J Shoulder Elbow Surg (2020) 29, 442–450

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

SHOULDER

A randomized single-blinded trial of early rehabilitation versus immobilization after reverse total shoulder arthroplasty

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Background: Reverse total shoulder arthroplasty (RTSA) does not have a standard postoperative protocol. Although instability is a worrisome complication, prolonged immobilization may also be disabling in the elderly population. This study aimed to determine if early vs. delayed range of motion (ROM) after RTSA affected postoperative ROM, patient-reported outcomes, and the dislocation rate.

Methods: A single-blinded, randomized controlled trial was performed enrolling patients from 2013 to 2017. Patients were randomly assigned to either a delayed-rehabilitation group (no ROM for 6 weeks) or early-rehabilitation group (immediate physical therapy for passive and active ROM) and followed up for a minimum of 1 year. Demographic characteristics, ROM, American Shoulder and Elbow Surgeons (ASES) scores, and complications were recorded.

Results: Of an initial enrollment of 107 shoulders, 80.3% completed 1-year follow-up: 44 shoulders in the delayed-therapy group and 42 shoulders in the immediate-therapy group. Both groups had significantly improved forward flexion (32° improvement) and abduction (22° improvement) by 3 months. Both groups showed significant improvements in ASES scores by 6 weeks (9.4-point improvement in composite score) with continued improvement through 6 months (35.1 points). No significant differences were found between groups for any postoperative measure, with the exception of the ASES functional score favoring the delayed-therapy group at 6 months (26.3-point improvement vs. 16.7-point improvement). No differences in complications, notching, or narcotic use were noted between groups.

Conclusions: Both early- and delayed-ROM protocols after RTSA demonstrated significant, similar improvements in ROM and outcomes. Early initiation of postoperative rehabilitation may benefit the elderly population by avoiding the limitations of prolonged immobilization postoperatively.

Level of evidence: Level I; Randomized Controlled Trial; Treatment Study

Keywords: Reverse total shoulder arthroplasty; postoperative rehabilitation; shoulder; range of motion; immobilization; physical therapy

The institutional review board at the University of California, San Francisco approved this study (study no. 13-11333).

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1058-2746/$ - see front matter © 2019 Published by Elsevier Inc. on behalf of Journal of Shoulder and Elbow Surgery Board of Trustees.
https://doi.org/10.1016/j.jse.2019.10.005

Reverse total shoulder arthroplasty (RTSA) has gained acceptance as a tool for managing end-stage cuff tear arthropathy, in addition to expanded indications such as massive irreparable rotator cuff tears, inflammatory and noninflammatory arthritis, proximal humeral fractures and their sequelae, failed hemiarthroplasty or total shoulder replacements, and proximal humeral tumors. An estimated 21,700 RTSAs are now performed annually in the United States.[30] Technique and implant design have evolved over the past 20 years to help decrease complications and improve outcomes.

Despite the growing popularity of RTSA, there is no standard postoperative protocol among studies of RTSA.[5] It is unknown if early range of motion (ROM) leads to improved final ROM by preventing scar formation. Furthermore, prolonged immobilization of the arm can be very disabling, especially as this procedure is most frequently performed in the elderly population.[1,13,23] Whether prolonged immobilization negatively impacts patient-reported outcome measures is unknown. On the other hand, it is unknown if early motion leads to an increased dislocation rate or pain. Instability remains a significant complication of RTSA, with rates ranging from 2.4% to 31%.[7] Known contributors to instability are soft-tissue tension, glenosphere diameter, constraints on the humeral socket, mechanical impingement, bony deficiency, erroneous version of the prosthesis, and axillary nerve or deltoid dysfunction.[7] Dislocation is typically anterior, occurring from extension, adduction, and internal rotation.[8] It usually occurs early, within the first 3 months after surgery, and early immobilization may have benefits on reducing instability.[6,8,14,27,31] Early dislocation is a significant complication because it frequently requires revision surgery.[6,8,14,27]

In light of the lack of a definitive postoperative rehabilitation protocol, we developed a randomized controlled trial to compare early vs. late motion after RTSA to determine any differences in ROM, patient-reported outcome measures via the American Shoulder and Elbow Surgeons (ASES) shoulder score, or dislocation rate. Our hypothesis was that there would be no difference between the 2 rehabilitation protocols.

