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Clinical and Magnetic Resonance Imaging Outcomes of Arthroscopic Intratendinous Human-Derived Collagen Injection for Partial-Thickness Rotator Cuff Tears: A Retrospective Comparative Study

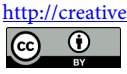
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Abstract

Background: Partial-thickness rotator cuff tears (PTRCTs) may progress despite symptomatic improvement. Human-derived collagen has been proposed as a biologic augmentation strategy to promote tendon remodeling; however, evidence for direct intratendinous application in PTRCTs remains limited. This study compared clinical and structural outcomes of arthroscopic acromioplasty with intratendinous human-derived collagen injection versus acromioplasty alone in articular-sided PTRCTs. **Methods:** This retrospective comparative study included 60 patients with symptomatic articular-sided PTRCTs involving less than 50% of tendon thickness: 30 underwent acromioplasty with intratendinous human-derived collagen injection (Group 1) and 30 underwent acromioplasty alone (Group 2). Clinical outcomes were assessed using the visual analog scale (VAS) and American Shoulder and Elbow Surgeons (ASES) score. Structural changes were evaluated using 3.0-T magnetic resonance imaging (MRI) at 6 months and categorized as decreased (>2-mm reduction), unchanged (≤2-mm change), or increased (>2-mm enlargement). Postoperative clinical outcomes were compared using analysis of covariance adjusted for baseline scores. **Results:** Both groups improved significantly in VAS and ASES scores at 6 months (all $p < 0.001$), with no significant between-group difference after baseline adjustment ($p = 0.597$ and $p = 0.432$, respectively). The overall distribution of MRI changes showed a borderline, nonsignificant difference ($p = 0.051$), whereas a post hoc exploratory dichotomous analysis found a higher frequency of >2-mm tear-size reduction in Group 1 than in Group 2

(36.7% vs. 10.0%; unadjusted $p = 0.030$; odds ratio, 5.21; 95% confidence interval, 1.28 - 21.24). **Conclusions:** No additional short-term clinical benefit of collagen injection was detected in pain or function compared with acromioplasty alone. An exploratory post hoc analysis showed a higher proportion of >2-mm tear-size reduction on MRI (unadjusted $p = 0.030$); this hypothesis-generating finding requires prospective confirmation. Larger prospective studies with longer follow-up are required.

Keywords

Partial-Thickness Rotator Cuff Tear, Human-Derived Collagen, Intratendinous Injection, Acromioplasty, Magnetic Resonance Imaging

1. Introduction

Rotator cuff tears are broadly classified as full-thickness or partial-thickness tears. Partial-thickness rotator cuff tears (PTRCTs) are a common cause of shoulder pain and functional impairment, particularly in middle-aged and older adults. The prevalence of PTRCTs diagnosed by magnetic resonance imaging (MRI) has been reported to range from 13% to 32%, with prevalence increasing with age [1]. PTRCTs may involve either the articular or bursal surface and are more commonly associated with degenerative tendon changes than with acute trauma.

Neer described rotator cuff disease as a continuum beginning with tendinopathy, progressing to partial-thickness tearing, and ultimately to full-thickness tearing [2]. Conservative treatment, including physical therapy, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroid injections, is generally recommended as first-line management; however, persistent pain and functional limitation remain in a substantial proportion of patients [3].

For symptomatic PTRCTs refractory to nonoperative treatment, surgical options include arthroscopic debridement, transtendinous repair, and completion of the tear followed by repair. Each strategy has inherent limitations. Tear-completion repair sacrifices residual intact tendon fibers, whereas transtendinous repair may be associated with postoperative stiffness or overtensioning [4]. Furthermore, structural healing may be inconsistent in degenerative tendon tissue with impaired biologic healing capacity.

Recent biologic therapies have focused on enhancing the intrinsic healing potential of the rotator cuff tendon. Collagen is the principal structural component of the tendon extracellular matrix and consists predominantly of type I collagen, which provides tensile strength and biomechanical stability [5]. Degenerative PTRCTs demonstrate histologic abnormalities including disorganized collagen architecture, increased type III collagen, and reduced cellularity [6]. Exogenous collagen may provide a scaffold for cellular infiltration and matrix remodeling, and preclinical studies have suggested that collagen-based scaffolds can improve tendon healing and biomechanical strength [7] [8].

