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original article

Early intervention of extracorporeal shockwave therapy sustained positive long-term effect on rotator cuff healing: A randomized controlled trial with 3-year follow-up[☆,☆☆]

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A R T I C L E I N F O

Keywords:
Extracorporeal shock wave therapy
Rotator cuff repair
Ultrasonography

A B S T R A C T

Background: The long-term effects of extracorporeal shockwave therapy (ESWT) on rotator cuff repair are unknown.
Objectives: To investigate the functional outcomes and structural changes of ESWT at 3-year follow-up after rotator cuff repair.
Methods: A randomized clinical trial was conducted, including patients who underwent rotator cuff repair. The patients were assigned to two groups based on whether they underwent radial ESWT 3 months postoperatively. The ESWT Group received 5 weeks of rehabilitation and ESWT weekly, whereas the CONTROL Group received only rehabilitation. Visual analog scale (VAS) pain score and functional scores were analyzed at 3 months (baseline), 6 months, and 3 years follow-up. In addition, MRI and ultrasonography were used to assess tendon maturation, integrity, tendon quality, acromiohumeral distance (AHD), and muscle fatty infiltration.
Results: Finally, 32 participants completed all the assessments. At the final follow-up, 2 patients in the ESWT Group (16.5 %) versus one patient in the CONTROL Group (6.25 %) had rotator cuff failure ($P = 0.176$). The ESWT treatment showed similar clinical outcomes in VAS-pain score, functional scores, tendon quality, AHD, and muscle fatty infiltration versus the CONTROL Group ($Ps > 0.05$). MRI analysis indicated improved tendon healing after ESWT treatment at both 6-month ($P = 0.036$) and 3-year follow-up ($P = 0.028$).
Conclusion: Early intervention with radial ESWT sustained long-term effects on the healing of the repaired rotator cuff and similar functional outcomes at long-term follow-up compared with standard rehabilitation.

1. Introduction

Arthroscopic repair of the rotator cuff is the most commonly performed surgical technique for symptomatic rotator cuff tear. However, the outcomes of rotator cuff repair remain debatable. High rate of retear is one of the most significant complication that may cause pain and disability for various reasons.[18] Poor tendon maturation is a significant concern in tendon-bone healing.

It was reported that retear occurred most commonly within 3 months postoperatively,[12] which means that within the first 3 postoperative months, well-healed tendons might predict intact cuff repair integrity with sufficient mechanical and biological healing after rotator cuff repair. Conservative treatments have been attempted to optimize the integrity of tendon-bone healing.[26] Radial extracorporeal shockwave therapy (ESWT) produces low-to medium-density energy that is transmitted radially from the tip of the applicator to the target zone[20] and is a non-invasive treatment for musculoskeletal disorders.[28,34,36] Recently, the effects of radial ESWT on shoulder disorders have attracted

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considerable attention. Shao et al. reported that early intervention with radial ESWT at 3-month postoperatively reduced early shoulder pain compared to rehabilitation alone and may lead to accelerated proximal supraspinatus tendon healing at the suture anchor site after rotator cuff repair at the 6-month follow-up.[26] Although ESWT can promote the healing of rotator cuff in the short term, long-term follow-up results indicate that this treatment method may cause tendon tears. Han et al. reported that preoperative ESWT might be related to posterior rotator cuff tears in the presence of calcific tendinitis exists.[9] This phenomenon reveals significant differences and potential risks in the impact of ESWT on patients after rotator cuff repair over different time periods. The contradiction between short-term and long-term effects suggests that while shockwave therapy may aid recovery initially, its long-term safety and efficacy require further research and careful clinical application.

Magnetic resonance imaging (MRI) is a useful tool to evaluate tendon structure integrity, fatty degeneration, and atrophy of the rotator cuff muscles. The signal intensity (SI) is validated for quantitative analysis and the signal noise quotient (SNQ) has been adopted as a measurement of graft quality.[26,35] It has been widely used in the evaluation of post-operative outcomes in patients received rotator cuff repair.[24] On the other hand, ultrasonography, featured by its portable, non-invasive and dynamic characteristics, has been evolvingly used in the follow-up evaluation of rotator cuff repair.[21] It is reported comparable accuracy for identifying rotator cuff tears versus MRI, and it also can evaluate fatty degeneration[31] and muscles atrophy,[2] while both modalities have advantages and shortcomings.[37]

Therefore, this study aimed to investigate the clinical outcomes and structural changes of radial ESWT in shoulder rotator cuff healing at 6 months and 3-year follow-up after rotator cuff repair. We hypothesized that postoperative radial ESWT would yield similar outcomes comparing with rehabilitation training.

2. Materials and methods

This study was approved by the Institutional Review Board and the Health Sciences Institutional Review Board of XXX. This study followed the process shown in the flow diagram [Fig. 1].

Between June and August 2020, 43 participants were screened and 38 were enrolled. After obtaining informed consent, 38 participants were enrolled and randomly assigned to the two groups in a 1:1 ratio. Participants in both groups underwent a 5-week advanced rehabilitation program that started 3 months postoperatively. The ESWT group received 5 sessions of shockwave therapy. A follow-up assessment was performed at 6 months and 3 years after repair and included clinical outcomes, ultrasound findings, and side effects. This study was performed at the XXX. All history-taking, rehabilitation, radial ESWT