Materials and methods

This was a single-blinded, randomized controlled trial evaluating postoperative rehabilitation protocols after RTSA. Patients were

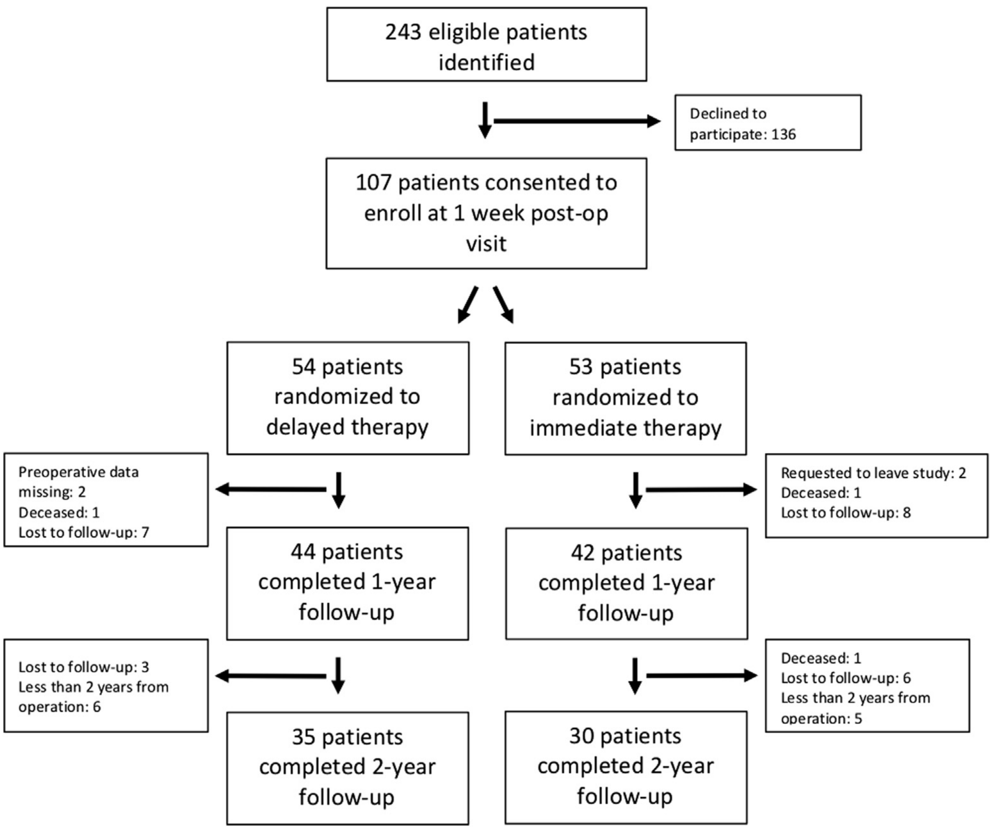

Figure 1 Flow diagram for patient follow-up. Patients were considered eligible if they underwent an uncomplicated reverse total shoulder replacement. One patient in the immediate-therapy group crossed over to the delayed-therapy group because of a complication in the first month postoperatively, but for the purposes of our intent-to-treat analysis, this patient was kept in the immediate-therapy group. *post-op*, postoperative.

Table I Preoperative and operative characteristics of delayed- and immediate-therapy cohorts

	Delayed therapy (n = 44)		Immediate therapy (n = 42)		*P* value
	n (%)	Mean ± SD	n (%)	Mean ± SD	
Age, yr		69.41 ± 7.50		68.31 ± 10.53	.577
Sex					.083
Male	22 (50.0)		29 (69.0)		
Female	22 (50.0)		13 (31.0)		
BMI		28.87 ± 6.33		30.84 ± 7.90	.204
Dominant arm					.498
Yes	26 (59.1)		25 (59.5)		
No	18 (40.9)		15 (35.7)		
Ambidextrous	0 (0.0)		2 (4.8)		
Diagnosis					.876
RCT arthropathy*	38 (86.4)		36 (85.7)		
Revision arthroplasty†	5 (11.4)		6 (14.3)		
Fracture malunion	1 (2.3)		0 (0.0)		
Symptom duration, yr		5.49 ± 6.86		9.67 ± 13.58	.095
Smoking status					.167
Never	30 (68.2)		20 (47.6)		
Former	12 (27.3)		20 (47.6)		
Current	2 (4.5)		2 (4.8)		
Narcotic use					.402
Yes	16 (36.4)		19 (45.2)		
No	28 (63.6)		23 (54.8)		
Surgeon					.597
C.B.M.	37 (84.1)		32 (76.2)		
B.T.F.	6 (13.6)		8 (19.0)		
A.L.Z.	1 (2.3)		2 (4.8)		
OR time, min		93.9 ± 21.8		101.7 ± 28.0	.154
Subscapularis repair					>.999
Yes	0 (0)		0 (0)		
No	44 (100)		42 (100)		
Biceps treatment					.781
Tenodesis	37 (84.1)		34 (81.0)		
Tenotomy	7 (15.9)		8 (19.0)		
Stem fixation					.117
Cement	40 (90.9)		42 (100)		
Press fit	4 (9.1)		0 (0)		
Hospital stay duration, d		1.68 ± 0.67		1.81 ± 0.99	.486

