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Factors associated with needle breakage of antegrade suture passer and effect of intratendinous remnant needle tip on clinical outcomes after arthroscopic rotator cuff repair

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ABSTRACT

Objective: The aim of this study was to evaluate factors associated with the needle breakage of antegrade suture passer and the effect of intratendinous remnant needle tip on clinical outcomes after rotator cuff repair.

Methods: We retrospectively reviewed 283 patients (138 men and 145 women; mean age: 59.7 ± 9.3 years) who underwent arthroscopic repair for full-thickness rotator cuff tear. We evaluated the characteristics of 16 patients in whose needle tip had been broken and embedded and remained in the rotator cuff (remnant needle group) and compared them with the remaining 267 patients (control group). Afterwards, another 64 patients were selected from control group (1:4 matching) after propensity score matching (PSM). The groups were compared anatomically with MRI or ultrasonography and functionally (serial pain VAS and ROM; ASES, Constant, UCLA and SST scores) at a minimum follow-up of 1 year.

Results: The remnant needle group showed preoperative thicker tendon (6.72 mm vs 5.33 mm, $p = 0.047$), higher tendinosis (mean grade, 1.88 vs. 1.43, $p = 0.029$), and more frequent delaminated tears ($p = 0.035$) compared with control group. When we compare the clinical outcomes after PSM, the initial pain VAS of the remnant needle tip group was higher up to 3 months (pain VAS: 4.13 ± 2.07 vs 2.48 ± 1.61 ($p = 0.032$) at 5 weeks and 3.79 ± 2.12 vs 2.25 ± 1.76 ($p = 0.044$) at 3 months), however the difference disappeared after 6 months postoperatively. In final evaluation, there was no significant differences in every outcome parameters (all $p > 0.05$).

Conclusion: Breakage of the needle of the antegrade suture passer occurred more frequently in the thicker tendon, higher tendinosis, and delaminated tears. The retained broken needle tip was associated with higher pain scores during the early postoperative period, but revealed no difference in final outcomes by using PSM.

Level of Evidence: Level III, Therapeutic Study

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Introduction

Rotator cuff tears frequently cause shoulder pain and disability, including weakness and decreased range of motion in the shoulder joint[1,2] Along with population aging and the increase of sports activities, the incidence of rotator cuff tear has shown a rapid increase.[3] Consequently, arthroscopic rotator cuff repair, a widely accepted treatment for full-thickness rotator cuff tear, has been performed with increasing frequency.

The position and configuration of sutures on the cuff repair has an important biomechanical effect on the tendon suture interface therefore precise suture passing devices should be used.[4] Among the suture passing devices, antegrade suture passers represent one type of device to place sutures in tendon, and are widely used due

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to their convenience and effectiveness in use. An antegrade suture passer penetrates the tendon using a flexible, small caliber needle loaded in the passer and the needle is made of nitinol which is known for excellent biocompatibility.[5] The suture threads that are hung in the groove of the needle, which is located at the end of the needle, can be passed through the tendon along with the needle passage. However, the needle of the antegrade suture passer is not strong because the needle should be flexible enough to be bent by almost 90° to go up to the tendon from the suture passer device, and the groove site of the needle is especially weak. Thus, if the tendon is too thick or stiff, the needle of the antegrade suture passer may be broken while penetrating the tendon, especially at the groove site. Following needle breakage, the broken needle tip is usually stuck inside the tendon, and may become difficult to find. In addition, even if it can be found, the removal of the embedded broken needle from the tendon may inflict considerable damage to the tendon. When the broken needle cannot be found easily, clinicians may leave the broken needle tip in the tendon, because either they cannot find it or out of fear of damaging the tendon while searching for the embedded broken needle tip in the tendon. This type of complication, while rare, but occurs to warrant study. In addition, this remnant needle tip inside the tendon prompts concern about the surgical result. However, to our knowledge, there is only one case report about suture passer breakage during arthroscopic rotator cuff repair and no comparative study has evaluated the effect of an intratendinous remnant needle tip on outcomes after arthroscopic rotator cuff repair surgery.[6]

Thus, the purpose of this study was to evaluate factors associated with the needle breakage of the antegrade suture passer, and the effect of intratendinous remnant needle tip on clinical outcomes after rotator cuff repair. We hypothesized that the intratendinous remnant needle tip would not affect the clinical outcomes after rotator cuff repair.

