

## Original Article

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# Onlay patch augmentation in rotator cuff repair for moderate to large tears in elderly patients: clinical and radiologic outcomes

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**Background:** This study evaluated the clinical and radiologic outcomes of onlay patch augmentation in rotator cuff repair for moderate-to-large tears in elderly patients.

**Methods:** We reviewed 24 patients who underwent onlay augmentation with dermal allograft after arthroscopic rotator cuff repair from January 2017 to March 2020. Inclusion criteria were patients aged >65 years with tears >2.5 cm, who were followed for >12 months after surgery, and patients who could raise their arms above 90° preoperatively. American Shoulder and Elbow Surgeons (ASES) score, Constant-Murley score, pain visual analog scale (VAS), and VAS for satisfaction were used as clinical outcomes. For the evaluation of cuff integrity, magnetic resonance imaging scans were performed every 3 months after surgery. The results were compared before and after surgery in all patients and between the retear and intact groups.

**Results:** The average follow-up period was 16.38 months, and the mean age of patients was 71.05 years. All patients showed significant improvement in ASES score, Constant-Murley score, and pain VAS at the last evaluation. The average value of satisfaction VAS was 7.27/10. The retear rate was 25% (6/24) if Sugaya type 3 was categorized in the retear group, otherwise 16.7% (4/24), if Sugaya type 3 was categorized into the intact group. Irrespective of Sugaya type 3 being included in the retear group, there was no significant difference in outcome variables between the intact and retear groups during follow-up.

**Conclusions:** In moderate-to-large rotator cuff tear in elderly patients, onlay patch augmentation improved clinical outcomes. Retear did not adversely affect clinical outcomes.

**Level of evidence:** IV.

**Keywords:** Moderate; Large; Arthroscopic surgery; Allograft; Augmentation

## INTRODUCTION

Most rotator cuff tears (RCTs) occur during the aging process, and the incidences of RCTs are increasing worldwide because of the increase in aging populations and the number of individuals

who participate in sports activities [1]. Patients in old age usually have larger tear sizes and a higher degree of tendon degeneration, which is potentially related to difficulty in repair. Elderly patients also frequently have comorbidities, medical problems and shoulder dysfunction, which have a negative influence on the healing

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process of the repaired tendon.

Studies evaluating the outcomes of RCT repair surgery have shown favorable outcomes; however, re-tear is a commonly reported complication [2]. Several studies have reported that the re-tear rate of rotator cuff repair (RCR) in patients who underwent rotator cuff surgery is between 11% and 94%. Major factors for failure of the RCR are age, tear size, advanced degree of muscular atrophy and fat infiltration, massive retraction of tendon, higher critical shoulder angle, lower acromiohumeral distance, high tendon tension after repair and inappropriate postoperative rehabilitation [3,4]. Among these factors, age and tear size are important factors [5-9].

Because of the difficulties for RCR in patients in old age, to improve the healing rate, attention is being drawn to various reconstruction and reinforcement procedures such as interval sliding technique, bone marrow stimulation and augmentation with allo or autograft [10]. Onlay homogeneous dermal augmentation is a subject of focus as one of the most popular methods [11]. Biomechanical and clinical evidence has shown that rotator cuff augmentation using this approach may be a safe and effective method [12].

Our hypothesis was that dermal allograft augmentation with onlay configuration in patients aged 65 years or over with medium to large RCT may yield a low re-tear rate after arthroscopic RCR and improve clinical outcome. In this study, we retrospectively monitored patients aged 65 years or over with medium to large RCT who had undergone rotator cuff augmentation procedures in addition to RCR.

## METHODS

All protocols were approved by the Institutional Review Board of Kangdong Sacred Heart Hospital (No. 2021-08-011). Informed consent was waived because the study was designed as a retrospective study.

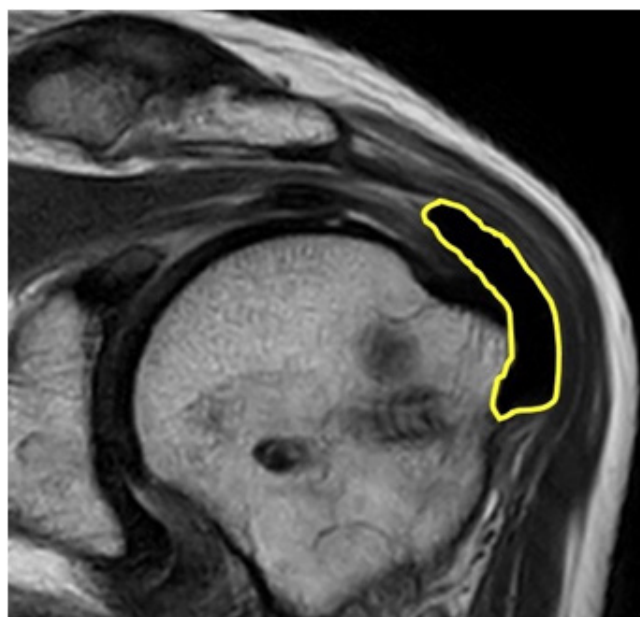
### Study Design

We retrospectively reviewed 28 patients who underwent onlay augmentation with dermal allograft after arthroscopic complete repair or incomplete repair for medium to large sized tears in our hospital from January 2017 to March 2020. Among patients over 65 years of age who underwent surgical treatment for a full-thickness RCT, patients with a tear of 2.5 cm or more measured in both dimensions (medial-lateral and anterior-posterior) after arthroscopic debridement were included. Tear size was measured and recorded in the medial-lateral tear dimension and the anterior-posterior tear dimension during the surgical procedure be-

cause there is a difference between the tear size measured on a magnetic resonance imaging (MRI) scan before surgery and the tear size measured after arthroscopic debridement during surgery. Patients with ipsilateral moderate to severe glenohumeral osteoarthritis or prior ipsilateral shoulder surgery and those who had severe pseudoparalysis with no visible active elevation in the glenohumeral joint (“shoulder shrug”) were excluded. Among the cases accompanied by rupture of the subscapularis tendon, cases with complete repair or requiring only debridement were included in this study. Patients who underwent tendon transfer or patch augmentation after repair were excluded. Patients with insufficient valid data or patients who were followed up less than 12 months after surgery were also excluded. A total of 24 cases were included in this study and their clinical records and images were reviewed.

