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Effectiveness of the Anti-adhesive Agent Protescal after Arthroscopic Rotator Cuff Repair: A Retrospective Study

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Background: Many hyaluronic acid (HA)-based anti-adhesive agents have been commercialized for clinical use in the pharmaceutical market. But their efficacy in arthroscopic rotator cuff repairs remains elusive. To determine their efficacy, we performed a comparative analysis of the effects of two hyaluronate/carboxymethylcellulose (CMC)-based anti-adhesive agents, Protescal and Guardix.
Methods: We recruited a total of 256 patients who had received an arthroscopic rotator cuff repair at our hospital between January 2014 and March 2015. Among them, 96 patients fulfilled the study's selection criteria and were enrolled as the final population sample. Thirty patients who had received a postoperative injection of Protescal were allocated into Group A. Another 30 patients who had received a postoperative injection of Guardix were allocated into Group B. As controls, 36 patients who did not receive any injection were allocated into Group C. The patients included in this study were aged between 19 and 75 years. For the clinical assessment, we measured the following clinical parameters—the visual analogue scale for pain (PVAS), the American Shoulder and Elbow Surgeons (ASES) score, and the constant score, as well as passive range of motions (ROMs)—at three time-points (preoperatively, 2-month postoperatively, and 6-month postoperatively).
Results: We found that Group A compared to Group B tended to show a swifter recovery in passive anterior elevation and in internal rotation by the 2-month postoperative follow-up, but the differences were not statistically significant.
Conclusions: We found that the effects of HA/CMC-based injections were minimal after arthroscopic rotator cuff repairs.
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Key Words: Rotator cuff tears; Anti-adhesive agents; Cuff healing rate

Introduction

The primary ends of surgeries for ligament injuries include controlling the inflammatory process, reducing cell adhesion of potentially adhesiogenic tissue surfaces surrounding the ligament, preventing collagen degradation whilst enhancing collagen synthesis, and enhancing cell proliferation. Ultimately, achieving these goals enhance the quality and the rate of healing that are unattainable through the natural healing process, thereby improving tissue remodeling and maturation of the healing wound. For the treatment of ligament injuries or arthritis, the beneficial effects of hyalurnoic acid or hyaluronan (hyaluronic acid, HA) have been reported previously.[1,2] HA is a high molecular weight polysaccharide found in many animals, and hyaluronan polymers have been shown to form a major component of the synovial fluid.[3] Previous studies have suggested that HA plays a critical role in minimizing pain and controlling the inflammatory process. But because these studies have used mainly animal models, it is difficult to apply their findings to humans. And although very few studies have investigated the role of HA in the treatment of shoulder disorders, let alone disorders of the rotator cuff, the potential application of HA for the repair of rotator cuff disorders has been proposed on the basis of a few in vitro studies.[2,4] Still, the benefits of HA with respect to ligament repair re-

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main controversia.[2] We thus investigated the effect of HA-based injections on clinical parameters after rotator cuff repairs in this study.

Hyaluronan-based anti-adhesive agents have been shown not only to prevent cell adhesion and other adverse events associated with surgeries related to ligament injuries and with abdominal surgeries[5,6] but also to minimize infertility induced by adhesions of the fallopian tube following gynaecological surgery.[3,7] To overcome the limitations of HA, which has a low half-life in the body, the Korean pharmaceutical industry developed an adhesion barrier whose effects last throughout the whole recovery period. This product Guardix consists of HA and sodium carboxymethylcellulose (CMC).[8] The injection of the HA/CMC formulation as a post-adjunct to arthroscopic rotator repairs has been shown to be associated with a good recovery of range of motion (ROM) and good clinical outcomes in cuff tear patients with few postoperative complications.[9] Another adhesion barrier that has been developed is Protescal, which consists of HA and CMC, as in Guardix, but also sodium alginate. In this study, we made a comparative analysis of the clinical outcomes after using either anti-adhesive agent as adjunct therapy after arthroscopic rotator repair.