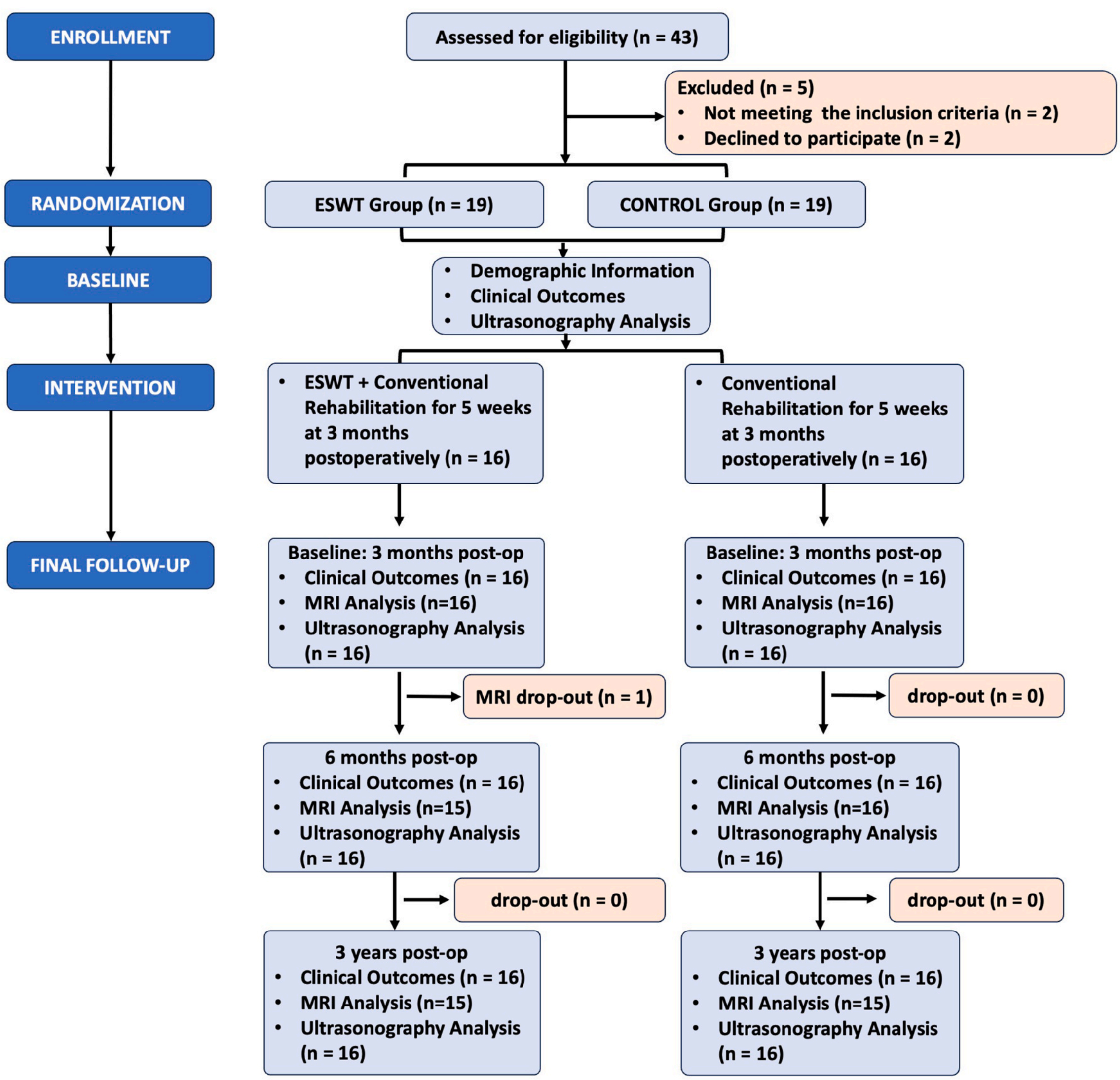

Fig. 1. Flow diagram ESWT: extracorporeal shockwave therapy.

intervention, physical examinations, and ultrasound examinations were performed at XXX.

2.1. Inclusion and exclusion criteria

The inclusion criteria were 1) age 40–70 years, 2) unilateral shoulder surgery, 3) tear size <5 cm confirmed by arthroscopic inspection, 4) presence of pain or limited passive range of motion (ROM) after surgery, and 5) ultrasound examination showing tendon integrity at 3 months post-operation. The exclusion criteria were 1) pregnancy; 2) biceps tendon fixation or tenotomy; 3) subscapular tendon repair; 4) massive rotator cuff repair (tear size >5 cm); 5) unstable or uncontrolled angina, uncontrolled heart failure, or serious uncontrolled ventricular arrhythmias; 6) prior shoulder surgery; 7) cardiac pacemaker implant; and 8) malignant tumors.

2.2. Arthroscopic surgery and postoperative rehabilitation

The participants enrolled in this study were diagnosed with a rotator cuff tear and underwent arthroscopic rotator cuff repair by two senior surgeons with >10 years of experience. Arthroscopic rotator cuff repair was performed by following a standard procedure previously described.[15] The glenohumeral joint and subacromial space were debrided, and then acromioplasty was performed when an anteroinferior acromial beak was observed. The tear size of the rotator cuff was measured and documented. If the torn tendons could be grasped to the original footprint, rotator cuff repair was performed using the single- or double-row technique. After the operation, all participants followed a 3-month standard postoperative rehabilitation program, including shoulder sling for 6 weeks, pain and swelling control, progressive passive-to-active ROM exercises, and muscle strengthening.[26]

2.3. Interventions

2.3.1. Advanced rehabilitation

Both the ESWT and CONTROL groups received a 5-week advanced rehabilitation 3-month postoperatively. It was conducted onsite to ensure that the participants performed the exercises correctly. Participants were required to attend sessions at least once weekly, each session lasting 40–45 min. One therapist followed the participants by clocking them online for the entire length of training program to ensure that each participant completed at least four home-based workouts weekly. The details of this advanced rehabilitation included ROM training, neuromuscular control, and muscle-strengthening exercises. Advanced rehabilitation aims to achieve full ROM in all planes, regain muscle strength, and return to normal daily activity levels.[26]

2.3.2. Radial ESWT

For patients who were randomized into the ESWT Group, radial ESWT (Swiss Dolor-Clast, EMS) was applied at the end of each session by the same physiotherapist, with 12 years of ESWT experience. The shockwave probe was directed to the supraspinatus tendon under the acromion [Suppl 2]. After the coupling agent was applied, ESWT was administered to the anterior and posterior aspects of the shoulder. A total of 0.08 mJ/mm^2 energy flux density, pressure of 2.5 bars, frequency of 6–8 Hz, and a total of 2000 impulses were applied. Five sessions of radial ESWT was administered, one session per week.