### Purpose and Design of the Onlay Patch Augmentation and Its Surgical Indication

The purpose of onlay patch augmentation (OPA) is the reduction of re-tear rate by promoting healing of the repaired rotator cuff. For all cases in this study, a dermal allograft patch was used for augmentation, not for bridging (Fig. 1). The native cuff tendon was secured to the footprint on the greater tuberosity and the patch was piled up on the top of the repaired cuff tendon and secured medially to the remaining rotator cuff and laterally to the greater tuberosity to act as a bumper or a protector during the



**Fig. 1.** The “onlay” augmentation procedure. We performed the overlapping technique in which the dermal allograft was placed over the repaired native rotator cuff tendon. The yellow border indicates the dermal allograft placed over the repaired rotator cuff.

tendon healing process [13].

The decision to perform the OPA after RCR was based on the reparability and the expected status of footprint coverage during arthroscopic RCR. (1) When the complete anatomical coverage of the insertional footprint of rotator cuff was possible, the OPA was applied in all patients over 65 years of aged with a tear greater than 2.5 cm in both dimensions (medial-lateral and anterior-posterior) after arthroscopic debridement. (2) When the complete anatomical coverage of the insertional footprint of rotator cuff was impossible, even if anatomical complete coverage was not achieved, OPA was applied if the articular cartilage of the humeral head was not visible. If it is expected that the articular cartilage of the humerus head will be greatly exposed after repair, partial repair with superior capsular reconstruction (SCR) was applied instead of the OPA.

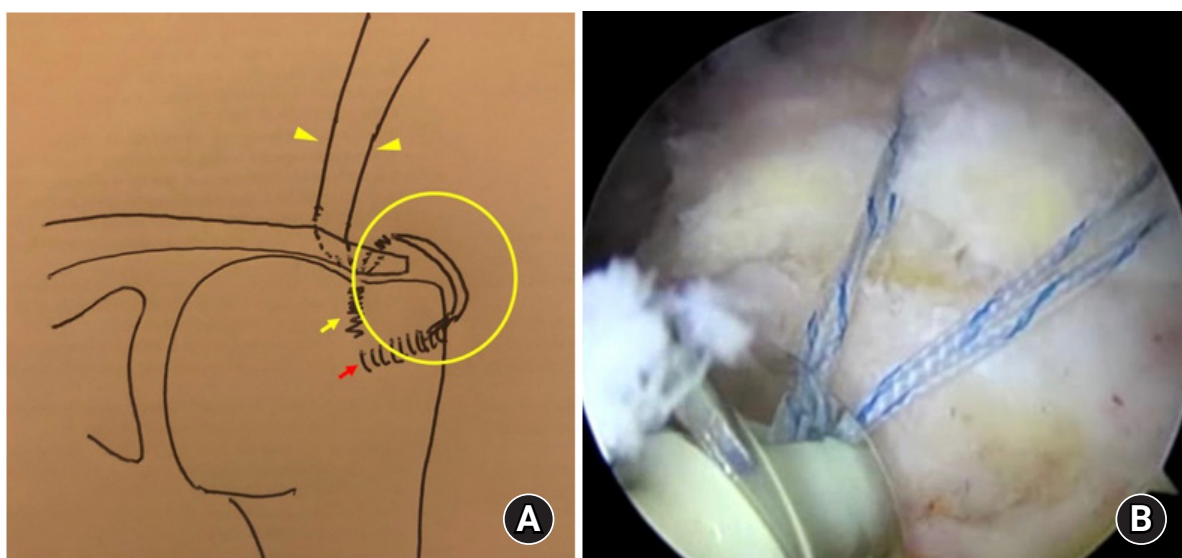
### Surgical Technique

After the administration of a regional interscalene block for post-operative pain control and induction of satisfactory general anesthesia, the patient was placed in the beach chair position on operation table. The operative field was prepared and draped in a sterile manner. Posterior and anterosuperior portals were established and diagnostic arthroscopy was performed for intra-articular pathologies. Except for the patients who show the “drive-through sign,” anterior and posterior glenohumeral ligaments were released to increase the working space for the patch augmentation that may be later performed [14,15]. Next, diagnostic examination was performed for the subacromial space. If a sub-

