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Patients with diabetes mellitus experience poorer outcomes after arthroscopic rotator cuff repair

Eli T. Sayegh, MD^a, Matthew J. Gooden, MS^b, Natalie A. Lowenstein, BS^a,
Jamie E. Collins, PhD^a, Elizabeth G. Matzkin, MD^{a,c,*}

^aDepartment of Orthopaedic Surgery, Brigham and Women's Hospital, Boston, MA, USA

^bTufts University School of Medicine, Boston, MA, USA

^cHarvard Medical School, Boston, MA, USA

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Hypothesis: The purpose of this study was to identify potential differences using validated clinical outcome instruments between patients with and without diabetes mellitus (DM) after arthroscopic rotator cuff repair (RCR).

Methods: Six-hundred eighty-four patients (32 with and 652 without DM) who underwent arthroscopic RCR were prospectively followed using the visual analog pain scale, Simple Shoulder Test, Single Assessment Numeric Evaluation, American Shoulder and Elbow Surgeons score, and Veterans RAND 12-item Health Survey (mental and physical component scores) preoperatively and at 3, 6, 12, and 24 months postoperatively.

Results: Patients with DM experienced significantly more pain ($P = .0172$) and had lower Simple Shoulder Test ($P = .0458$) and American Shoulder and Elbow Surgeons ($P = .0200$) scores than patients without DM 6 months after surgery. Although differences between groups are seen at other post-operative time points, none are statistically significant.

They also exhibited lower self-rated mental health status at 12 months ($P = .0034$) and 24 months ($P = .0077$), as well as lower self-rated physical health status at 12 months ($P = .0223$) and 24 months ($P = .0077$). Changes in scores from preoperatively to postoperatively were not different for patients with DM vs. without DM.

Conclusion: Patients with DM experience significantly more pain, exhibit significantly poorer shoulder function, and report persistently diminished mental and physical health status compared with their counterparts without DM after undergoing arthroscopic RCR. Although these differences did not reach the minimal clinically important difference, orthopedic surgeons should be cognizant of DM as an outcome-modifying variable when selecting, counseling, and treating patients with rotator cuff tears. Glycemic control should be scrutinized and optimized during the perioperative medical evaluation and ultimately factored into the surgical risk profile and prognosis.

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Rotator cuff tears are the most common source of shoulder disability in individuals over the age of 50 years.²³ These injuries increase with age and are prevalent in up to one quarter of the population,¹⁸ coinciding with a more than two-fold rise in rotator cuff repair (RCR) surgeries performed in the United States over a 10-year period.⁶ Health-related risk factors such as smoking, hyperlipidemia, diabetes mellitus (DM), body mass index (BMI), and

percentage of body fat are known to biologically predispose individuals to the occurrence or severity of rotator cuff tears.^{13,23,25}

DM affects approximately 382 million people worldwide and is projected to increase beyond 592 million by 2035.¹⁵ Uncontrolled DM causes numerous adverse end-organ effects by inducing tissue glycosylation abnormalities, microvascular insult, reduced collagen synthesis, aberrant cytokine release, and disruption of normal angiogenic and growth factor signaling.^{4,8} Its musculoskeletal implications include slowed connective tissue healing and diminished tissue biomechanical properties.¹ On a microscopic level, DM leads to a weakened tendon unit and compromises tendon healing due to reduced fibroblast proliferation and lymphocyte infiltration.^{1,8} In an animal model of RCR, sustained hyperglycemia impaired

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*Corresponding author: Elizabeth G. Matzkin, MD, Brigham and Women's Hospital, 75 Francis St., Boston, MA 02115, USA.

E-mail address: ematzkin@bwh.harvard.edu (E.G. Matzkin).

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supraspinatus tendon-bone healing and led to a significantly weakened and disorganized enthesis.² DM is of clinical concern in patients undergoing shoulder surgery because it threatens soft tissue, tendon, and bone healing.²⁷ Cross-sectional study of patients with DM suggests they are significantly more susceptible to shoulder complaints even in the absence of a formal musculo-skeletal diagnosis, such that the presence of DM may influence the experience of shoulder pain.²⁴

The purpose of this study was to identify potential differences using validated clinical outcome instruments between patients with and without DM after arthroscopic RCR.