2.3.3. Evaluations

All participants underwent physical and radiographic examinations at baseline (3-month postoperatively), 6-month, and 3 years (the final follow-up). Physical examination and functional score collection were performed by a different surgeon XX.

The primary outcome was failure rate, assessed by ultrasonography showing full-thickness discontinuity of the repaired tendon. The secondary outcomes including the functional scores such as the Visual analog scale (VAS) pain score, CMS, ASES, UCLA and FUSS[7]; active shoulder motions, including flexion, abduction, and external rotation[22]; and structural analysis by MRI and ultrasonography.

Ultrasound assessments were performed by a single physician XX with 5 years of experience in musculoskeletal ultrasonography with the SONIMAGE HS2 (Konica Minolta, Japan) using a 12 MHz frequency linear transducer to allow automatic volumetric data acquisition. Participants were seated with the affected arm positioned on the side of the trunk. The supraspinatus and infraspinatus tendons were examined with the arm in adduction and internal rotation, the subscapularis tendon was evaluated in external rotation, and the LHBT quality was measured on the longitudinal axis when the patient's arm was positioned in supination with the thigh. Tendon integrity was tested along the long and short axes. Dynamic maneuvers were also performed to optimize visualization and aid in the assessment of integrity. The repair tendon quality was evaluated using the Sugaya classification system,[29] which was validated for sonography based on studies by Barth et al.[1] and Collin et al.[4] Simultaneously, the acromiohumeral distance (AHD)[10] was measured as the distance between the point of entry of the tendon at dynamic abduction and the humeral head cortex. Furthermore, the quality of the LHBT was measured following the classification reported by Seo JB et al.,[25] and fatty infiltration of the supraspinatus and infraspinatus muscles was evaluated and graded, as reported by Wall LB et al.[31] [Fig. 2A–D].

MRI was performed with a 3.0T-MRI scanner (MAGNETOM Verio, A Tim system, Siemens, Germany). Imaging was performed with the participant supine and the arms resting in neutral. The sequences included oblique coronal short time inversion recovery (STIR), oblique coronal T1-weighted, oblique sagittal T2-weighted, and oblique axial proton density-fat saturation (PD-FS) images. The MRI assessment was performed by a fellowship-trained musculoskeletal radiologist (blinded to group allocation), and all images were imported into imaging software (Horos, v3.3.6) for data acquisition. The repaired tendon quality was measured on oblique coronal short time inversion recovery images and a senior musculoskeletal radiologist (blind to group allocation) performed the MRI examinations and evaluated tendon integrity based on the continuity of the repaired tendon. Then the oblique coronal proton density sequence were used. Four regions of interest (ROIs) of repaired tendon were selected and the SI were measured. Afterwards, signal noise quotient (SNQ) was quantitatively calculated as SI of tendon versus SI of background. Higher SNQs indicated higher water content or hypervascularity, suggesting poorer quality tendon healing.[26]

2.4. Statistical analysis

The sample size was calculated using a priori statistical power analysis with a difference of 1.4 points in VAS-pain scores as the minimal clinically important differences.[30] Considering a dropout rate of 20 %, with a power of 80 %, and an alpha value of 0.05, a sample size of at least 24 was required, with at least 12 individuals in each group. Data analyses were performed by SPSS 21.0 software (Inc., Chicago, IL, USA), and the data were reported as means ± SDs. The chi-square test was used to compare categorical variables. Comparisons between groups were made using the Student's t-test for normally distributed data or the Wilcoxon rank sum test for nonparametric data. The significance level was set at $P < 0.05$.

3. Results

Forty-three participants were screened and 38 were enrolled in the study. At the final follow-up, 32 participants completed final evaluations, and six participants dropped out during intervention period due to the COVID-19 pandemic, so that the follow-up rate was 84.2 %. No significant differences were found between the ESWT and CONTROL groups with regards demographic variables from the baseline assessment [Table 1].