However, clinical evidence for direct arthroscopic intratendinous injection of human-derived collagen, specifically micronized acellular dermal matrix (mADM), in PTRCTs remains limited. The purpose of this study was to compare clinical and MRI-based structural outcomes after arthroscopic acromioplasty combined with intratendinous human-derived collagen injection versus arthroscopic acromioplasty alone in patients with symptomatic articular-sided PTRCTs involving less than 50% of tendon thickness. We hypothesized that collagen augmentation would be associated with greater structural improvement on follow-up MRI without necessarily producing additional short-term improvement in patient-reported clinical outcomes.

2. Materials and Methods

2.1. Study Design and Patients

This retrospective comparative study was approved by the Institutional Review Board (IRB) of Himchan Hospital (IRB No. 116655-01-202603-01), and the requirement for additional consent was waived (see Ethics Statement).

We retrospectively reviewed the medical records of all patients who underwent arthroscopic surgery for articular-sided partial-thickness rotator cuff tears at our institution between April 2024 and May 2025 due to persistent unilateral shoulder pain despite at least 6 weeks (range, 6 weeks to 3 months) of conservative treatment. All patients who met the inclusion criteria during the study period were consecutively enrolled, regardless of surgical order. Treatment was not randomized; the choice between acromioplasty with intratendinous collagen injection and acromioplasty alone was made by each patient after consultation with the operating surgeon.

Patients who did not undergo follow-up magnetic resonance imaging (MRI) at 6 months postoperatively were excluded from the analysis. Of the 65 patients initially identified, two were excluded before treatment allocation based on the exclusion criteria, and three (two in Group 1 and one in Group 2) were excluded because 6-month follow-up MRI data were absent. Consequently, a total of 60 patients were included in the final analysis. Of these, 30 patients underwent arthroscopic acromioplasty combined with intratendinous injection of human-derived collagen (Group 1), while the remaining 30 patients underwent arthroscopic acromioplasty alone (Group 2). All procedures were performed by a single experienced shoulder surgeon.

All patients underwent history taking, physical examination, preoperative anteroposterior and axial shoulder radiographs, and preoperative and postoperative shoulder MRI. Eligible tears showed high signal intensity involving only part of the tendon thickness on T2-weighted or proton-density fat-suppressed MRI without full-thickness discontinuity and were classified as Ellman grade II or lower, with involvement of less than 50% of tendon thickness [9]. Patients were required to have functional limitation and persistent symptoms despite conservative treatment.

Exclusion criteria were: 1) active infection; 2) humeral deformity affecting assessment of rotator cuff function; 3) neurologic conditions, including significant cognitive impairment or paralysis, or systemic disease such as heart failure or severe pulmonary disease that limited postoperative exercise or daily activity; and 4) a history of alcohol or drug abuse.

2.2. Magnetic Resonance Imaging Evaluation

Preoperative MRI was used for diagnosis, and follow-up MRI was obtained at 6 months postoperatively to evaluate structural changes while avoiding the early postoperative inflammatory period. All examinations were performed at the same institution using a 3.0-T MRI system. Oblique coronal, oblique sagittal, and axial fast spin-echo T2-weighted sequences and oblique coronal T1-weighted sequences were used to assess tear size.

Tear extent was assessed on oblique coronal and oblique sagittal MRI images. For each patient, the larger tear extent measured in either plane was used as the tear size at baseline and follow-up. This measurement did not represent tear depth through the tendon thickness. The baseline tear size reported in Table 1 was also based on this measurement method. According to the criteria described by Maman *et al.* [10], changes in tear size were classified as decreased (reduction of >2 mm), unchanged (absolute change of ≤2 mm), or increased (increase of >2 mm). No patients in the present cohort exhibited discordant changes, defined as a decrease in tear extent in one plane and an increase in the other; therefore, no additional classification criteria were required. Furthermore, no patients exhibited a change of exactly 2.0 mm.

Table 1. Baseline characteristics and clinical outcomes.

