Knee Surgery, Sports Traumatology, Arthroscopy (2019) 27:259–266
https://doi.org/10.1007/s00167-018-5135-8

SHOULDER

Increasing the deltoid muscle volume positively affects functional outcomes after arthroscopic rotator cuff repair

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Received: 26 March 2018 / Accepted: 6 September 2018 / Published online: 8 September 2018

Abstract

Purpose The aim of this study was to determine the effect of changes in deltoid muscle volume (DMV) on the clinical outcomes of patients who underwent arthroscopic repair due to chronic rotator cuff rupture.

Methods A total of 54 patients (35 females, 19 males) between 40 and 70 years of age who underwent single-row arthroscopic repair due to chronic rotator cuff tears were compared via preoperative (preop) and postoperative (postop) (6–12 months) magnetic resonance imaging (MRI) to determine the total DMV (tDMV). A clinical evaluation was performed with American Shoulder and Elbow Surgeons (ASES) and Constant scores in both the preop and postop groups. tDMV values were also measured in a randomly selected control group (50 patients). A standardized rehabilitation program was recommended for all patients.

Results Positive correlations were found between the change in tDMV (ΔtDMV) and ASES and Constant scores ($p<0.03$ and $p<0.032$, respectively). The preop tDMV value was significantly lower in the patient group than in the control group ($p<0.02$). Significantly lower ΔtDMV and body mass index (BMI)-adjusted tDMV values [Δ(tDMV/BMI)] were observed in patients who had rerupture at the postop MRI.

Conclusions According to the present study, changes in DMV impact clinical outcomes after rotator cuff repair. Rehabilitation of the DMV or increasing the preop DMV values positively affects postop clinical outcomes. In addition, if the DMV is below the cutoff value during the preop period, there is insufficient improvement in clinical scores. The clinical relevance of this study is the finding that in patients with a chronic rotator cuff tear and a hypotrophic deltoid muscle, increasing the preop DMV could help achieve better functional outcomes.

Level of evidence Prognostic, Level 3, case–control study.

Keywords Chronic rotator cuff tear · Arthroscopic single-row repair · Functional outcome · Rehabilitation · Deltoid muscle volume

Abbreviations

DMV	Deltoid muscle volume
ΔtDMV	Difference between the preop and postop total deltoid muscle volumes
ΔASES	Difference between the preop and postop ASES scores
ΔConstant	Difference between the preop and postop Constant scores
Preop	Preoperative
Postop	Postoperative
MRI	Magnetic resonance imaging
tDMV	Total deltoid muscle volume
ASES	American Shoulder and Elbow Surgeons
BMI	Body mass index
n.s.	Non-significant

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Introduction

Chronic rotator cuff tears are common in the middle-aged population [14, 15]. Surgical treatment enables an early return to work, better results, and lower costs [19]. For this reason, the frequency of surgical treatment for rotator cuff tears is steadily increasing.

Muscle hypotrophy can develop due to a pain-related decrease in upper extremity use in chronic cases and is exacerbated by postoperative (postop) immobilization and pain. Muscle atrophy can be seen not only in the rotator cuff, but also in the peripheral shoulder muscles. The deltoid muscle is at least as important as the rotator cuff for the movement and stability of the glenohumeral joint. Recent studies examined the function and volume of the deltoid muscle in patients with reverse shoulder prostheses [21, 22]. However, to our knowledge, no such study has been performed after arthroscopic rotator cuff repair.

The aim of the study was to determine the effect of deltoid muscle volume (DMV) changes on the clinical outcomes of patients who underwent arthroscopic repair due to chronic rotator cuff rupture.

The hypothesis was that the postop DMV would increase relative to the preoperative (preop) volume, and this increase would have a positive effect on clinical scores. This is the first report to directly investigate the effectiveness and importance of DMV changes with respect to functional outcomes. The findings of the present study highlight the clinical efficacy of preop deltoid muscle rehabilitation in patients who undergo arthroscopic rotator cuff repair.

Materials and methods

A total of 103 patients who underwent chronic rotator cuff tear surgery in the Umraniye Training and Research Hospital of Saglik Bilimleri University in the past 2 years were included in the study.

