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Research Article

Pro ultra-Mesh Augmentation in the Rotator Cuff Repair: A Randomized, Single-Blind, Controlled Trial

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Abstract

Background: Rotator cuff tears present in about 20% of the population. This has prompted surgeons to look for techniques to augment the rotator cuff tear repair. This study aimed to assess the results of Ultrapro mesh augmentation in patients with massive and large rotator cuff tears as a clinical trial.
Methods: The study was a single-blind randomized controlled trial in which patients were randomly divided into two groups. Both groups underwent surgery. In one, Ultrapro mesh was used to augment the repair. Therapeutic outcome was assessed by using a joint range of motion, Simple Shoulder Test (SST), Oxford Shoulder Score (OSS), and visual analogue scale (VAS).
Results: 60 patients were included, of whom 47 were men. Forward flexion (FF), abduction, external rotation (ER), and internal rotation (IR) degree increased significantly in both groups ($P < 0.01$), but no significant difference was found between the two groups in terms of changes in these angles ($P > 0.05$). During the study period and in both groups, the OSS score decreased, and the SST score increased. The pain in both groups decreased until the sixth month and increased after that up to the twelfth month.
Conclusion: Although the use of Ultrapro mesh augmentation in the rotator cuff tear has been associated with better long-term results in the abduction and ER of patients, the effect on the patients' clinical results is not significant. Further studies are needed to make a more accurate judgment.

Keywords: Treatment Outcome; Randomized Controlled Trial; Rotator Cuff Injuries

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Background

Rotator cuff tears are present in about 20% of the population. In 60% of them, complaints of shoulder pain and disability indicate rotator cuff tears, and 16% of rotator cuff tears are asymptomatic (1).

There are many disagreements in the treatment of patients with rotator cuff tears. However, rotator cuff repair surgery is accepted by many surgeons in patients whose symptoms do not improve despite conservative treatments. Various surgical techniques, including arthroscopic and open surgery, for treating rotator cuff rupture are described. Rotator cuff rupture has successive divisions that have four stages according to the Cofield classification, which is considered a large rupture if the rupture is 5 cm or more (2, 3).

One of the main concerns after rotator cuff tearing surgery, especially in large ones, is the failure of tendon repair to the bone or its rupture again. Recurrence rates have been reported in up to 50% in various studies, although not all of these ruptures are symptomatic. The risk of rupture is directly related to the initial size of the rupture and the degree of muscle atrophy before the surgery (4).

Some studies also consider the possibility of repairing the rotator cuff in large ruptures less than in smaller ruptures; the reason is the degeneration in the pathology of torn tendons (5). The rate of re-rupture, especially in large ones, prompted surgeons to seek techniques to enhance rotator cuff rupture repair. Different methods with biological and biomechanical properties are described (6).

This study aimed to assess the clinical outcome of augmentation in the large rotator cuff repair by ultra-mesh augmentation.

Methods

The study protocol was approved by the Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran (IR.TUMS.IKHC.REC.1398.155). Participants were apprised of the research protocol and design and were guaranteed that their confidential information would be protected.

In this randomized, single-blind clinical trial, patients with massive rotator cuff tearing administered to Imam Khomeini Hospital, Tehran, approved by magnetic resonance imaging (MRI) or clinical examination, candidates for orthopedic surgery, and aged 18 to 75 years old were included. As a pilot clinical study, a limited number of patients were enrolled. Those with past medical histories of autoimmune, inflammatory, or infectious disease were excluded.

participants were randomly divided into ultra-mesh augmentation and control groups using the block randomization method in which the number of subjects in each group was kept similar. For block randomization, a block size of 6 was used and the randomization list was prepared by a statistician (Figure 1).

Both groups underwent routine open orthopedic surgery for massive rotator cuff repair, so that the mesh augmentation group received augmentation by Ultrapro mesh (surgical polypropylene mesh, Asia Jarah Pishro Company, Tehran, Iran).

