



Improved patient reported outcomes with knotless double-row rotator cuff repair with and without lateral row biceps tenodesis at 2- and 5-years

Giovanna Medina, MD, PhD^{a,*}, Mathew Quattrocchi, DO^b, Natalie Lowenstein, BS, MPH^{c,d}, Jamie Collins, PhD^c, Elizabeth Matzkin, MD^c

^aDepartment of Orthopaedic Surgery, Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA

^bAdvent Health Medical Group Orthopedics, Daytona Beach, FL, USA

^cDepartment of Orthopaedic Surgery, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA

^dSidney Kimmel Medical School, Thomas Jefferson University, Philadelphia PA, USA

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Background: The purpose of this study is to report outcomes of an arthroscopic knotless double-row (DR) rotator cuff repair (RCR) technique at 2- and 5- years postoperatively, and to compare clinical outcomes in patients undergoing knotless DR RCR with incorporated lateral row biceps tenodesis (LRT) vs. those without LRT.

Methods: All primary RCR surgeries were performed by a single surgeon at a single institution using a knotless transosseous equivalent (TOE) technique. The postoperative rehabilitation protocol was standardized for all patients. The primary outcomes collected included American Shoulder and Elbow Surgeons (ASES) Function, ASES Index, Single Assessment Numeric Evaluation (SANE), Simple Shoulder Test (SST), Veterans RAND 12-Item Health Survey (VR-12) physical and mental, and Visual Analogue Scale (VAS) scores.

Results: Three hundred forty-two patients met inclusion criteria, of which 262 patients underwent isolated RCR and 61 underwent RCR with a concomitant LRT, 15 underwent RCR with concomitant tenotomy and 4 had RCR with débridement of the biceps. Significant improvements in VAS, ASES, SANE, SST, and VR-12 scores were observed at all-time points in all patient groups. No statistically significant differences in outcomes were noted in patients undergoing RCR with a lateral row tenodesis vs. those undergoing RCR alone. Similarly, no differences were seen when stratified by age, sex, body mass index, Worker's Compensation status, smoking, and diabetes mellitus. Based on ASES, 81% of patients met minimum clinically important difference, and 64% met maximal outcome improvement at 1-year postoperatively.

Conclusion: Knotless DR TOE arthroscopic RCR significantly improves patient-reported clinical outcomes at 1-, 2- and 5-year follow-ups. These results are reflected in clinical practice because 80% achieve minimum clinically important difference postoperatively. Patient-related factors, including body mass index, age, sex, Worker's Compensation, and diabetes mellitus do not significantly affect patient-reported outcomes in the first 5 years after surgery. Smokers have worse baseline scores which persist at 2-year follow-up. Lastly, adding an arthroscopic LRT in knotless DR TOE arthroscopic RCR provides similar clinical outcomes to knotless DR TOE arthroscopic RCR without biceps tenodesis.

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*Corresponding author: Giovanna Medina, MD, PhD, Department of Orthopaedic Surgery, Massachusetts General Hospital, Harvard Medical School, 55 Fruit St, Boston, MA 02114, USA.

E-mail address: gmedina@mggh.harvard.edu (G. Medina).

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The double-row (DR) transosseous equivalent (TOE) arthroscopic rotator cuff repair (ARCR) technique has been shown to be biomechanically superior to standard DR and single-row technique. It has become a popular method of fixation in recent years.^{2,16,23,28} In particular, knotless DR ARCR has been shown to produce significant clinical improvement, high patient satisfaction and low

revision rates at 2-, 5- and 10-year outcomes.^{12,24,25} A meta-analysis of knotless and knotted constructs has also shown no significant difference in clinical outcomes.²⁶ Patient factors affecting healing and retear of RCR include osteoporosis, smoking, higher body mass index (BMI), age, female sex, and diabetes mellitus (DM).^{6,27} However, data is less complete regarding patient related factors on clinical improvement after knotless DR ARCR. Millet et al previously identified Worker's Compensation (WC) and prior ARCR as negative predictors of patient-reported outcome measures (PROMs), while higher preoperative baseline had a positive effect in knotless TOE ARCR.²⁴