Variable	Group 1 (n = 30)	Group 2 (n = 30)	*p*-value
Age, years	60.84 ± 2.91	62.10 ± 2.87	0.097
Sex, M/F	12/18	13/17	0.793
Symptom duration, months	9.60 ± 0.84	9.43 ± 0.70	0.387
Preoperative tear size, mm	6.09 ± 0.68	6.11 ± 0.74	0.942
Preoperative VAS	6.96 ± 0.47	6.66 ± 0.40	0.010
Adjusted VAS difference (Group 1 - Group 2), 95% CI	0.07 (−0.21 to 0.35)		0.597
Postoperative VAS	2.19 ± 0.52	2.15 ± 0.49	0.767
Adjusted postoperative VAS[a]	2.20 (2.01 to 2.39)	2.13 (1.94 to 2.32)	0.597
Preoperative ASES	52.81 ± 3.94	49.17 ± 5.09	0.003
Adjusted ASES difference (Group 1 - Group 2), 95% CI	−1.14 (−4.04 to 1.75)		0.432
Postoperative ASES	86.39 ± 5.57	88.77 ± 5.15	0.092

Continued

Adjusted postoperative ASES[a]	87.01 (85.03 to 88.98)	88.15 (86.18 to 90.12)	0.432

Values are presented as mean ± standard deviation or number of patients. [a]Estimated marginal means (95% confidence interval) obtained from analysis of covariance adjusted for the corresponding baseline score. Between-group differences were calculated as Group 1 minus Group 2 using the baseline-adjusted ANCOVA model.

Preoperative and postoperative MRI examinations were obtained under comparable imaging conditions, including magnetic field strength and slice thickness, and measurements were performed using the institutional picture archiving and communication system. MRI assessments were performed independently by two orthopedic surgeons, both of whom were blinded to treatment allocation. The observers did not have access to each other's measurements. For primary analyses, tear size was defined as the mean of the two observers' measurements, and the structural change category was derived by applying the 2-mm threshold to this averaged value; category-level agreement between the two observers' independent measurements was assessed separately as part of the reliability analysis.

2.3. Human-Derived Collagen

The human-derived collagen product used in this study was S Gen Inject (MedPark Co., Ltd., Busan, Republic of Korea), an injectable suspension composed of micronized acellular dermal matrix (mADM) and sterile water. The material is derived from legally procured human dermal tissue processed in accordance with the Act on Safety and Management of Human Tissue of the Republic of Korea. Human dermal tissue undergoes decellularization using sodium dodecyl sulfate to remove cellular components and minimize immunogenicity. The resulting acellular dermal matrix is freeze-dried and micronized into particles with a mean size of approximately 100 μm, then mixed with sterile water at a predetermined ratio to produce the injectable formulation.

2.4. Surgical Procedure

Arthroscopy was performed under brachial plexus block anesthesia with the patient in the semi-lateral position. Standard posterior viewing and anterolateral portals were used, with an additional lateral portal when required (**Figure 1**). After identification of the articular-sided partial-thickness tear, the lesion was marked with a spinal needle introduced through the anterolateral portal (**Figure 2**). The arthroscope was then transferred to the subacromial space, and arthroscopic acromioplasty was performed. In Group 1, 3 mL of S Gen Inject was slowly injected intratendinously through the spinal needle, with the needle tip positioned within the supraspinatus tear site. Group 2 underwent the same arthroscopic acromioplasty without collagen injection. The surgical procedures performed were identical between the two groups except for collagen injection, and no other concomitant procedures (e.g., tear debridement or biceps procedures) were performed in either group.