SD, standard deviation; *BMI*, body mass index; *RCT*, rotator cuff tear; *OR*, operating room.
No statistically significant differences were found between the delayed- and immediate-therapy groups for preoperative demographic and surgical data.
* Prior rotator cuff repair was performed in 2 delayed-therapy patients and 3 immediate-therapy patients.
† In 1 delayed-therapy patient and 1 immediate-therapy patient, fixation of a proximal humeral fracture initially failed, with subsequent failure of hemiarthroplasty.

enrolled from October 1, 2013, to April 30, 2017, at the University of California, San Francisco Medical Center. We included any patient who underwent RTSA at the University of California, San Francisco Medical Center performed by 1 of 3 surgeons (A.L.Z., B.T.F., or C.B.M.). All surgical indications and demographic characteristics were considered eligible. Patients were randomly assigned at their 1-week follow-up to 1 of 2 groups: (1) delayed rehabilitation (sling immobilization with no passive or active motion of the shoulder for 6 weeks) or (2) immediate rehabilitation (immediate physical therapy for passive and active ROM and weaning of sling use as tolerated but no resistance training for 6 weeks) (Supplementary Table S1). The providers and investigators who assessed the outcomes were unaware of the rehabilitation assignment. All patients provided written informed consent.

Consenting patients were evaluated preoperatively for demographic characteristics, baseline ROM, and ASES scores. Operative details were recorded on the day of surgery. All procedures were performed with patients in the beach-chair position by use of the Zimmer Biomet Trabecular Metal reverse shoulder system (Zimmer Biomet, Warsaw, IN, USA). A standard deltopectoral approach was used. The subscapularis tendon was not repaired at the end of the case.

At the 1-week postoperative visit, enrolled patients received a numbered envelope with their randomly generated treatment

Table II Preoperative range of motion and ASES shoulder scores

	Delayed therapy (n = 44) Mean ± SD	Immediate therapy (n = 44) Mean ± SD	P value
FF, °			
Active	81.6 ± 37.7	84.6 ± 43.0	.729
Passive	96.3 ± 41.1	97.9 ± 48.9	.871
Abd, °			
Active	72.5 ± 34.9	78.7 ± 42.9	.461
Passive	85.2 ± 38.9	89.2 ± 48.1	.668
ER, °			
Active	27.5 ± 22.9	37.9 ± 20.0	.028*
Passive	34.3 ± 25.8	43.0 ± 22.7	.098
CBA, °			
Active	32.6 ± 14.7	34.6 ± 14.1	.521
Passive	31.7 ± 14.6	33.7 ± 13.9	.537
ASES shoulder score			
Pain	26.3 ± 15.3	27.1 ± 13.5	.795
Function	12.3 ± 7.2	17.6 ± 11.3	.016*
Composite	38.5 ± 18.9	44.2 ± 17.4	.172

ASES, America Shoulder and Elbow Surgeons; *SD*, standard deviation; *FF*, forward flexion; *Abd*, abduction; *ER*, external rotation; *CBA*, cross-body adduction.
The values were not statistically different between the delayed- and immediate-therapy cohorts, with the exception of active external rotation and the ASES function score.
* Statistically significant result ($P < .05$).