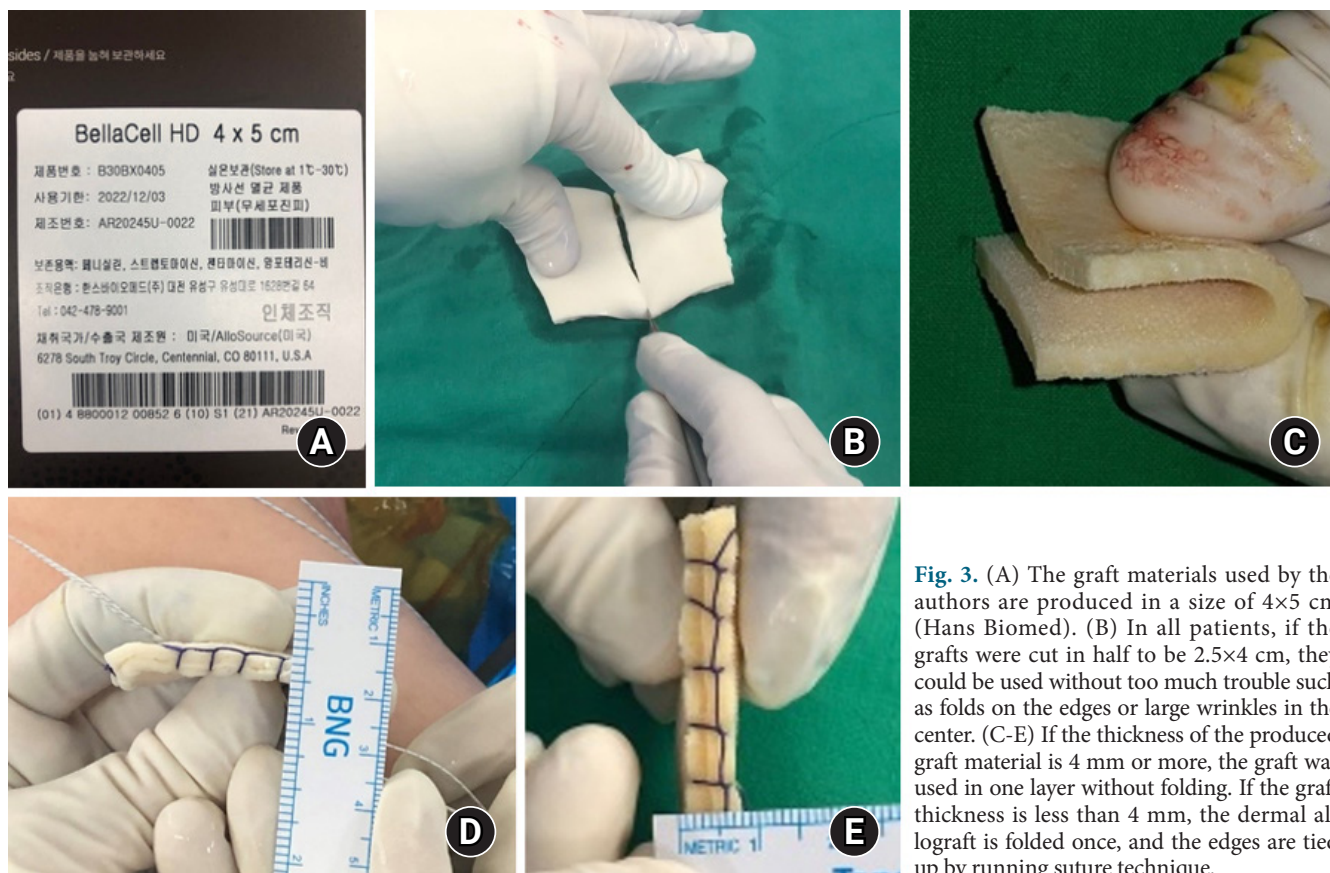
acromial bony spur was identified, acromioplasty was performed. An additional working portal was established anterolaterally, and an 8-mm cannula was placed on the portal for cuff repair procedure. Posterolateral portal for viewing with the arthroscope was established. The RCT site was debrided for removal of the devitalized tendon tissues and the exact size was measured in both dimensions (medial-lateral and anterior-posterior).

Using a grasper, we checked whether the torn tendon could be repaired completely and whether the OPA could be performed. If the pulled tendons did not completely cover the insertional footprint of the rotator cuff, margin convergence techniques and anterior interval slide technique were used to close the defect [16,17]. If the suture-bridge technique was used for RCR, the greater tuberosity footprint was also debrided using a shaver and burr for the insertion of the anchor. Two double limbed suture anchors and lateral anchor were used for main repair by the suture-bridge technique. Of the two suture limbs passed through the tendon, the more inward limb was left to fix the patch later. The suture-bridge configuration was first completed using the suture limb passed through the outside of the tendon (Fig. 2).

The graft for the OPA was prepared so that it covers the defect. The graft materials were acellular dermal allograft (BellaCell HD, Hans Biomed), which are produced in the pre-hydrated form for the increase of the resistance of failure. The BellaCell HD is produced as a 4×5 cm graft, so if they were cut in half to be 2.5×4 cm, they could be used without too much trouble. There were no problems such as folds on the edges or large wrinkles in the center (Fig. 3A and B). If the thickness of the produced graft materi-



**Fig. 2.** (A) For the repair of native torn rotator cuff tendon, two double limbed suture anchors (yellow arrow) were inserted into the medial edge of the insertion footprint of torn tendon. Of the two suture limbs through which the tendon is passed, the more inward limb (yellow arrowheads) is left to fix the patch later. (B) And then lateral anchor (red arrow in A) was used for suture-bridge configuration (yellow circle in A).