The inclusion criteria were as follows: individuals with a class 2, 3, or 4 sagittal plane tear and a class 2 frontal plane tear, according to Patte [13]; individuals who underwent arthroscopic rotator cuff single-row repair; individuals with an age greater than 40 years; and individuals who underwent postop rehabilitation in the study clinic.

The exclusion criteria were as follows: individuals who underwent open surgery; individuals for whom patient postop rehabilitation was performed outside of the study clinic; individuals who underwent superior labrum anterior to posterior (SLAP) lesion repair; individuals who participated in a rehabilitation program other than the program employed in this study; individuals who failed to follow the home rehabilitation program during routine surveillance or who quit the program; individuals who underwent preop or postop magnetic resonance imaging (MRI) using a different device; individuals for whom different reference lines were used for preop and postop MRIs or for whom reference lines were unavailable; individuals who had a technically inappropriate MR image; and individuals who had preop or postop frozen shoulder, fatty atrophy in the supraspinatus muscle (Goutallier 2 or 3), pseudoparalysis, neurological disease, os acromiale or cervical discopathy [18].

The age, gender, body mass index (BMI), operation date, and preop and postop MRI dates of all patients were noted. A total of 33 patients were excluded because the preop MRI or postop MRI was technically inadequate. A total of 12 patients were excluded from the study because they did not meet the standard physical therapy rehabilitation program requirements or failed to comply with the home exercise program. In addition, two patients had postop frozen shoulder, one patient had pseudoparalysis after rerupture, and one patient underwent cervical disc surgery. Thus, the final study population included 54 patients (35 females, 19 males). The control group was composed of patients who did not have a rotator cuff tear and deltoid muscle atrophy, patients who matched the age and gender of the study group, and patients who had undergone shoulder MRI for any reason except shoulder pathology. A total of 50 patients comprised the control group (36 females, 14 males). A first-come-first-serve method was implemented to randomly select patients for the control group on the basis of age and gender criteria. In the study group, the tear shape, elongation, configuration, and size of the rotator cuff were determined according to Patte's [13] classification based on MRI in the sagittal and coronal planes. Fatty atrophy in the supraspinatus was identified according to the Goutallier classification [18].

Surgical technique

One surgeon (IT) performed all the surgeries, which were performed under general anesthesia on a shoulder table in the beach chair position. Standard anterior, posterior, posterolateral and anterolateral portals were routinely opened in all patients. In cases (five patients) for which standard portals did not allow for anchor placement at the appropriate angle, a mini-stab incision of a sufficient size was made so that the anchor could be placed. Disposable cannulas were placed in the anterior and anterolateral portals (7.5 and 8.5 mm diameter, respectively).

Postoperative period and rehabilitation

One physiotherapist in the clinic rehabilitated all of the patients. A shoulder arm sling at a 30° abduction was routinely used for 3 weeks. Postop rehabilitation was performed as two separate periods: a clinical rehabilitation program and a home exercise program. Beginning on the first postop day, neck, hand–wrist, and elbow active range of motion (ROM) exercises and passive Codman exercises for shoulder joints were carried out three times each day. The following techniques were applied at the end of the immobilization period (after the third week) at a rate of five times each week for a total of 20 sessions: 20 min, hot pack (HP); 20 min, transcutaneous electrical nerve stimulation (TENS); and 5 min, ultrasound (1 W/cm^2).

In the first phase, pendulum movements, passive glenohumeral ROM movements, active scapulothoracic movements, and elbow and wrist active ROM movements were performed. The criteria for the beginning of the second phase included 125° passive flexion (at minimum), 90° passive abduction, and 75° internal and external rotation.

In the second phase, active assistive movements were made. When the patients were confirmed to have a painless full ROM in the absence of scapular dyskinesia, they moved on to the third phase. In the third phase, active reinforcement exercises began, and in the fourth phase weight lifting exercises began. After the patients entered the fourth phase and continued until the 6th month, the patients in the study group were examined monthly in the outpatient clinic. To control the home exercise program, the patients were given a daily checklist that included tick boxes for every stretching, strengthening, ROM, and weight lifting exercise. The home exercise program was assessed during these examinations.