Arthroscopic lateral row biceps tenodesis (LRT) has likewise been described by several authors^{11,15,19} with excellent clinical outcomes.^{13,24} In the presence of rotator cuff tears, the long-head biceps tendon is a potential source of pain due to subluxation, hypertrophy, delamination, and contracture. In the setting of the previous factors, tenotomy or tenodesis is often indicated.^{7,14,20,22,32} Surgeons can choose from a variety of tenodesis techniques based on location in the proximal humerus, such as suprapectoral and subpectoral; as well as fixation methods including onlay, inlay, suture anchor, cortical button, and interference screw fixation. Studies of arthroscopic suprapectoral tenodesis vs. mini-open subpectoral tenodesis have failed to show a significant difference in clinical outcomes.^{1,10,25} Furthermore, no difference in clinical outcome has been seen in suprapectoral tenodesis anchored within the biceps groove vs. incorporation into the lateral row.⁸

The purpose of this study was three-fold: (1) to report the outcomes of knotless DR TOE ARCR technique at 1-, 2- and 5- years postoperatively; (2) to report the clinical outcomes of patients undergoing knotless DR TOE ARCR with incorporated LRT and those without LRT; and (3) to evaluate the effect of age, sex, BMI, smoking, WC, and DM on clinical outcomes. We hypothesized that knotless DR TOE arthroscopic RCR yields excellent clinical outcomes at 1-, 2- and 5- years postoperatively when performed with or without LRT. Moreover, we expected a worse outcome in smokers and patients with DM, while no difference should be noticed regarding the other variables.

Methods

This study received institutional review board approval (#2011P002663) and was compliant with the Health Insurance Portability and Accountability Act. All patients who had an ARCR by one surgeon (EM) at a single institution provided informed consent and were prospectively enrolled in a global registry, Surgical Outcome System (Arthrex, Naples, FL). We performed a retrospective analysis of the registry data to include all patients that had a knotless DR TOE ARCR consisting of 2 medial and 2 lateral row anchors, completed the preoperative and postoperative questionnaires, and had a minimum of 1-year postoperative follow-up. Exclusion criteria were failure to complete preoperative and postoperative PROMs, greater or fewer than 4 total anchors, open RCRs, revision surgeries, superior capsular reconstructions or surgeries with concomitant procedures other than biceps tenodesis.

All participants were asked to respond to an electronic survey before and at 3 months, 6 months, 1, 2 and 5 years after surgery. At each time, we sent a reminder email if questionnaires were not completed on time. The PROM scores typically collected for the global registry are American Shoulder and Elbow Surgeons (ASES) Function, ASES Index, Single Assessment Numeric Evaluation (SANE), Simple Shoulder Test (SST), Veterans RAND 12-Item Health Survey (VR-12) physical and mental, and Visual Analogue Scale (VAS) scores. However, for this study, we used ASES Function (ASES-F) and ASES Index (ASES-I) as the primary outcome scores most comparable to the previously reported literature.

Statistical analysis

Data were described using frequencies and percentages for dichotomous and categorical variables, means and standard deviations for normally distributed continuous data, and medians and interquartile ranges for nonparametric continuous data. Age was categorized as <55 vs. 55+ and BMI was categorized as normal weight (BMI < 25), overweight (BMI > 25 and <30), and obese (BMI ≥ 30).

For each PROM, the association between covariates and PROM were assessed using linear mixed effects models with repeated measures. Interaction terms of time variables and patient factors were included to assess whether change in PROM over time was different for different patient factors. Patient factors included age group, BMI group, sex, and biceps tenodesis.

Achievement of minimum clinically important difference (MCID) was determined using the parameters described by Tashjian et al³⁰ for ASES, SST, and VAS pain scores, which were 27.1, 4.3, and 2.4 points, respectively. The percentage of patients achieving MCID was collected at 1-, 2-, and 5 years postoperatively based on ASES, SST, and VAS scores, and these percentages were further stratified between age and sex.

Maximal Outcome Improvement (MOI) in ASES and SANE scores for ARCR was determined as achieving 69.5% of maximal ASES score improvement and 75% maximal SANE score improvement, as described by Beck et al.⁴ These were collected at 1-, 2- and 5-years postoperatively and further stratified between age and sex.

Statistical analysis was performed using SAS 9.4 (SAS Institute, Cary NC). $P < .05$ was considered statistically significant.

