COVID-19−related rotator cuff repair delay

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Background: Although nonoperative treatment is effective for degenerative rotator cuff tears (RCTs), it remains unclear whether the delay created by a trial of nonoperative treatment negatively influences the outcome of a subsequent surgical repair. In March 2020, the COVID-19 pandemic resulted in an involuntary delay in the surgical treatment of rotator cuff disease, creating a natural experiment. The purpose of this study was to evaluate the outcomes and healing of patients who underwent delayed surgical treatment of chronic degenerative RCTs as compared with the nondelayed surgical treatment of RCTs.
Methods: This was a prospective study of two groups: patients planned to undergo arthroscopic rotator cuff repair between March 16, 2020 and May 1, 2020—the end of the ban on elective surgery—and patients who underwent rotator cuff repair starting six weeks after the ban on elective surgery had been lifted. Preoperatively and at six months postoperatively, we collected the Simple Shoulder Test, the American Shoulder and Elbow Surgeons (ASES) score, and the visual analog scale for pain. We also obtained magnetic resonance imaging (MRI) at six months postoperatively. A power analysis was conducted, and assuming a mean $\pm$ standard deviation ASES score of 93.1 $\pm$ 13.9 points and a minimum clinically important difference in the ASES score of 27.1 points, 7 patients per group (14 patients in total) would be necessary to have 90% chance of finding a difference.
Results: We included 15 patients within each group and obtained 100% follow-up at six months. In the delay group, the mean $\pm$ standard deviation delay was 63 $\pm$ 24 days. There were no significant preoperative differences between groups in demographics or tear characteristics. Intraoperatively, there were no differences between groups in repair characteristics. Using a repeated-measures analysis of variance, there were significant preoperative vs. postoperative differences in ASES scores ($P < .001$), visual analog scale scores ($P < .001$), and Simple Shoulder Test scores ($P < .001$), but no differences between groups ($P = .910$, .519, and 0.852, respectively). On MRI, within the delay group, 58% had healed, whereas within the control group, 85% had healed ($P = .202$).
Conclusion: COVID-19 caused a two-month delay in the operative treatment of RCTs. This delay did not significantly alter patient-reported outcomes. This delay resulted in a 27% difference in MRI healing rates, which was not statistically significant in this small study. Larger studies should be conducted as our results suggest that a delay in treatment may negatively impact healing rates.

Rotator cuff tears (RCTs) are common, occurring in up to 30%-40% of those over 65 years old.[13] The optimal treatment of RCTs remains controversial. Although nonoperative treatment is

effective,[3] and is successful in the majority of cases,[4] rotator cuff repair (RCR) has been demonstrated to have superior outcomes in both a randomized clinical trial[10] and a comparative study.[7] Among the most common questions asked by patients considering both operative and nonoperative treatment is "If I want to try physical therapy but am not sure if it will work, how long can I wait before my outcome with surgery is compromised?" The evidence surrounding this issue is conflicting. For instance, animal studies have demonstrated that even a 12-week delay in surgical treatment can lead to a deterioration in the biomechanical properties of the tendon and loss of tuberosity bone,[5] as well as a greater loss of muscle.[17] However, other animal studies demonstrated that a

12-week delay did not impair enthesis formation.[9] Clinically, some retrospective studies have demonstrated that a 3-month delay in surgical treatment of acute RCTs[1] or even a 6-month delay[8] in surgical treatment of partial-thickness RCTs did not influence outcomes. It may take up to 18 months before significant muscular atrophy occurs, after atraumatic RCTs.[6] However, others have shown that delay in treatment of degenerative RCTs correlates with a decreased improvement in the Constant score postoperatively[12] and that those with delayed surgical treatment have significantly worse outcomes than those that undergo nondelayed surgical treatment.[10,11]

Within general clinical research, this question has been difficult to address. Few patients will consent to be randomized to a delay in treatment, so any randomized study would suffer significant selection bias. In addition, this question is difficult to address retrospectively. Certainly, many patients experience an involuntary delay in treatment, but the reasons for this delay (medical comorbidities, social issues, etc.) may themselves impair the outcome.[16] However, in March of 2020, the COVID-19 pandemic resulted in a six-week ban on elective surgery within our center. During this time period, no RCRs were performed, and there was thus a universal involuntary delay in the surgical treatment of rotator cuff disease. This created a natural experiment to allow us to better address this question.