Methods

We recruited a total of 256 patients who had received an arthroscopic rotator cuff repair at Orthopedic Department of Samsung Medical Center between January 2014 and March 2015. Of the 256 patients, a subset of patients who fulfilled the selection criteria of our study was selected. The inclusion criteria included patients with partial or all-thickness rotator cuff tears; patients with tears that had been classified according to size (small to massive); patients who underwent an arthroscopic rotator cuff repair using the suture bridge technique and the double-row repair; and patients who received a postoperative magnetic resonance imaging (MRI) within 6 months of the operation. The exclusion criteria included the following: an open excision repair; a recurrent rotator cuff repair; a single-row repair; an incomplete suture (type 3 or 4 sutures)[10]; a medical history of fractures or infection at the site of surgery; and a medical history of disease such as connective tissue disease or degenerative arthritis. Once the inclusion and exclusion criteria were applied, a total of 96 patients were available for enrollment. The nature of the study design meant that we could not allocate patients into treatment groups randomly. Group A consisted of 30 patients who received a Protescal injection, Group B consisted of 30 patients who received a Guardix injection, and Group C consisted of 36 control patients who did not receive any injection. The anti-adhesive agents were administered through the subacromial space immediately after the arthroscopic rotator cuff repair. Abduction braces were used to restrict movement in all patients for 5 to 6 weeks postoperatively.

All arthroscopic procedures were carried out by a single experienced surgeon. The following protocol has been used on all patients. First, the patients under general anesthesia were placed into a bilateral decubitus position tilted 30° posteriorly throughout the surgery. We assessed the patients' ROMs preoperatively, and if the patients' ROM was restricted we ensured that the joints were manipulated carefully. We palpated the glenohumeral joint and inserted the arthroscope into the subacromial space. We carried out an acromioplasty if after the subacromial bursectomy the acromion became revealed.

The bursal-sided rotator cuff was debrided so that the rotator cuff was revealed. Then we classified the tear size in diameter in accordance to the classification system developed by Post et al.[11] as small (<1 cm), medium (1–3 cm), large (3–5 cm), or massive (>5 cm). We used a probed marked with a 5 mm scale bar to measure the size of all tears. A double-row suture bridge technique was used for all repairs. One or two suture screws were used on the inner row, and two screws, on the outer row. For patients with partial tears, we used a liberating knife to complete the tear before the repair was performed. We fixed a spine needle to a syringe filled with either Guardix or Protescal; then we positioned the arthroscope into the subacromial space and injected the agent immediately after the suture. To prevent any leakage of the agent, we extruded the synovial fluid completely from the subacromial space before the suture.

The patients were placed in 5 to 6 weeks of immobilization in a 30° abduction brace, and joint exercises were prohibited for a certain duration according to size (5 weeks for small- and medium-sized tears and 6 weeks for large and massive tears). During this period, active motion of the hand, elbow, and wrist was permitted. With de-application of the immobilization brace, active-assisted passive shoulder ROM was gradually begun and muscle exercises were implemented from the 10th to 12th postoperative week.

All clinical outcomes were measured at the following timepoints: preoperatively, 2 months postoperatively, and 6 months postoperatively. Because we hypothesized that HA/CMC injection into the subacromial space will reduce postoperative adhesion, we measured passive ROM as opposed to active ROM. The passive ROMs flexion elevation, abduction, external rotation, and internal rotation were measured. We measured clinical parameters such as the visual analogue scale for pain (PVAS), the American Shoulder and Elbow Surgeons (ASES) score, and the constant score. All patients received an MRI examination at the 5-month follow-up, and all images were taken using the 3.0-T MRI (Gyroscan Interna Achieva; Philips Medical System, Best, The Netherlands). MRI as well as T1, T2 contrast-enhanced images were taken in coronal, sagittal, and axial planes (slice thickness, 3 mm; inter-slice gap, 0.4 mm). Postoperatively, we measured the continuity of the rotator cuff on the basis of MRI

findings, which were classified following the Sugaya classification system into 5 sub-types.[12] A homogeneous low intensity signal with sufficient thickness was defined as type I; a partial high intensity signal but with sufficient thickness was defined as as type II; a signal not with discontinuity but with insufficient thickness was defined as as type III; a signal with minor discontinuity, as type IV; and a signal with major discontinuity, as type V. On the basis of these radiological measurements, we considered MRI types I to III as a healed rotator cuff with good integrity. Two physicians specializing in shoulder disorders assessed the postoperative images in a blinded fashion at an interval of 2 weeks, and the kappa coefficiency factor was used to calculate the inter- and the intra-observer variation.

To compare the preoperative and postoperative scores, we used the paired t-test or the Wilcoxon signed rank test. To compare the preoperative scores of the two patient groups, we used the two-sample t-test. The distribution of sex and preoperative tear sizes were compared using the χ^2 test. Fisher exact test was used to compare the re-tear rates among groups. All statistical analyses were performed using the IBM SPSS statistics ver. 20.0 software (IBM Co., Armonk, NY, USA) and the confidence interval was set as 95%. Statistical significance was accepted at $p<0.05$.