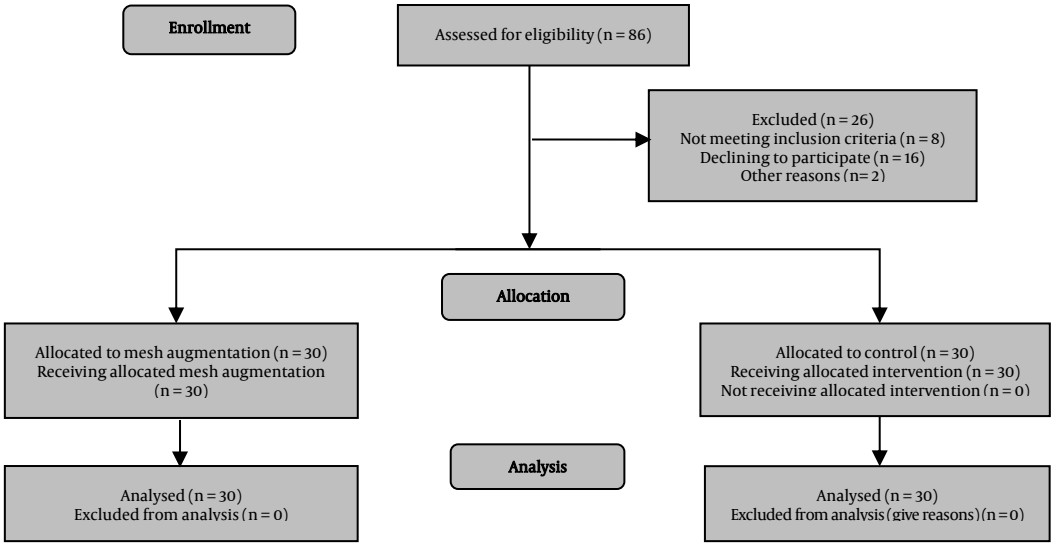

Figure 1. Flow diagram for study enrollment

The deltopectoral approach and double row technique by using non-absorbable and intraosseous sutures were recruited. Besides, an informed consent was obtained from each participant, although some of the participants underwent the mesh augmentation; hence, the study was considered as single blind.

The data collection tools were a registry form of patients who were a candidate for shoulder arthroplasty, which examined the ranges of motion such as forward flexion (FF) degree, abduction degree, external rotation (ER) degree, and internal rotation (IR) degree, and Simple Shoulder Test (SST) score, Oxford Shoulder Score (OSS), and visual analogue scale (VAS) score to grade the amount of pain in the shoulder.

Moreover, demographic data such as gender, age, and past medical history were collected using a checklist.

SST is a standardized instrument developed to document shoulder function systematically. This questionnaire consists of 12 questions with "yes" or "no" answers about the function of the affected shoulder. Answers to these questions provide a standardized way of recording shoulder function before and after treatment. It also provides a functional assessment of treatment outcomes for certain conditions of the shoulder (7, 8).

The OSS is a simple questionnaire that includes the patient's perception of concerning their shoulder and related quality of daily activities; moreover, it is easy to administer by untrained people. As a joint-specific instrument, this clinical measure minimizes the influence of other simultaneous morbidities in the upper limb and has been reported as valid and reliable for degenerative and inflammatory disorders of the shoulder in many global studies (9).

The VAS pain score assesses pain in the involved shoulder on a Likert scale of 0 to 10, with 0 point representing no pain at all and 10 points representing the worst pain ever felt.

Participants were visited in the 1st, 3rd, 6th, and 12th months after the operation, and the desired factors were reviewed and recorded.

Finally, the data were analyzed by using SPSS software (version 16, SPSS Inc., Chicago, IL, USA). P-value less than 0.05 was considered significant. Repeated measures analysis of variance (ANOVA) for assessing the trends in variables, and t-test and chi-square test for quantitative and qualitative data were employed.

Results

Overall, 60 patients were included, of whom 47 (78.3%) were men. Mean age and body mass index (BMI) were determined to be 59.1 ± 7.0 years and 27.9 ± 5.6 kg/m^2. The baseline characteristics did not indicate any significant difference between groups (Table 1).

Table 1. Baseline demographic characteristics of participants

Characteristics	Mesh augmentation group	Control group	P-value
Male gender	24.0 (80.0)	23.0 (76.7)	0.70
Age (year)	59.4 ± 5.7	58.8 ± 8.1	0.70
BMI (kg/m2)	27.4 ± 3.8	28.4 ± 7.0	0.50
Smoker	12.0 (40.0)	7.0 (23.3)	0.10
Diabetic	6.0 (20.0)	9.0 (30.0)	0.30

Data are presented as mean ± standard deviation (SD) or number and percentage
BMI: Body mass index

In all four angles, generally increased, and according to the repeated measures ANOVA test, the effect of time was significant (P < 0.001), while there was not a significant difference between the two groups in terms of degree changes during the study (P > 0.05; FF: 0.112, abduction: 0.438, ER: 0.454, IR: 0.940) (Figure 2).

The mean of OSS decreased significantly (P < 0.001), although there was no significant difference between groups (P = 0.740).