Therefore, the purposes of this study are as follows: (1) to determine the effect of the delay in treatment caused by the COVID-19 outbreak upon short-term clinical outcomes after RCR and (2) to determine the effect of the delay in treatment caused by the COVID-19 outbreak upon tendon healing after RCR. Our hypothesis was that a delay in surgical treatment would result in a clinically significant decrease in both outcomes and tendon healing after RCR.

Materials and methods

Patient selection

This is a prospective clinical study consisting of two groups. In the delayed group, patients planned to undergo arthroscopic RCR between March 16, 2020 and May 1, 2020 (the end of the ban on elective surgery at our institution) were included. In the nondelayed group, patients who underwent arthroscopic RCR once the ban on elective surgery at our institution had been lifted for a minimum of six weeks—so as to allow time to work through the surgical back-log—were included (Fig. 1). From both groups, we excluded patients with refusal to consent and return for follow-up, patients felt to be indicated for urgent or emergent surgical treatment, patients with lack of complete preoperative data, patients with concomitant graft augmentation or interposition or tendon transfer, and patients with an inability to obtain a magnetic resonance imaging (MRI).

Data collection

With institutional review board approval, patients who met the inclusion criteria described previously were contacted and offered inclusion. Informed consent was collected over the phone. The following outcomes were collected preoperatively: the Simple Shoulder Test (SST), the American Shoulder and Elbow Surgeons (ASES) score, and the visual analog scale (VAS) for pain. The following demographics were collected for all patients: age, sex, body mass index, American Society of Anesthesiologists score, smoking status, type of repair construct, whether or not a concomitant subscapularis repair was performed, biceps treatment, preoperative tear width, preoperative tear retraction, supraspinatus muscle atrophy, infraspinatus muscle atrophy, number of

anchors used, and the time from injury to surgery. The patients were then followed, and the following outcomes were collected preoperatively and at six weeks, three months, and six months postoperatively: the SST, the ASES score, and the VAS for pain. MRI was also obtained at six months to assess tendon healing using similar protocols to prior studies.[2,14] All portions of this study consist of standard of care except for the collection of outcomes.

Statistical methods

At two years postoperatively, in a randomized clinical trial, the mean ± standard deviation ASES score after primary surgical tendon repair was 93.1 ± 13.9 points.[11] In a recent study, the minimum clinically important difference for the ASES score after arthroscopic RCR was 27.1 points.[15] Assuming equal variances between groups, a power analysis was conducted, determining that 7 patients per group (14 patients in total) would be necessary to have 90% chance of finding a difference of this magnitude between groups, should one exist. To account for attrition rates, a study with 30 patients (15 per group) was planned. With regard to purpose 1, we performed a repeated-measured analysis of variance analysis comparing between groups, using the Greenhouse-Geisser correction for *P* values as Mauchly's test revealed asphericity. With regard to purpose 2, all MRIs were interpreted by two fellowship-trained orthopedic shoulder surgeons and by one surgeon on two occasions separated by 2 weeks. Each MRI was evaluated as follows: if there were no fluid-filled gaps between the rotator cuff and the tuberosity on any axial, coronal, or sagittal image, then the repair was considered to be intact. If there was a fluid-filled gap on any image, then the repair was considered to be failed (Fig. 2). Inter-rater and intrarater reliability was measured using Cohen's κ. These surgeons then met, and cases of disagreement were addressed using a consensus methodology, with the consensus read used within the analysis. To analyze demographics, discrete variables were compared using chi-square tests and Fisher's exact tests as appropriate depending on cell populations, and continuous data were analyzed using student's t-tests and Mann-Whitney U tests as appropriate depending on cell populations.