Materials and methods

Patients selection

Institutional review board approval was obtained for this study protocol (KUH1060129). Between September 2012 and July 2015, 283 patients underwent arthroscopic repair for full-thickness rotator cuff tear at the authors' institute. The indications for surgery included shoulder pain or disability refractory to supervised nonsurgical treatment, including medication, local steroid injections, and physical therapy program, for a minimum of 6 months. Among these, we identified 16 consecutive patients who had the incident that the needle tip of the antegrade suture passer (Arthrex Scorpion, Arthrex, Naples, FL, USA) was broken and embedded in their tendon during surgery (remnant needle (+) group, Fig. 1). In case of needle breakage of the antegrade suture passer during the needle penetration through the tendon, if the needle tip is embedded inside the tendon and hard to remove, we did not overdo our strength to remove it from the tendon because in our practice we experienced that most of the patients with the remnant needle tip inside the tendon had showed good function and satisfied with the surgery in spite of the remnant needle tip. In 5 cases, the broken needle tips were floating in the subacromial space after breakage (No case of broken tips in the joint). In these cases, the floating broken needle tips were removed from the subacromial space without inflicting harm to the surrounding tissue, and they were belonged to the remnant needle tip (−) group. Of these 16 patients, 11 were followed up more than 1 year after surgery, but 5 were lost to follow-up after 6 months postoperatively. We contacted these 5 patients via telephone and asked to visit for the regular check-up. All agreed to visit and took evaluations. Finally, all 16 patients had preoperative magnetic resonance imaging (MRI) and postoperative MRI or ultrasonogram performed at least 1 year after surgery for the anatomical outcome evaluation, and underwent pain visual analogue scale (VAS) evaluation preoperatively, 2, 5 weeks, 3, 6 months, and at least 1 year after surgery, range of motion (ROM) evaluation preoperatively, 5 weeks, 3, 6 months, and at least 1 year after surgery, and various functional outcome measurements such as American shoulder and Elbow Surgeon's (ASES) score, Constant score, Simple Shoulder Test (SST) score, and University of California, Los Angeles (UCLA) score at least 1 year after surgery. In addition, the shoulder anteroposterior and axial X-rays were checked at every follow-up visit. None of 16 patients had isolated subscapularis tear, incomplete repair, worker's compensation status, or previous surgery on the same shoulder.

Evaluation of various factors

The characteristics of the remnant needle (+) group was compared with the remaining 267 patients without a retained needle tip (remnant needle tip (−) group). Various demographic and clinical factors which can affect outcomes, including age, gender, symptom duration, hand dominance, steroid injection history, mechanism of injury, preoperative stiffness, smoking, diabetes mellitus, hypercholesterolemia, sports level, work level, tear size, number of medial suture anchors, the times of suture passing from the medial anchor, fatty infiltration of each rotator cuff

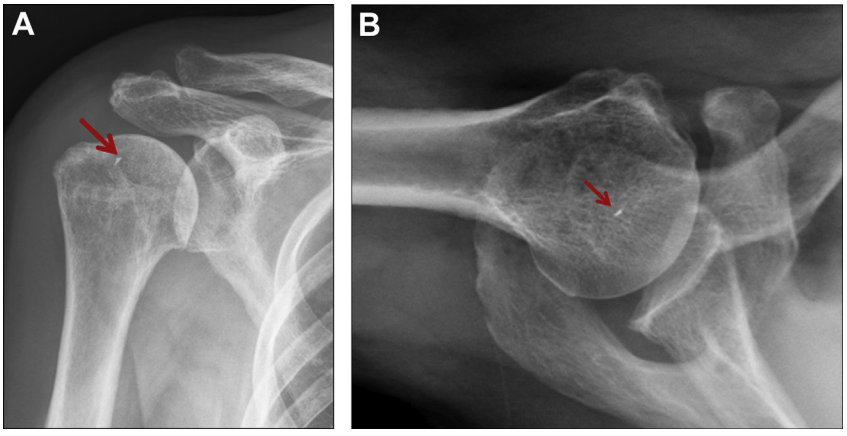

Fig. 1. The plain anteroposterior (A) and axial (B) radiograph of the shoulder show the remnant needle tip around the medial side of the footprint (arrows).

