



# Associations of preoperative patient mental health status and sociodemographic and clinical characteristics with baseline pain, function, and satisfaction in patients undergoing primary shoulder arthroplasty

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**Hypothesis and background:** Shoulder pain and dysfunction are common indications for shoulder arthroplasty, yet the factors that are associated with these symptoms are not fully understood. This study aimed to investigate the associations of patient and disease-specific factors with preoperative patient-reported outcome measures (PROMs) in patients undergoing primary shoulder arthroplasty. We hypothesized that worse mental health status assessed by the Veterans RAND 12-Item Health Survey (VR-12) mental component score (MCS), glenoid bone loss, and increasing rotator cuff tear severity would be associated with lower values for the preoperative total Penn Shoulder Score (PSS) and its pain, function, and satisfaction subscores.

**Methods:** We prospectively identified 12 patient factors and 4 disease-specific factors as possible statistical predictors of preoperative PROMs in patients undergoing primary shoulder arthroplasty at a single institution over a 3-year period. Multivariable statistical modeling and Akaike information criterion comparisons were used to investigate the unique associations with, and relative importance of, these factors in accounting for variation in the preoperative PSS and its subscores.

**Results:** A total of 788 cases performed by 12 surgeons met the inclusion criteria, with a preoperative median total PSS of 31 points (pain, 10 points; function, 18 points; and satisfaction, 1 point). As hypothesized, a lower VR-12 MCS was associated with lower preoperative PSS pain, function, and total scores, but patients with intact status or small to medium rotator cuff tears had modestly lower PSS pain subscores (ie, more pain) than patients with large to massive superior-posterior rotator cuff tears. Glenoid bone loss was not associated with the preoperative PSS. Female sex and fewer years of education (for all 4 outcomes), lower VR-12 MCS and preoperative opioid use (for all outcomes but satisfaction), and rotator cuff tear severity (for pain only) were the factors most prominently associated with preoperative PROMs.

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This study was approved by Cleveland Clinic's Institutional Review Board (no. 06-196).

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**Conclusion:** In addition to mental health status and rotator cuff tear status, patient sex, years of education, and preoperative opioid use were most prominently associated with preoperative PROMs in patients undergoing shoulder arthroplasty. Further studies are needed to investigate whether these factors will also predict postoperative PROMs.

**Level of evidence:** Level III; Cross-sectional Study

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The number of shoulder arthroplasty procedures performed in the United States continues to rise, with current estimates ranging from 55,000-80,000 per year, and increases  $\geq 300\%$  expected in the coming years.<sup>10,24,34</sup> Baseline preoperative symptoms related to pain and function are often used as indications for performing primary shoulder arthroplasty,<sup>12,25,30,53</sup> yet the relationships of general patient factors and pathologic characteristics with preoperative pain and function in patients undergoing primary shoulder arthroplasty have not been studied.

To address the need for high-quality, prospective, standardized data surrounding orthopedic procedures, the Cleveland Clinic has developed the Outcomes Management and Evaluation system (OME).<sup>11,35,39</sup> Currently, OME prospectively collects sociodemographic factors, joint-specific disease severity and treatment variables, and joint-specific, validated patient-reported outcome measures (PROMs), preoperatively and at 1 year after treatment, for  $>30$  elective orthopedic procedures. Data are electronically stored in a secure Research Electronic Data Capture (REDCap)<sup>16</sup> database. As of November 2019, OME has been used by 72 orthopedists at 16 sites within the Cleveland Clinic health system to document episode-of-care details and preoperative PROMs in 97% of  $>44,000$  elective knee, hip, and shoulder surgical procedures, including  $>2500$  cases of shoulder arthroplasty. The OME cohort has been successfully used to evaluate the relationships of general patient factors and pathologic characteristics with preoperative pain and function in patients undergoing other elective orthopedic procedures, including lower-extremity arthroplasty<sup>52</sup> and rotator cuff (RC) repair surgery.<sup>40</sup>

We hypothesized that worse mental health status, glenoid bone loss, and increasing RC tear severity would be associated with lower (worse) values for the preoperative total Penn Shoulder Score (PSS) and its pain, function, and satisfaction subscores in patients undergoing primary shoulder arthroplasty. We tested this hypothesis and examined additional relationships in the prospectively collected, comprehensive, standardized OME cohort data using multivariable modeling with control for confounding by general patient and disease-specific factors.

## Materials and methods

### Primary shoulder arthroplasty surgical cohort

Patients undergoing primary shoulder arthroplasty (anatomic arthroplasty, reverse arthroplasty, or hemiarthroplasty) within the

Cleveland Clinic health system between February 2015 and February 2018 and having a diagnosis of glenohumeral osteoarthritis (OA) or rotator cuff tear arthropathy (CTA) were eligible for the study. Patients having a history of joint infection in the operative shoulder, undergoing primary shoulder arthroplasty for a diagnosis other than OA or CTA, or having incomplete preoperative PROM data were sequentially excluded.

### Variable selection

The PSS was selected for use as the PROM. The PSS is a valid and reliable outcome tool scored from 0 to 100 points. Its subdomains include pain (3 items, each scored on a 10-point scale; 0-30 points), function (20 items, each scored on a 4-point scale; normalized to 0-60 points), and satisfaction (1 item; 0-10 points), with higher scores representing less pain, better function, and higher satisfaction.<sup>26</sup>

No outcome-driven variable selection was performed. A total of 16 preoperative patient and disease-specific variables were prospectively identified as possible predictors of preoperative pain, function, and satisfaction and as possible confounders of the relationships of mental health, glenoid bone loss, or tear severity with these outcomes. These preselected baseline variables included 12 general patient factors (age, sex, race, body mass index [BMI], smoking status [nonsmoker, former smoker, or current smoker], preoperative opioid use, years of education, employment status [not employed, employed, or retired], workers' compensation status, mental health status as assessed by the Veterans RAND 12-Item Health Survey [VR-12] mental component score [MCS], comorbidities [Charlson Comorbidity Index (CCI)], and chronic pain) and 4 disease-specific factors (prior shoulder surgery, glenoid bone loss, superior-posterior RC tendon status, and subscapularis tendon status).