Table 1. Preoperative Demographic Data of Patients by Group

Variable	Group A	Group B	Group C
No. of patients	30	30	36
Age (yr)	60.1 ± 5.4	60.7 ± 7.5	61.9 ± 7.5
Sex (male/female)	20/10	21/9	19/17
Operation site (right/left)	22/8	24/6	26/10
Tear size*			
Small	11	8	13
Medium	16	21	18
Large	2	1	3
Massive	1	0	2
Past medical history			
Diabetic mellitus	4	6	6
Cardiovascular	9	11	8
Thyroid disorders	5	3	4
Smoking	9	11	12

Values are presented as number only or mean ± standard deviation. All *p*-values are not significant.
Group A: Protescal-injected group, Group B: Guardix-injected group, Group C: control group.
*The tear size in diameter in accordance to the classification system developed by Post et al.[11] as small (< 1 cm), medium (1–3 cm), large (3–5 cm), or massive (> 5 cm).

Results

The average age of the patients was 60.8 years (Group A, 60.1 years; Group B, 60.7 years; Group C, 61.9 years). And the male to female gender ratio was 60:36 (Group A, 20:10; Group B, 21:9; Group C, 19:17) The proportion of tears by size were as follows (small:medium:large:massive): Group A, 11:16:2:1; Group B, 8:21:1:0; and Group C, 13:18:3:2. We compared parameters such as dominance, presence of preexisting comorbidities such as diabetes and thyroid disorders, and tobacco smoking; we found that the two groups did not statistically differ across all parameters (Table 1).

The follow-up MRIs were taken at an average 4.9 ± 0.6 months postoperatively in Group A; at 5.0 ± 0.7 months postoperatively in Group B; and at 5.2 ± 0.5 months postoperatively in Group C. For the re-tear rates derived in this study, we found that the intra- and inter-observer variation, measured using the kappa co-efficiency factor, were 0.89 (absolute agreement) and 0.82 (substantial agreement), respectively. The re-tear rates were 6.7% (n=2) for Group A, 13.3% (n=4) for Group B, and 8.3% (n=3) for Group C. Although the differences were not statistically significant, compared to Group A, Groups B, and C showed relatively higher re-tear rates ($p=0.166$) (Table 2).

The clinical parameters PVAS, ASES, and constant scores significantly improved by the 2-month and the 6-month postoperative follow-ups with respect to the corresponding preoperative scores for both treatment groups (Table 3–5). However, the extent of these improvements did not significantly differ between the two groups (A vs. B, A vs. C). (Table 6, 7) Most passive ROMs at the 2-month postoperative follow-up worsened relative to their respective preoperative values in all three groups, but by the 6-month postoperative follow-up, we found that most passive ROMs improved relative to their preoperative values (Table 3–5). Yet we did not observe any statistically significant differences between the groups (Table 6, 7).

Discussion

We found that sodium alginate-combined HA/CMC injections were more effective than HA/CMC-only injections in preventing recalcitrant cuff tears, although this effect was without statistical significance. Recent studies have demonstrated the

Table 2. Repair Integrity Based on Postoperative MRIs at the Five-month Follow-up

MRI finding	Group A	Group B	Group C
Re-tear (Sugaya type IV, V)	2	4	3

Values are presented as number only.
MRI: magnetic resonance imaging, Group A: Protescal-injected group, Group B: Guardix-injected group, Group C: control group.

Table 3. Preoperative and Postoperative Average Range of Motions and Clinical Scores in Group A

Variable	Preoperative follow-up	Postoperative 2-month follow-up	Postoperative 6-month follow-up	*p*-value
FE (°)	140.7 (90–180)	136.7 (90–150)	156.7 (120–180)	0.114
ER (°)	40.2 (30–90)	35.2 (20–50)	55.2 (20–90)	0.142
IR (°)	11.4 (6–17)	12.4 (8–17)	9.4 (5–17)	0.066
AB (°)	137.2 (90–180)	132.2 (80–150)	142.2 (70–180)	0.091
PVAS score	4.5 (2–7)	3 (2–5)	1 (0–4)	0.036
Constant score	51.6 (35–85)	59.6 (45–75)	79.6 (65–95)	0.031
ASES score	59.4 (46–80)	65.4 (50–80)	90.4 (70–100)	0.013

Values are presented as median (range).
Group A: Protescal-injected group, FE: flexion elevation, ER: external rotation, IR: internal rotation, AB: abduction, PVAS: visual analogue scale for pain, ASES: American Shoulder and Elbow Surgeons.