allocation. The envelope included a cover letter and rehabilitation packet with instructions for group-specific therapy. The patients were then followed up at 6 weeks, 3 months, 6 months, 1 year, and 2 years postoperatively. At each visit, a blinded research assistant assessed the patients for passive and active ROM, ASES scores, and any adverse events. Specific ROM parameters included forward flexion, abduction, external rotation at 0° of abduction, and cross-body adduction. The ASES score was organized into pain, function, and composite components.[16] Adverse-event recording was confirmed at the time of final analysis with a retrospective chart review. Patient radiographs at final follow-up were graded for scapular notching by a blinded orthopedic resident trained on using the Nerot-Sirveaux classification system.[33]

An a priori power analysis was calculated by using forward flexion as a proxy for the primary outcome of ROM. With a previously cited minimal clinically important difference of 12° and standard deviation of 18°,[19] 76 subjects (or 38 per group) were required for a 2-tailed correlation. To account for an estimated 25% patient dropout rate, at least 50 patients were planned per group. This was an intent-to-treat analysis. We used 2-tailed *t* tables with equal variance and the Fisher exact test for statistical comparisons for continuous and categorical variables, respectively. The α level for significance was set at .05, and the minimal clinically important difference for the ASES score was 9 points.[29]

Results

Of an initial enrollment of 107 shoulders (103 patients), 86 (80.3%) completed 1-year follow-up and were included for analysis (Fig. 1), with 44 shoulders in the delayed-therapy group and 42 in the immediate-therapy group. Of these shoulders, 65 (35 in delayed-therapy group and 30 in immediate-therapy group) also completed 2-year follow-up. One patient in the immediate-therapy group crossed over to the delayed-therapy group after experiencing a glenosphere dissociation and undergoing revision RTSA at 1 month postoperatively. As this was an intent-to-treat analysis, this patient's outcomes are presented with the immediate-therapy group. No statistically significant differences were found between the groups' baseline demographic characteristics or operative data (Table I). For the combined cohorts, the mean age at the time of surgery was 68.9 years and there were more men (59.3%) than women. Most cases (>85% in both groups) were performed for cuff tear arthropathy. A biceps tenodesis was performed in the majority of cases (>80% in both groups), and cemented stem fixation was used in all but 4 cases. All humeral components were placed in 10° of retroversion, and all glenospheres were size 36 mm except for one size 40 mm.

Baseline mean preoperative values for ROM and ASES scores demonstrated no significant differences between the 2 groups for most categories, with the exception of active external rotation (favoring the immediate-therapy group) and the ASES function score (favoring the immediate-therapy group), as shown in Table II. For this reason, when comparing postoperative ROM and ASES score results between groups, we analyzed the average change in motion or score rather than the actual ROM values and ASES scores.

Within-group analysis demonstrated that both groups had statistically and clinically significant improvements in forward flexion and abduction by 3 months postoperatively (Fig. 2). However, no significant improvement occurred in external rotation at 0° of abduction or cross-body adduction—in fact, external rotation showed a significant decline at 6 weeks postoperatively before returning to baseline (Fig. 3). Both groups also had statistically and clinically significant improvements in ASES scores by 6 weeks postoperatively, except that the function component score did not improve until 3 months postoperatively (Fig. 4).

The findings of between-group analysis of the change in ROM from preoperative motion were the same between groups at all time points. Moreover, no differences in the change in ASES scores were found between the 2 groups at any time point except 6 months: The change in the ASES pain score favored the delayed-therapy group at 6 months (mean improvement of 26.3 ± 16.3 points in delayed-therapy group vs. 16.7 ± 11.6 points in immediate-therapy group, $P = .008$) and, thus, so did the change in the ASES