### Data source

Data on 11 of the 16 preoperative patient and disease-specific factors were obtained from the Cleveland Clinic's OME database,<sup>35</sup> which has been shown to be a valid and efficient tool for collecting comprehensive and standardized data on multiple orthopedic surgical procedures.<sup>3,13,31,35,39,44</sup> The 4 disease-specific factors were entered prospectively into the OME database within 48 hours of surgery by the operating surgeon using a smartphone, laptop computer, or desktop computer to access an e-mail link sent by the system immediately after procedure completion. Data on 5 preoperative factors (race, comorbidities, preoperative opioid use, chronic pain, and workers' compensation status) were obtained from the Cleveland Clinic's electronic medical record (EMR; Epic Systems, Verona, WI, USA),

Perioperative Health Documentation System (PHDS) database, and Epic Cost of Goods Sold (COGS) system. The CCI was calculated from the comorbidity data.<sup>37</sup> Preoperative opioid use was counted as yes if an opioid was prescribed in the patient's EMR and/or ordered from the Epic Cost of Goods Sold (COGS) system between 3 months and 24 hours before surgery. Chronic pain was counted as yes if the patient's EMR contained an *International Classification of Diseases, Ninth Revision (ICD-9)* diagnostic code of 338.2 (chronic pain) and/or 304.0x (opioid dependence). Occasional data inconsistencies missed by routine database consistency checking were corrected when possible prior to analysis.

## Statistical analysis

Distributions of continuous variables were summarized as median (interquartile range), and distributions of categorical variables were calculated as frequency counts (percentages) for each category. The frequency counts for categorical predictors were assessed a priori for appropriate opportunities to group clinically similar categories or to identify categories likely too small to allow identification of distinguishable effects. Glenoid bone loss, categorized in OME by glenoid region (central, anterior, posterior, or superior) based on surgeon assessment of preoperative imaging and intraoperative findings, was condensed into a categorization of yes or no for analysis. RC pathology was assessed intraoperatively by the operating surgeon and classified, separately for the superior-posterior RC and for the subscapularis, as intact status or full-thickness tear (small, 0-1 cm; medium, 1-3 cm; large, 3-5 cm; or massive, >5 cm). For our analyses, each variable was initially reduced to a trichotomy of intact status, small to medium tears, and large to massive tears owing to small counts in some categories. Then, because certain tear combinations were strongly associated (Table 1), the categories were further reduced into a single composite "RC status" variable, with subgroup 1 defined as intact status or small to medium tears of both the superior-posterior RC and subscapularis; subgroups 2, 3, and 4 defined as large to massive tears of the superior-posterior RC with the subscapularis status classified as being intact, having small to medium tears, and having large to massive tears, respectively; and subgroup 5 defined as large to massive subscapularis tears with intact status or small to medium tears of the superior-posterior RC. Given the small size of subgroup 5 ( $n = 5$ ), this subgroup was dropped from further analysis (Fig. 1). The distinction between RC status subgroup 1 and subgroups 2-4 was found to almost perfectly capture preoperative diagnosis, with 99.6% of subgroup 1 patients (550 of 552)

having a diagnosis of glenohumeral OA and 94.1% of subgroup 2-4 patients (222 of 236) having a diagnosis of CTA. This almost complete collinearity allowed inclusion of either RC status or diagnosis—but not both—in multivariable models. Therefore, for statistical analysis, RC status was retained as providing more information while essentially conveying the diagnostic distinction when dichotomized by thresholding between subgroup 1 and subgroups 2-4.

Within the remaining sample ( $n = 788$ ), 81 patients (10.2%) had missing data on race; 10 (1.3%), employment status; 2 (0.2%), education; 1 (0.1%), smoking status; and 1 (0.1%), VR-12 MCS. Data on all other predictors and PSS values were complete. The missing data were multiply imputed using multivariate imputation by chained equations (MICE), an iterative, fully conditional multiple imputation approach (mice R package<sup>45</sup>). The 16 predictors and 4 outcome variables were all included in the imputation model. Subsequent statistical analyses were performed identically and in parallel on all imputations, with results from the separate imputation sets combined using the standard formula of Rubin.<sup>38</sup>

Multivariable modeling was performed to investigate the unique associations of the 3 hypothesized correlates (VR-12 MCS, glenoid bone loss, and RC status) with preoperative PSS (total score, as well as pain, function, and satisfaction subscores) while adjusting to control for potential confounding by each of these measures; by the 11 other general patient factors; and by the single other disease-specific factor, prior shoulder surgery. Total PSS and pain and function subscores were modeled using linear regression, whereas PSS satisfaction subscores were modeled using proportional (cumulative) odds logistic regression owing to violations of linear regression assumptions. Age, BMI, years of education, VR-12 MCS, and CCI were treated as continuous variables, and their effects were modeled by linear trends in their respective measurement units on the appropriate scale of the response. Trichotomous nominal predictors (race, smoking status, and employment status) were modeled categorically. For the effect of RC status on preoperative PSS, we focused attention on the effect of large to massive superior-posterior tendon tears (RC status subgroup 1 vs. subgroups 2-4) and the "pseudo-linear" effects of increasing subscapularis tear severity in the presence of a large to massive superior-posterior tendon tear (RC status subgroup 2 through 4 trend). We also conducted exploratory analysis of nonlinear differences among those 3 categories (RC status subgroups 2-4).

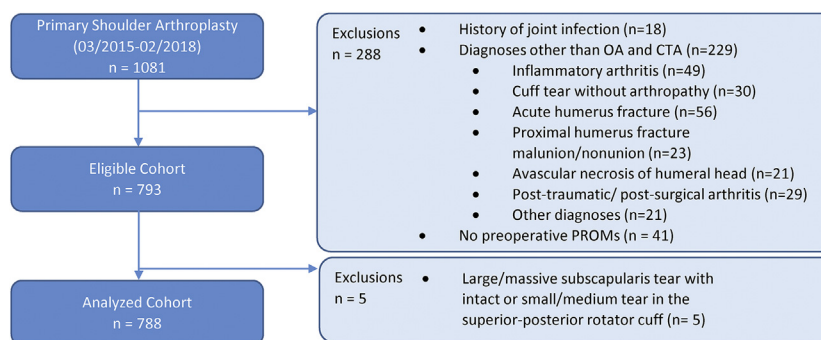
The effects of each predictor on the total PSS, as well as the pain and function subscores, and the cumulative odds ratios of

**Table 1** Coupled frequencies of superior-posterior RC and subscapularis status across patient cohort used for classification of RC status subgroups

Subscapularis status	Superior-posterior RC status		
	Intact	Small to medium tear	Large to massive tear
Intact	520 (subgroup 1)	30 (subgroup 1)	153 (subgroup 2)
Small to medium tear	1 (subgroup 1)	1 (subgroup 1)	45 (subgroup 3)
Large to massive tear	5 (subgroup 5)	0 (subgroup 5)	38 (subgroup 4)

RC, rotator cuff.