Methods

Study design

From July 2012 to January 2021, a cohort of 684 adult patients undergoing primary arthroscopic RCR was prospectively enrolled after institutional review board approval. Three orthopedic surgeons at an academic medical center performed these procedures. Patient-reported data were entered into a Health Information Portability and Accountability Act compliant global registry database (Surgical Outcome System, Arthrex, Naples, FL). Informed consent was obtained in the clinic for patient participation in the study. Participants completed an electronic questionnaire at designated intervals including preoperatively and 3, 6, 12, and 24 months postoperatively. Demographic information was recorded. Validated clinical outcome instruments were obtained and included the visual analog pain scale (VAS),^{20,21} American Shoulder and Elbow Surgeons (ASES) score,¹⁷ Single Assessment Numeric Evaluation (SANE) score,²⁶ Simple Shoulder Test (SST) score,¹¹ and Veterans RAND 12-item Health Survey (VR-12) physical and mental components.²² Patient characteristics were recorded and included age, BMI, sex, ethnicity, race, documented medical history of type I or type II DM, preoperative narcotic use, smoking status, worker’s compensation status, and concomitant biceps tendon procedure. Rotator cuff tear characteristics were recorded by the surgeon at the time of the procedure and included tear acuity (acute, ≤3 months; or chronic, >3 months) and Cofield tear size classification (small, medium, large, or massive).⁷ The surgical technique used in this study was a double-row RCR with knotless anchors. Subacromial decompression and biceps tenodesis/tenotomy were performed as indicated. Patients were given a preoperative nerve block and were placed in an abducted sling postoperatively. All patients followed the same postoperative protocol and were prescribed ibuprofen, acetaminophen, and oxycodone. Patients were instructed to alternate the ibuprofen and acetaminophen and use the oxycodone only for breakthrough pain.

To be included in the analysis, patients had to provide outcome data preoperatively and at one or more follow-up visits as well as descriptive data on the primary exposure (DM status) and key covariates (BMI, age, and worker’s compensation status).

Revision surgeries were excluded.

Statistical analysis

Means, standard deviations, and medians are presented for continuous variables. Number and percentage are presented for categorical variables. Clinical outcome scores were compared between cohorts of patients with and without DM at each of the preoperative (baseline) and postoperative follow-up intervals. This was performed with the construction of a linear mixed-effects model, with adjustment for age, BMI, worker’s compensation status, and concomitant biceps tendon procedure. Adjusted means, adjusted between-group differences, and 95% confidence intervals

were computed. Change from preoperative baseline to one- and two-year postoperative follow-up intervals was compared between the two cohorts. All P values less than 0.05 were considered statistically significant. All statistical analyses were performed using SAS, version 9.4, (SAS Institute, Cary, NC).

Results

Demographic and clinical characteristics

A total of 802 patients qualified for the study and had outcome data at both the preoperative baseline and at least one postoperative follow-up interval, of which 684 patients met the inclusion criteria (Table 1). The remaining patients were excluded because of missing key covariate data including BMI (n = 110), worker’s compensation status (n = 5), or age (n = 3). Outcome data were available at 3 months (n = 684), 6 months (n = 606), 12

Table 1
Patient and rotator cuff tear characteristics across patient cohorts with and without diabetes mellitus.

Label	Diabetes mellitus	
	No	Yes
Age		
<55	248 (38%)	5 (16%)
55-69	346 (53%)	23 (72%)
70+	58 (9%)	4 (13%)
Body mass index (BMI) group		
Underweight <18.5	2 (0%)	0 (0%)
Normal weight 18.5-25	165 (25%)	4 (13%)
Overweight 25-30	261 (40%)	4 (13%)
Obese >=30	224 (34%)	24 (75%)
Sex		
Female	269 (42%)	14 (44%)
Male	376 (58%)	18 (56%)
Missing	7	0
Ethnicity		
Not Hispanic or Latino	612 (97%)	32 (100%)
Hispanic or Latino	20 (3%)	0 (0%)
Missing	20	0
Race		
Asian	8 (1%)	2 (6%)
Black or African American	11 (2%)	2 (6%)
White	534 (95%)	28 (88%)
Other	7 (1%)	0 (0%)
Missing	92	0
Smoker		
No	617 (95%)	31 (97%)
Yes	30 (5%)	1 (3%)
Missing	5	0
Preoperative narcotic use		
No	174 (93%)	14 (88%)
Yes	14 (7%)	2 (13%)
Missing	464	16
The worker’s compensation case		
No	591 (91%)	26 (81%)
Yes	61 (9%)	6 (19%)
Concomitant biceps tendon procedure		
No	398 (61%)	17 (53%)
Yes	254 (39%)	15 (47%)
Tear acuity		
Acute	105 (29%)	5 (20%)
Chronic	262 (71%)	20 (80%)
Missing	285	7
Cofield tear size classification		
Small (<1 cm)	46 (10%)	1 (4%)
Medium (1-3 cm)	242 (52%)	15 (60%)
Large (3-5 cm)	114 (25%)	5 (20%)
Massive (>5 cm)	61 (13%)	4 (16%)
Missing	189	7