Results

Patient demographics

Fifteen patients were included within each group, and 100% follow-up was obtained at six months for clinical outcome data; 86.7% (13/15) follow-up MRI data were obtained for the delay group, and 93.3% (14/15) follow-up MRI data were obtained for the control group. A total of 10 subjects were excluded from the study (Fig. 1). The mean ± standard deviation surgical delay was 63 ± 24 days. The mean time from injury to surgery was not different between groups (1000 ± 1189 days in the delay group and 447 ± 477 days in the control group, *P* = .106). There were no significant preoperative differences between groups in any factor, including age (*P* = .841), sex (*P* = .450), body mass index (*P* = .106), Charlson comorbidity index (*P* = .399), American Society of Anesthesiologists score (*P* = .875), smoking status (*P* = 1.000), laterality (*P* = 1.000), active forward elevation (*P* = .219), active external rotation (*P* = .248), active internal rotation (*P* = .586), tear width (*P* = .095), tear retraction (*P* = .406), or Goutallier grade in the supraspinatus (*P* = .187), infraspinatus (*P* = .435), or subscapularis (*P* = .341). Intraoperatively, there were no differences between groups including the number of anchors used (*P* = .104), the incidence of concomitant biceps tenodesis (*P* = 1.000), and the incidence of subscapularis repair (*P* = .427) (Table I).
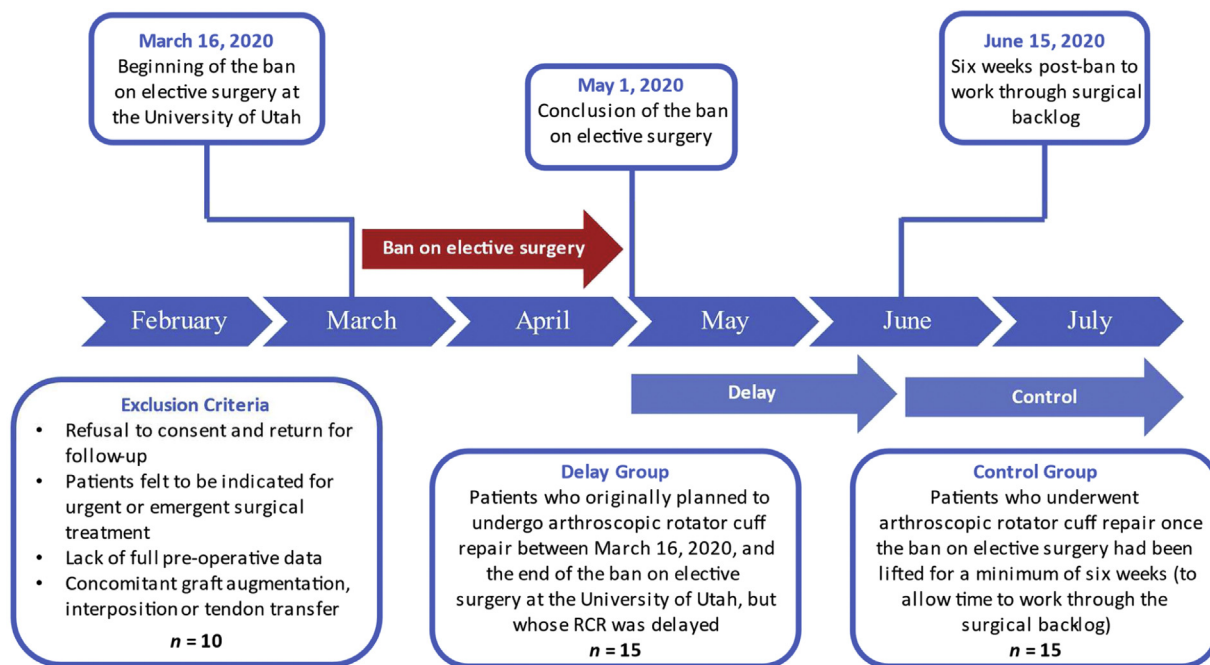
Figure 1 Timeline demonstrating the inclusion and exclusion criteria for selecting our arthroscopic rotator cuff delayed vs. nondelayed groups.
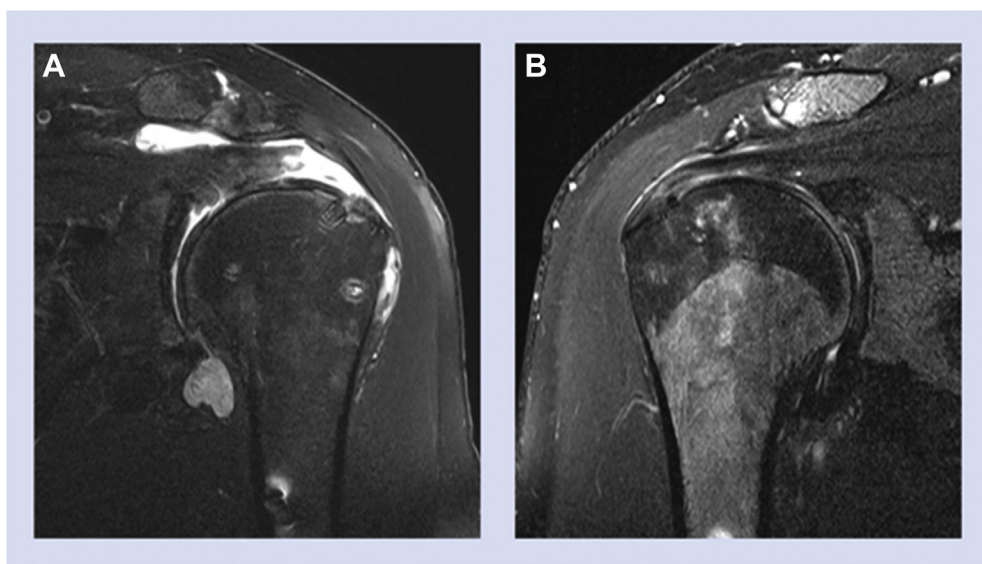
Figure 2 These are two T-2 weighted, coronal magnetic resonance imaging (MRI) snapshots of two of our surgical rotator cuff repair patients 6 months after surgery. (**A**) This image shows evidence of a fluid-filled gap, and thus, this patient's repair was considered failed. (**B**) This image shows no evidence of a fluid-filled gap, and this patient's repair was considered healed.