Coupled frequencies of superior-posterior RC and subscapularis status across the patient cohort for the RC status subgroups were used to reduce patients into 1 of 5 RC status subgroups.



**Figure 1** Flow diagram describing sequential patient exclusions to arrive at primary shoulder arthroplasty surgical cohort. OA, osteoarthritis; CTA, cuff tear arthropathy; PROMs, patient-reported outcome measures.

each variable on the PSS satisfaction subscore were estimated; in addition, their 95% confidence intervals and the  $P$  values and adjusted  $R^2$  values for each model (Nagelkerke  $R^2$  for satisfaction) were reported. The relative importance of each variable in explaining variation in preoperative PROMs was assessed by calculating and ranking the increases in the Akaike information criterion<sup>20</sup> upon removal of that variable from the full model.

Separately testing relationships of each variable of interest with the total PSS and each of the 3 subscores, as well as separately comparing multiple pairs of levels of factors with >2 levels, is conducive to false-positive findings. We therefore limited false-positive errors by using the Bonferroni-Holm multiple-comparisons adjustment, with a family-wise type I error rate of .05, to conduct simultaneous tests of each variable in relation to the 4 PSS measures and by using multiple degree-of-freedom omnibus tests rather than paired comparisons to assess differences among levels of categorical variables with >2 levels.

We used sensitivity analyses to examine the effect of diagnosis on our results. Given the very few discrepancies between RC status subgroup 1 and glenohumeral OA, for consistency with all other analyses we used the RC status dichotomization introduced earlier (subgroup 1 vs. subgroups 2-4) for this purpose rather than the diagnosis of record. We checked for whether associations of preoperative variables with preoperative PROMs varied with the 2 diagnostic categories by fitting models in which relationships between the preoperative variables and PROMs were allowed to vary between RC status subgroup 1 (99.6% glenohumeral OA patients) and the combined RC status subgroups 2-4 (94.1% CTA patients). This was achieved by expanding the primary multivariable model to include a separate effect of each predictor in RC status subgroup 1, both in nested models, in which this was performed for each predictor individually, and in a single mutually adjusted nested model with separate effects of all predictors in subgroup 1 distinct from their effects in subgroups 2-4.

In addition, possible interactions of any statistically significant focal variable (VR-12 MCS, glenoid bone loss, and RC status) with other statistically significant predictors were examined by augmenting the models for each outcome simultaneously by this subset of first-order interactions. Because correlated predictors may conceal each other's effects, we not only examined models containing all of these interactions simultaneously but also used forward and backward selection to check that prominent interactions were not hidden by mutual adjustments. Next, we removed plausible causal mediators, specifically 6 patient factors (mental health status, chronic pain, preoperative opioid use, smoking status, employment status, and workers' compensation

status), from our prespecified primary models because such mutual-adjustment models may overmatch, obscuring stronger relationships by analytically mistaking causal mediators for confounders. We heuristically evaluated the potential masking of covariate effect by fitting 6 additional separate partial models, each including 1 of these 6 variables in turn and examining, in each model, the decrease in the retained variable's effect magnitude in the full model compared with the partial model. All statistical analyses were performed using R software (version 3.5.0 [2018-4-23]; R Foundation for Statistical Computing, Vienna, Austria). Consistent with recent appeals by many leaders in the statistical profession for a de-emphasis of dichotomous, null-hypothesis significance testing in scientific practice,<sup>49,50</sup> we use statistical tests of hypotheses to inform but not dictate our assessments of scientific findings, and we subordinate use of the technical term "statistical significance" to more holistic descriptions.

## Results

A total of 1081 cases undergoing primary shoulder arthroplasty at Cleveland Clinic facilities between February 2015 and February 2018 were captured in the OME database (Fig. 1). Of these cases, 288 were sequentially excluded based on study-specific exclusion criteria: (1) a history of joint infection ( $n = 18$ ), (2) a diagnosis other than glenohumeral OA or CTA ( $n = 229$ ), and (3) incomplete preoperative PROM data ( $n = 41$ ). Ultimately, 793 primary shoulder arthroplasty cases performed by 12 surgeons were retained, with 5 cases in the rare RC status subgroup (ie, subgroup 5) further excluded, leaving a cohort of 788 patients for analysis. Table II shows the distribution of cases by diagnosis and arthroplasty type.

## General patient and disease-specific characteristics

Table III presents the general patient and disease-specific characteristics of this sample. The patients had a median age of 68 years, BMI of 30.1, length of education of 14 years, VR-12 MCS of 52.1, and CCI of 2. The great majority were white (92%). Of the patients, 55% were men,



**Table II** Cross classification of type of primary shoulder arthroplasty by primary diagnosis

Arthroplasty type	Diagnosis, n (%)		Total, n (%)
	Glenohumeral osteoarthritis	Rotator cuff tear arthropathy	
Anatomic	354 (100)	0 (0)	354 (45)
Reverse	182 (47)	209 (53)	391 (50)
Hemiarthroplasty	28 (65)	15 (35)	43 (5)
Total	564 (72)	224 (28)	788

50% were current or former smokers, 43% had chronic pain, and 36% had used opioids preoperatively between 3 months and 24 hours before surgery. Glenoid bone loss was noted in 52% of patients, and 18% had a history of shoulder surgery. Regarding RC status, 66% of patients had an intact superior-posterior RC and 89% had an intact subscapularis tendon. The diagnosis was glenohumeral OA in 72% of cases and CTA in 28%.

### Preoperative PSS

Table IV presents the preoperative PSS (total score and pain, function, and satisfaction subscores) in the 788 patients. The patients had median total PSS of 31 points, pain subscore of 10 points, function subscore of 18 points, and satisfaction subscore of 1 point.