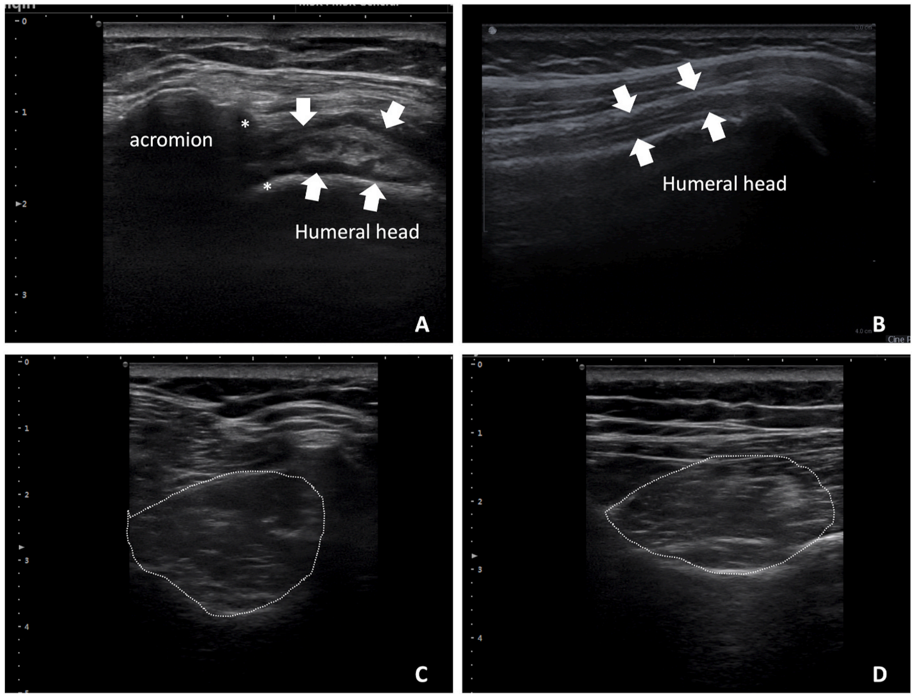

Fig. 2. The ultrasonography assessments of rotator cuff repair. A: In the parasagittal scan, the repaired tendon viewed as indicated by the arrows. The measurement of the subacromial space is indicated by asterisks between the point of entry of the tendon under the acromion and the humeral-head cortex. B: The longitudinal image of ultrasound showed homogenous of long head biceps tendon as indicated by white arrows. C: The short axis view of supraspinatus muscle is illustrated by the dotted line. The ultrasound image showing isoechoic echogenicity of supraspinatus muscle to the overlying trapezius. D. The short axis view showing a grade 0 infraspinatus muscle as indicated by the white dotted line. The echogenicity was isoechoic to the overlying deltoid muscle.

Table 1
Demographic information.

	ESWT Group (n = 16)	CONTROL Group (n = 16)	*P* value
Age, y	51.4 ± 8.2	55.7 ± 9.2	0.172
BMI, kg/m^2	22.9 ± 1.84	22.7 ± 1.77	0.142
Male: female	3:13	7:9	0.252
Elapse from onset of symptom to operation, months	6.4 ± 3.5	5.2 ± 4.2	0.391
SR: DR	10:6	11:5	1.000
Surgery side, left: right	3:13	7:9	0.252
Tear size, cm	2.7 ± 0.7	2.7 ± 0.6	0.793
Follow-up time, months	40.6 ± 4.3	42.8 ± 2.2	0.054

3.1. Clinical outcomes

At 3-year follow-up, two patients had retear in the ESWT Group (12.5 %) versus one patient in the CONTROL group (6.25 %, $P = 0.176$), which confirmed the study hypothesis that postoperative radial ESWT would not show increased repair failure in the long term. In both the ESWT and CONTROL groups, the functional scores including VAS pain, CMS, UCLA, ASES, and FUSS were all significantly improved at the final follow-up (*P*s < 0.01) compared to the results at baseline. At 6-month follow-up, VAS pain and ASES showed significant improvement after ESWT treatment, but at final follow-up, no significant differences were observed between the ESWT and CONTROL groups in functional scores (*P*s > 0.05). Active ROM, including forward flexion, abduction, and internal and external rotation improved significantly in both groups (*P*s < 0.01), with no between-group differences in ROM at follow-up (*P*s > 0.05) [Table 2]. No severe complications were observed in the radial ESWT group. Only two patients experienced increased pain and skin erythema after the first shockwave treatment. After three days of ice application, the symptoms disappeared.

3.2. Ultrasound evaluation

Ultrasound testing was completed in all participants at both baseline and the final follow-up. None of the participants reported full-thickness tears in either groups at both baseline ($P = 1.000$) and 6-month follow-up ($P = 0.176$). At the final follow-up, two participants in the ESWT Group were found to have type-4 lesions, indicating a full-thickness retear of the supraspinatus tendon. One participant was diagnosed with type-4 lesion in the control group, while no significant difference was detected ($P = 0.874$). In both groups, AHD had a markable increase from baseline to final follow-up (ESWT: $P = 0.001$, CONTROL: $P = 0.002$), and no between-group differences were found at 6-month ($P = 0.875$) or 3-year follow-up ($P = 0.885$). No LHBT rupture was found in either group at each follow-up. However, 6 out of 12 cases of tendinitis were remained at the 3-year follow-up in the ESWT group, while 8 out of 11 cases in the CONTROL group ($P = 0.175$). Both groups reported fatty infiltration in the supraspinatus and infraspinatus muscles at baseline ($P = 0.885$), which did not worsen at the 3-year follow-up (*P*s = 1.000). Only two participants in the ESWT Group and one in the CONTROL Group reported severe supraspinatus fatty infiltration at the final follow-up [Table 3].

3.3. MRI evaluation

There were 15 patients in ESWT Group and 16 patients in Control Group completed MRI evaluation at 3-year follow-up. Sagittal and coronal views of shoulders after rotator cuff repair are shown in Appendix Figures. Two patients in ESWT Group and one patient in Control Group reported Sugaya Type V lesion at final follow-up, indicating full-thickness tear of rotator cuff repair, which was consistent with ultrasonographic findings. The quantitative analysis showed improved tendon quality after 3 years follow-up(*P*s = 0.001), and lower SNQ in the repaired tendon after ESWT treatment at 6-month ($P = 0.036$) and 3-year follow-up ($P = 0.028$). The magnitude of fatty degeneration of

Table 2
Comparisons of clinical outcomes between the ESWT and the control groups.