In the interval comparison in both groups, the mean of OSS in the third- and twelfth-month visits were significantly reduced compared to the previous visit (P < 0.001) (Table 2).

The score of the SST increased significantly in both groups (P < 0.001), but there was no significant difference between the two groups in these changes (P = 0.593). In the interval comparison in both groups, there was a significant increase in the third- and sixth-month visits compared to the previous ones (P < 0.001 and P = 0.009) (Table 2).

During the study, Changes in pain based on the VAS index were significantly reduced in both groups (P < 0.001), although there was no significant difference in reduction between groups. In the interval comparison in both groups, in the third- and twelfth-month visits, a significant decrease in pain score compared to the previous visit was indicated (P = 0.005 and P < 0.001) (Table 2).

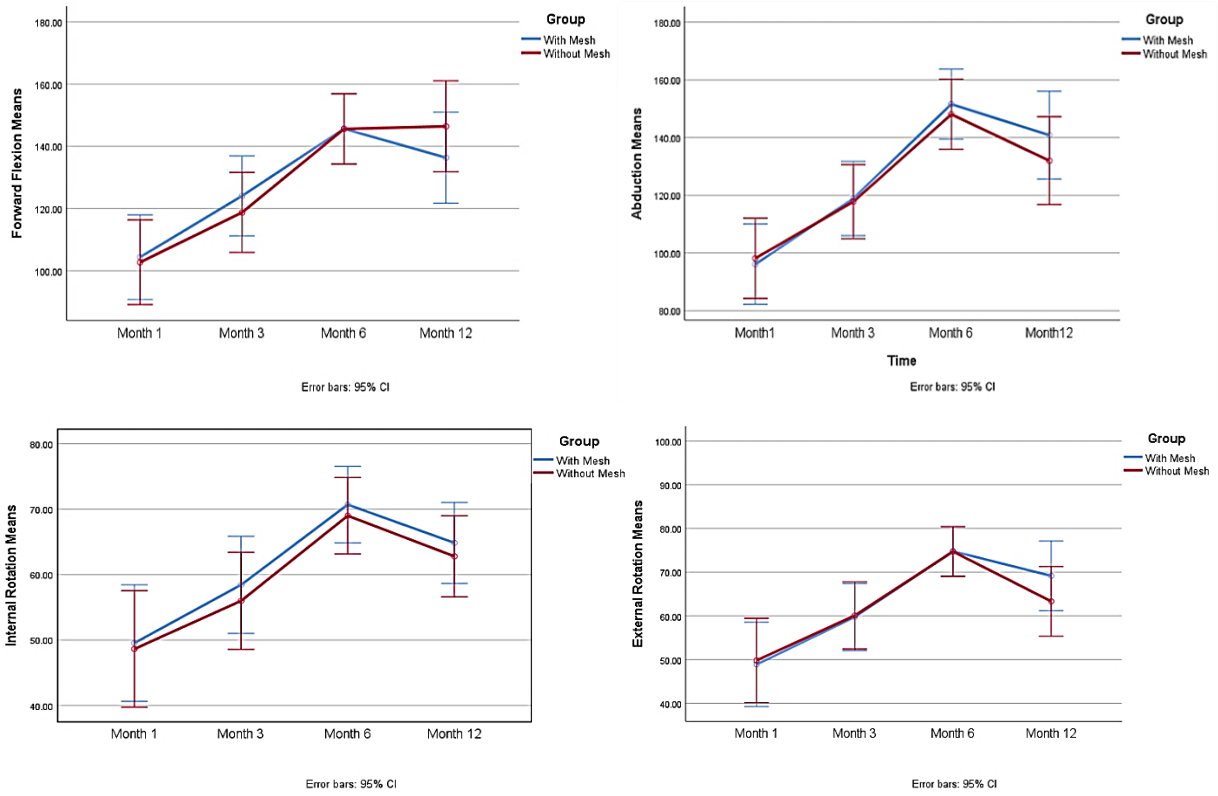

Figure 2. Changes of the angles of the shoulder in movements in consecutive visits (with mesh: augmentation with mesh; without mesh: routine operation)

Discussion

The present study investigated the clinical effects of using Ultrapro mesh on large rotator cuff repair. This study was performed on 60 patients with a mean age of 59.0 ± 7.0 years, of whom 47 participants (78.3%) were men. For 30 patients, Ultrapro mesh was used to augment the repair. The results in both groups were assessed by using shoulder joint examination, SST, OSS, and patients' pain based on the VAS index in the first, third, sixth, and twelfth months after the operation.