### Multivariable modeling

By adjusted  $R^2$  analysis, the 15 general patient and disease-specific factors in the full models accounted for 21%-23% of the variability in the 3 continuous outcome variables (total PSS, pain subscore, and function subscore). Table V reports the estimated effects, confidence intervals, and multiple comparisons-adjusted test results for the 12 general patient and 3 disease-specific factors (including the combined superior-posterior RC and subscapularis tendon statuses) for preoperative PSS and each subscore; Figure 2 graphically portrays these data. Of the 3 hypothesized predictors, a lower VR-12 MCS was associated with lower (worse) PSS pain, function, and total scores, with a total score difference of 5.1 points between patients with scores in the upper and lower VR-12 MCS quartiles. Consistent with our hypothesis, patients with glenoid bone loss exhibited lower values for the total PSS and PSS subscores than those without glenoid bone loss, but the estimated effect sizes were modest (-2.1 points on total score) and all differences were within the multiple comparisons-adjusted range of chance variation. Patients with intact status or small to medium RC tears (RC status subgroup 1) had modestly lower (-1.6 points) PSS pain subscores on average than patients with large to massive superior-posterior RC tears (subgroups 2, 3, and 4 combined). Among the patients with large to massive superior-posterior

RC tears (subgroups 2-4), there was no substantial evidence to suggest an effect of increasing subscapularis tear size on PSS values (Table V).

In looking at the other general patient factors within the same comprehensive multivariable models, we found notable associations for female sex and less education with lower total PSS (-7.7 points and -3.7 points per 4 years, respectively) and all 3 subscores; preoperative opioid use with lower total PSS (-4.0 points), as well as pain and function subscores; and older age with lower PSS function subscore (-2.1 points per 13 years) (Table V).

### Relative prominence of predictor associations with preoperative PSS

Figure 3 compares the Akaike information criterion increases from removal of each variable from the full model as a gauge of the relative importance of each variable's contributions. The top 5 variables accounted for 95%-98% of the total variances explained by the 15 predictors in the full models for total PSS and the pain and function subscores and accounted for 78% of the relative likelihood improvement (Nagelkerke  $R^2$ ) in the model for the satisfaction subscore. Sex and education were among the most important variables for all 4 outcomes, whereas VR-12 MCS and preoperative opioid use were important factors for all outcomes but the PSS satisfaction subscore. RC status, reflecting tear severity, was an important contributor only to the PSS pain subscore.

### Effect of preoperative diagnosis on preoperative PSS

The results of the mutually adjusted models with separate effects for predictors in RC status subgroup 1 (glenohumeral OA patients) did not differ notably from the results of models in which this was performed for each predictor individually; hence, we report only the former data. Retirement was associated with a 3-point lower preoperative total PSS than current employment among glenohumeral OA patients (RC status subgroup 1) but a 5-point higher score among CTA patients (RC status subgroups 2-4). This result was primarily driven by the function subscore but with contributions from the satisfaction and pain

**Table III** Preoperative patient demographic and disease-specific characteristics of 788 patients undergoing primary shoulder arthroplasty

Variable	Data
<b>Demographic characteristics</b>	
Age, yr	68 (61-74)
BMI	30.1 (26.7-34.3)
CCI	2 (0-4)
Education, yr	14 (12-16)
VR-12 MCS	52 (41.8-60.8)
Sex, n (%)	
Female	356 (45)
Male	432 (55)
Race, n (%)	
White	650 (92)
Black	49 (7)
Other	8 (1)
Not available*	81
Smoking status, n (%)	
Current	76 (10)
Quit	312 (40)
Never	399 (51)
Not available*	1
Preoperative opioid use, n (%)	
Yes	285 (36)
No	503 (64)
Chronic pain, n (%)	
Yes	338 (43)
No	450 (57)
Employment status, n (%)	
Employed	194 (25)
Retired	253 (32)
Not employed	331 (42)
Not available*	10
Workers' compensation status	
Yes	16 (2)
No	772 (98)
<b>Disease-specific characteristics, n (%)</b>	
Prior shoulder surgery	
Yes	142 (18)
No	646 (82)
Glenoid bone loss	
Yes	411 (52)
No	377 (48)
Superior-posterior RC status	
Large to massive tear	236 (30)
Small to medium tear	31 (4)
Intact	521 (66)
Subscapularis status	
Large to massive tear	38 (5)
Small to medium tear	47 (6)
Intact	703 (89)
RC status <sup>†</sup>	
1	552 (70)
2	153 (19)
3	45 (6)
4	38 (5)

(continued on next page)

**Table III** Preoperative patient demographic and disease-specific characteristics of 788 patients undergoing primary shoulder arthroplasty (continued)

Variable	Data
<b>Diagnosis</b>	
Glenohumeral osteoarthritis	564 (72)
RC tear arthropathy	224 (28)

BMI, body mass index; CCI, Charlson Comorbidity Index; VR-12, Veterans RAND 12-Item Health Survey; MCS, mental component score; RC, rotator cuff.

Data are presented as median (interquartile range) for numeric variables and count (percentage) for categorical variables.

\* Cases for which data were not available were not included in the percentage calculations.

<sup>†</sup> Rotator cuff status subgroup 1 comprised intact status or small to medium tears in both the superior-posterior rotator cuff and subscapularis, whereas subgroups 2, 3, and 4 comprised large to massive tears in the superior-posterior rotator cuff with the subscapularis status classified as being intact, having small to medium tears, and having large to massive tears, respectively.

subscores. The total PSS was slightly (1.3 points) lower among patients at the 75th percentile of BMI than among those at the 25th percentile in the glenohumeral OA group but slightly (1.8 points) higher among patients in the CTA group—a result driven by the function subscore with contributions from the pain subscore but not the satisfaction subscore. Patients with prior surgery scored 0.2 points lower than those without prior surgery in the glenohumeral OA subgroup but 2.8 points higher among patients in the CTA group—a result driven by both the function and pain subscores but not the satisfaction subscore. The intergroup differences in the effects of retirement and BMI on total score and the function subscore and the effects of prior surgery on pain exceeded chance variation. Other differences in associations between glenohumeral OA and CTA patients were neither clinically nor statistically notable, and only the 2 associations with the function subscore withstood Bonferroni-Holm multiple-comparisons correction for parallel analyses of the total PSS and the 3 subscores. Overall, there was minimal evidence of substantively meaningful differences between the effects of predictors

**Table IV** Preoperative PSS (total score and pain, function, and satisfaction subscores) in 788 patients undergoing primary shoulder arthroplasty

	Preoperative PSS, median (IQR), points	Possible range, minimum-maximum, points
Total	31 (20-42)	0-100
Pain	10 (6-15)	0-30
Function	18 (11-27)	0-60
Satisfaction	1 (0-3)	0-10

PSS, Penn Shoulder Score; IQR, interquartile range.