	ESWT Group (n = 16)		CONTROL Group (n = 16)		p[a]
Failure Rate n, (%)					
Baseline	0, (0 %)		0, (0 %)		1
3-year follow-up	2, (12.5 %)		1, (6.25 %)		0.176
VAS-pain	mean ± SD	95 % CI	mean ± SD	95 % CI	
Baseline	4.2 ± 2.3	3.0–5.4	4.1 ± 2.2	3.0–5.3	0.834
6-month	0.5 ± 0.6	0.2–0.8	1.9 ± 1.1	1.4–2.5	**<0.01**
3-year	0.5 ± 1.0	0.0–1.0	0.1 ± 0.3	0.1–0.2	0.088
p[b]	**< 0.01**		**< 0.01**		
CMS					
Baseline	54.7 ± 13.0	47.8–61.6	53.9 ± 8.1	49.6–58.2	0.985
6-month	87.4 ± 9.7	82.2–92.5	81.3 ± 6.8	77.7–84.9	0.079
3-year	93.5 ± 7.2	90.1–97.0	93.8 ± 4.2	91.6–96.0	0.894
p[b]	**< 0.01**		**< 0.01**		
UCLA					
Baseline	20.0 ± 6.1	16.7–23.3	21.1 ± 3.7	19.2–23.1	0.395
6-month	31.8 ± 2.8	30.2–33.3	30.9 ± 2.5	30.1–31.7	0.400
3-year	32.6 ± 4.3	30.5–34.6	32.9 ± 2.6	31.7–34.2	0.748
p[b]	**< 0.01**		**< 0.01**		
ASES					
Baseline	47.3 ± 18.0	37.7–56.9	43.9 ± 13.4	36.7–51.0	0.806
6-month	86.2 ± 10.3	80.6–91.7	74.6 ± 7.2	70.8–78.4	**0.002**
3-year follow-up	96.2 ± 3.8	94.3–98.0	95.5 ± 3.0	94.1–96.9	0.542
p[b]	**< 0.01**		**< 0.01**		
FUSS					
Baseline	54.3 ± 16.9	45.2–63.3	54.1 ± 11.9	47.7–60.4	0.850
6-month	87.9 ± 8.3	83.5–92.3	83.7 ± 5.8	80.6–86.8	0.108
3-year follow-up	91.6 ± 5.5	89.0–94.3	93.7 ± 3.3	93.8–97.2	0.175
p[b]	**< 0.01**		**< 0.01**		
Abduction, deg					
Baseline	98.9 ± 37.2	79.1–118.7	108.3 ± 22.5	96.3–120.3	0.806
6-month	146.4 ± 26.1	132.5–160.2	154.8 ± 13.6	147.5–162.0	0.940
3-year follow-up	140.9 ± 26.6	128.1–153.8	141.4 ± 23.1	130.8–152.0	0.958
p[b]	**< 0.01**		**< 0.01**		
Forward Flexion, deg					
Baseline	89.6 ± 32.6	72.2–106.9	93.6 ± 25.6	80.0–107.3	0.327
6-month	136.6 ± 31.6	119.8–153.5	139.4 ± 23.1	127.1–151.8	0.776
3-year follow-up	162.1 ± 16.7	154.0–170.1	156 ± 14.9	149.1–162.9	0.238
p[b]	**< 0.01**		**< 0.01**		
External rotation, deg					
Baseline	30.7 ± 20.3	19.8–41.5	28.6 ± 13.7	21.3–35.9	0.91
6-month	58.8 ± 20.4	48.0–69.7	53.5 ± 15.0	45.5–61.5	0.484
3-year follow-up	67.4 ± 15.8	59.7–75.0	63.6 ± 8.0	59.4–67.8	0.368
p[b]	**< 0.01**		**< 0.01**		

Data are presented as mean ± SD.
ESWT, extracorporeal shock wave therapy; CMS: Constant-Murley Score; ASES: American Shoulder and Elbow Surgeons, FUSS: Fudan University shoulder score; UCLA, University of California, Los Angeles; VAS, visual analog scale.
[a] Nonparametric Mann−Whitney U tests: between group.
[b] Nonparametric Wilcoxon signed-rank test: within-group.

supraspinatus and infraspinatus did not differ between the ESWT and control groups(*Ps* > 0.05). The quality of LHBT in both groups improved after rotator cuff repair based on the MRI evaluation and no ruptured was reported [Table 3].

4. Discussion

Our study proved that the intervention of ESWT at 3-month post-operation had similar long-term follow-up outcomes with patients received only regular rehabilitation training. This results dispute the concern that early intervention of ESWT may have detrimental effect on the cuff healing after rotator cuff repair. Further, radial ESWT could improve tendon quality at 6 months and 3 years follow-up, suggesting that early intervention of radial ESWT could have positive long-term effect.

There has been an increasing concern that the application of shock waves could have a negative effect on rotator cuff tendon quality or may be related to tendon tears in cases with calcific deposits.[9] This unproven concern is possible because the posterior portion of the supraspinatus is more vulnerable to injury,[11] and after shock wave neovascularization, ingrowth is stimulated by repeated microtrauma.[32] Increasing evidence has shown that the energy flux density of ESWT is an important variable in treatment protocol.[6] The energy flux densities of over 0.28 mJ/mm^2, introduced by focused ESWT are associated with tendon swelling and infiltration by inflammatory cells.[23] In contrast, the energy flux density of the radial ESWT used in this study was 0.08 mJ/mm^2, which may affect the tendon remodeling.[36] In our previous research, we found that under this energy flux density, repetitive treatment with radial ESWT on a weekly basis can reduce postoperative pain and improve accelerated proximal supraspinatus tendon healing at the suture anchor site after rotator cuff repair at 6 months follow-up,[26] and this study proved that this effect can be sustained until 3 years.

Intervention at three-month post operation is crucial. Previous studies have suggested that retears commonly appear in the early postoperative period around 3 months.[17] The biological healing of the repaired rotator cuff tendon to the humerus was estimated to require a minimum of 8–12 weeks,[13] and during this period, the collagen type III fibers holding the bone-tendon junction together did not appear in considerable numbers before 12 weeks.[27] The process of collagen III switching to collagen I to complete the healing response usually takes approximately 6–12 months.[16]

The assessment of postoperative shoulder integrity using ultrasonography has become the preferred method because of its convenience and ability to produce results similar to MRI.[19,31] In the present study, AHD, LHBT quality, and fatty infiltration were assessed both in MRI and ultrasonography. Previously, AHD was measured using a standard X-ray of the shoulder; however, it was affected by both the patient's position and the X-ray beam direction.[5] The reliability of ultrasonography measuring AHD has been proven in recent studies.[3,14,33] Similar to previous evidence, the AHDs assessed by MRI and ultrasonography in the present study significantly increased after successful rotator cuff repair, while in the retear patients, the AHDs were less than 4 mm as measured.