Table 4. Preoperative and Postoperative Average Range of Motions and Clinical Scores in Group B

Variable	Preoperative follow-up	Postoperative 2-month follow-up	Postoperative 6-month follow-up	*p*-value
FE (°)	135.7 (100–180)	130 (100–155)	150 (130–170)	0.214
ER (°)	42.2 (20–90)	33.9 (20–60)	63.9 (40–90)	0.102
IR (°)	12.1 (6–17)	13.2 (9–17)	10.2 (6–17)	0.166
AB (°)	137.2 (90–180)	139.4 (70–145)	149.4 (100–180)	0.191
PVAS score	4.2 (1–7)	2.5 (2–6)	1.1 (0–6)	0.026
Constant score	45.6 (39–80)	49.1 (47–71)	79.1 (55–90)	0.041
ASES score	60.4 (52–77)	68.5 (55–79)	88.5 (65–100)	0.031

Values are presented as median (range).
Group B: Guardix-injected group, FE: flexion elevation, ER: external rotation, IR: internal rotation, AB: abduction, PVAS: visual analogue scale for pain, ASES: American Shoulder and Elbow Surgeons.

Table 5. Preoperative and Postoperative Range of Motions and Clinical Scores in Group C

Variable	Preoperative follow-up	Postoperative 2-month follow-up	Postoperative 6-month follow-up	*p*-value
FE (°)	129.3 (100–170)	132.0 (100–155)	148.6 (130–170)	0.134
ER (°)	38.5 (25–80)	30.5 (10–50)	55.4 (40–70)	0.192
IR (°)	11.4 (6–17)	14.8 (9–17)	9.8 (6–16)	0.096
AB (°)	139.5 (90–180)	125.4 (70–140)	144.4 (100–180)	0.111
PVAS score	5.2 (2–7)	3.8 (2–7)	1.9 (0–6)	0.016
Constant score	48.1 (39–85)	50.7 (32–71)	76.1 (52–90)	0.033
ASES score	43.8 (35–75)	57.1 (30–75)	83.5 (65–93)	0.015

Values are presented as median (range).
Group C: control group, FE: flexion elevation, ER: external rotation, IR: internal rotation, AB: abduction, PVAS: visual analogue scale for pain, ASES: American Shoulder and Elbow Surgeons.

effects of alginate, of which the two most commonly reported effects are its antimicrobial and hemostatic effects.[13] Na et al.[14] hypothesized that the antimicrobial and hemostatic effects of alginate ultimately prevent tissue adhesion, and Kim et al.[9] reported that alginate-combined HA/CMC injections are more effective at preventing adhesion formation after hysteroscopic surgery than alginate-lacking HA/CMC injections.

Indicators of a successful rotator cuff repair include the resolution of pain and the restoration of shoulder function. The rotator cuff undergoes a substantive reparative reaction at the fibrovascular layer of scar tissue between the ligament and the bone. And this cuff region undergoing reparation becomes filled with and held together by Sharpey's fibers.[9,15] But postoperative pain may resolve even in situations where the repair of the rota-

Table 6. Comparison of Postoperative Range of Motions and Clinical Scores between Group A and Group B

Variable	Group A	Group B	*p*-value
Postoperative 2-month follow-up			
FE (°)	136.7 (90–150)	130 (100–155)	0.074
ER (°)	35.2 (20–50)	33.9 (20–60)	0.122
IR (°)	12.4 (8–17)	13.2 (9–17)	0.446
AB (°)	132.2 (80–150)	139.4 (70–145)	0.761
PVAS score	3 (2–5)	2.5 (2–6)	0.616
Constant score	59.6 (45–75)	49.1 (47–71)	0.765
ASES score	65.4 (50–80)	68.5 (55–79)	0.963
Postoperative 6-month follow-up			
FE (°)	156.7 (120–180)	150 (130–170)	0.034
ER (°)	55.2 (20–90)	63.9 (40–90)	0.122
IR (°)	9.4 (5–17)	10.2 (6–17)	0.246
AB (°)	142.2 (70–180)	149.4 (100–180)	0.761
PVAS score	1 (0–4)	1.1 (0–6)	0.616
Constant score	79.6 (65–95)	79.1 (55–90)	0.765
ASES score	90.4 (70–100)	88.5 (65–100)	0.963

Values are presented as median (range).
Group A: Protescal-injected group, Group B: Guardix-injected group, FE: flexion elevation, ER: external rotation, IR: internal rotation, AB: abduction, PVAS: visual analogue scale for pain, ASES: American Shoulder and Elbow Surgeons.