**Table V** Estimated effects and odds ratios of general patient factors and disease-specific factors for preoperative PSS and 95% CIs for each predictor in full models in patients undergoing primary shoulder arthroplasty

Variable	PSS pain subscore, estimated effect (95% CI), points	PSS function subscore, estimated effect (95% CI), points	PSS satisfaction subscore, odds ratio (95% CI), points	Total PSS, estimated effect (95% CI), points
<b>Demographic characteristics</b>				
Age	0.4 (-0.3 to 1.0)	-2.1 (-3.2 to -0.9)*	0.91 (0.72 to 1.13)	-1.8 (-3.4 to -0.1)
BMI	-0.01 (-0.4 to 0.4)	-0.4 (-1.2 to 0.4)	1.1 (0.93 to 1.29)	-0.4 (-1.5 to 0.8)
CCI	0.2 (-0.4 to 0.8)	0.9 (-0.1 to 1.9)	1 (0.82 to 1.23)	1.2 (-0.3 to 2.6)
Education	1.7 (1.2 to 2.3)*	1.8 (0.9 to 2.7)*	1.28 (1.06 to 1.54)*	3.7 (2.3 to 5.0)*
VR-12 MCS	1.9 (1.3 to 2.5)*	3.1 (2.1 to 4.2)*	1.04 (0.84 to 1.29)	5.1 (3.5 to 6.6)*
<b>Sex</b>				
Female	Ref	Ref	Ref	Ref
Male	2.3 (1.5 to 3.1)*	5.2 (3.7 to 6.6)*	1.43 (1.08 to 1.89)*	7.7 (5.6 to 9.7)*
<b>Race</b>				
White	Ref	Ref	Ref	Ref
Black	-1.4 (-3.0 to 0.1)	-1.3 (-4.3 to 1.8)	0.76 (0.4 to 1.46)	-2.8 (-7.1 to 1.6)
Other or missing	0.3 (-3.3 to 3.9)	-1.8 (-8.2 to 4.6)	1.53 (0.41 to 5.75)	-0.8 (-10.1 to 8.5)
<b>Smoking status</b>				
Never	Ref	Ref	Ref	Ref
Quit	0.0 (-0.8 to 0.8)	-0.4 (-1.8 to 1.0)	0.82 (0.62 to 1.08)	-0.54 (-2.6 to 1.5)
Current	-0.9 (-2.2 to 0.5)	-0.4 (-2.8 to 2.0)	0.79 (0.49 to 1.29)	-1.3 (-4.8 to 2.1)
<b>Preoperative opioid use</b>				
No	Ref	Ref	Ref	Ref
Yes	-1.4 (-2.2 to -0.6)*	-2.5 (-4.0 to -1.1)*	0.86 (0.65 to 1.15)	-4.0 (-6.0 to -1.9)*
<b>Chronic pain</b>				
No	Ref	Ref	Ref	Ref
Yes	-0.5 (-1.3 to 0.3)	-0.5 (-1.9 to 0.9)	0.77 (0.58 to 1.01)	-1.3 (-3.3 to 0.8)
<b>Employment status</b>				
Employed	Ref	Ref	Ref	Ref
Retired	-0.6 (-1.7 to 0.4)	-1.1 (-3.0 to 0.9)	1.22 (0.84 to 1.76)	-1.4 (-4.2 to 1.4)
Not employed	-0.6 (-1.6 to 0.5)	-2.5 (-4.4 to -0.6)	1.08 (0.75 to 1.57)	-2.7 (-5.5 to -0.01)
<b>Workers' compensation status</b>				
No	Ref	Ref	Ref	Ref
Yes	-2.9 (-5.6 to -0.2)	-5.6 (-10.4 to -0.8)	1.13 (0.39 to 3.28)	-7.4 (-14.4 to -0.5)
<b>Surgical characteristics</b>				
<b>Prior surgery</b>				
No	Ref	Ref	Ref	Ref
Yes	0.4 (-0.7 to 1.4)	0.8 (-1.0 to 2.6)	0.93 (0.64 to 1.34)	1.1 (-1.5 to 3.7)
<b>Glennoid bone loss</b>				
No	Ref	Ref	Ref	Ref
Yes	-0.5 (-1.3 to 0.2)	-1.4 (-2.8 to -0.02)	0.89 (0.68 to 1.16)	-2.1 (-4.0 to -0.1)
<b>RC status<sup>†</sup></b>				
1	Ref	Ref	Ref	Ref
2	1.7 (0.7 to 2.7)	1.4 (-0.4 to 3.2)	0.94 (0.65 to 1.35)	3.1 (0.5 to 5.8)
3	0.05 (-1.6 to 1.7)	0.6 (-2.3 to 3.6)	1.41 (0.76 to 2.62)	1.5 (-2.7 to 5.8)
4	2.8 (1.0 to 4.6)	-0.9 (-4.0 to 2.2)	0.95 (0.51 to 1.75)	1.7 (-2.8 to 6.2)
1 vs. 2-4	-1.6 (-2.4 to -0.7)*	-0.9 (-2.4 to 0.7)	0.99 (0.72 to 1.36)	-2.6 (-4.8 to -0.3)
2 through 4 trend	0.2 (-0.6 to 1.1)	-1.1 (-2.7 to 0.5)	1.09 (0.80 to 1.49)	-0.8 (-3.1 to 1.4)

PSS, Penn Shoulder Score; CI, confidence interval; BMI, body mass index; CCI, Charlson Comorbidity Index; VR-12, Veterans RAND 12-Item Health Survey; MCS, mental component score; Ref, reference category; RC, rotator cuff.

The effects for numeric variables (age, BMI, education, VR-12 MCS, and CCI) are comparing the 25th vs. 75th percentiles shown in Table III. Examples of interpretation of the total PSS and pain and function subscores (standard linear regression model) are as follows: (1) Male patients have total PSS, pain subscore, and function subscore values that are 7.7, 2.3, and 5.2 points higher on average, respectively, than those in female patients, after controlling for all other variables. (2) A patient with a VR-12 MCS of 60.8 (75th percentile) has total PSS, pain subscore, and function subscore values that are 5.1, 1.9, and 3.1 points higher on average, respectively, than those in a patient with a VR-12 MCS of 41.8 (25th percentile), after controlling for all other variables. Examples of interpretation of the PSS satisfaction subscore (proportional-odds regression model): (1) The odds that male patients have a PSS satisfaction subscore of at least  $X$  (eg, 5) are 43% higher (calculated as  $[1.43 - 1] \times 100 = 43\%$ ) than the odds that female patients have a PSS satisfaction subscore of at least  $X$  (eg, 5), after adjusting for all other variables. (It should be noted that this interpretation holds regardless of the value of  $X$ , hence proportional odds). (2) The odds that a patient with 16 years of education (75th percentile) has a PSS satisfaction subscore of at least  $X$  are

28% higher (calculated as  $[1.28 - 1.00] \times 100 = 28\%$ ) than the odds of a patient with 12 years of education (25th percentile), after controlling for all other variables.