Table II
Comparison of clinical outcome scores between patients with and without diabetes mellitus (DM) at preoperative baseline and at 3, 6, 12, and 24 months postoperatively.

Outcome	Interval (months)	Patients without DM adjusted mean (95% CI)	Patients with DM adjusted mean (95% CI)	Adjusted between-group difference			
				Δ	Lower 95% CI	Upper 95% CI	P value
VAS	0	4.8 (4.6, 5.0)	4.9 (4.0, 5.7)	-0.05020	-0.9048	0.8044	.9082
VAS	3	2.2 (2.0, 2.4)	2.3 (1.6, 3.0)	-0.1162	-0.8267	0.5942	.7481
VAS	6	1.4 (1.3, 1.6)	2.2 (1.6, 2.8)	-0.7621	-1.3888	-0.1354	.0172
VAS	12	1.2 (1.0, 1.4)	1.8 (1.1, 2.4)	-0.5421	-1.2158	0.1315	.1145
VAS	24	1.1 (0.9, 1.3)	1.7 (1.0, 2.5)	-0.6072	-1.3617	0.1474	.1146
SST	0	40.2 (37.7, 42.6)	37.0 (27.7, 46.3)	3.1390	-6.3439	12.6219	.5159
SST	3	45.3 (42.9, 47.7)	43.7 (34.7, 52.7)	1.6203	-7.5169	10.7575	.7278
SST	6	68.7 (66.4, 71.1)	59.4 (50.5, 68.4)	9.3091	0.1735	18.4446	.0458
SST	12	79.5 (77.1, 81.9)	75.4 (66.7, 84.1)	4.1244	-4.7726	13.0215	.3629
SST	24	82.5 (80.1, 85.0)	75.0 (65.2, 84.9)	7.4949	-2.5297	17.5195	.1425
SANE	0	38.3 (36.4, 40.1)	35.4 (27.9, 42.9)	2.9083	-4.7467	10.5633	.4559
SANE	3	48.4 (46.5, 50.2)	51.3 (43.9, 58.7)	-2.9121	-10.4343	4.6100	.4474
SANE	6	68.6 (66.7, 70.6)	67.8 (60.0, 75.6)	0.8450	-7.1278	8.8178	.8352
SANE	12	79.1 (77.1, 81.1)	77.6 (69.4, 85.8)	1.4906	-6.9029	9.8840	.7274
SANE	24	80.2 (77.8, 82.6)	78.7 (67.2, 90.2)	1.4393	-10.2819	13.1605	.8095
ASES	0	50.3 (48.6, 51.9)	48.9 (42.6, 55.3)	1.3308	-5.1282	7.7899	.6859
ASES	3	63.8 (62.3, 65.3)	63.6 (57.8, 69.5)	0.2100	-5.7436	6.1636	.9448
ASES	6	78.6 (77.1, 80.1)	71.7 (66.0, 77.4)	6.8762	1.0876	12.6647	.0200
ASES	12	85.5 (84.0, 87.1)	82.9 (76.9, 88.9)	2.6033	-3.4973	8.7040	.4024
ASES	24	87.9 (86.3, 89.5)	82.8 (76.1, 89.6)	5.0536	-1.8351	11.9423	.1502
VR12-M	0	54.1 (53.2, 55.0)	51.5 (48.1, 55.0)	2.5697	-0.9751	6.1145	.1551
VR12-M	6	55.3 (54.4, 56.3)	49.8 (46.3, 53.4)	5.5220	1.8919	9.1520	.0029
VR12M	12	56.3 (55.4, 57.1)	51.7 (48.7, 54.7)	4.5427	1.5037	7.5816	.0034
VR12-M	24	56.0 (55.2, 56.9)	48.8 (45.2, 52.5)	7.2066	3.4796	10.9336	.0002
VR12-P	0	37.0 (36.3, 37.8)	35.5 (32.6, 38.4)	1.5172	-1.4092	4.4435	.3091
VR12-P	6	44.4 (43.6, 45.1)	42.9 (40.0, 45.7)	1.5285	-1.3649	4.4220	.3000
VR12-P	12	48.0 (47.2, 48.8)	44.5 (41.6, 47.4)	3.4638	0.4937	6.4338	.0223
VR12-P	24	49.0 (48.2, 49.8)	44.3 (40.8, 47.7)	4.7418	1.2602	8.2233	.0077