Surgical technique

All patients received an interscalene block preoperatively and were operated in the lateral decubitus position, with the operative arm in balanced suspension. After standard diagnostic arthroscopy, the biceps tendon was inspected at the biceps labral anchor and at the bicipital groove by retraction with a probe. If pathology was noted, a luggage tag suture was placed distal to the biceps labral anchor) and tenotomy was performed proximal to the tagging suture (Fig. 1A). The stump was debrided to a smooth edge (Fig. 1B) and the suture limbs were retrieved through the anterolateral portal. The arthroscope was then placed in the subacromial space for a DR TOE ARCR. After preparation of the tuberosity, two knotless medial row anchors were inserted adjacent to the articular margin (Fig. 2). The two limbs of the suture/tape from each medial anchor were passed through the tendon in a mattress configuration. One strand of each medial row anchor is inserted into the eyelet of each one of the lateral row anchors (bridge technique) (Fig. 3). Additionally, the suture limbs of the biceps tendon were included in the anterior-most lateral anchor eyelet (Fig. 3). After loading the suture/tapes, the lateral-row anchors are inserted at the anterolateral and posterolateral aspect of the greater tuberosity (Fig. 3). All patients were placed in an abduction sling postoperatively for 6 weeks. They followed a standardized rehabilitation protocol which started 2 weeks after surgery.

Results

The final analytic cohort included 342 subjects with 178 (52%) females, 163 (48%) males (one missing sex data) and a mean age of 56 years. The cohort's population demographic characteristics are depicted in Table I. Seventy-seven percent of patients did not have a concomitant biceps procedure. Of the 342 subjects, 286 (84%) had complete 1-year postoperative data, 253 (75%) had complete 2-year data. Only 90 patients (26%) had completed 5-year data because

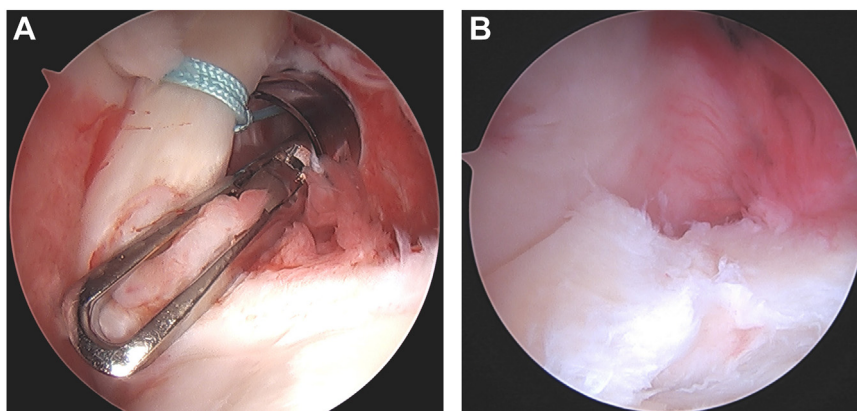


Figure 1 Intraarticular view of the right shoulder in lateral decubitus position from the posterior portal. (A) A luggage tag suture is placed through the biceps tendon distal to the biceps labral anchor and tenotomy is performed proximal to the tagging suture. (B) The stump is débrided to a smooth edge.

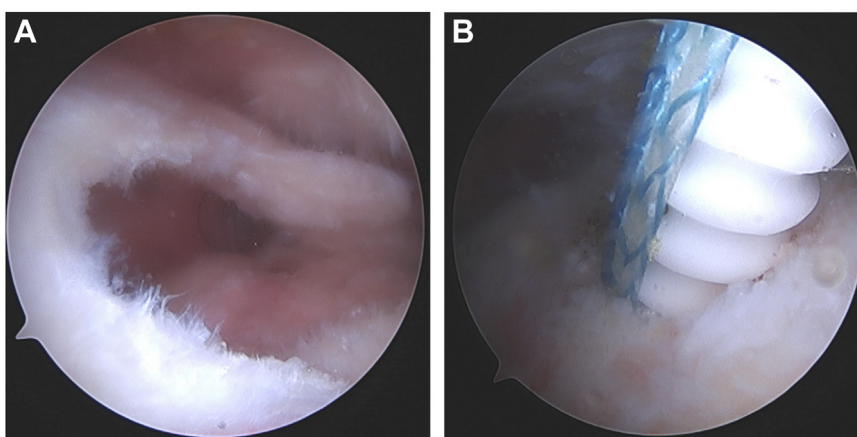


Figure 2 Subacromial view from the posterior portal. (A) Crescent shape tear of the supraspinatus tendon (B) Knotless medial row anchor inserted adjacent to the articular margin.

they had not reached 5 years after surgery at the time this study was completed.