Large tear size and tendon retraction suggest chronicity of the rotator tear; therefore, severe muscle atrophy and fatty infiltration can be observed on both ultrasonography and MRI. In our assessment, three cases of severe muscle fatty infiltration were observed (ESWT versus CONTROL: 2 versus1), which was consistent with the retear cases. We also found minimal deterioration of fatty infiltration of the supraspinatus from Grade 0 to Grade 1 on ultrasonography while Grade 1 to Grade 3, even when the torn tendons were successfully repaired. The reversibility of fatty muscle infiltration remains controversial. Successful repair does not lead to improvement or reversal of muscle degeneration, and failed repair results in significantly more progression.[8] Although in our previous study, early intervention with radial ESWT resulted in accelerated proximal supraspinatus tendon healing at the

Table 3
Ultrasonography and MRI evaluations of ESWT Group and CONTROL Group.

	ESWT Group (n = 16)		CONTROL Group (n = 16)		p-value	
	Ultrasonography	**MRI**	**Ultrasonography**	**MRI**	**Ultrasonography**	**MRI**
Repaired Tendon Quality ([a]) Ultrasonography Type I:II:III:IV MRI Sugaya：I:II:III:IV:V						
3 month FU	3:10:3:0	6:8:2:0:0	2:9:5:0	7:6:2:1:0	0.684	0.834
6 month FU	3:10:2:1	6:7:1:1:0	2:7:7:0	6:6:4:0:0	0.724	0.684
3 year FU	8:6:0:2	7:4:2:0:2	8:6:1:1	7:7:1:0:1	0.874	0.919
***p*[a] (*3 year versus baseline*)**	0.055	0.262	0.056	0.639		
MRI-SNQ						
3 month FU	/	16.76 ± 2.31	/	15.19 ± 3.94	/	0.175
6 month FU	/	12.29 ± 1.99	/	15.8 ± 2.01	/	**0.036**
3 year FU	/	5.73 ± 0.77	/	7.52 ± 1.03	/	**0.028**
***p*[a] (*3 year versus baseline*)**		**0.001**		**0.001**		
AHD, mm						
3 month FU	5.77 ± 2.31	6.27 ± 0.78	6.12 ± 2.31	5.89 ± 1.01	1.000	0.874
6 month FU	6.83 ± 2.59	7.11 ± 1.23	7.42 ± 3.01	6.21 ± 0.98	1.000	0.885
3 year FU	8.21 ± 3.01	8.15 ± 2.23	9.16 ± 2.89	7.01 ± 1.31	0.329	1.000
***p*[a]**	**0.001**	**0.028**	**0.002**	**0.002**		
Supraspinatus Fatty Infiltration ([b]) Ultrasonography Grade 0:1:2 MRI Goutallier: Grade 0:1:2:3:4						
3 month FU	05:10:01	10:5:0:0:0	07:08:01	10:5:1:0:0	0.757	0.542
6 month FU	05:10:01	12:3:1:0:0	07:08:01	11:5:0:0:0	0.757	0.175
3 year FU	05:09:02	11:2:0:2:0	07:08:01	11:4:0:1:0	0.696	0.724
***p*[a] (*3 year versus baseline*)**	0.824	0.480	1.000	0.320		
Infraspinatus Fatty Infiltration Ultrasonography Grade 0:1:2 MRI Goutallier: Grade 0:1:2:3:4						
3 month FU	12:02:02	12:3:0:0:0	11:03:02	10:5:1:0:0	0.885	0.368
6 month FU	12:02:02	11:4:0:0:0	12:04:02	11:5:0:0:0	0.885	0.542
3 year FU	12:02:02	11:3:1:0:0	11:03:02	10:5:1:0:0	0.885	0.885
***p*[a] (*3 year versus baseline*)**	0.247	0.663	0.202	0.659		
LHBT Quality([c]) Ultrasonography Grade 0:1:2:3 MRI：Type I:II:III:IV:V						
3 month FU	4:9:3:0	6:6:3:0:0	5:8:3:0	1:5:10:0:0	0.919	0.238
6 month FU	4:9:3:0	4:9:2:0:0	5:8:3:0	5:10:1:0:0	0.919	0.542
3 year FU	10:5:1:0	11:3:1:0:0	8:6:2:0	10:5:1:0:0	0.724	0.175
***p*[a] (*3 year versus baseline*)**	0.070	0.057	0.555	0.462		

Data are presented as n unless otherwise indicated; ESWT, extracorporeal shockwave therapy; AHD, acromiohumeral head distance; LHBT, long head biceps tendon; FU, follow-up.
Student's t-test was used to determine the differences in AHDs, and Fisher's exact test was used to analyze the differences in categorical variables between the ESWT and CONTROL groups.
[a] Ultrasonographic classification of repaired tendons. Type I: sufficient thickness >2 mm with normal echo structure; Type II: a repaired cuff with sufficient thickness (>2 mm) associated with partial hypo-echogenicity or heterogenicity; Type III: a repaired cuff that had insufficient thickness (<2 mm) without discontinuity; Type V: the presence of a major discontinuity in which the medial border was not visible under the acromial arch, suggesting a medium or large tear.
[b] Ultrasound grading scale for rotator cuff muscle fatty degeneration: Grade 0: intramuscular tendons were clearly visible and the muscle had isoechogenicity to the overlying muscle; Grade 1: intramuscular tendons were partially visible and the muscle had slightly increased echogenicity compared to the overlying muscle; Grade 2: no discernible intramuscular tendons were seen and the muscle's echogenicity was markedly increased compared to the overlying muscle.
[c] Ultrasonographic classification of the LHBT. Grade 0: normal findings of the bicep tendon and tendon sheath; grade 1: mild filling of the tendon sheath appearing as an anechoic ring around the tendon (<2 mm). Grade 2: An anechoic ring around the tendon was clearly visible and measured 2–3 mm. The structure of the tendon was mildly inhomogeneous (<50 %); Grade 3: the tendon sheath appeared as an anechoic structure surrounding the tendon and was severely widened and extended further distally than medially. The tendon was at least moderately-to-severely inhomogeneous (≥50 %), thickened, or reduced to a stump.