VAS, Visual Analog Pain Scale; SST, Simple Shoulder Test; SANE, Single Assessment Numeric Evaluation; ASES, American Shoulder and Elbow Surgeons; VR12-M, Veterans RAND 12-item (VR-12) Health Survey mental component; VR12-P, Veterans RAND 12-item (VR-12) Health Survey physical component. Adjusted means, adjusted between-group differences, and 95% confidence intervals (95% CIs) are represented.

months (n = 571), and 24 months (n = 483). Thirty-two patients with DM and 652 patients without DM were included in the analysis. Patient characteristics across the cohorts are represented in Table I. These were generally similar between cohorts except that patients with DM were more likely to be obese (75% vs. 34%) than patients without DM. Most patients were nonsmokers aged between 55 and 69 years. Rotator cuff tears were most likely to be chronic and medium-sized.

Visual Analog Pain Scale

The mean preoperative VAS score was similar in both groups (4.8 in patients with DM and 4.9 in patients without DM; P = .9082) (Table II). The postoperative VAS score was significantly higher in patients with DM at 6 months (2.2 vs. 1.4; P = .0172). There were no significant differences between the groups in change from preoperative baseline to one- and two-year postoperative follow-up (Table III).

Simple Shoulder Test

The mean preoperative SST score was similar in both groups (37.0 in patients with DM and 40.2 in patients without DM; P = .5159). The postoperative SST score was significantly lower in patients with DM at 6 months (59.4 vs. 68.7; P = .0458). There were no significant differences between the groups in change from preoperative baseline to one- and two-year postoperative follow-up.

Single assessment numeric evaluation

The mean preoperative SANE score was similar in both groups (35.4 in patients with DM and 38.3 in patients without DM; P = .4559). There were no significant differences in the SANE score between patients with and without DM at any of the postoperative follow-up intervals. There were no significant differences between the groups in change from preoperative baseline to one- and two-year postoperative follow-up.

American Shoulder and Elbow Surgeons

The mean preoperative ASES score was similar in both groups (48.9 in patients with DM and 50.3 in patients without DM; P = .6859). The postoperative ASES score was significantly lower in patients with DM at 6 months (71.7 vs. 78.6; P = .0200). There were no significant differences between the groups in change from preoperative baseline to one- and two-year postoperative follow-up.

Veterans RAND 12-item health survey mental component

The mean preoperative VR-12 mental component was similar in both groups (51.5 in patients with DM and 54.1 in patients without DM; P = .1551). The postoperative VR-12 mental component score was significantly lower in patients with DM at 6 months (49.8 vs. 55.3; P = .0029), 12 months (51.7 vs. 56.3; P = .0034), and 24 months (48.8 vs. 56.0; P = .0002). Patients with DM fared significantly poorer than patients without DM from preoperative baseline

Table III
Comparison of change in clinical outcome scores from preoperative baseline to one- and two-year postoperative follow-up between patients with and without diabetes mellitus (DM).