\* Statistically significant associations (in Bonferroni-Holm adjusted pair-wise comparisons for 4 outcomes and omnibus tests for trichotomous variables).

† RC status subgroup 1 comprised intact status or small to medium tears in both the superior-posterior RC and subscapularis, whereas subgroups 2, 3, and 4 comprised large to massive tears in the superior-posterior RC with the subscapularis status classified as being intact, having small to medium tears, and having large to massive tears, respectively.

studied in glenohumeral OA and CTA patients, and none of the variables for which evidence was found showed notable overall associations in our primary analyses. [Supplementary Table S1](#) summarizes the fitted, mutually adjusted models.

### Remaining interaction analysis

In analyses of interactions among other variables, no additional pair-wise interactions among those screened exceeded chance variation after multiple-comparisons adjustment. Removal of possible causal mediators from the full model left the effects of VR-12 MCS for all 4 PSS values relatively unchanged. The most dramatic increases in effect sizes from the full to partial models were in the associations of chronic pain, employment status, and smoking status with the pain and function subscores and total PSS, although their associations with the satisfaction subscore were insensitive to the level of adjustment ([Supplementary Table S2](#)). Among the increased associations, those of employment status with PSS function subscores and total scores satisfied the Bonferroni-Holm criterion for family-wise false-positive error control.

### Discussion

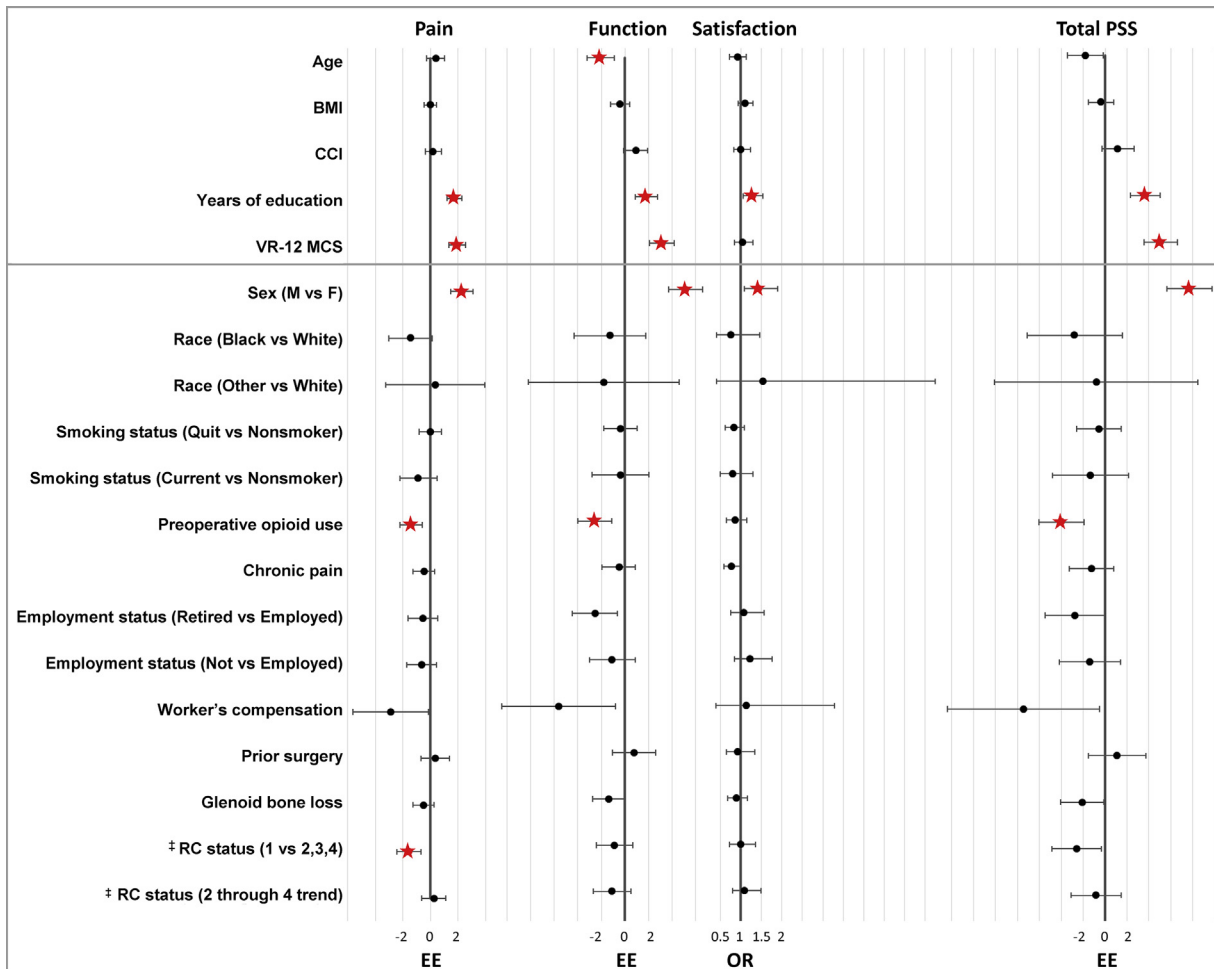
The purpose of this study was to investigate the extent to which general patient factors and disease-specific factors are associated with preoperative PROMs in patients undergoing primary shoulder arthroplasty. We hypothesized that worse mental health status, glenoid bone loss, and increasing RC tear severity would be associated with worse values for the preoperative total PSS and its pain, function, and satisfaction subscores. Using prospectively collected data on 16 potential general patient and disease-specific correlates of preoperative symptoms, we performed multi-variable analyses of 788 patients undergoing primary shoulder arthroplasty for a diagnosis of glenohumeral OA or CTA. After simultaneous adjustment for the other variables, lower mental health status was, as hypothesized, associated with worse preoperative PSS (total score and pain and function subscores). The associations of glenoid bone loss with PSS did not exceed chance variability, and contrary to our hypothesis, large to massive superior-posterior RC tears were associated with higher preoperative

PSS pain subscores (ie, less pain) than intact status or small to medium tears.