Outcome scores and rotator cuff tendon healing

There were significant preoperative vs. postoperative differences in ASES scores ($P < .001$), VAS scores ($P < .001$), and SST scores ($P < .001$), but there were no differences between groups in postoperative scores ($P = .910$, $.519$, and 0.852, respectively). Both interobserver reliability and intraobserver reliability for MRI tendon healing were good ($\kappa = 0.68$ and 0.58, respectively). On MRI, within the delay group, 58.3% (7/12) had healed, whereas within the control group, 84.6% (11/13) had healed ($P = .202$).

Discussion

Within our institution, COVID-19 caused a two-month delay in the operative treatment of RCTs. This study demonstrates that although preoperative vs. postoperative ASES, VAS, and SST scores were significantly improved between preoperatively and postoperatively, there were no significant differences in score improvement between the delay and control groups. On MRI, although 27% more patients in the delay group had a retear of the rotator cuff, this difference was not significant in this small study ($P = .202$). Although statistically insignificant, this difference is

Table I

Preoperative demographics of each group (age, BMI, and CCI), average time from injury to surgery, preoperative shoulder function, preoperative MRI differences, and intraoperative characteristics.

Variable	Cohort	n	Mean	P value	Std. deviation	Std. error mean
Age	Delay	15.00	56.15	.841	10.24	2.65
	Control	15.00	55.41		9.74	2.51
Delay from COVID-19 (days)	Delay	15.00	62.67	N/A	23.62	6.10
Delay from injury onset (days)	Delay	15.00	999.60	.106	1189.26	307.07
	Control	15.00	446.73		477.06	123.18
BMI	Delay	15.00	29.27	.978	6.81	1.76
	Control	15.00	29.33		6.18	1.60
CCI	Delay	15.00	1.20	.399	1.70	0.44
	Control	15.00	1.73		1.71	0.44
Preoperative shoulder active forward elevation (degrees)	Delay	14.00	136.43	.219	42.22	11.28
	Control	14.00	115.00		47.64	12.73
Preoperative shoulder external rotation in adduction (degrees)	Delay	14.00	51.79	.248	18.57	4.96
	Control	14.00	59.29		14.79	3.95
Tear width (mm)	Delay	15.00	26.13	.095	15.88	4.10
	Control	15.00	16.40		14.94	3.86
Tear retraction (mm)	Delay	15.00	18.80	.406	13.52	3.49
	Control	15.00	14.93		11.51	2.97
Number of anchors used	Delay	15.00	3.07	.104	1.58	0.41
	Control	15.00	2.13		1.46	0.38
Active forward elevation at 4.5 months after RCR (degrees)	Delay	10.00	161.00	.926	11.01	3.48
	Control	11.00	160.45		14.91	4.50
External rotation in adduction at 4.5 months after RCR (degrees)	Delay	8.00	61.25	.775	18.27	6.46
	Control	10.00	64.00		21.19	6.70