**Fig. 3.** (A) The graft materials used by the authors are produced in a size of 4×5 cm (Hans Biomed). (B) In all patients, if the grafts were cut in half to be 2.5×4 cm, they could be used without too much trouble such as folds on the edges or large wrinkles in the center. (C-E) If the thickness of the produced graft material is 4 mm or more, the graft was used in one layer without folding. If the graft thickness is less than 4 mm, the dermal allograft is folded once, and the edges are tied up by running suture technique.

al was 4 mm or more, the graft was used in one layer without folding. If the graft thickness was less than 4 mm, the dermal allograft is folded once, and the edges are tied up by running suture technique which is thick enough to act as a bumper at the range of motion of shoulder joint (Fig. 3C-E).

The additional incision was made extending to the working portal for the passage of the graft. Before inserting the patch graft, it is important to make sure that the threads that will pass through the patch graft are not twisted together. The patch is placed on the exact site with knot pusher technique and position checking with arthroscope (Fig. 4). The patch is fixed using lateral anchor-suture by suture-bridge technique (Fig. 5). The tendon is repaired with one limb from each of the two suture anchors and fixed by a lateral anchor, and the remaining limbs are passed through the patch graft and fixed to the humerus with another lateral anchor. The graft was inserted, and threads were tied up by a knot pusher technique.

**Postoperative Management**

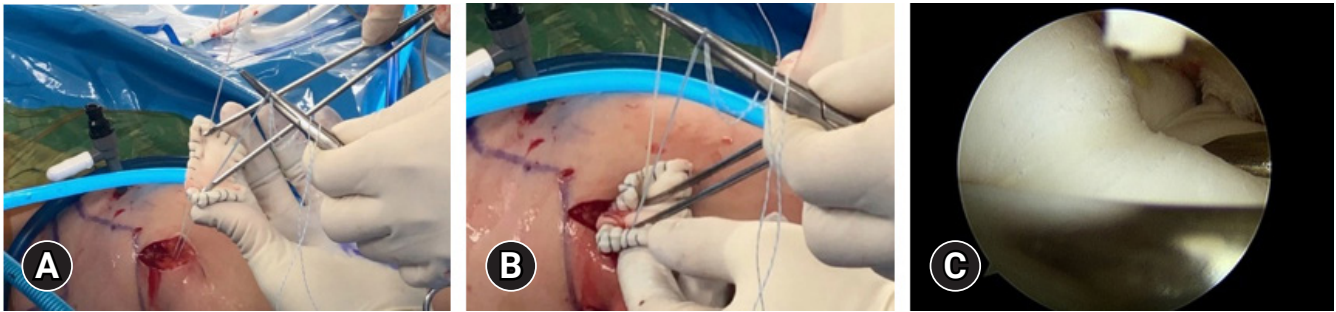
During the 8 weeks of immobilization after surgery, patients wore an abduction brace and only passive exercise of arm elevation less than 90° was allowed postoperatively. Two months after

the operation, after confirming whether there was a retear by MRI scan, the forward elevation exercise, which was limited to 90°, was allowed to the maximum possible. In addition, one passive exercise, the Backside Arm-Curl, was added; active rehabilitation exercise was not included during the follow-up period due to concerns about retear of the repaired tendon. The Backside Arm-Curl exercise is a rehabilitation exercise performed to restore movement that is essential in daily life such as personal hygiene management. It is an exercise in which the operated arm is brought to the ipsilateral thigh and then the operated hand is held with the opposite hand and brought to the center of the back.

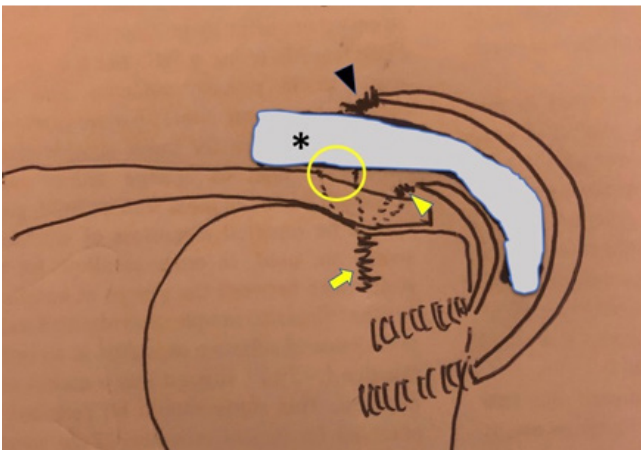
During the outpatient follow-up, only patients with worsening pain at bedtime and pain at rest while at the same time exacerbating the limitation of shoulder joint range of motion were treated with intra-articular injection of steroid (40 mg of triamcinolone acetonide) after confirming that there was no retear in the MRI scan [18].

**Patient Assessment**

All patients underwent preoperative imaging with simple radiographs and MRI. Clinical evaluations were performed on the day



**Fig. 4.** (A-C) The patch is placed on the exact site with knot pusher technique and position checking with arthroscope.



**Fig. 5.** The schematic diagram of onlay patch augmentation. Of the two suture limbs of medial anchor (yellow arrow), the more inward limb (yellow circle) is passed through the tendon and used for fixation of patch (asterisk), and the more lateral limb (yellow arrowhead) is used for the repair of native torn tendon. That is, the tendon is repaired with one limb from each of the two suture anchors (yellow arrow) and fixed by a lateral anchor, and the remaining limbs are passed through the patch graft and threads were tied up (black arrowhead). And then graft fixation was finished with suture bridge technique.

before surgery and at 6, 12, and 24 months postoperatively; a final functional evaluation was performed at a minimum of 12 months postoperatively. Clinical evaluations used the Constant-Murley (Constant) score; the shoulder index of the American Shoulder and Elbow Surgeons (ASES); and a visual analog scale (VAS) to assess the satisfaction of surgery (satisfaction VAS) and pain during active daily life (pain VAS). The VAS was scored from 0 to 10, with 0 indicating no pain and 10 indicating the worst pain in pain assessment. A value closer to 0 indicates it should not be recommended to people, and a value closer to 10 indicates it should be highly recommended.