Outcomes of knotless double-row transosseous equivalent arthroscopic rotator cuff repair

All PROMs, including VAS, ASES, SST, SANE, and VR-12 physical score, demonstrated significant improvement in scores from baseline to 1-, 2-, and 5- years postoperatively (Table II). The exception was the VR-12 mental health score which showed significant improvement from baseline to year one, however this difference was not observed in years 2 and 5 postoperatively (Table II).

Bicep tenodesis

There was a statistically significant improvement in ASES-F and ASES-I from baseline to 1, 2 and 5 years' time points in both groups, with and without biceps tenodesis. However, between-group differences at these same time points were insignificant (Table III).

Age

Both age groups (<55 and ≥ 55) demonstrated significant improvement in ASES-F and ASES-I scores from baseline to 1-, 2-,

and 5 years postoperatively (Table IV). There was no significant difference in ASES score over time between age groups.

Sex

While males started with a slightly higher mean ASES-F score compared to their female counterparts (14.7 and 13.4 respectively) and ASES-I (50.6 and 44.4 respectively) at baseline, between-group differences were not significant at any follow-up time point. Both males and females significantly improved ASES-F and ASES-I scores from baseline to 1-, 2- and 5-year postoperative timepoints (Table V).

BMI

In all classes of BMI, the ASES-F and ASES-I significantly improved from baseline to 1-, 2- and 5-year follow-up, and there were no significant differences in ASES-F and ASES-I between BMI groups at any time points (Supplemental Table 1).

Diabetes mellitus (DM)

ASES-F and ASES-I scores showed significant improvement from baseline to 1-, 2- and 5-year follow-up in subjects with and without DM. These two groups of patients were significantly different at baseline when comparing ASES-F; however, no difference was

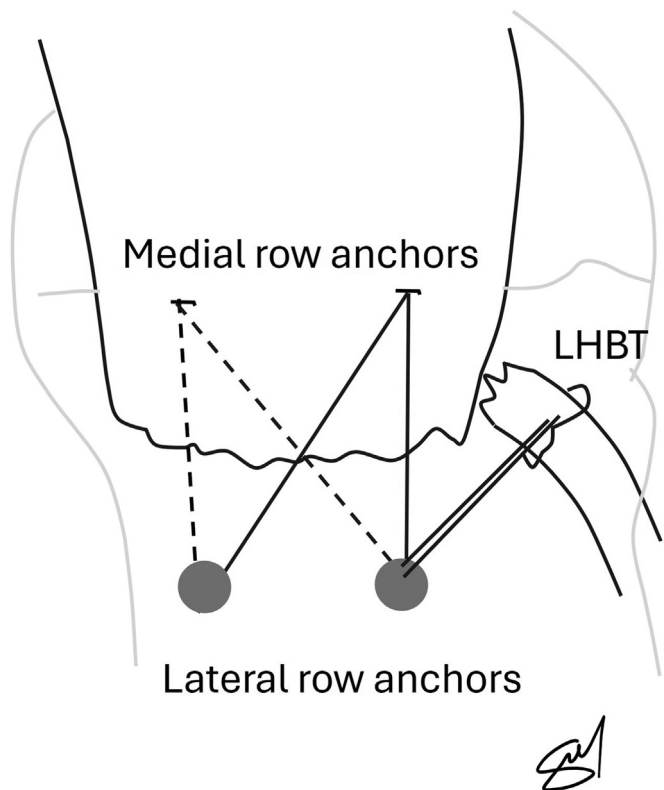


Figure 3 Drawing of the technique for rotator cuff repair with LHBT tenodesis, which is fixed on the anterior anchor of the lateral row. LHBT, long head of biceps tendon.

noted in any of the time points after that. Data for patients with and without DM are depicted in [Supplemental Table 2](#).