During the study period, in groups, the OSS score decreased, and the SST score increased similarly, but there was no significant difference between the two groups in any follow-up. Patients' pain based on VAS also decreased in both groups by the sixth month but increased at 12 months compared to the sixth month. Patients' pain levels did not differ significantly between the two groups in any of the four follow-up sessions.

The first use of synthetic patches in repairing human rotator cuff amplification was investigated by Ozaki et al. In 1986, polyester grafts such as Teflon mesh and Marlex mesh were used to reinforce the restoration and generally, satisfactory results were reported, especially for Teflon mesh (10).

Many preliminary studies in this field have examined the results of the use of restoration reinforcement methods and have not made comparisons with non-reinforcement methods. A study in 1991 by Visuri et al. also reported satisfactory results from the use of carbon fiber in boosting rotator cuff repair (11). The use of various synthetic patches to enhance rotator cuff repair has been studied, some of the most important of which were: carbon filament-polylactic acid, Dacron polyester, GORE-TEX patch, and polypropylene (12-15).

Another study examined the use of a porcine dermal patch to enhance rotator cuff repair; no significant difference was reported between the two groups in terms of Disabilities of Arm, Shoulder, and Hand (DASH) score and SST score, although in comparison to the routine manner, rotator cuff augmented group showed a significant increase in Constant score and muscle strength (16). According to the results of a review study by Bailey et al., the use of augmented rotator cuff repair techniques has no effect on reducing patients' pain after surgery (17), which is in line with the findings of our study.

Table 2. Clinical parameter scores at first, third, sixth, and twelfth visits

Parameter		1st month	3rd month	6th month	12th month	P-value
OSS	With mesh	44.9 ± 9.4	31.7 ± 12.9	32.9 ± 14.8	26.6 ± 11.0	1st vs. 3rd: < 0.001, 3rd vs. 6th: 0.130, 6th vs. 12th: < 0.001
	Control	43.3 ± 9.7	32.4 ± 14.2	34.6 ± 15.2	27.4 ± 10.1	1st vs. 3rd: < 0.001, 3rd vs. 6th: < 0.001, 6th vs. 12th: < 0.001
	P-value	0.519	0.842	0.656	0.765	-
SST	With mesh	3.5 ± 1.9	6.6 ± 2.8	7.3 ± 2.9	7.4 ± 3.1	1st vs. 3rd: < 0.001, 3rd vs. 6th: 0.009, 6th vs. 12th: > 0.999
	Control	3.8 ± 1.5	6.4 ± 3.3	7.1 ± 3.5	7.7 ± 3.2	1st vs. 3rd: < 0.001, 3rd vs. 6th: 0.015, 6th vs. 12th: > 0.999
	P-value	0.449	0.800	0.779	0.741	
Pain	With mesh	4.8 ± 6.1	3.4 ± 2.6	3.1 ± 2.6	3.7 ± 2.5	1st vs. 3rd: 0.005, 3rd vs. 6th: > 0.999, 6th vs. 12th: < 0.001
	Control	6.1 ± 2.3	4.1 ± 3.0	3.1 ± 3.0	3.6 ± 2.8	1st vs. 3rd: < 0.001, 3rd vs. 6th: 0.081, 6th vs. 12th: < 0.001
	P-value	0.037	0.306	0.986	0.888	-

Data are shown as mean ± standard deviation (SD). Multi-comparison tests were performed with analysis of variance (ANOVA), and Bonferroni correction of P-value was used in pairwise comparison into groups. The pain was assessed using visual analogue scale (VAS).
OSS: Oxford Shoulder Score; SST: Simple Shoulder Test

A systematic review and meta-analysis results showed that the use of synthetic patches to enhance rotator cuff repair, although reducing the risk of re-rupture, would lead to a slight improvement in shoulder function and pain in patients and, in some cases, increase the incidence of postoperative complications (18).

This study shows that a dramatic effect of augmentation on the rotator cuff repair cannot be expected, and a definite decision in this area requires further studies. Moreover, due to the use of different patches in different studies and clinical evaluation of patients using different tools, accurate comparison of these patches with each other is not possible.

This study has some limitations. Convincing the patients to participate was challenging, but it should be noted that none of the participants' follow-ups remained incomplete. Due to the avascular nature of the rotator cuff, participants' follow-up is expected to be more than 12 months. Further research is needed to clarify the long-term effects of this intervention.

Conclusion

The OSS score decreased, and the SST score increased similarly, but there was no significant difference between the two groups in any follow-up. Moreover, patients' pain decreased in both groups, but there was not an obvious and significant distinction.

Conflict of Interest

The authors declare no conflict of interest in this study.

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