Outcome	Comparison	Patients without DM			Patients with DM			Adjusted between-group difference		
		Change estimate	95% CI change	P value	Change estimate	95% CI change	P value	Estimate	95% CI change	P value
VAS	Δ BL to 1yr	-3.5974	-3.80, -3.40	<.0001	-3.1055	-3.99, -2.22	<.0001	-0.4920	-1.40, 0.41	.2852
VAS	Δ BL to 2yr	-3.7181	-3.93, -3.51	<.0001	-3.1611	-4.17, -2.16	<.0001	-0.5570	-1.59, 0.47	.2879
SST	Δ BL to 1yr	39.3120	36.97, 41.65	<.0001	38.3266	27.93, 48.73	<.0001	0.9854	-9.68, 11.65	.8560
SST	Δ BL to 2yr	42.3513	39.96, 44.74	<.0001	37.9954	26.67, 49.32	<.0001	4.3559	-7.22, 15.93	.4602
SANE	Δ BL to 1yr	40.8473	38.43, 43.27	<.0001	42.2650	31.42, 53.11	<.0001	-1.4178	-12.53, 9.69	.8022
SANE	Δ BL to 2yr	41.9064	39.23, 44.58	<.0001	43.3755	30.29, 56.46	<.0001	-1.4690	-14.82, 11.88	.8290
ASES	Δ BL to 1yr	35.2569	33.69, 36.82	<.0001	33.9844	26.98, 40.98	<.0001	1.2725	-5.90, 8.44	.7277
ASES	Δ BL to 2yr	37.6313	35.95, 39.31	<.0001	33.9086	25.99, 41.82	<.0001	3.7227	-4.37, 11.82	.3667
VR12-M	Δ BL to 1yr	2.1488	1.36, 2.93	<.0001	0.1758	-3.32, 3.67	.9214	1.9730	-1.61, 5.56	.2800
VR12-M	Δ BL to 2yr	1.9209	1.08, 2.76	<.0001	-2.7160	-6.77, 1.33	.1884	4.6369	0.50, 8.77	.0281
VR12-P	Δ BL to 1yr	10.9531	10.23, 11.67	<.0001	9.0065	5.81, 12.20	<.0001	1.9466	-1.33, 5.22	.2433
VR12-P	Δ BL to 2yr	11.9762	11.22, 12.73	<.0001	8.7516	5.10, 12.41	<.0001	3.2246	-0.51, 6.96	.0903

BL, baseline; 1yr, one year after surgery; 2yr, two years after surgery; VAS, Visual Analog Pain Scale; SST, Simple Shoulder Test; SANE, Single Assessment Numeric Evaluation; ASES, American Shoulder and Elbow Surgeons; VR12-M, Veterans RAND 12-item (VR-12) Health Survey mental component; VR12-P, Veterans RAND 12-item (VR-12) Health Survey physical component.

Adjusted means, adjusted between-group differences, and 95% confidence intervals (95% CIs) are represented for the change estimates.

to two-year postoperative follow-up (-2.7160 vs. 1.9209; P = .0281).

Veterans RAND 12-item health survey physical component

The mean preoperative VR-12 physical component was similar in both groups (35.5 in patients with DM and 37.0 in patients without DM; P = .3091). The postoperative VR-12 physical component score was significantly lower in patients with DM at 12 months (44.5 vs. 48.0; P = .0223) and 24 months (49.0 vs. 44.3; P = .0077). There were no significant differences between the groups in change from preoperative baseline to one- and two-year postoperative follow-up.

Discussion

Recognition of patient-related risk factors is paramount for optimizing patient selection, patient counseling, rotator cuff healing, and functional outcomes associated with arthroscopic RCR. Our study sought to identify potential differences in postoperative outcomes between patients with DM vs. patients without DM undergoing arthroscopic RCR, using validated clinical outcome instruments. This prospective study demonstrated that patients with DM experience significantly more pain and exhibit significantly poorer ASES and SST scores 6 months after surgery. Patients with DM experienced significantly more pain (P = .0172) and had lower SST (P = .0458) and ASES (P = .0200) scores than patients without DM at the 6-month postoperative time point. They also exhibited lower self-rated mental health status at 12 months (P = .0034) and 24 months (P = .0077), as well as lower self-rated physical health status at 12 months and 24 months (P = .0077). Furthermore, patients with DM display lower self-rated perspectives of mental health status at 12 months (P = .0034) and 24 months (P = .0077) and physical health status at 12 months (P = .0223) and 24 months (P = .0077) postoperatively than patients without DM.

