poorer outcomes, and psychosocial factors may be less important than fracture-related variables.

The main strength of the study is the large consecutive cohort of patients, who were examined during the first year after the injury using PROMs. This allowed a more precise estimation of the PROM scores, and the factors affecting it, than previously possible. A primary surgical procedure was only used for a minority of patients, but, due to their severe fracture patterns, it is likely that their functional outcomes after nonoperative treatment would have been poor. Our estimation of the PROM scores may be overly optimistic, and the results may not be generalizable to centers using different thresholds for operative treatment or with different patient demographic characteristics. Our model should be retested to assess its validity in other geographic settings. As with all studies in elderly populations, many patients were unsuitable for inclusion, due to cognitive impairment and loss to follow-up. Their exclusion may have skewed our results, but the pragmatic nature of our study made this unavoidable.

Although 15.5% of patients reported worse-than-death status at 1 year, these results must be interpreted in the context of how the EQ-5D-3L score was calculated, using 5 domains to generate 243 possible health states[14]. The score assigned to each state was determined on a population basis using time trade-off methodology, with one-third of the possible scores being negative or worse than death. As such, a negative score is a hypothetical value, based on the beliefs regarding health-related quality of life in a population sample. These scores are therefore not experiential valuations and must be interpreted with caution, because they may underestimate the actual quality of life.

These findings should facilitate counseling regarding the outcome that a patient with a proximal humeral fracture can expect to achieve after nonoperative treatment. At present, there has been some limited clinical evidence that treatment to address psychosocial factors improves pain perception and disability after musculoskeletal injury, through the use of better communication

and behavioral therapy[35-38]. Further study would be required to evaluate whether such interventions improve the outcomes after proximal humeral fractures treated nonoperatively.

Nonoperative treatment is widely used to treat minimally displaced proximal humeral fractures. The evidence in favor of operative treatment for displaced proximal humeral fractures and those with tuberosity involvement is conflicting. Clinical trials have shown that this method of treatment produces only equivalent results to nonoperative treatment[15-18], although good results have been achieved when the surgical procedure is performed in high-volume specialist centers[5]. Therefore, surgeons have few guidelines when considering whether a patient might benefit from operative treatment. A surgical procedure aimed solely at improving outcomes by preventing nonunion or problems related to residual tuberosity displacement exposes patients to the risk of complications that are not encountered with nonoperative treatment. However, given the importance of displaced and multipart fractures in predicting a poorer functional outcome, we believe that patients with these factors, who are at higher risk for nonunion, should be counseled about the possible benefits that they might gain from surgical intervention to prevent this debilitating complication.

More clinical trials are needed to compare the PROMs after nonoperative and operative treatments. Due to the ceiling effects in younger individuals and the importance of psychosocial factors in predicting outcome, future studies should include stratification by these factors, if they are to adjust for their confounding effects and thus more accurately evaluate differences between different treatment modalities. ■

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