suture anchor site after arthroscopic rotator cuff repair, the long-term benefits of cuff healing and functional improvement remain debatable.

This study has limitations. First, the sample size was small. Although this sample size met the minimal requirements for statistical analysis, it was still insufficient for subgroup analyses of repair configuration, fatty infiltration, tendon retraction, and delamination, which can all affect surgical outcomes. Second, only patients with medium-to-large rotator cuff tears were included. Thus, the conclusions of this study cannot be generalized to individuals with massive or irreparable tears. Third, ultrasound evaluation is subjective. Objective measurement or tools need to be developed in the future studies.

5. Conclusion

Patients received the intervention with radial ESWT at 3-month postoperation had similar pain score, functional outcomes and failure rate at long-term follow-up compared with advanced rehabilitation.

Authors' contributions statement

Concept/idea/research design: Yunshen Ge; Acquisition of data: Yang Wu, Shurong Zhang, Junru Lu, Li Cao; Analysis and interpretation of data: Hong Shao, Mingru Huang, Shurong Zhang, Writing/review/editing of manuscript: Shurong Zhang, Yang Wu, Yunxia Li, Yunshen Ge. Final approval of the manuscript: Yunshen Ge, Shurong Zhang.

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Clinical trial registration

This study was registered in the Chinese Clinical Trial Registry (ChiCTR2000033566, https://www.chictr.org.cn/searchprojEN.html)

Patient involvement statement

Not applicable.

Key points

Findings

1.Early intervention of radial ESWT improved rotator cuff healing at 6 months, and this effect can be sustained to 3 years.
2.ESWT will not cause tendon rupture in the long term.

Implications

Radial ESWT could be used after rotator cuff repair to improve pain and tendon healing.

Caution

This study only include patients received rotator cuff repair. For the patients with massive irreparable rotator cuff tear, calcific tendinopathy, rheumatoid arthritis or infection, ESWT may not be effective or may have detrimental consequences.

Declaration of competing interest

All authors state no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.asmart.2024.09.004.