Clinical evaluation

American Shoulder and Elbow Surgeons (ASES) and Constant–Murley scores were used to evaluate pain and shoulder function in the preop and postop patient analyses [1, 10]. Joint movements were recorded with a goniometer. For a strength measurement as a subtest of the Constant score, one end of a simple handheld band was held by the patient standing upright, with the upper extremity at a 90° elevation with the elbow extended and the forearm pronated.

Radiological evaluation

Patients were compared preoperatively and postoperatively (6 months at the earliest and 12 months at the latest). The shoulders of both groups were evaluated with a General Electric Medical Systems, LLC, Optima MR 450 W Gemsuite 1.5 T MRI spectrometer using an HD8-channel Shoulder Array by Neocoil. The arm was fixed to the patient's body in the anatomical position. The reference lines were placed parallel to the clavicle with the glenoid at a right angle [field of view (FOV), 20.0; slice thickness, 4.0 mm; and spacing, 1.0 mm].

To ensure the accuracy of measurements, MRI evaluation was performed by two authors who were experienced in musculoskeletal system imaging and who used two different picture archiving and communication systems (PACS); these authors were blinded to each other and to patient names. The first author used OSiriX MD (Pixmeo, Bernex, Switzerland), and the second author used ExtremePACS (Ankara, Turkey). The measurements obtained by the two authors were subjected to interobserver testing. The correlation between the two authors was evaluated by the interclass correlation coefficients (ICCs) from replicability analyses. Agreement was considered excellent if the ICC was > 0.80, very good if the ICC was 0.70–0.80, good if the ICC was 0.60–0.70, fair if the ICC was 0.40–0.60, and poor if the ICC was < 0.40. The interobserver alpha value was 0.945.

In the MRIs, each cross-sectional area of the deltoid muscle was determined by manually drawing the outer border of the muscle on an axial section of the muscle at the T1-sequence (Figs. 1, 2). Thus, two-dimensional axial MRI images were demarcated, and the areas of each section were measured. The most proximal part of the deltoid muscle area was noted as D1, and the most distal part was noted as Dn. The distance between each section (slice thickness) was calculated to be 4 mm. The total deltoid muscle volume (tDMV) was calculated by using the modified Cavalieri method [(D1 + D2 + D3 + ··Dn) × 4 = total muscle volume (cm^3)] [11]. As a result, three-dimensional measurement of the muscle was achieved. The humeral anatomical neck length of each patient was measured at the greatest distance on coronal preop and postop MRIs to control the magnitude of the images with a bony landmark.

This study was approved by the ethics committee of Saglik Bilimleri University, Umraniye Training and Research Hospital (25.1.2017/ID no.: BD2431089072).

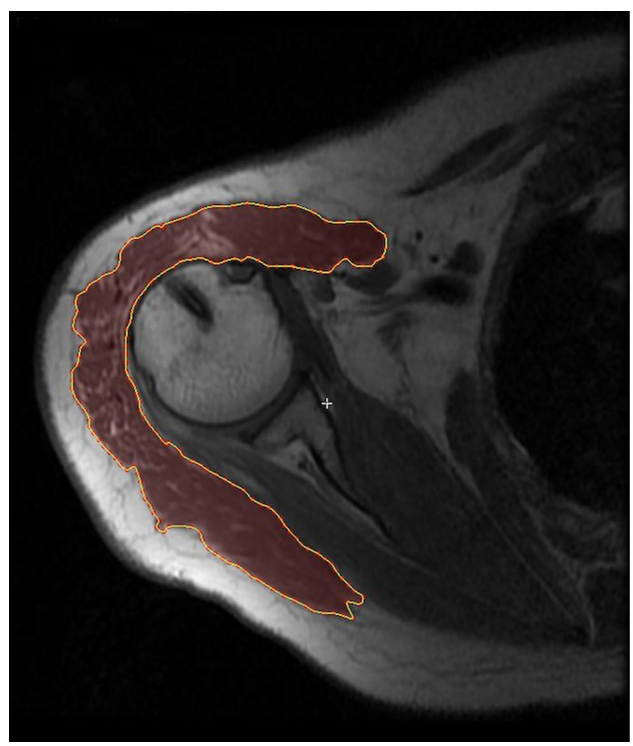

Fig. 1 Cross-sectional area of the deltoid muscle (ExtremePACS program)