For the evaluation of rotator cuff integrity, MRI scans were performed immediately after surgery, and then, 2 months after surgery, before the range of rehabilitation was increased, and thereafter, it was performed at 3 months, 6 months, and 1 year

after surgery. After 1 year after surgery, MRI examinations were performed every 6 months only if consent was given. Sugaya classification was used to analyze postoperative rotator cuff tendon integrity with the last follow-up MRI [19].

For various variables for clinical evaluation, preoperative values and values measured 12 months after surgery were compared, and each clinical evaluation value according to the occurrence of re-rupture was also compared. We used the size of the tear measured after arthroscopic debridement in the operating room instead of the size of the tear seen on MRI. However, we did not analyze the difference between the tear size in preoperative MRI scan and after arthroscopic debridement.

### Statistical Analyses

Mann-Whitney test, one of the nonparametric tests, was conducted to statistically compare continuous variables such as ASES score, Constant score, VAS for pain and VAS for satisfaction between two independent groups that do not follow a normal distribution. To compare the outcome variables before and after surgery, the paired t-test was performed for variables (ASES scores, Constant scores) that do follow a normal distribution and the Wilcoxon signed-rank test was conducted for variables (VAS for pain) that do not follow a normal distribution. The Fisher's exact test was performed to verify the correlation between the occurrence of retear and two variables (sex, whether the anatomical footprint is completely covered and whether the subscapularis is repaired concomitantly) and logistic regression analysis was performed to identify the risk factor of retear. Data analysis was performed using the IBM SPSS ver. 26.0 (IBM Corp.). A  $P < 0.05$  indicated statistical significance.

## RESULTS

A total of 24 patients met the inclusion criteria, including nine male patients and 15 female patients. The average follow-up period was 16.38 months (range, 12–45 months). The average age of

**Table 1.** Demographic data of patients

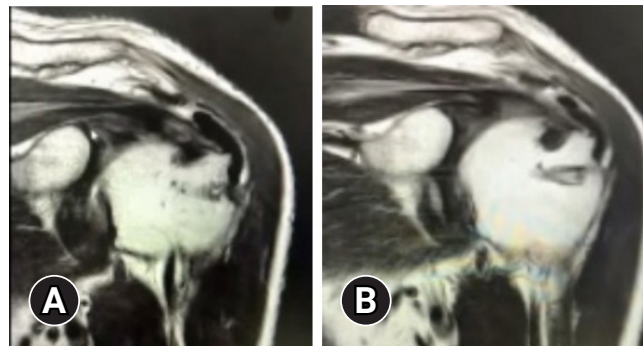
Variable	Value
Age (yr)	71.05 ± 4.31 (65–78)
Sex (male:female)	9:15
Tear size (cm)	
Medial–lateral tear	3.0 ± 0.44 (2.5–4)
Anterior–posterior tear	2.7 ± 0.26 (2.5–3.5)
Follow-up period after surgery (mo)	16.38 ± 8.0 (12–45)
Number of patients with subscapularis repair	5

Values are presented as mean ± standard deviation (range).

patients was 71.05 years old (Table 1). Among the 24 patients, eight patients (33.3%) were Sugaya type 1, 10 patients (41.7%) were type 2, two patients (8.3%) were type 3, three patients (12.5%) were type 4 and one patient (4.2%) was type 5 in the last follow-up MRI (Fig. 6). Retear rate was 25% (6/24) if Sugaya type 3 was categorized in the re-tear group, otherwise 16.7% (4/24) if Sugaya type 3 was categorized into intact (Table 2). Among the four patients with Sugaya type 4 or 5, one case was confirmed at 3-month follow-up and three cases were confirmed at 6-month follow-up. Two cases with Sugaya type 3 were confirmed at 12-month follow-up.

Regarding the coverage of anatomical rotator cuff footprint, complete coverage was accomplished in 17 patients. An intra-articular steroid injection was administered to four patients who showed severe continued pain and aggravated stiffness like frozen shoulder. No re-tear was found in these patients during the follow-up period. All patients showed significant improvement in ASES score, constant score and VAS for pain at last evaluation compared with preoperative evaluation. The average value of VAS for satisfaction was 7.3 of 10 (Table 3). Whether Sugaya type 3 was included in re-tear group or not, there was no significant difference in outcome variables and tear size between intact and re-tear groups during the follow-up period (Table 4). There was a statistically significant difference between the re-tear group and the intact group only in the constant score at last follow-up and improvement of VAS for pain when Sugaya type 3 was categorized into the re-tear group. While not statistically significant, the pain severity seemed to show more improvement in the patient group without re-tear when Sugaya type 3 was categorized into the intact group. The constant score also seemed to show more improvement in the patient group without re-tear regardless of whether Sugaya type 3 is considered a re-tear or not (Table 4).

After dividing the patients into two groups according to whether the subscapular tendon was repaired concomitantly, we compared whether there were any differences in all variables between the groups. Additionally, male patients had significantly higher postoperative satisfaction than female patients (Table 5).



**Fig. 6.** Postoperative rotator cuff integrity after onlay patch augmentation based on Sugaya [20] classification. (A) The Sugaya type 2 integrity in magnetic resonance imaging (MRI) scan. (B) The Sugaya type 3 integrity in MRI.