MRI, magnetic resonance imaging; *BMI*, body mass index; *CCI*, Charlson comorbidity index; *mm*, millimeter; *RCR*, rotator cuff repair.

numerically large, which suggests that further study is necessary and that a delay may result in a clinically significant difference in healing rates.

This study demonstrated that there were no differences in ASES, pain VAS, and SST score improvement between delayed surgical RCR and immediate surgical RCR at 6 months after surgery. Our findings are consistent with prior studies. In a retrospective analysis of full-thickness RCTs, researchers found no difference in patient-reported outcomes irrespective of whether the surgical treatment had been performed within 3 weeks, 6 weeks, or 3 months.[1] Kim et al conducted a randomized controlled trial of 78 patients and reported higher 6-month postoperative ASES scores and lower VAS pain scores in patients who delayed surgical RCR by 6 months.[8] A systematic review conducted in 2013 reported that earlier time to surgery resulted in greater improvement in patient-reported outcomes; however, the authors concluded that these differences in improvement were likely driven by low range of motion in the nondelayed patient as a result of the more restrictive early stage of RCT. Interestingly, patients in the delay group of their study (>3 months) had higher postoperative Constant scores.[12] Moosmayer et al conducted a randomized controlled trial of physiotherapy vs. surgical RCR with 14 patients eventually choosing surgical management after a physical therapy trial, who demonstrated significantly inferior Constant scores.[10,11] However, the reasons for these patients opting out of nonoperative management may in themselves impair the results.

Within our small study, there was a 27% difference in healing rates between groups, but this difference was not statistically significant. Few studies have analyzed differences in healing using MRI post-RCR between delayed surgical treatment and nondelayed surgical treatment of RCTs. In a randomized controlled trial conducted by Kim et al, 1 patient in the control group and 2 patients in their delay group experienced a retear at 12 months postoperatively confirmed via MRI; however, the incidence was so small that statistical significance could not be established.[8] Another study reported no structural differences in healing on ultrasound and plain radiographs within 12 weeks of delayed surgical treatment, which is also consistent with our findings; however, different imaging modalities were used.[1] Animal studies have also demonstrated that a 12-week delay did not impair enthesis formation.[9] However, other animal studies have shown that even a 12-week delay in surgical treatment can lead to a deterioration in the biomechanical properties of the tendon and loss of tuberosity bone,[5] as well as a greater loss of muscle.[17] Considering our findings regarding patient-reported outcomes and tendon healing, further clinical studies should be performed as even a six-week trial of physical therapy could potentially decrease healing rates with RCR. In addition, these results call into question current guidelines from many insurance companies that all RCRs undergo a six-week trial of physical therapy.

One limitation to any study of this type is defining the length time of between injury and treatment. All patients included had a specific injury that they recalled, but likely all tears occurred on a background of chronic degenerative changes within the cuff. In addition, our study is limited by its relatively small sample size. Although our study was powered adequately to detect a statistically significant difference in ASES scores, it may be underpowered to detect differences in tendon healing. Rotator cuff tendon healing was evaluated only via MRI, which has potential to introduce observer bias. However, our method had good intraobserver and interobserver reliability, and a consensus methodology was used to develop the most accurate read possible. In addition, we did not homogenize the surgical methods for cuff repair in each group. However, these repairs were performed by two orthopedic surgeons of the same institution who share similar philosophies, which does reduce heterogeneity. In addition, there were no significant differences in intraoperative tear or repair characteristics between groups.

Conclusion

The COVID-19 pandemic caused a two-month delay in the operative treatment of RCTs. This delay did not significantly alter patient-reported outcomes. This delay resulted in a 27% difference in MRI-verified tendon healing rates, which was not statistically significant in this small study. Larger studies should be conducted

as our results suggest that a delay in treatment may negatively impact healing rates.

Disclaimers:

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