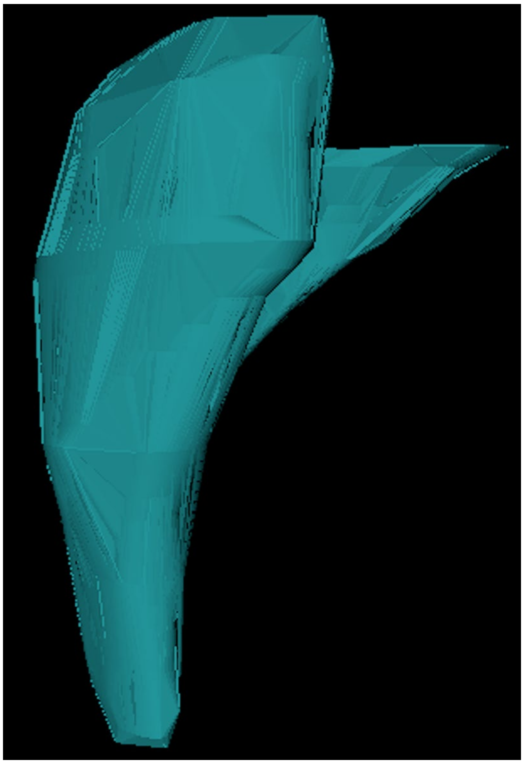

Fig. 2 Frontal view of the right shoulder. A three-dimensional structure of the deltoid muscle is presented (OSirix MD program)

Statistical analysis

Statistical analyses were performed using IBM SPSS software (Statistical Package for Social Sciences for Windows, Version 21.0, IBM Corp., Armonk, NY, USA). The Kolmogorov–Smirnov test was used to determine population distributions. The Shapiro–Wilk test was used for normally distributed data, and Levene's test was used to determine the homogeneity of the variances. The use of Student's *t* test was found to be inappropriate due to the lack of an appropriate condition. *p* values less than 0.05 were considered statistically significant. Optimum cutoff values were measured from hierarchical cluster analysis.

Because the data were not normally distributed, Spearman's rank correlation test was used to calculate the correlations between specific variables. The *R* value was used to determine the magnitude of the relationship between two variables.

The sample size calculation was performed using G*Power 3 (Heinrich Heine Universitat Dusseldorf, Germany). Based on the calculations, a minimum sample size of 79 patients was required for each group to observe a correlation between the DMV values of the study and control groups [type 1 error (α) of 0.05, power ($1 - \beta$) of 0.80].

Table 1 Comparison of values between the study and control groups

	Mean ± SD	Median (Min–Max)
Study group		
Age (years)	54.4 ± 7.7	53 (40 to 70)
Preop tDMV	218 ± 45	210.5 (134 to 313.4)
Postop tDMV	240 ± 53.3	224.4 (145 to 354.1)
ΔtDMV	22 ± 21.1	14.6 (– 17 to 74.6)
Δ(tDMV/BMI)	0.7 ± 0.7	0.6 (-0.5 to 0.2)
ΔASES	56.5 ± 20.6	63.2 (5.1 to 86.6)
ΔConstant	48.6 ± 17.1	50.5 (6 to 78)
BMI	28.4 ± 4.3	27.3 (20.2 to 42)
Preop ASES	23 ± 10.6	20 (5 to 51.6)
Postop ASES	79.6 ± 16.7	85.6 (33.3 to 100)
Preop Constant	28.9 ± 8.1	29 (5 to 57)
Postop Constant	77.5 ± 16.9	77.5 (37 to 98)
Control group		
Age (years)	54.2 ± 8.1	53 (40 to 70)
tDMV	237.3 ± 49.5	230.1 (134 to 359.2)
BMI	28.5 ± 4	27.8 (21.3 to 41.2)

ΔtDMV difference between the preop and postop total deltoid muscle volumes, *ΔASES* difference between the preop and postop ASES scores, *ΔConstant* difference between the preop and postop Constant scores

Results

In the study group, the postop tDMV and BMI-adjusted tDMV (tDMV/BMI) values were higher than the corresponding preop values. However, there were no statistically significant differences between the preop and postop tDMV or tDMV/BMI values (Table 1).