The associations between disease-related factors (eg, RC status, glenoid bone loss, and prior shoulder surgery) and preoperative shoulder pain and function in patients undergoing primary shoulder arthroplasty have not been previously reported. In our investigation, lower PSS pain subscores (ie, more pain) in patients with an intact RC or smaller tears of the superior-posterior RC may be explained by a compressive effect of an intact or nearly intact RC in an arthritic joint, although the difference (1.6 points in PSS pain subscore) may not be clinically significant. This finding may also suggest that the primary driver of pain complaints in this patient population is the advanced arthritic changes rather than the RC status. Glenoid bone loss, which is common in advanced glenohumeral OA and advanced CTA, leads to more complex glenoid deformities that can be more difficult to correct at the time of surgery and have been associated with worse postoperative outcomes.<sup>18,19,48</sup> Our data demonstrate lower preoperative total PSS values and PSS function subscores in patients with glenoid bone loss; however, the estimated differences (2.1 points in total PSS and 1.4 points in PSS function subscore) were neither clinically significant nor statistically significant after Bonferroni-Holm adjustment. Prior shoulder surgery was not notably associated with lower preoperative PROMs, although prior surgery is associated with poorer outcomes such as worse pain, lower range of motion, and inferior PROMs, as well as increased infection risk, in patients following shoulder arthroplasty.<sup>28,29,42,51</sup> Finally, although glenohumeral OA and CTA are separate disease processes, the diagnoses were found to be highly correlated with RC status in our cohort. Nested models with separate effects of factors in the RC status subgroups, which were nearly identical to the glenohumeral OA (subgroup 1) and CTA (subgroups 2-4) groups, were run to determine whether the predictors of preoperative PROMs differed with these 2 diagnoses. Although some small differences were seen based on diagnosis, overall there was minimal evidence of substantively meaningful differences between the associations of preoperative PROMs and the predictors we studied in glenohumeral OA and CTA patients.

The associations between general patient factors and preoperative shoulder PROMs in patients undergoing primary shoulder arthroplasty have also received very limited investigation to date.<sup>21,32,33,55</sup> Previous studies have shown



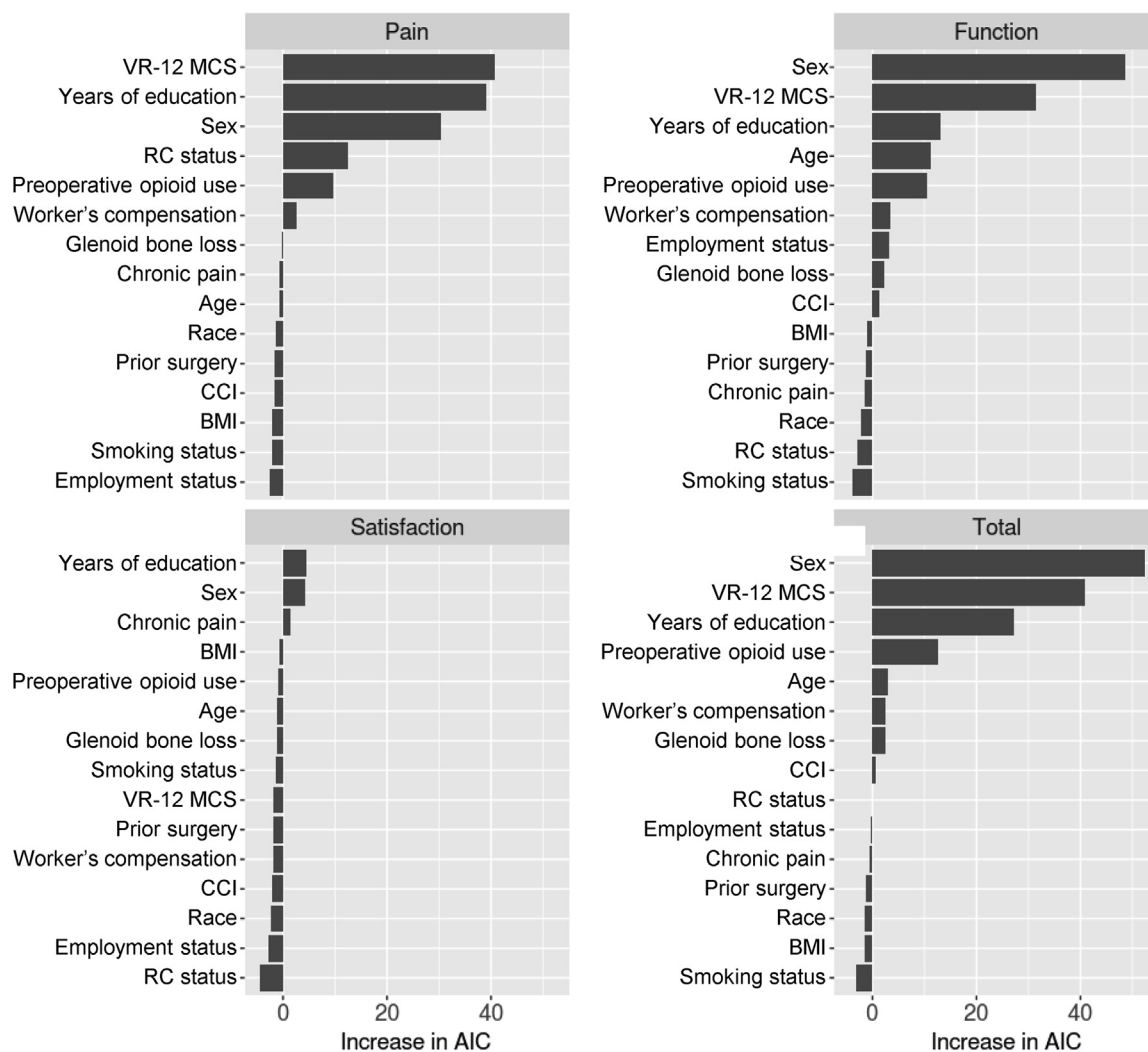


**Figure 2** Forest plot showing estimated regression coefficients (*EE*) for pain and function subscores and total Penn Shoulder Score (*PSS*) and showing odds ratios (*OR*) for satisfaction subscore, each with 95% confidence intervals, for predictors in full models of patients undergoing primary shoulder arthroplasty. The effects for numeric variables (age, body mass index [*BMI*], education, Veterans RAND 12-Item Health Survey mental component score [*VR-12 MCS*], and Charlson Comorbidity Index [*CCI*]) are comparing the 75th vs. 25th percentiles shown in Table III. Predictors having statistically significant associations with preoperative *PSS* values, both in omnibus tests and in Bonferroni-Holm adjusted pair-wise comparisons for trichotomous variables, are marked in red. †Rotator cuff (*RC*) status subgroup 1 comprised intact status or small to medium tears in both the superior-posterior *RC* and subscapularis, whereas subgroups 2, 3, and 4 comprised large to massive tears in the superior-posterior *RC* with the subscapularis status classified as being intact, having small to medium tears, and having large to massive tears, respectively. *M*, male; *F*, female.