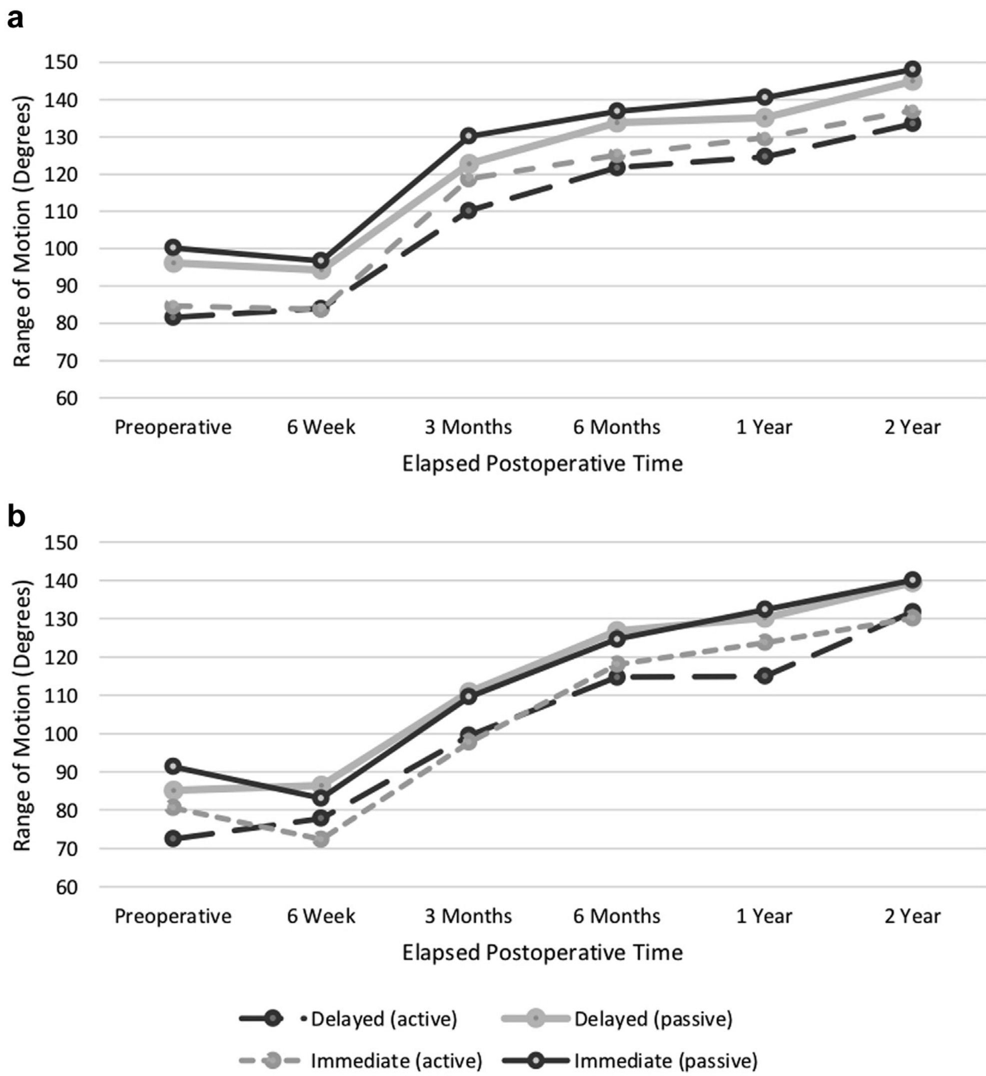

Figure 2 Forward flexion (**a**) and abduction (**b**) range-of-motion capability in delayed- and immediate-therapy groups. Both groups demonstrated statistically significant improvements in forward flexion and abduction at 3 months postoperatively and beyond compared with preoperative motion. Both active range of motion and passive range of motion are presented.

composite score (mean improvement of 40.2 $\pm$ 20.1 points vs. 30.0 $\pm$ 18.8 points, $P = .038$). Figure 4 demonstrates the absolute ASES scores by component in the delayed- vs. immediate-therapy groups over time postoperatively.

Regarding complications, the immediate-therapy group had 1 glenosphere dissociation requiring surgery (<1 month postoperatively), 1 acromial stress fracture managed nonoperatively, and 1 postoperative pulmonary embolism. The delayed-therapy group had 1 prosthetic shoulder dislocation requiring surgery (<1 month postoperatively), 1 periprosthetic fracture (at 1 year postoperatively), 1 deep venous thromboembolism, and 1 case of lymphedema. Radiographic notching was statistically the same between groups at 1 year postoperatively. The delayed-therapy group had 20 cases of Nerot-Sirveaux class 0 and 24 cases of Nerot-Sirveaux class 1. The immediate-therapy group had 27 cases of Nerot-Sirveaux class 0, 13 cases of Nerot-Sirveaux class 1, and 2 cases of Nerot-Sirveaux class 2. There was no difference in opioid prescription use at any time point postoperatively (Table III).