The preop tDMV value [mean ± standard deviation (SD), 218 ± 45] was significantly lower in the study group than in the control group (237.3 ± 49.5 mean ± SD, $p < 0.02$) (Table 1).

Significant positive correlations were observed among the postop–preop changes in tDMV values (ΔtDMV), tDMV/BMI values [Δ(tDMV/BMI)], ASES scores (ΔASES), and Constant scores (ΔConstant) (Table 2).

Significantly lower ΔtDMV and Δ(tDMV/BMI) values were observed in patients who exhibited rerupture on postop MRI. There were no significant differences between the clinical scores of patients with and without rerupture (Table 3).

The ΔtDMV and Δ(tDMV/BMI) values were higher in patients treated with biceps tenotomy than in other patients; however, there was no significant difference in clinical scores between the two groups of patients treated with biceps tenotomy (Table 3).

No significant differences were found between the acromioplasty groups (Table 3).

There was no significant difference in age between the two groups (40–55 and 56–70 years) (Table 4).

Table 2 Association between changes in muscle volume and clinical scores

	ΔtDMV		Δ(tDMV/BMI)	
	r	*p**	*r*	*p**
ΔASES	n.s	0.036	n.s	0.03
ΔConstant	n.s	0.033	n.s	0.032

ΔtDMV difference between the preop and postop total deltoid muscle volumes, *ΔASES* difference between the preop and postop ASES scores, *ΔConstant* difference between the preop and postop Constant scores

*p** Spearman's correlation test

Table 3 Association of rerupture and biceps tenotomy and acromioplasty with changes in muscle volume and clinical scores

	Yes Mean ± SD	No Mean ± SD	*p**
Rerupture (7/54)			
Preop tDMV	190.9 ± 29.4	222 ± 45.8	n.s
Postop tDMV	200.8 ± 44.2	245.9 ± 67.3	0.04
ΔtDMV	9.8 ± 14.7	23.8 ± 21.5	0.04
Δ(tDMV/BMI)	0.3 ± 0.5	0.8 ± 0.7	0.03
ΔASES	56.9 ± 23.1	56.5 ± 20.5	n.s
ΔConstant	45.1 ± 19.0	49.2 ± 17.0	n.s
Preop ASES	21.6 ± 7.0	23.3 ± 11.1	n.s
Postop ASES	78.5 ± 19.6	79.8 ± 16.5	n.s
Preop Constant	25.9 ± 3.9	29.4 ± 8.6	n.s
Postop Constant	71.0 ± 17.7	78.6 ± 16.8	n.s
Biceps tenotomy (37/54)			
ΔtDMV	30.2 ± 23.4	18.2 ± 19.2	0.03
Δ(tDMV/BMI)	1 ± 0.8	0.6 ± 0.6	0.04
ΔASES	58.2 ± 23.5	55.8 ± 19.5	n.s
ΔConstant	52.3 ± 18.6	47.0 ± 16.4	n.s
Preop ASES	23.6 ± 9.4	22.0 ± 13.1	n.s
Postop ASES	79.4 ± 16.0	80.1 ± 18.7	n.s
Preop Constant	29.1 ± 6.2	28.5 ± 11.6	n.s
Postop Constant	76.1 ± 16.2	80.8 ± 18.5	n.s
Acromioplasty (27/54)			
ΔtDMV	22 ± 18.8	22 ± 23	n.s
Δ(tDMV/BMI)	0.7 ± 0.6	0.7 ± 0.8	n.s
ΔASES	60.2 ± 16.7	53.9 ± 23.0	n.s
ΔConstant	53.0 ± 12.9	45.4 ± 19.3	n.s
Preop ASES	22.7 ± 9.3	23.3 ± 11.6	n.s
Postop ASES	82.9 ± 11.4	77.2 ± 19.6	n.s
Preop Constant	28.4 ± 6.5	29.3 ± 9.3	n.s
Postop Constant	81.4 ± 11.4	74.7 ± 19.7	n.s

ΔtDMV difference between the preop and postop total deltoid muscle volumes, *ΔASES* difference between the preop and postop ASES scores, *ΔConstant* difference between the preop and postop Constant scores

*p** Kruskal–Wallis *H* test

There was no significant difference in gender between the two groups (Table 4).