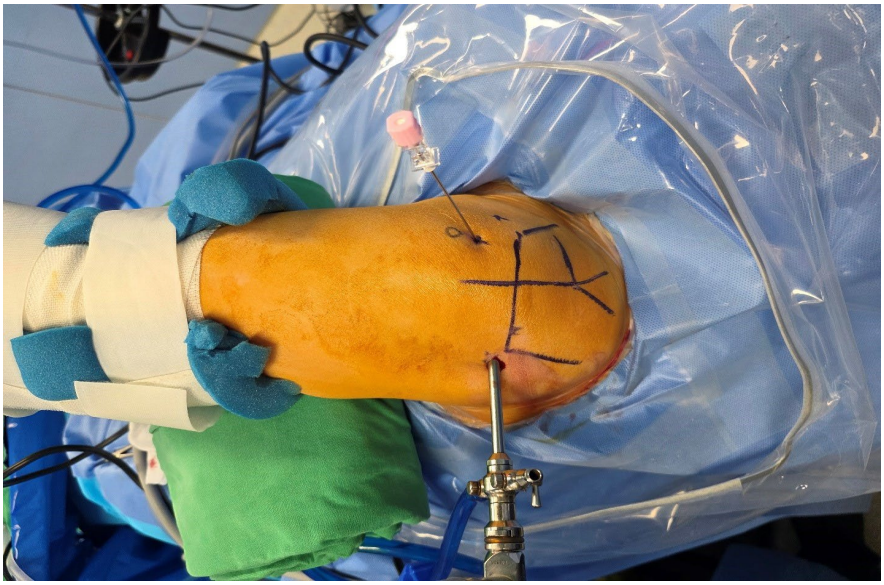


Figure 1. Intraoperative photograph during shoulder arthroscopy showing the semi-lateral patient position and portal placement for intratendinous collagen injection.

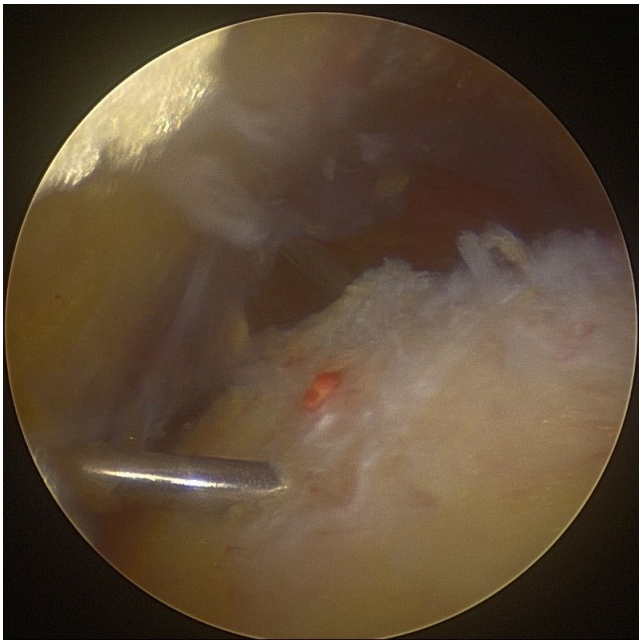


Figure 2. Arthroscopic view demonstrating a spinal needle positioned within the partial-thickness supraspinatus tendon tear for intratendinous collagen injection.

2.5. Rehabilitation

All patients followed the same home-based rehabilitation protocol. Pendulum exercises and posterior capsular stretching were initiated first. Once approximately 80% of pain-free passive range of motion had been restored in the operated shoulder, resistance-band strengthening exercises were added. NSAIDs were permitted for intolerable exercise-related pain, whereas no additional injections into the operated shoulder were allowed during follow-up.

2.6. Clinical Assessment

Patients were evaluated at 2 weeks, 6 weeks, 3 months, and 6 months postoperatively. The primary clinical analysis was based on the 6-month visit, which coincided with follow-up MRI. Pain and shoulder function were assessed using the visual analog scale (VAS) and American Shoulder and Elbow Surgeons (ASES) score. Clinical assessments were performed by the operating surgeon. Postoperative adverse events, including infection, inflammatory reactions, shoulder stiffness, and reoperation, were evaluated by retrospective review of postoperative clinic notes and follow-up medical records at the scheduled visits through 6 months.

2.7. Statistical Analysis

Continuous variables are presented as means and standard deviations, and categorical variables as frequencies and percentages. Between-group comparisons of continuous variables were performed using independent-samples t tests. Categorical variables were compared using the chi-square test or an exact test when expected cell counts were small. Within-group changes in VAS and ASES scores from baseline to 6 months were assessed using paired t-tests.