**Table 2.** Postoperative evaluation of rotator cuff integrity by Sugaya classification [20]

	Sugaya classification type				
	I	II	III	IV	VI
Number of patients (%)	8 (33.3)	10 (41.7)	2 (8.3)	3 (12.5)	1 (4.2)

**Table 3.** Comparison of preoperative and postoperative clinical outcome scores in entire study group

Variable	Preoperative	Last evaluation	P-value
ASES score	41.42 ± 8.49	65.21 ± 8.02	< 0.001
Constant-Murley score	51.58 ± 7.23	60.75 ± 7.16	< 0.001
Pain VAS score	6.95 ± 0.95	3.13 ± 1.39	< 0.001
Satisfaction VAS score	NA	7.27 ± 1.47	NA

Values are presented as mean ± standard deviation.

ASES: American Shoulder and Elbow Surgeons, VAS: visual analog scale, NA: not available.

In Fisher's exact test, the occurrence of re-tear did not show any correlation with sex, whether the anatomical footprint was completely covered and whether the subscapularis was repaired concomitantly (Table 6).

In logistic regression analysis, when Sugaya type 3 was regarded as re-tear as well as type 4 and 5 (when six patients showed a re-tear), only the degree of pain improvement showed a correlation (Table 7). When only Sugaya type 4 and 5 were regarded as re-tear, no risk factors that increase the likelihood of re-tear were identified. Other variables such as age, clinical scores, VAS scores, tear size, whether the anatomical footprint was completely covered and whether the subscapularis was repaired concomitantly did not show any correlation with the occurrence of re-tear in logistic regression analysis.

## DISCUSSION

As a result of treatment with OPA using the dermal allograft for

**Table 4.** Comparison of preoperative and postoperative clinical outcome scores between intact and retear groups

Variable	When Sugaya type 3 is considered as retear			When Sugaya type 3 is not considered as retear		
	Intact*	Retear <sup>†</sup>	P-value	Intact <sup>‡</sup>	Retear <sup>§</sup>	P-value
ASES score						
Preoperative	39.3 ± 8.6	43.8 ± 10.6	0.45	39.2 ± 8.1	46.5 ± 12.5	0.21
Last evaluation	66.4 ± 7.0	61.5 ± 10.3	0.25	65.6 ± 7.2	63.5 ± 12.6	0.79
Improvement value	25.8 ± 12.2	17.7 ± 5.2	0.09	25.2 ± 11.8	17.0 ± 5.7	0.14
Constant-Murley score						
Preoperative	51.6 ± 7.2	51.6 ± 8.1	0.78	51.2 ± 7.1	53.5 ± 8.4	0.34
Last evaluation	62.6 ± 5.9	55.2 ± 8.2	0.04	61.8 ± 6.2	55.8 ± 10.5	0.24
Improvement value	11.1 ± 9.8	3.5 ± 6.4	0.06	10.6 ± 9.6	2.3 ± 6.8	0.08
VAS pain						
Preoperative	7.0 ± 1.0	6.8 ± 0.8	0.67	7.0 ± 1.0	6.8 ± 1.0	0.63
Last evaluation	2.8 ± 1.1	4.2 ± 1.8	0.10	2.9 ± 1.1	4.3 ± 2.2	0.27
Improvement value	4.2 ± 1.3	2.7 ± 1.2	0.03	4.1 ± 1.3	2.5 ± 1.3	0.06
VAS satisfaction	7.6 ± 0.8	6.3 ± 2.5	0.16	7.3 ± 1.1	7.0 ± 2.9	0.85
Tear size						
Medial-lateral tear	2.9 ± 0.4	3.3 ± 0.6	0.20	2.9 ± 0.4	3.4 ± 0.5	0.10
Anterior-posterior tear	2.7 ± 0.3	2.8 ± 0.3	0.23	2.7 ± 0.3	2.9 ± 0.2	0.06

Values are presented as mean ± standard deviation.

Sugaya: Sugaya classification [20], ASES: American Shoulder and Elbow Surgeons, VAS: visual analog scale.

\*Intact group which include Sugaya type 1 and 2; <sup>†</sup>Retear group which include Sugaya type 3, 4, and 5; <sup>‡</sup>Intact group which include Sugaya type 1, 2, and 3; <sup>§</sup>Retear group which include Sugaya type 4 and 5.

**Table 5.** Comparison of variables according to whether subscapularis tendon is sutured and sex

Variable	Subscapularis is repaired			Comparison between sexes		
	Yes	No	P-value	Male	Female	P-value
Number of patients	5	19	NA	9	15	NA
Follow-up period (mo)	12.2 ± 0.4	17.5 ± 8.7	0.45	16.2 ± 6.1	16.5 ± 9.2	0.52
ASES score						
Preoperative	42.4 ± 11.8	39.9 ± 8.5	0.45	44.4 ± 11.1	38 ± 6.9	0.12
Last evaluation	61.8 ± 8.9	66.1 ± 7.8	0.33	67.2 ± 8.7	64 ± 7.6	0.32
Improvement value	14.6 ± 10.9	26.2 ± 10.5	0.08	22.8 ± 14.9	22.4 ± 9.2	0.68
Constant-Murley score						
Preoperative	55.6 ± 4.8	50.2 ± 7.5	0.18	51.3 ± 5.3	51.7 ± 8.3	0.86
Last evaluation	61.2 ± 7.3	60.6 ± 7.3	1.00	61.7 ± 7.5	60.2 ± 7.1	0.77
Improvement value	5.6 ± 7.8	10.1 ± 10	0.33	10.3 ± 9.6	8.5 ± 9.8	0.68
VAS pain						
Preoperative	7.2 ± 0.9	6.2 ± 0.8	0.08	6.6 ± 1	7.2 ± 0.9	0.16
Last evaluation	3.4 ± 1.1	3.1 ± 1.5	0.49	2.9 ± 1.4	3.3 ± 1.4	0.52
Improvement value	2.8 ± 0.8	4.1 ± 1.4	0.04	3.7 ± 1.6	3.9 ± 1.4	0.45
VAS satisfaction	7.5 ± 0.6	7.2 ± 1.6	0.89	8.0 ± 0.9	6.8 ± 1.6	0.03
Tear size						
Medial-lateral tear	3.2 ± 0.5	3.0 ± 0.4	0.41	2.9 ± 0.3	3.1 ± 0.5	0.48
Anterior-posterior tear	2.8 ± 0.4	2.7 ± 0.2	0.84	2.8 ± 0.3	2.6 ± 0.2	0.16