The findings from hierarchical cluster analysis suggested that patients with preop tDMV values below 160 cm^3 or preop tDMV/BMI values below 5 $cm^3/kg/m^2$ tend to have significantly lower ΔASES and ΔConstant values than patients with higher preop tDMV values.

Patients with ΔtDMV values below 14 cm^3 or Δ(tDMV/BMI) values below 0.5 $mm^3/kg/m^2$ tend to have significantly lower ΔASES and ΔConstant values than patients with higher ΔtDMV values.

Patients without biceps tenotomy who have preop tDMV values below 200 cm^3 or preop tDMV/BMI values below 7 $cm^3/kg/m^2$ tend to have significantly lower ΔASES and ΔConstant values than patients with higher preop tDMV values.

Patients without biceps tenotomy who have ΔtDMV values below 10 cm^3 or Δ(tDMV/BMI) values below 0.7 $cm^3/kg/m^2$ tend to have significantly lower ΔASES and ΔConstant values than patients with higher ΔtDMV values.

Discussion

The principal findings of this study show that patients who underwent single-row rotator cuff repair had higher postop than preop tDMV values. This increase can be attributed to the increased use of the extremity due to both decreased pain after surgery and physiotherapy. The ASES and Constant scores (6 months postop at the earliest) of the patients who were treated in the same postop rehabilitation program also increased. However, although the increase in the postop clinical scores was statistically significant, the increase in DMV values was not. Furthermore, having a preop muscle volume below the cutoff value led to worse clinical outcomes.

In the present study, patients with chronic shoulder rotator cuff tears had lower tDMV values during the preop period than the individuals in the healthy control group. The tDMV values in the postop period increased compared to those in the preop period, although the difference was not statistically significant. The need for the deltoid muscle decreases as the rotator cuff begins to work during the postop period. Thus, this condition provides a state of equilibrium regarding the DMV with postop rehabilitation.

Meyer et al. reported that the deltoid muscle area and thickness of pseudoparalytic shoulders were not affected by prolonged immobilization [9]. However, the study provided information about the change in the entire deltoid volume without a control group and only for the areas measured in a single axial slice. According to a recently published study, muscle atrophy in a single MRI slice does not predict three-dimensional (3-D) measurements and may not provide sufficient information about the whole muscle [20]. In this study,

Table 4 Comparison of the age and sex groups regarding changes in muscle volume and clinical scores

Age (years)	40–55 years ($n=34$) Mean ± SD	56–70 years ($n=20$) Mean ± SD	p*
ΔtDMV	25.1 ± 22.1	16.8 ± 18.9	n.s
Δ(tDMV/BMI)	5.9 ± 0.8	7.5 ± 0.6	n.s
ΔASES	55.8 ± 20.2	57.8 ± 21.8	n.s
ΔConstant	47.3 ± 17	51.0 ± 16	n.s
Preop ASES	22.6 ± 11.1	23.8 ± 10.0	n.s
Postop ASES	78.5 ± 17.1	81.6 ± 16.4	n.s
Preop Constant	28.6 ± 9.2	29.4 ± 6.2	n.s
Postop Constant	75.9 ± 17.5	80.5 ± 15.7	n.s
Gender	Male ($n=19$) Mean ± SD	Female ($n=35$) Mean ± SD	p*
ΔtDMV	24.1 ± 20.1	20.9 ± 21.9	n.s
Δ(tDMV/BMI)	0.8 ± 0.7	0.7 ± 0.7	n.s
ΔASES	60.4 ± 17.5	54.5 ± 22.0	n.s
ΔConstant	55.9 ± 14.1	44.7 ± 17.5	0.02
Preop ASES	24.4 ± 10.9	22.4 ± 10.5	n.s
Postop ASES	84.8 ± 13.9	76.8 ± 17.6	n.s
Preop Constant	28.4 ± 10.9	29.2 ± 6.4	n.s
Postop Constant	84.3 ± 14.1	73.9 ± 17.4	n.s