References

1. Barth J, Fotiadis E, Barthelemy R, Genna S, Saffarini M. Ultrasonic evaluation of the repair integrity can predict functional outcomes after arthroscopic double-row rotator cuff repair. *Knee Surg Sports Traumatol Arthrosc*. 2015;23(2):376–385.
2. Brasseur JL, Morvan G, Godoc B. [Dynamic ultrasonography]. *J Radiol*. 2005;86(12 Pt 2):1904–1910.
3. Cholewinski JJ, Kusz DJ, Wojciechowski P, Cielinski LS, Zoladz MP. Ultrasound measurement of rotator cuff thickness and acromio-humeral distance in the diagnosis of subacromial impingement syndrome of the shoulder. *Knee Surg Sports Traumatol Arthrosc*. 2008;16(4):408–414.
4. Collin P, Yoshida M, Delarue A, Lucas C, Jossaume T, Lädermann A. Evaluating postoperative rotator cuff healing: prospective comparison of MRI and ultrasound. *Orthop Traumatol Surg Res*. 2015;101(6 Suppl):S265–S268.
5. Fehringer EV, Rosipal CE, Rhodes DA, et al. The radiographic acromiohumeral interval is affected by arm and radiographic beam position. *Skeletal Radiol*. 2008;37(6):535–539.
6. Foldager CB, Kearney C, Spector M. Clinical application of extracorporeal shock wave therapy in orthopedics: focused versus unfocused shock waves. *Ultrasound Med Biol*. 2012;38(10):1673–1680.
7. Ge Y, Chen S, Chen J, Hua Y, Li Y. The development and evaluation of a new shoulder scoring system based on the view of patients and physicians: the Fudan University shoulder score. *Arthroscopy*. 2013;29(4):613–622.
8. Gladstone JN, Bishop JY, Lo IK, Flatow EL. Fatty infiltration and atrophy of the rotator cuff do not improve after rotator cuff repair and correlate with poor functional outcome. *Am J Sports Med*. 2007;35(5):719–728.
9. Han J, Jeong HJ, Kim YK, Oh JH. Posterior rotator cuff tears: is extracorporeal shockwave therapy a risk factor? *Clin Orthop Surg*. 2023;15(2):281–289.
10. Hunter DJ, Rivett DA, McKiernan S, Snodgrass SJ. Acromiohumeral distance and supraspinatus tendon thickness in people with shoulder impingement syndrome compared to asymptomatic age and gender-matched participants: a case control study. *BMC Muscoskel Disord*. 2021;22(1):1004.
11. Kim HM, Dahiya N, Teefey SA, et al. Location and initiation of degenerative rotator cuff tears: an analysis of three hundred and sixty shoulders. *J Bone Joint Surg Am*. 2010;92(5):1088–1096.
12. Kim JH, Hong IT, Ryu KJ, Bong ST, Lee YS, Kim JH. Retear rate in the late postoperative period after arthroscopic rotator cuff repair. *Am J Sports Med*. 2014;42(11):2606–2613.
13. Kim KC, Shin HD, Cha SM, Kim JH. Repair integrity and functional outcomes for arthroscopic margin convergence of rotator cuff tears. *J Bone Joint Surg Am*. 2013;95(6):536–541.
14. Leong HT, Tsui S, Ying M, Leung VY, Fu SN. Ultrasound measurements on acromio-humeral distance and supraspinatus tendon thickness: test-retest reliability and correlations with shoulder rotational strengths. *J Sci Med Sport*. 2012;15(4):284–291.
15. Liu S, Xie Y, Chen Q, et al. Tendon healing progression evaluated with magnetic resonance imaging signal intensity and its correlation with clinical outcomes within 1 Year after rotator cuff repair with the suture-bridge technique. *Am J Sports Med*. 2020;48(3):697–705.
16. Longo UG, Berton A, Khan WS, Maffulli N, Denaro V. Histopathology of rotator cuff tears. *Sports Med Arthrosc Rev*. 2011;19(3):227–236.
17. McCarron JA, Derwin KA, Bey MJ, et al. Failure with continuity in rotator cuff repair "healing". *Am J Sports Med*. 2013;41(1):134–141.
18. McElvany MD, McGoldrick E, Gee AO, Neradilek MB, Matsen 3rd FA. Rotator cuff repair: published evidence on factors associated with repair integrity and clinical outcome. *Am J Sports Med*. 2015;43(2):491–500.
19. Nho SJ, Adler RS, Tomlinson DP, et al. Arthroscopic rotator cuff repair: prospective evaluation with sequential ultrasonography. *Am J Sports Med*. 2009;37(10):1938–1945.
20. Ogden JA, Tóth-Kischkat A, Schultheiss R. Principles of shock wave therapy. *Clin Orthop Relat Res*. 2001;387:8–17.
21. Park BK, Hong SH, Jeong WK. Effectiveness of ultrasound in evaluation of fatty infiltration in rotator cuff muscles. *Clin Orthop Surg*. 2020;12(1):76–85.
22. Park YB, Ryu HY, Hong JH, Ko YH, Yoo JC. Reversibility of supraspinatus muscle atrophy in tendon-bone healing after arthroscopic rotator cuff repair. *Am J Sports Med*. 2016;44(4):981–988.
23. Rompe JD, Kirkpatrick CJ, Küllmer K, Schwitalle M, Krischek O. Dose-related effects of shock waves on rabbit tendo Achillis. A sonographic and histological study. *J Bone Joint Surg Br*. 1998;80(3):546–552.
24. Samim M, Beltran L. The postoperative rotator cuff. *Magn Reson Imag Clin N Am*. 2020;28(2):181–194.
25. Seo JB, Yoo JS, Ryu JW. Sonoelastography findings of biceps tendinitis and tendinosis. *J Ultrasound*. 2014;17(4):271–277.
26. Shao H, Zhang S, Chen J, et al. Radial extracorporeal shockwave therapy reduces pain and promotes proximal tendon healing after rotator cuff repair: randomized clinical trial. *Ann Phys Rehabil Med*. 2023;66(4), 101730.
27. Sonnabend DH, Howlett CR, Young AA. Histological evaluation of repair of the rotator cuff in a primate model. *J Bone Joint Surg Br*. 2010;92(4):586–594.
28. Speed C. A systematic review of shockwave therapies in soft tissue conditions: focusing on the evidence. *Br J Sports Med*. 2014;48(21):1538–1542.
29. Sugaya H, Maeda K, Matsuki K, Moriishi J. Repair integrity and functional outcome after arthroscopic double-row rotator cuff repair. A prospective outcome study. *J Bone Joint Surg Am*. 2007;89(5):953–960.
30. Tashjian RZ, Hung M, Keener JD, et al. Determining the minimal clinically important difference for the American Shoulder and Elbow Surgeons score, Simple Shoulder Test, and visual analog scale (VAS) measuring pain after shoulder arthroplasty. *J Shoulder Elbow Surg*. 2017;26(1):144–148.
31. Wall LB, Teefey SA, Middleton WD, et al. Diagnostic performance and reliability of ultrasonography for fatty degeneration of the rotator cuff muscles. *J Bone Joint Surg Am*. 2012;94(12), e83.
32. Wang CJ, Wang FS, Yang KD, Weng LH, Sun YC, Yang YJ. The effect of shock wave treatment at the tendon-bone interface-an histomorphological and biomechanical study in rabbits. *J Orthop Res*. 2005;23(2):274–280.
33. Xu M, Li Z, Zhou Y, Ji B, Tian S, Chen G. Correlation between acromiohumeral distance and the severity of supraspinatus tendon tear by ultrasound imaging in a Chinese population. *BMC Muscoskel Disord*. 2020;21(1):106.
34. Zhang S, Li H, Yao W, Hua Y, Li Y. Therapeutic response of extracorporeal shock wave therapy for insertional achilles tendinopathy between sports-active and nonsports-active patients with 5-year follow-up. *Orthop J Sports Med*. 2020;8(1), 2325967119898118.
35. Zhang S, Liu S, Yang L, Chen S, Chen S, Chen J. Morphological changes of the femoral tunnel and their correlation with hamstring tendon autograft maturation up to 2 Years after anterior cruciate ligament reconstruction using femoral cortical suspension. *Am J Sports Med*. 2020;48(3):554–564.
36. Zhang S, Wen A, Li S, et al. Radial extracorporeal shock wave therapy enhances graft maturation at 2-year follow-up after ACL reconstruction: a randomized controlled trial. *Orthop J Sports Med*. 2022;10(9), 23259671221116340.
37. Zoga AC, Kamel SI, Hynes JP, Kavanagh EC, O'Connor PJ, Forster BB. The evolving roles of MRI and ultrasound in first-line imaging of rotator cuff injuries. *AJR Am J Roentgenol*. 2021;217(6):1390–1400.