Smoking

Current smokers and nonsmokers significantly improved their ASES-F and ASES-I scores from baseline to 1, 2 and 5 years. When comparing both groups, current smokers had significantly worse ASES-F at 2-year postoperative follow-up. When comparing ASES-I, current smokers' scores were significantly worse than nonsmokers at baseline, but this difference was not sustained moving forward in follow-up. A summary of these findings can be seen in [Supplemental Table 3](#).

Worker's compensation

ASES-F and ASES-I scores showed significant improvement from baseline to 1, 2 and 5 years after surgery in patients with and without WC issues. Patients on WC had significantly worse ASES-F scores at baseline when compared with patients with no WC. However, no difference was seen at 1-, 2- and 5-year follow-ups when comparing ASES-F and ASES-I scores between these two groups of patients ([Supplemental Table 4](#)).

Minimal clinically important difference (MCID) and Maximal Outcome Improvement (MOI)

MCID and MOI were achieved in a predictable manner in ASES-I, SST, and VAS. Most patients (81%) achieved MCID by 1-year postoperatively, increasing only slightly at years 2 and 5. MOI followed a more delayed trend with the majority (64%) achieving MOI at 1-year postoperatively, an additional 12% achieving MOI between

Table 1
Descriptive statistics of cohort characteristics.

Descriptive statistics of cohort characteristics	Overall stat
Age at treatment (mean (SD))	56.1 (10.0)
Age	
<55	143 (42%)
55-69	173 (51%)
70+	26 (8%)
Patient information 1 body mass index (BMI) (mean (SD))	28.7 (5.9)
BMI	
1. Normal weight < 25	92 (27%)
2. Overweight 25-30	123 (37%)
3. Obese ≥ 30	121 (36%)
Missing	6
Gender	
Female	178 (52%)
Male	163 (48%)
Missing	1
Race	
Asian	3 (1%)
Black or African American	6 (2%)
White	296 (95%)
Other	7 (2%)
Missing	30
Ethnicity	
Not Hispanic or Latino	329 (97%)
Hispanic or Latino	11 (3%)
Missing	2
Diabetic	
No	318 (93%)
Yes	23 (7%)
Missing	1
Smoker	
No	312 (93%)
Yes	25 (7%)
Missing	5
Workman compensation case	
No	307 (91%)
Yes	32 (9%)
Missing	3
Concomitant biceps procedure	
0. No concomitant biceps procedure	262 (77%)
1. Tenodesis	61 (18%)
2. Tenotomy	15 (4%)
3. Débridement	4 (1%)
Cofield classification of tear size	
Small (<1 cm)	52 (16%)
Medium (1-3 cm)	193 (59%)
Large (3-5 cm)	64 (20%)
Massive (>5 cm)	16 (5%)
Missing	17
Tear acuity acute or chronic	
Acute	87 (26%)
Chronic	243 (74%)
Missing	12

SD, standard deviation.

years 1 and 2, and only 3% achieving MOI between years 2-5 based on ASES-I.

Discussion

Our study demonstrates that knotless DR TOE ARCR significantly improves PROMs at 1-, 2-, and 5 years after surgery. These findings corroborate the study by Johannsen et al on TOE RCR outcomes at 10-year follow-up, which included both knotted medial row and knotless constructs.¹² Additionally, a recent meta-analysis showed no difference in clinical outcomes when comparing knotted to knotless DR TOE ARCR.²⁶ The literature suggests that knot tying leads to strangulation of the rotator cuff tendon at the medial row,³¹ is technically more demanding and time-consuming. Knotless techniques have the advantages of easier suture management

Table II

Overall PROM at baseline, 1-, 2-, and 5-year after surgery.