Because significant baseline differences were observed in VAS and ASES scores, analysis of covariance (ANCOVA) was performed to compare postoperative outcomes after adjusting for the corresponding baseline score. Postoperative VAS or ASES score was entered as the dependent variable, treatment group as the fixed factor, and the corresponding baseline score as the covariate. Adjusted postoperative values are reported as estimated marginal means with 95% confidence intervals (CIs). Adjusted between-group differences (Group 1 minus Group 2) and their 95% CIs were estimated from the ANCOVA model to quantify the magnitude and precision of the treatment effect.

MRI structural change was analyzed in three categories: decreased (>2-mm reduction), unchanged (≤2-mm absolute change), and increased (>2-mm enlargement). Because some expected cell counts were <5, the Fisher-Freeman-Halton exact test for a 2×3 contingency table was used as the primary analysis rather than Pearson's chi-square test.

Following examination of the initial three-category MRI results, a post hoc exploratory dichotomous analysis was performed to further examine the proportion of patients with structural improvement. Structural improvement was defined as a >2-mm reduction in tear size and was dichotomized against all other outcomes. The frequency of structural improvement was compared between groups using Fisher's exact test. Odds ratios (ORs) and 95% CIs were calculated with Group 2 as the reference group. Interobserver reliability for continuous preoperative tear-size measurements was assessed using a two-way random-effects, absolute-agreement, single-measure intraclass correlation coefficient [ICC (A, 1)]; the 95% CI was estimated using 20,000 bootstrap resamples. Agreement for the three-category MRI structural-change classification and for the dichotomous structural-im-

provement endpoint was assessed using Cohen's kappa coefficient (κ), together with raw percentage agreement. All tests were two-sided, and $p < 0.05$ was considered statistically significant for the prespecified analyses. No adjustment for multiple comparisons was performed. Consequently, the unadjusted p-value from the post hoc dichotomous MRI analysis was considered exploratory and hypothesis-generating rather than confirmatory.

3. Results

A total of 60 patients were included in the final analysis, with 30 patients in each group. There were no significant between-group differences in age, sex distribution, symptom duration, or preoperative tear size. Mean ages, male-to-female distributions, symptom durations, and mean preoperative tear sizes for Groups 1 and 2 were 60.84 ± 2.91 and 62.10 ± 2.87 years ($p = 0.097$), 12:18 and 13:17 ($p = 0.793$), 9.60 ± 0.84 and 9.43 ± 0.70 months ($p = 0.387$), and 6.09 ± 0.68 and 6.11 ± 0.74 mm ($p = 0.942$), respectively.

Baseline clinical scores differed significantly between groups. Preoperative VAS and ASES scores were significantly higher in Group 1 than in Group 2 (6.96 ± 0.47 vs. 6.66 ± 0.40, $p = 0.010$; 52.81 ± 3.94 vs. 49.17 ± 5.09, $p = 0.003$, respectively).

Both groups demonstrated significant clinical improvement at 6 months. VAS score decreased from 6.96 ± 0.47 to 2.19 ± 0.52 in Group 1 and from 6.66 ± 0.40 to 2.15 ± 0.49 in Group 2 (both $p < 0.001$). ASES scores increased from 52.81 ± 3.94 to 86.39 ± 5.57 in Group 1 and from 49.17 ± 5.09 to 88.77 ± 5.15 in Group 2 (both $p < 0.001$). The unadjusted postoperative VAS and ASES scores did not differ significantly between the groups ($p = 0.767$ and $p = 0.092$, respectively). No infections, inflammatory reactions, shoulder stiffness, or reoperations were documented in Group 1 (0/30, 0%) or Group 2 (0/30, 0%) during the 6-month follow-up period.