Discussion

To our knowledge, this is the first study to compare early vs. late rehabilitation after RTSA. We found no differences between the therapy cohorts for dislocation rates, and complications were rare. Although both groups had clinically and statistically significant improvements in forward flexion, abduction, and ASES scores by 3 months postoperatively, there were almost no differences between the groups' change in ROM or patient-reported outcome measures from preoperatively to any of the postoperative

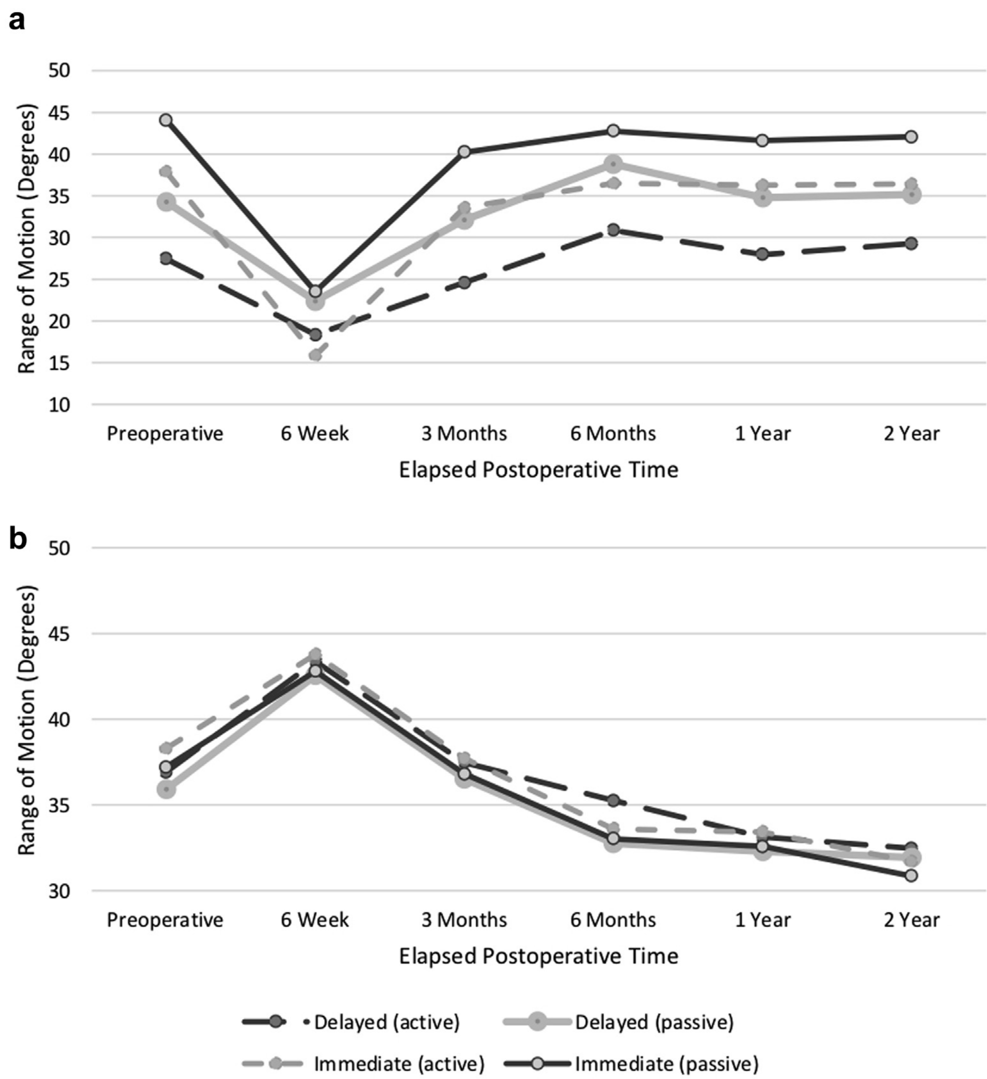

Figure 3 External rotation (**a**) and cross-body adduction (**b**) in delayed- and immediate-therapy groups. Neither group demonstrated any significant improvement in external rotation (at 0° of adduction) or cross-body adduction postoperatively compared with preoperative motion. A statistically significant decline in external rotation occurred at 6 weeks that returned to baseline at 3 months and beyond.