Values are presented as mean ± standard deviation.

NA: not available, ASES: American Shoulder and Elbow Surgeons, VAS: visual analog scale.

moderate to large RCTs in patients 65 years of age or older, Sugaya type 4 or 5 was found in 16.7% of patients. All patients showed improved clinical results at the last evaluation after surgery compared with before surgery. This indicates that the risk of retear increases when the degree of improvement in pain after surgery is relatively small.

To prevent retear, various methods are used, such as muscle advancement, bridging technique using patch graft and OPA [4]. After advent of the dermal allograft, patch augmentation using this approach has been widely applied in patients with poor tissue quality of massive RCTs [21]. The graft tissue is processed to render it acellular and therefore less immunogenic while the col-

**Table 6.** Fisher’s exact test for verification of the correlation between retear and three variables (sex, SSC repair, and anatomical footprint coverage)

	SSC repaired				Sex				Anatomical footprint coverage			
	No	Yes	OR	P-value	Male	Female	OR	P-value	Incomplete	Complete	OR	P-value
When Sugaya classification type 3 is considered as retear			1.27	1.00			0.7	1.00			0.4	0.63
Intact*	14	4			7	11			12	6		
Retear†	5	1			2	4			3	1		
When Sugaya classification type 3 is not considered as retear			1.33	1.00			0.54	0.66			0.78	1.00
Intact‡	16	4			7	13			14	6		
Retear§	3	1			2	2			3	1		

SSC: subscapularis, OR: odds ratio, Sugaya: Sugaya classification [20] for the integrity of rotator cuff after arthroscopic repair. \*Intact group which include Sugaya type 1 and 2; †Retear group which include Sugaya type 3, 4 and 5; ‡Intact group which include Sugaya type 1, 2 and 3; §Retear group which include Sugaya type 4 and 5.

**Table 7.** Logistic regression analysis for identification of retear risk factors after onlay patch augmentation

	Risk factor	OR	95% CI for OR	P-value
Retear group (Sugaya* type 4, 5) & intact group (Sugaya type 1, 2, 3)	Pain improvement	0.298	0.096–0.925	0.04
Retear group (Sugaya* type 3, 4, 5) & intact group (Sugaya type 1, 2)	Pain improvement	0.305	0.9–1.036	0.06

OR: odds ratio, CI: confidential interval, Sugaya: Sugaya classification [20] for the integrity of rotator cuff after arthroscopic repair.

lagen extracellular matrix is left intact to provide strength and a scaffold into which new host tissue can regenerate [20]. The *in vivo* behavior of the human dermal allograft used for cuff repairs in human is not known. However, animal studies have shown promising results. This study shows that at 6 months, the use of human dermal allograft or the autologous tendon for the full-thickness infraspinatus tears mimicked normal tendon structure grossly and histologically [22].

It is important to consider tissue mobility, quality and tension when determining the ideal RCR method with patch graft. If the rotator cuff tendon is unable to mobilize enough to cover the footprint or there is excessive tension on the mobilizable tendon, SCR or bridging technique using patch graft should be indicated over primary repair. If the tissue quality is poor for the somehow repairable tear in terms of mobility, it is necessary to provide additional thickness by OPA as we used in this study [23].

In a systematic review comparing bridging and augmentation techniques with patch graft in 12 studies, the authors concluded that bridging is a better option than augmentation in irreparable cuff tear as the overall healing rate of patch augmentation was 64% and that of bridging was 77.9% [24]. However, this study was conducted for patients with large to massive RCTs and there was no statistically significant difference (P=0.205) in terms of tendon healing. In our study, the retear rate changed according to whether Sugaya type 3 was assigned to the retear group [25]. The

retear rate was 16.7% (4/24) if Sugaya type 3 was categorized as intact and 25% (6/24) if Sugaya type 3 was categorized in the retear group.

Among the six retear cases, retear was confirmed at 3-month follow-up in one case, 6-month follow-up in three cases and 12-month follow-up in two cases. Two cases with Sugaya type 3 were confirmed at 12-month follow-up. The two patients showed Sugaya type 2 integrity at 6-month follow-up MRI scan and shifted to type 3 at 12-month follow-up. These results suggest that further follow-up of all patients may detect changes in rotator cuff integrity. Although long-term follow-up up to at least 15 months was needed for some cases to compare the outcome with previous studies, the cases in our study that underwent OPA had a low retear rate.