Table 7. Comparison of Postoperative Range of Motions and Clinical Scores between Group A and Group C

Variable	Group A	Group C	*p*-value
Postoperative 2-month follow-up			
FE (°)	136.7 (90–150)	132.0 (100–155)	0.115
ER (°)	35.2 (20–50)	30.5 (10–50)	0.312
IR (°)	12.4 (8–17)	14.8 (9–17)	0.149
AB (°)	132.2 (80–150)	125.4 (70–140)	0.361
PVAS score	3 (2–5)	3.8 (2–7)	0.196
Constant score	59.6 (45–75)	50.7 (32–71)	0.365
ASES score	65.4 (50–80)	57.1 (30–75)	0.293
Postoperative 6-month follow-up			
FE (°)	156.7 (120–180)	148.6 (130–170)	0.418
ER (°)	55.2 (20–90)	55.4 (40–70)	0.148
IR (°)	9.4 (5–17)	9.8 (6–16)	0.272
AB (°)	142.2 (70–180)	144.4 (100–180)	0.161
PVAS score	1 (0–4)	1.9 (0–6)	0.492
Constant score	79.6 (65–95)	76.1 (52–90)	0.136
ASES score	90.4 (70–100)	83.5 (65–93)	0.105

Values are presented as median (range).
Group A: Protescal-injected group, Group C: control group, FE: flexion elevation, ER: external rotation, IR: internal rotation, AB: abduction, PVAS: visual analogue scale for pain, ASES: American Shoulder and Elbow Surgeons.

tor cuff was unsuccessful—that is independently of the action of Sharpey's fibers. Thus, it would be misleading to regard resolution of pain as the only parameter of successful cuff repairs, but other parameters such as restored normal tension in ligaments should also be evaluated.

Some studies have suggested that HA acts as a physical barrier to tendon repair, whilst others have reported that its actions are only pharmacological.[6,16,17] According to a study by Mitsui et al.,[18] HA has been shown to contribute to cell proliferation and to the expression of mRNA encoding pro-collagen alpha 1 (III), which is a precursor to type III collagen, but not of pro-collagen alpha 1 (I), which is a precursor to type I collagen; as a result of their findings, they proposed the adhesion barrier role of HA. Further, Oryan et al.[15] reported that HA injection into injured flexor digitorum superficialis of rabbits reduced postoperative bleeding, odema, and inflammatory reactions. And Tuncay et al.[19] reported that HA controls vascular genesis by inducing the expression of vascular endothelial growth factor during the repair of Achilles tendons.

Such findings of previous studies suggest that injecting either HA/CMC or alginate-combined HA/CMC into the subacromial space after rotator cuff repairs may help prevent postoperative subacromial adhesions and, hence, shoulder stiffness. In this study, we found that the severity of postoperative stiffness did not differ between those who received an HA/CMC-only injection and an alginate-combined HA/CMC injection, although the former group had more unfavorable clinical outcomes. Both stiffness and pain associated with postoperative adhesion may spontaneously resolve with early intervention, such as rehabilitative exercise, irrespectively of the adhesion severity. However, because a single injection may not bring about the desired effect, multiple injections may be required to bring about a significant clinical effect of HA, and future studies are required to prove this.

One of the many strengths of this study is that we compared the effect of variables among three patient groups who had all received treatment from a single surgeon and had undergone a common rehabilitation protocol. And these patients were allocated into three groups, where two differed in terms of the type of anti-adhesive agent received and one was a control group that did not receive any adjunct therapy. Further, we used a common method to perform the comparative analysis of clinical findings and re-tear rates of these groups. Neither factors such as age, sex, and smoking status nor baseline characteristics of patients significantly differed among the three groups. In addition, when we compared the preoperative ROMs and the postoperative ROMs at the 2-month and the 6-month follow-ups, most ROMs were comparable to those reported in other studies.

There are a few limitations to this study. First, it comes with inherent limitations of a retrospective study, and the study design consisted of a relatively short-term follow-up covering only 6 months. Second, determining a statistically significant or a clinically important effect from a single injection alone is unrealistic. Third, we cannot rule out the possibility that the occurrence of re-tears is related to rehabilitative factors or to demographic factors. And the effects of these potential confounding variables, which are often difficult to quantitatively measure, undermines the association between anti-adhesive agents and re-tear rates suggested in this study. Fourth, selection bias may have been introduced with the selection of only patients who had received MRI. Lastly, although the two MRI assessments were made independently by two orthopedic specialists with a 2-week interval between the two readings, errors in measurements are inevitable.

Conclusion

We found that patients who received an alginate-combined HA/CMC injection were associated with lower re-tear rates after arthroscopic rotator cuff repairs than those who received an HA/CMC-only injection, although the differences were statistically insignificant. None of the clinical parameters measured in this study significantly differed between the two groups. However, further studies with longer follow-up periods are required to determine a more accurate long-term prognosis of these patients.

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