time points, up to 2 years. A slight statistically significant difference in ASES pain scores was noted at 6 months postoperatively, favoring the delayed-therapy group, but not a clinically significant difference.[29]

Current postoperative physical therapy protocols after RTSA vary widely.[5] Prior to this study, the practice at our institution was to immobilize all patients for 6 weeks in a sling. A commentary from the *Journal of Orthopaedic & Sports Physical Therapy* recommends immediate passive forward flexion and external rotation from postoperative day 1, with active ROM at 6 weeks.[4] However, ROM in this recommendation is limited, as a precaution for dislocation, for the first 12 weeks by restricting shoulder motion behind the lower back (combined adduction, internal rotation, and extension) and glenohumeral extension beyond neutral. A recent systematic review evaluating rehabilitation protocols after anatomic total shoulder arthroplasty and RTSA highlighted the heterogeneity in rehabilitation practices after RTSA.[5] One group has proposed a personalized rehabilitation protocol stratified by level of care, with a higher level of care signifying more complex patients who followed more conservative and monitored rehabilitation protocols.[21] Another group suggested limiting passive ROM for up to the first 2 to 6 weeks (immobilization period dictated by patient factors) in addition to starting deltoid strengthening at the end of 6 weeks.[31] In contrast, our study allowed for both passive and active ROM immediately in the early-rehabilitation group, only limiting resisted motion prior to 6 weeks. A study on subscapularis repair and the dislocation rate after RTSA allowed patients who did not undergo tendon repair to immediately progress to active ROM as tolerated without restriction.[9] In a recent multicenter retrospective review of outcomes after RTSA in *The Journal of Bone &*

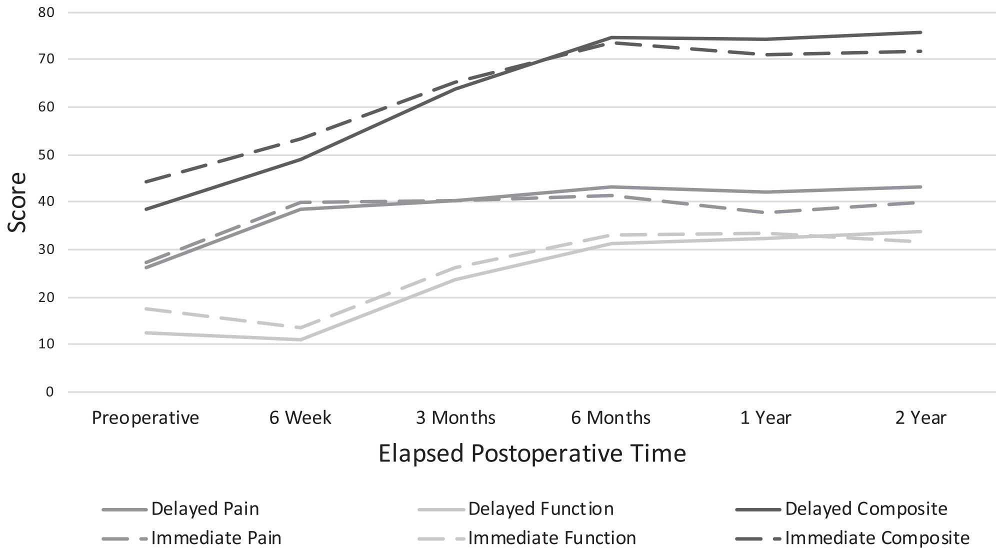

Figure 4 Patient-reported outcome measures in immediate- vs. delayed-therapy groups in terms of American Shoulder and Elbow Surgeons pain, function, and composite scores. Both groups showed statistically and clinically significant improvements in American Shoulder and Elbow Surgeons scores by 6 weeks postoperatively, except that the function component score did not improve until 3 months postoperatively.

Joint Surgery, the 3 surgeons all had different postoperative therapy protocols ranging from sling use for 6 weeks to active motion after 1 week.[18] As our results show no difference between early and delayed therapy, early mobilization may decrease the inconvenience and limitations caused by sling immobilization. It is important to note, though, that early ROM and early weaning of sling use did not have any immediate impact on patient-reported outcome measures. It may be that the ASES assessment does not contain questions that would provoke distinct responses for patients using slings. In a prospective study, albeit limited by lack of a matched control group, a standardized physical therapy program at mid- to long-term follow-up proved beneficial to ROM and function but not to pain, strength, or patient-reported outcomes as assessed by Constant and Disabilities of the Arm, Shoulder and Hand scores.[26] Similarly, in our study, early ROM did not seem to impact patient impressions.