patient factors such as female sex, less education, lower mental health status, preoperative opioid use, older age, higher *BMI*, smoking, more comorbidities, and receipt of workers' compensation to be significantly and negatively associated with PROMs following shoulder arthroplasty.<sup>9,14,17,43,46,47,54-56</sup> Our results showed that female sex and less education were associated with lower values for the total preoperative *PSS* and all 3 subscores and showed that lower *VR-12 MCS* and preoperative opioid use were associated with lower values for the total preoperative *PSS*, as well as the pain and function subscores. Two much smaller previous studies did not find evidence of sex-associated differences in preoperative shoulder PROMs in patients undergoing shoulder arthroplasty.<sup>21,55</sup> In addition to the lower statistical power of smaller studies, these differences may result from prior studies' narrower patient

selection criteria (eg, inclusion of only anatomic or reverse total shoulder arthroplasty) and much more limited control for confounding. Furthermore, it is not clear why some general patient factors impacted only postoperative PROMs but not preoperative PROMs in the previous literature. We plan to investigate the associations of these general patient factors with postoperative PROMs in the OME cohort in future work.

The association between lower mental health status and worse preoperative shoulder PROMs has previously been demonstrated in patients undergoing *RC* repair,<sup>1,5-7,36,40,56,57</sup> but such an association has not been shown prior to shoulder arthroplasty.<sup>54</sup> Lower preoperative pain and function subscores in patients with lower preoperative *VR-12 MCS* values could be due to pre-existing mental health issues in such patients that may alter how they



**Figure 3** Relative variable importance of patient demographic and disease-specific characteristics on preoperative Penn Shoulder Score (PSS) based on increase in Akaike information criterion (AIC) upon removal from full model. The most influential variables are listed at the top of the respective charts. *VR-12 MCS*, Veterans RAND 12-Item Health Survey mental component score; *RC*, rotator cuff; *CCI*, Charlson Comorbidity Index; *BMI*, body mass index.

perceive their shoulder pain and function. Alternatively, physical and functional limitations resulting from the underlying pathology necessitating shoulder arthroplasty may adversely affect work performance, social activities, and mood reported in the VR-12 instrument,<sup>22,41</sup> lowering the VR-12 MCS.

In principle, mental health status, as reflected by the VR-12 MCS, could also exert effects on PSS values indirectly through effects on employment status and workers' compensation status, perception of chronic pain, and use of drugs including opioids and nicotine. Although our fully adjusted models would have concealed such indirect effects, no changes in VR-12 MCS associations suggestive of indirect mental health status effects emerged in the sensitivity analysis using partially adjusted models in which such mediated effects could appear. However, the effects of

smoking status, chronic pain, and employment status noticeably increased in partially adjusted models as compared with fully adjusted models. Such increases may reflect either understatement of plausibly causal effects in the fully adjusted models owing to inadvertent adjustment for causal mediators or inadequate adjustment for confounding in the partially adjusted models, explanations that cannot be differentiated statistically by analyses of such cross-sectional preoperative data.

Similar to our results, preoperative opioid use has been previously shown to be associated with worse preoperative shoulder PROMs in patients undergoing shoulder arthroplasty,<sup>32,33</sup> as well as with higher rates of certain comorbidities (including depression and chronic pain conditions), inferior postoperative outcomes, and continued postoperative opioid consumption after shoulder

arthroplasty.<sup>2,4,8,15,23,27,32,33</sup> Taken together, these findings suggest that a patient's preoperative opioid use may need to be considered when expectations regarding arthroplasty outcomes are being established.

This study has several strengths. Though cross-sectional in nature, our data derive from a large, prospectively ascertained cohort that captures a wide range of patient and surgical factors relevant to shoulder arthroplasty. Factors either cited or judged to influence preoperative symptoms were prospectively chosen and used in multivariable models to identify statistically meaningful associations. This is the first study, to our knowledge, that identifies factors associated with preoperative symptoms in a shoulder arthroplasty patient population while extensively controlling for general patient and disease-specific factors. Furthermore, we used the PSS, which is unique among the various shoulder-specific PROMs as it measures patient satisfaction related to the shoulder on a 10-point scale, in addition to measuring shoulder pain and function.

This study also has limitations. First, it was performed in a single tertiary hospital network using data from patients who have undergone surgery. Hence, our findings may not be generalizable to the broader group of patients with glenohumeral OA or CTA who are treated nonoperatively or to other patient populations or surgical practice settings. Second, the database used in our study does not include all possible factors that might influence preoperative symptoms, and some potentially important factors may not have been investigated. The database was prospectively designed by specialty-specific orthopedic surgeons at our institution to collect sociodemographic factors, joint-specific variables of disease severity and treatment, and joint-specific validated PROMs at baseline and 1 year after treatment for >30 elective orthopedic procedures. The number of questions asked and the number of factors collected were thus carefully selected so as not to overburden the patient or the surgeon. Third, although we identified clinically relevant factors that were associated with preoperative symptoms to a degree not plausibly explainable by chance variation, our cross-sectional analyses cannot adequately evaluate the causal component, if any, or clinical significance of associations. In particular, we acknowledge that our models explained <25% of the variation in all PSS values, and most statistical effects of individual variables on the PSS were generally small.

## Conclusion

In addition to mental health status and RC tear status, patient sex, years of education, and preoperative opioid use were most prominently associated with preoperative PROMs in patients undergoing shoulder arthroplasty. Our future work will use multivariable prediction modeling of this large, prospective cohort to investigate the extent to which risk factors associated with poor

preoperative pain, function, and satisfaction in this study, together with disease-related and surgical factors, can predict postoperative PROMs  $\geq 1$  year after primary shoulder arthroplasty. If associations of risk factors with postoperative PROMs are notably stronger than with preoperative PROMs, such multivariable models could be clinically useful for identifying patients with poorer prognoses and, conceivably, for better understanding any associations of outcomes with preoperative pathology and surgical approaches.

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Kurt P. Spindler is an inventor with rights to royalties from nPhase/REDCap Cloud for technology related to the subject of this article.

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## Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jse.2020.08.003>.

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