	Baseline mean (SD)	1 y mean (95%CI)	<i>P</i> *	2 y mean (95%CI)	<i>P</i> *	5 y mean (95%CI)	<i>P</i> *
VAS	5.2 (2.3)	1.4 (1.2, 1.6)	<.0001	1.1 (0.9, 1.3)	<.0001	1.0 (0.7, 1.4)	<.0001
SST	36.9 (23.5)	78.8 (76, 81.6)	<.0001	83.3 (80.5, 86.1)	<.0001	83.4 (79.2, 87.6)	<.0001
SANE	38.2 (19.1)	79.4 (77, 81.9)	<.0001	79.3 (76.0, 82.5)	<.0001	81.9 (77.2, 86.7)	<.0001
ASES Function	14.0 (5.4)	25.2 (24.6, 25.7)	<.0001	26.5 (25.9, 27.0)	<.0001	26.9 (26.0, 27.7)	<.0001
ASES Index	47.2 (17.4)	84.9 (83.0, 86.7)	<.0001	88.7 (87.0, 90.4)	<.0001	89.4 (86.5, 92.2)	<.0001
VR12 Physical	36.2 (7.7)	47.7 (46.8, 48.6)	<.0001	48.9 (47.9, 49.9)	<.0001	49.9 (48.8, 51.0)	<.0001
VR12 Mental	53.6 (10.2)	55.2 (54.1, 56.2)	0.0021	54.1 (53.0, 55.2)	0.3787	54.1 (52.8, 55.4)	0.4516

ASES, American Shoulder and Elbow Surgeons; SD, standard deviation; PROM, patient-reported outcome measure; SST, Simple Shoulder Test; VR-12, Veterans RAND 12-Item Health Survey; VAS, Visual Analogue Scale; SANE, Single Assessment Numeric Evaluation.

*Compared to baseline.

Table III

Mean ASES index by biceps tenodesis groups and between-group difference.

Time point	BT mean (95% CI)	<i>P</i> *	No BT mean (95% CI)	<i>P</i> *	Differences of mean (95% CI)	<i>P</i>
Baseline	46.1 (41.9, 50.4)	<.0001	47.6 (45.5, 49.7)	<.0001	−1.5 (−6.3, 3.2)	.5301
Year 1	87.7 (82.9, 92.4)	<.0001	84.2 (82.0, 86.5)	<.0001	3.4 (−1.8, 8.7)	.1992
Year 2	90.1 (85.2, 94.9)	<.0001	88.1 (85.7, 90.5)	<.0001	2.0 (−3.4, 7.4)	.4720
Year 5	88.0 (81.5, 94.6)	<.0001	88.7 (84.3, 93.2)	<.0001	−0.7 (−8.6, 7.2)	.8610

CI, confidence interval; BT, biceps tenodesis; ASES, American Shoulder and Elbow Surgeons.

*Compared to baseline.

Table IV

Mean ASES index by age group and between-group difference.

Time point (years)	Age group < 55 Mean (95% CI)	<i>P</i> *	Age group > 55 mean (95% CI)	<i>P</i> *	Differences (95% CI)	<i>P</i>
Baseline	45.9 (43.0, 48.8)	<.0001	48.4 (45.9, 50.9)	<.0001	−2.5 (−6.3, 1.3)	.1958
1	84.6 (81.5, 87.8)	<.0001	85.0 (82.3, 87.7)	<.0001	−0.4 (−4.5, 3.7)	.8536
2	89.1 (85.7, 92.5)	<.0001	88.0 (85.2, 90.8)	<.0001	1.1 (−3.3, 5.5)	.6366
5	89.2 (83.5, 94.8)	<.0001	87.7 (82.9, 92.6)	<.0001	1.4 (−6.0, 8.9)	.7032

CI, confidence interval; ASES, American Shoulder and Elbow Surgeons.

*Compared to baseline.

Table V

Mean ASES index by sex and between-group difference.

Time point	Male mean (95% CI)	<i>P</i> *	Female mean (95% CI)	<i>P</i> *	Differences (95% CI)	<i>P</i>
Baseline	50.6 (47.9, 53.3)	<.0001	44.4 (41.8, 47.0)	<.0001	6.2 (2.5, 9.9)	.0012
1	86.1 (83.2, 89.0)	<.0001	83.7 (80.9, 86.5)	<.0001	2.4 (−1.6, 6.5)	.2366
2	89.5 (86.3, 92.6)	<.0001	87.6 (84.6, 90.5)	<.0001	1.9 (−2.4, 6.2)	.3859
5	90.7 (86.0, 95.4)	<.0001	85.0 (79.2, 90.7)	<.0001	5.8 (−1.7, 13.2)	.1298

CI, confidence interval; ASES, American Shoulder and Elbow Surgeons.