A further contribution of this study is its addition of prospective outcomes to the literature on shoulder ROM, patient-reported outcome measures, and complications after RTSA. Active forward flexion and abduction both improved by over 40° in both rehabilitation groups by 1 year postoperatively, and these results were maintained at 2 years. External rotation and cross-body adduction did not see such improvement. Wall et al[28] reported similar findings with an improvement of 50° in forward elevation but a 2° loss of external rotation at 0° of abduction. Boileau et al[2] found a substantial improvement of almost 70° in forward elevation but no improvement in external rotation. External rotation may suffer for a variety of reasons, such as a deficient teres minor or a change in the vector orientation and tensioning of the external rotators after medialization of the center of rotation.[3] Several studies have demonstrated that external rotation may be optimized in RTSA with positioning of the glenosphere laterally and inferiorly.[12,15] It is interesting that several studies contradict our findings and have shown significant improvements in external rotation after RTSA, perhaps because of this positioning.[10,17,20,22]

We found an approximately 30-point improvement in the ASES composite score at 1 year postoperatively, with the results maintained at 2 years. This is similar to the ASES score results in a number of studies[20,24,26] and

Table III Narcotic use

	Delayed therapy n (%)	Immediate therapy n (%)	*P* value
Preoperative narcotic use	16 (36.4)	19 (45.2)	.402
Postoperative narcotic use			
6 wk	17 (39.5)	14 (35.0)	.821
3 mo	15 (38.5)	13 (39.4)	>.999
6 mo	6 (15.8)	10 (25.6)	.401
1 yr	10 (22.7)	13 (31.9)	.468
2 yr	6 (17.1)	9 (31.0)	.242

No statistically significant differences were found between the delayed- and immediate-therapy groups in the number of patients using narcotics preoperatively or postoperatively at any time point.

slightly lower than the ASES score results in a few studies, which reported gains of 40 to 45 points.[11,17,22] The improvement of 30 points is well above the minimal clinically important change of 6 to 15 points[16,25,29]; it is also above the "substantial clinical benefit" change of 23 points.[29] It has been shown that preoperative scores such as the visual analog scale score, ASES score, and 12-item Short Form Health Survey score are predictive of postoperative patient-reported outcomes, thus emphasizing the importance of the prospective study design to detect a change in score.[32] We did not have enough numbers to delineate the effect of the preoperative diagnosis on postoperative results as cuff tear arthropathy was the leading surgical indication in our cohort.

There are shortcomings to this study. Although the strength of this study lies in its single-blinded, randomized population, with a 1-year follow-up rate over 80%, the follow-up at 2 years was limited and underpowered (about 60%). However, we assume that any differences due to early variation in rehabilitation would have been evident by 1 year. In addition, we note the maintenance of results in those patients who did undergo follow-up at 2 years compared with their 1-year data. Another study limitation is that we were unable to assess patient compliance with the rehabilitation protocol, which carries a disadvantage of potentially mixing treatment groups but also an advantage of enhancing generalizability. A final weakness is that our study was powered to detect clinically important differences in ROM; thus, dislocation—which has shown an incidence of 2% to 9% in the most recent studies[8,9]—may not be apparent with the sample size in our study, which had a dislocation rate of 2%. Despite these limitations, we are optimistic about the results of this study and its potential to influence the postoperative therapy protocol after RTSA.

Conclusion

In this randomized controlled trial, both the early- and delayed-therapy groups showed significant improvements in ROM and patient-reported outcome measures. These results support the safety of early initiation of postoperative rehabilitation to avoid the limitations of prolonged immobilization in an elderly population; however, the theoretical convenience of early mobilization does not appear to have any impact on patient-reported outcomes as assessed by ASES scores.

Acknowledgments

The authors thank Mya Sandi Aung, research coordinator, for her support of the project and organization of data.

Disclaimer

No outside grants or funding were obtained related to this study. An internal grant (James O. Johnston, $5000) was received to support data collection and analysis.

C. Benjamin Ma has previously received research support from Zimmer Biomet. The remaining authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jse.2019.10.005.

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