The retear rate was correlated with age and initial tear size in many previous studies. Boileau et al. [6] reported a retear rate of 5% in patients younger than 55 years, 25% in patients between 55 and 64 years and 57 % in patients older than 65 years of age. De-Franco et al. [26] reported that patients in the no tear group were significantly younger than those in the recurrent tear group and suggested that age was a predictor of retear after RCR. Diebold et al. [27] reported the rate of rotator cuff retears is low in patients <50 years of age. There was a linear relationship between age and rotator cuff retears in patients 50 to 69 years of age, and it increases substantially in patients ≥70 years old. In the current



study, patients with massive RCT had a higher retear rate and worse clinical outcomes compared with those with small to medium and large RCT regardless of the age or sex. Men and women with massive tears in the group of patients in their 60s and men with massive tears and women with large and massive tears in the group of patients in their 70s were at high risk for repeated tearing, with retear rates greater than 70% in each of these populations [28]. According to Chona et al. [29], the retear rate for medium sized tears increased for approximately 15 months, reaching approximately 20%. The retear rate for large tears progressed for about 12 months and approached 40%.

There was no correlation in the re-tear rate depending on whether the anatomical footprint was completely covered. We excluded patients with pseudoparalysis patient in which the force couple of the rotator cuff, one of the essential elements for actively elevating the arm, was disrupted. We speculate that the main reason for the patients in our study to undergo surgery was because of pain rather than the decline in the ability to lift the arm. Thus, we are concerned about the occurrence of re-tear because of the deterioration in the pain and clinical function rather than the re-tear itself. Although whether OPA can reduce the tension applied to the repaired site or the resulting re-tear has not been determined, it is assumed that it contributes to reducing pain caused by external impingement to the repaired site that can occur during rehabilitation. To support this inference, there was no difference in clinical outcome according to the presence or absence of re-tear in this study.

The retear rate is also related to concomitant subscapularis tear. According to Rhee et al., a higher retear rate was reported in the patients with concomitant subscapularis tears underwent bridging patch graft. There was subscapularis tear in all cases of our study. However, the retear rate was lower than that of previous studies (36%–41.7%) [30,31]. This may be due to differences in the onlay and bridging patch graft technique.

In our study, although male patients had significantly higher postoperative satisfaction than female patients, the occurrence of retear did not show any correlation with sex and whether the subscapularis was repaired concomitantly. Whether to judge Sugaya type 3 as retear is controversial [25], but it may be meaningful to investigate risk factors for retear. When Sugaya type 3 was regarded as retear as well as type 4 and 5, that is, when 6 cases were return, only the degree of pain improvement was correlated. When only Sugaya type 4 and 5 were regarded as retear, risk factors that increase the likelihood of retear were not identified. Other variables such as age, clinical scores, VAS scores, tear size and whether the subscapularis was repaired concomitantly did not show any correlation with the occurrence of retear.

As we mentioned, the tendon is repaired on the lateral row with one limb from each of the two suture anchors and fixed by a lateral anchor; the remaining limbs on the medial row without knot are passed through the patch graft, tied by the knot pusher technique and fixed to the humerus with another lateral anchor. It may likely be possible to reduce hypoxic stress and promote healing of the RCT by making the first knot for the limb on the medial row after passing graft. In addition, according to Petri et al., this may be also due to the bumper effect of the patch (Fig. 5) [13]. That is, although the repaired rotator cuff is damaged, the allograft remaining in the greater tubercle may prevent the greater tubercle from direct collision with the surrounding acromion or the top of the glenoid and relieve the pain when the shoulder is abducted.

Graft thickness is important for optimizing the outcome of SCR with dermal allograft, although there was no previous study on the correlation between the thickness of dermal allograft and the retear rate of repaired tendon in the treatment using dermal allograft as an augmentation. Several studies on SCR report that the reconstructed upper joint capsule with a thickness of 4 mm or more produced better clinical and biomechanical results than those with a thickness of less than 4 mm [32-35]. Thus, we also tried to keep the thickness of the inserted dermal allograft at least 5 mm. If that was not possible, the dermal allograft is folded once, and the edges were tied up by running suture technique.

This study has several limitations. This was a retrospective study with a small number of patients and a short follow-up period. Further analysis should be performed using a mid- to long-term follow-up. While it was not possible to provide a meaningful result because it was not possible to make an accurate measurement method, the dermal allograft tends to thin over time. These results suggest that further follow-up of all patients may detect changes in rotator cuff integrity (Fig. 6). There was no control group without OPA. Patients over 65 years of age with moderate to severe RCTs who had undergone surgery without OPA at this hospital had a high rate of retear within 6 months after surgery, followed by no follow-up or artificial joint replacement. It was difficult to find a control group because the follow-up period was insufficient. The severity of fatty infiltration and muscle atrophy in preoperative MRI scan were not included in this study; both variables might affect the rate of retear after OPA. Some patients had preoperative MRI scans performed at our hospital, but others did not. Because MRI imaging protocols are different for each institution and image quality was also different, it was possible to measure the size of the rupture, but we could not accurately measure fatty degeneration or muscle atrophy.

Despite the above-mentioned limitations, our OPA was able to obtain good clinical and imaging results, and in terms of reducing re-tear and increasing the healing rate of repaired tendons, additional OPA after repair procedures are thought to be helpful in concluding that it will not have a worse effect in the surgical treatment of patients over the age of 65 who have more than 2.5-cm-sized tear. In moderate to large RCT in elderly patients, OPA leads to improvement of clinical outcomes. Although the impact of onlay augmentation on re-tear rate was not evaluated, it is assumed that re-rupture itself did not significantly affect the clinical outcomes during the short-term follow-up period.

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