These results are consistent with the existing literature. Berglund et al demonstrated that patients with DM undergoing arthroscopic RCR experienced more pain and had poorer ASES and SST scores at 6 and 12 months, while also plateauing earlier in their recovery than patients without DM.³ Gagnier et al demonstrated an inverse relationship between burden of medical comorbidities and patients' baseline and post-treatment ASES and Western Ontario Rotator Cuff Index scores after surgical or nonsurgical treatment of

symptomatic, full-thickness rotator cuff tears.¹⁰ In their retrospective cohort study, Cho et al investigated the clinical effect of uncontrolled hyperglycemia on tendon-to-bone healing after arthroscopic RCR. Although patients with and without DM exhibited similar Constant and University of California, Los Angeles scores at the final follow-up, retear on postoperative magnetic resonance imaging was significantly more common in patients with DM.⁵ Moreover, patients with a hemoglobin A1c level ≥7.0% were significantly predisposed to tendon retear. In their retrospective cohort study, Miyatake et al found that although patients with DM had significantly poorer preoperative baseline Japanese Orthopaedic Association and University of California, Los Angeles scores, their outcome scores at the final postoperative follow-up were similar to those of patients without DM.¹⁹ Patients with DM also had significantly limited forward flexion, abduction, external rotation, and internal rotation preoperatively compared with patients without DM, but these differences dissipated at the final follow-up, except for persistently limited internal rotation. There was also no significant difference in the retear rate on postoperative magnetic resonance imaging between the two cohorts. In that study, patients with DM who had poor glycemic control were preoperatively admitted for intensive glycemic control. Notably, a recent meta-analysis of 1065 patients revealed that patients with DM have a greater than two-fold retear risk after arthroscopic RCR than patients without DM.¹⁴

There are noteworthy limitations to this study. First, our study did not utilize postoperative imaging to determine if poorer outcomes in patients with DM were related to differences in rotator cuff structural integrity. We binarily stratified patients as those with or without DM based on their medical history, which may overlook heterogeneity within hemoglobin A1c level, perioperative fasting glucose level, insulin dependence, and/or disease chronicity. Next, we did not perform an a priori power analysis, and thus, our study was powered to detect effect sizes of approximately 0.5 standard deviations.

In other words, our study is powered to find moderate to large differences between groups, but may be underpowered for smaller differences. We also recognize that the statistical significance of our results is distinct from their clinical significance. Recognition of the minimal clinically important difference (MCID), substantial clinical benefit, and/or patient acceptable symptomatic state for the clinical outcome instruments used in our study is a prerequisite for contextualizing our findings. Prior studies have established an

MCID of 28.8 points for the SANE score and 8.1 points for the VR-12 score, a substantial clinical benefit of 50.2 points for the SANE score and 20.7 points for the ASES score, and a patient acceptable symptomatic state of 81.9 points for the SANE score and 75.5 points for the ASES score.^{12,16} Another study limitation was mild attrition of eligible subjects as the length of the follow-up period progressed in this study.

Strengths of this study include its prospective design, large study population, use of multiple validated clinical outcome instruments, and use of a linear mixed-effects model with adjustment for sources of heterogeneity and potential confounding covariates such as BMI.

Furthermore, our interpretation of postoperative outcome scores in the context of a preoperative baseline, which may significantly vary between individuals, achieves normalization and minimizes selection bias.⁹

Future research is necessary to determine whether the poorer outcomes seen in patients with DM are reflective of rotator cuff structural integrity or potentially mediated by another pathophysiological arm of this disease. For example, hyperglycemia can form nonenzymatic glycosylation products and subsequent advanced glycosylation end-products, which increase cross-linking in collagen, tendons, and ligaments. Advanced glycosylation end-products can negatively impact structural integrity and cause increased stiffness and weakness, which can present as poorer patient-reported outcome measures. In addition, it would be informative to stratify patients with DM on the basis of hemoglobin A1c level, insulin dependence, disease chronicity, and type I vs. type II DM to determine how these variables further modulate outcomes. Our data also provide an opportunity for future studies to assess how perioperative counseling and multidisciplinary medical or behavioral interventions might modify postoperative outcomes.

Conclusion

Patients with DM experience significantly more pain, exhibit significantly poorer shoulder function, and report persistently diminished mental and physical health status compared with their counterparts without DM after undergoing arthroscopic RCR. Although these differences are only seen at the 6-month time point and did not reach the MCID, orthopedic surgeons should be cognizant of DM as an outcome-modifying variable when selecting, counseling, and treating patients with rotator cuff tears. Glycemic control should be scrutinized and optimized during the perioperative medical evaluation and ultimately factored into the surgical risk profile and prognosis.

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Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jseint.2021.08.007>.

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