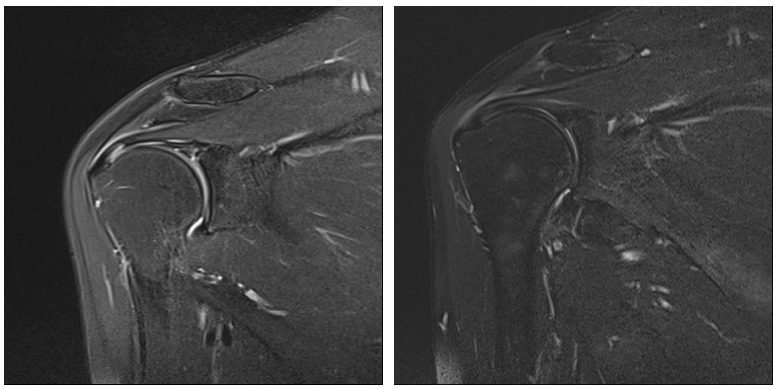
After adjustment for baseline scores using ANCOVA, the estimated marginal mean postoperative VAS score was 2.20 (95% CI, 2.01 - 2.39) for Group 1 and 2.13 (95% CI, 1.94 - 2.32) for Group 2, with no significant between-group difference ($p = 0.597$). The adjusted postoperative ASES scores were 87.01 (95% CI, 85.03 - 88.98) and 88.15 (95% CI, 86.18 - 90.12) for Groups 1 and 2, respectively ($p = 0.432$) (Table 1). The baseline-adjusted between-group difference (Group 1 minus Group 2) was 0.074 points for VAS (95% CI, −0.205 to 0.353; $p = 0.597$) and −1.143 points for ASES (95% CI, −4.037 to 1.750; $p = 0.432$).

On follow-up MRI, a >2-mm reduction in tear size was observed in 11 patients (36.7%) in Group 1 and 3 patients (10.0%) in Group 2 (Figure 3). Tear size remained unchanged in 17 (56.7%) and 25 (83.3%) patients in Groups 1 and 2, respectively, whereas >2-mm enlargement occurred in two patients (6.7%) in each group. The overall three-category distribution showed a borderline but nonsignificant between-group difference on the Fisher-Freeman-Halton exact test ($p = 0.051$) (Table 2).

Table 2. MRI structural outcomes.

MRI tear-size change	Group 1 (n = 30)	Group 2 (n = 30)	*p*-value
Decrease (>2 mm)	11 (36.7%)	3 (10.0%)	
Unchanged (≤2 mm)	17 (56.7%)	25 (83.3%)	0.051[a]
Increase (>2 mm)	2 (6.7%)	2 (6.7%)	
Structural improvement (>2-mm decrease)	11/30 (36.7%)	3/30 (10.0%)	0.030[b]
Odds ratio (95% CI)	5.21 (1.28 - 21.24)	Reference	

[a]Fisher-Freeman-Halton exact test for the overall 2 × 3 distribution (exact $p = 0.05048$, reported as $p = 0.051$). [b]Post hoc exploratory Fisher's exact test comparing >2-mm tear-size reduction with all other outcomes; *p*-value unadjusted for multiple comparisons.



(a) (b)

Figure 3. Representative oblique coronal fat-suppressed T2-weighted shoulder MRI. (a) Preoperative MRI showing increased signal intensity and an articular-sided partial-thickness tear at the supraspinatus footprint. (b) Six-month postoperative MRI showing decreased extent of the tear-related high-signal lesion and improved tendon continuity.

In the post hoc exploratory dichotomous analysis, a >2-mm reduction in tear size was observed in 11 patients (36.7%) in Group 1 and 3 patients (10.0%) in Group 2 (unadjusted $p = 0.030$; OR, 5.21; 95% CI, 1.28 - 21.24). This comparison was conducted after the initial three-category analysis and was not adjusted for multiple comparisons; accordingly, the finding is exploratory rather than confirmatory.

Interobserver reliability was excellent. For continuous preoperative tear-size measurements, ICC (A, 1) was 0.985 (95% CI, 0.976 - 0.991). Mean preoperative tear size was 6.10 mm for Observer 1 and 6.09 mm for Observer 2; the mean absolute difference between observers was 0.09 mm (maximum, 0.20 mm). Agreement for the three-category MRI structural-change classification was 96.7% (58/60), with $\kappa = 0.929$ (95% CI, 0.834 - 1.000). The two discordant cases were both disagreements between the unchanged and increased categories; no disagreement involved the structural-improvement category. Accordingly, agreement for the dichotomous structural-improvement endpoint (>2-mm decrease vs. all other out-

comes) was 100% (60/60; $\kappa = 1.000$).