ΔtDMV difference between the preop and postop total deltoid muscle volumes, *ΔASES* difference between the preop and postop ASES scores, *ΔConstant* difference between the preop and postop Constant scores

p* Kruskal–Wallis H test

all of the axial sections were measured individually, and the tDMV was calculated by the modified Cavalieri method [11]. Studies on lower extremity arthroplasties have shown a correlation between muscle atrophy induced by chronic inactivity and functional outcomes [5, 6, 8]. The same relationship has been demonstrated in patients with chronic rotator cuff tears and Goutallier stage 2 or higher fatty atrophy [12]. In addition, deltoid muscle degeneration and atrophy after reverse shoulder arthroplasty have been shown to lead to worse functional outcomes [4, 14, 21].

Rerupture in the rotator cuff was found on postop MRI in seven patients. In this patient group, ASES and Constant scores increased to the same extent observed in the group without rerupture after rotator cuff repair, although there was no increase in DMV. Previous studies have shown that an increase in clinical scores is not connected to surgical treatment alone [3]. Fucentes et al. reported that patients with isolated symptomatic supraspinatus tears (who refused the recommended surgery) had good clinical outcomes and no larger tears after 3.5 years [3]. These results suggest that postop tDMV values are significantly lower in patients with rerupture than in patients without rerupture. A weak postop deltoid muscle could lead to higher stress on the repaired rotator cuff and might be one cause of rotator cuff rerupture.

The majority of longhead biceps pathologies are associated with degenerative rotator cuff disease. Maynou et al. recommended long head biceps tenotomy for the treatment of full-thickness rotator cuff tears because some or all of the pain is caused by the long head of the biceps [8]. Klinger et al. compared the results of arthroscopic debridement with biceps tenotomy and arthroscopic debridement alone on patients with massive rotator cuff tears. There was no difference in Constant scores between the two groups. These results demonstrated that adding longhead biceps tenotomy to the procedure did not change the outcomes [6].

Good postop rehabilitation is necessary to increase the success of the procedure, to promote a complete return to functional activity, to eliminate pain and restore muscular function, and to improve the quality of life of the patient. Rehabilitation is performed not only to improve the ROM of the joints and to reduce pain, but also to prevent atrophy of the muscles around the joint [2, 7, 16, 17]. In this study, all of the patients participated in the same rehabilitation program. It was found that patients had lower ASES and Constant scores when the total preop deltoid volume or the postop–preop change in deltoid volume was below the determined cutoff values; these results emphasize the importance of rehabilitation before and after rotator cuff repair.

There are limitations to this work. This study had a limited sample size. Because the time to relaxation/time to echo (TR/TE) values of the MRIs were different, muscle quality and fatty degeneration could not be evaluated. MRI of the contralateral shoulders could not be performed because of financial restrictions. Although the home exercise program was monitored monthly via checklists, this method could lead to failure to standardize rehabilitation. One strength of this study was the inclusion of a randomly selected age-matched control group. Additionally, to our knowledge, this is the first study to investigate the change in DMV in rotator cuff repair patients.

Clinically, based on the evidence presented in this study, surgeons should take into consideration that preop rehabilitation of the deltoid muscle is as important as postop rehabilitation.

Conclusion

According to this study, changes in DMV impact clinical outcomes after rotator cuff repair. Rehabilitation of the DMV or increasing the preop DMV values positively affects postop clinical outcomes. In addition, if the DMV is below the cutoff value during the preop period, there is insufficient improvement in clinical scores.

Acknowledgements We thank our radiology technician Cengiz Han Cavli, physiotherapist Secil Teoman, and statistician Fatih Usen for helping us with our study.

Author contributions IT: study design, data collection and analysis, critical revision, manuscript drafting. GA: collection and acquisition of data, manuscript drafting.

Funding There is no funding source.

Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest. No benefits have been or will be received from a commercial party related directly or indirectly to the subject matter of this article.

Ethical approval This article does not contain any studies with animals performed by any of the authors. This study had an ethical committee approval from the local institution (no.).

Informed consent Informed consent was obtained from all individual participants included in the study.

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