*Compared to baseline.

and decrease in surgical time,³ without compromising biomechanical strength.⁵

As hypothesized, no differences in PROMs were observed when comparing patients with and without anterior LRT. Meghpara et al reported the clinical outcomes of an all-arthroscopic biceps tenodesis using the anterolateral anchor during concomitant DR RCR. They demonstrated high patient satisfaction rates and significant improvement in PROMs and pain scores.²¹ Incorporating the sutures from the biceps tenodesis into the anterior lateral row anchor is a fast and technically easy arthroscopic method. Furthermore, it avoids the morbidity of an open incision such as that required for subpectoral tenodesis. Moreover, it is a cost-effective alternative as no additional implants are needed.

This study also shows that age does not significantly affect postoperative PROMs at any timepoint. While males had a significantly higher ASES-I at baseline, there were no differences when compared to females at 1-, 2- and 5-year follow-ups. Similarly, obese patients have worse ASES scores at baseline compared to normal-weight group, but this difference was not observed moving

forward in the postoperative period. This is an interesting finding as age and BMI are reported risk factors of rotator cuff retear.^{17,27,29,33} Our data indicates that, despite these risk factors, patient-reported clinical outcomes of this higher-risk population are not significantly influenced by the arthroscopic RCR surgery herein described.

We found that patients with DM, current smoking, and WC had significantly worse ASES score at baseline; however, no difference was seen at 1-, 2-, and 5- years postoperatively. This finding is supported by a recent meta-analysis that showed that DM may be related to higher retear rates and cuff unhealing, but patients still achieve improved clinical outcomes.¹⁸ Likewise, smoking is a risk factor for failure after RCR. Nevertheless, Fan et al demonstrated no significant differences in the clinical scores after RCR between smokers and nonsmoker.⁹

Our analysis of MCID and MOI further showed that approximately 80% of patients achieved MCID at 1-year and improved slightly at the 2- and 5-year postoperative time points. Most improvement, however, occurred in the first year after surgery. Females achieved MCID at a slightly higher rate than males at most

time points, while males achieved MOI at a slightly higher rate than females at most time points. MCID and MOI based on age showed roughly equivalent outcomes at the 1- and 2-year postoperative time points, however higher rates of achieving MCID and MOI were seen in the <55 age group in all outcome scales at the 5-year timepoint. This difference could be due to the significantly higher 5-year follow-up rates in the younger population.

The strengths of this study are that all patients were treated by one surgeon using the same technique with the same postoperative rehabilitation allowing for comparison of groups. Moreover, we used prospective data collection and patient-focused metrics as the outcome of choice. We also report MCID and MOI, which are patient-centered and reflect the impact in clinical practice. Limitations include the relatively small sample size of 341 patients. Statistical power may be low for some comparisons, especially for covariates with small group sizes (e.g., diabetes, smoking, workers' compensation status). We only required that participants have 1- or 2-year follow-ups; thus, the number with 5-year follow-ups was low. We thought it was important to report these numbers, but they should be interpreted cautiously. A larger data set would be necessary to make further assertions on patient-related factors and clinical outcomes, particularly for relatively rare patient factors. Although tear size and morphology data are collected, this study did not analyze them. All tears were assumed to be of similar size to have been arthroscopically repaired with 2 medial and 2 lateral row anchors, and tears that required greater or fewer than 4 anchors were excluded. Also, psychological factors such as fear-avoidance beliefs and restricted range of motion are known to negatively influence ASES scores,¹⁴ and these were not integrated into the current study.

Conclusions

Knotless DR TOE ARCR significantly improves patient-reported clinical outcomes at 1-, 2- and 5-year follow-ups. These results are reflected in clinical practice by the fact that 80% of patients achieved MCID postoperatively. Patient related factors, including BMI, age, sex, WC, and DM, do not significantly affect patient reported outcomes in the first 5 years after surgery. Smokers have worse baseline scores which persist at 2-year follow-up. Lastly, adding an arthroscopic LRT in knotless DR TOE ARCR provides similar clinical outcomes to knotless DR TOE RCR without biceps tenodesis.

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Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jseint.2024.06.013>.

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