4. Discussion

The principal finding of this study was that both arthroscopic acromioplasty with intratendinous human-derived collagen injection and acromioplasty alone produced significant improvements in pain and shoulder function, whereas baseline-adjusted postoperative VAS and ASES scores did not differ between groups. The primary three-category MRI analysis did not reach statistical significance ($p = 0.051$). A post hoc exploratory dichotomous analysis found a >2-mm reduction in tear size in 36.7% of patients in the collagen group versus 10.0% in the acromioplasty-alone group (unadjusted $p = 0.030$). Because this comparison was conducted after review of the initial results without multiplicity adjustment, it provides a hypothesis-generating signal rather than confirmatory evidence of a structural treatment effect.

Structural preservation or recovery may be clinically relevant in PTRCTs because these lesions are not necessarily static. Despite preservation of partial tendon continuity, PTRCTs may cause substantial pain. Gotoh *et al.* [11] reported higher levels of afferent nerve pain mediators in the subacromial bursa of patients with partial-thickness tears than in those with full-thickness tears. Longitudinal studies have also demonstrated that partial-thickness tears can enlarge over time and progress to full-thickness tears. Frandsen *et al.* [12] reported progression in 42% of PTRCTs and progression to full-thickness tearing in 29% during long-term conservative follow-up. Similarly, Mall *et al.* [13] demonstrated that the likelihood of progression increased with greater tendon involvement. These observations support consideration of the structural course of the tendon, in addition to symptom relief, as an important treatment outcome.

Although arthroscopic acromioplasty with or without debridement can provide satisfactory symptomatic improvement in patients with PTRCTs, it may not necessarily prevent structural progression of the residual tendon. Weber [14] reported that, among patients with significant PTRCTs involving ≥50% of tendon thickness, healing of the partial tear was not observed at second-look arthroscopy after debridement and acromioplasty, and three patients subsequently developed further tearing of the residual cuff. Similarly, Kartus *et al.* [15] reported progression to full-thickness tears in 9 of 26 patients (34.6%) who underwent ultrasonographic follow-up at a mean of 101 months after arthroscopic acromioplasty and debridement. Moreover, Ranebo *et al.* [16], in a mean 22-year follow-up after acromioplasty without tendon repair, observed tear progression in 42% of patients with partial-thickness tears despite generally favorable long-term clinical outcomes. Collectively, these findings indicate that symptomatic improvement after acromioplasty does not necessarily imply structural healing or prevention of tear progression, highlighting the potential value of therapeutic strategies aimed at preserving residual tendon integrity. This distinction is particularly relevant to the present study, in which both treatment groups demonstrated substantial clinical

improvement, whereas the patterns of structural change on follow-up MRI differed between groups.

Short-term improvements in pain and function may largely reflect the symptomatic effects of acromioplasty and postoperative rehabilitation rather than changes in tendon structure. VAS and ASES scores improved in both groups, but no additional short-term clinical benefit of collagen augmentation was detected after baseline adjustment. The adjusted between-group differences were small (VAS, 0.074 points [95% CI, −0.205 to 0.353]; ASES, −1.143 points [95% CI, −4.037 to 1.750]). These confidence intervals did not encompass the magnitudes of commonly reported minimal clinically important difference (MCID) benchmarks for rotator cuff disorders (approximately 1.4 points for VAS and 11 - 17 points for ASES). However, MCID thresholds depend on the patient population and are generally derived from within-patient changes; comparison with between-group effects is therefore contextual and does not establish treatment equivalence. The post hoc exploratory MRI analysis identified a higher frequency of tear-size reduction exceeding 2 mm in the collagen group, but this observation cannot establish a structural treatment effect.

A recent prospective randomized trial of human-derived collagen augmentation in rotator cuff repair also reported no significant superiority in final pain or functional scores, despite better MRI-based tendon integrity in the collagen-treated group [17]. That study involved repaired full-thickness tears and differs from the present cohort. Together with the exploratory nature of our MRI results, this comparison raises a hypothesis about potential structural effects of collagen augmentation that requires prospective confirmation.

The present study differs from much of the existing collagen-augmentation literature in an important respect. Previous studies have frequently evaluated tendon-to-bone healing after rotator cuff repair or have used animal-derived collagen products. In the present study, human-derived mADM was injected directly into the residual tendon of articular-sided PTRCTs involving <50% of tendon thickness without performing rotator cuff repair. Accordingly, the observed MRI changes cannot be attributed to mechanical restoration by sutures and may instead reflect structural remodeling within the residual tendon.

Nevertheless, reduction in tear size on MRI should not be interpreted as histologically confirmed tendon healing. The primary three-category MRI analysis was not statistically significant ($p = 0.051$). The dichotomous comparison of >2-mm reduction versus all other outcomes was introduced post hoc after examination of the initial results and yielded an unadjusted p-value of 0.030. In the absence of multiplicity adjustment, this finding is exploratory and should not be interpreted as confirmatory evidence of a structural benefit or as proof of tendon regeneration.

High interobserver reliability supports the reproducibility of MRI measurements in this cohort. However, reproducibility does not establish that a tear-size reduction exceeding 2 mm represents a clinically important improvement, nor does it demonstrate histologic tendon regeneration.

The divergence between similar 6-month clinical scores and different structural outcomes generates an important hypothesis. The clinical value of collagen augmentation may not lie primarily in additional short-term pain relief, but potentially in the preservation of residual tendon tissue or reduction of subsequent tear progression. If confirmed, the therapeutic objective in selected PTRCTs could extend beyond symptom modification toward tendon preservation. Long-term serial MRI studies are required to determine whether the structural changes observed in this study are sustained and whether they translate into lower rates of tear enlargement, progression to full-thickness tearing, or subsequent surgery.

This study has several limitations. First, its retrospective, nonrandomized design introduces the potential for selection bias and residual confounding. Baseline VAS and ASES scores differed between groups, although these differences were addressed using ANCOVA. Second, this was a single-center study with a relatively small sample size, which limits generalizability and statistical power. Third, the 6-month follow-up was relatively short and does not establish whether the observed MRI changes persist or prevent long-term tear progression. Fourth, although interobserver reliability was excellent, the 2-mm MRI threshold remains susceptible to measurement variability and does not directly establish biologic tendon healing. Fifth, clinical assessments were performed by the operating surgeon and were not independently blinded, introducing the possibility of observer bias in the clinical outcomes. Finally, tear-size reduction was used as an imaging marker of structural improvement; histologic regeneration and biomechanical properties of the tendon were not directly assessed. Despite these limitations, this study provides comparative clinical and serial MRI data after direct arthroscopic intratendinous administration of human-derived collagen in articular-sided PTRCTs involving less than 50% of tendon thickness. The post hoc exploratory observation of a higher frequency of >2-mm tear-size reduction after collagen augmentation, despite similar short-term clinical outcomes, warrants evaluation in prospectively designed studies with prespecified MRI endpoints.

5. Conclusion

In patients with articular-sided PTRCTs, both arthroscopic acromioplasty alone and acromioplasty combined with intratendinous human-derived collagen injection were associated with short-term improvements in pain and shoulder function. No additional short-term clinical benefit of collagen augmentation was detected after baseline adjustment. A post hoc exploratory analysis observed a higher frequency of tear-size reduction exceeding 2 mm in the collagen group (unadjusted $p = 0.030$), but this finding is hypothesis-generating and does not establish a structural benefit or clinical importance of the 2-mm threshold. Larger prospective studies with prespecified MRI endpoints and longer follow-up are required.

Ethics Statement

This study was approved by the Institutional Review Board (IRB) of Himchan

Hospital (IRB No. 116655-01-202603-01; approved March 1, 2026). Written informed consent for the surgical procedure was obtained from all participants as part of routine clinical care at the time of treatment. Given the retrospective design of this study, the requirement for additional consent for retrospective data review was waived by the IRB. All procedures were performed in accordance with the ethical standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments.

Author Contributions

Dong Nyoung Lee: Conceptualization, formal analysis, writing-original draft preparation, and writing-review and editing. Chang Hyun Nam: Investigation and resources. Jung Hoon Lee: Resources and validation. Ji-Hoon Baek: Investigation and visualization. Soon Yong Yoo: Methodology and investigation. Kyungwon Choi: Methodology and investigation. Hye Sun Ahn: Formal analysis and data curation. Su Chan Lee: Conceptualization, writing-review and editing, supervision, and project administration. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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