muscle, delamination tear, concomitant biceps procedures, tendon thickness and tendinosis grade were prospectively collected and evaluated. Shoulder stiffness was defined as forward elevation less than 120° passively, external rotation less than 30° passively, and internal rotation at the back lower than L3 passively.[7] The level of sports activity was defined as high (dynamic or contact sports such as boxing, basketball, rugby, and tennis), medium (static sports such as yoga and jogging), or low (mild or no sports activities).[8] Work level was defined as high, medium, or low, if the work involved heavy manual labor, manual labor with less physical activity, or sedentary physical activity, respectively.[9] The tear size was measured arthroscopically using a calibrated probe at the time of surgery, and classified according to the rating system of DeOrio and Cofield.[10] The fatty infiltration of each rotator cuff muscle (supraspinatus, infraspinatus, and subscapularis) was evaluated according to the criteria established by Goutallier et al[11] and modified by Fuchs et al[12] from the results of preoperative magnetic resonance imaging (MRI; 3.0-T system; SignaHDx; GE Healthcare). Delamination tears were defined as horizontal retraction of either the bursal or articular surface of the tendon, manifest as thickening of the torn retracted edge, and/or interstitial splitting of the tendon, and confirmed under arthroscopic view.[13] Tendon thickness was defined as the vertical width of the thickest tendon portion in the MR T1-weighted fat-suppression oblique coronal image where the retraction of the torn cuff tendon is the most prominent (Fig. 2).[14] In cases of delaminated tears, the vertical width of bursal and articular side delaminated tendons were measured at each and added numerically. In addition, the tendinosis grade was evaluated by the tendinosis grading system suggested by Sein et al[15]: grade 0 is a tendon with complete homogeneous low intensity on all pulse sequences, grade 1 is a mild focal increase in tendon signal (mild tendinosis) on proton density (PD) and fat-suppressed (FS) T2 sequencing not equal to that of fluid, grade 2 is a moderate focal increase in tendon signal (moderate tendinosis) on PD and FS T2 sequencing not equal to that of fluid, and grade 3 is a marked generalized increase in tendon signal (marked tendinosis) without frank fluid signal intensity, which could be applied to the rotator cuff tear patients in same manner according to the study of Chung et al.[16] The tendinosis grade was evaluated electronically with a picture archiving and communication system (PACS) workstation (Centricity; RA1000, GE Healthcare IT, Seoul, Korea). To evaluate the reliabilities of each measurement, two orthopedic surgeons with 4 and 13 years of experiences respectively measured the fatty infiltration, tendon thickness, and tendinosis grade, and the mean of the 2 values was analyzed.

Fig. 2. Shows measurement of the cuff tendon thickness. Tendon thickness was defined as the vertical width of the thickest tendon portion in the MR T1-weighted fat-suppression oblique coronal image where the retraction of the torn cuff tendon is the most prominent (red line).

The interobserver agreement of the fatty infiltration, tendon thickness, and tendinosis grade were generally acceptable with an intraclass correlation coefficients of 0.813 for the fatty infiltration of the supraspinatus, 0.731 for the fatty infiltration of the infraspinatus, and 0.685 for the fatty infiltration of the subscapularis, 0.706 for the tendon thickness, and 0.714 for the tendinosis grade (all $p < 0.01$).

Comparison of the surgical results after propensity score matching

To reduce bias, we used propensity score matching (PSM) statistical technique and selected another 64 patients from the control group (matched remnant needle (−) group) by 1:4 matching for age, fatty infiltration, tear size, tendinosis grade, and presence of diabetes, which are known to be prognostic factors to outcomes after rotator cuff repair.[17] The matched remnant needle (−) group patients were selected from the control group after excluding patients under exclusion criteria. The exclusion criteria were an isolated subscapularis tear (n = 4), incomplete repair (n = 5), workers' compensation status (n = 11), previous surgery on the same shoulder (n = 7), and those who were lost to follow-up before reaching 1 year after surgery (n = 84). The flowchart is depicted in Fig. 3. The result of propensity score matching was good, with a c-statistic of 0.741 and a p value for the goodness-of-fit test of 0.320 from the logistic regression model.[17] The boxplots before and after propensity score matching showed well-adjusted variables after matching (Fig. 4). After 1:4 propensity score matching, we could acquire similar baseline characteristics between matched groups (Table 2).

Between those matched remnant needle (+) group and matched remnant needle (−) group, we compared the anatomical (by MRI or ultrasonography) and functional outcomes in terms of pain VAS, ROM, ASES, Constant, UCLA and SST scores at a minimum of 1 year postoperatively. The integrity of the repaired rotator cuff was verified by ultrasonography or MRI at least 1 year after surgery (mean, 15.3 ± 4.4 months; range, 12–19 months) in each patient. An experienced musculoskeletal radiologist with over 10 years of experience and who was blinded to the present study performed and interpreted the sonography and MRI and further evaluated the healing of the rotator cuff to the greater tuberosity using an HDI 5000 or IU-22 system sonography (both from Philips Healthcare, Bothel, WA) and 3.0-T system MRI (SignaHDx; GE Healthcare, Pewaukee, Wisconsin, USA). Sugaya's classification types IV and V were defined as a healing failure.[18] In addition, the shoulder ROM, pain VAS score, ASES score, Constant score, SST score, and UCLA score were evaluated in all patients. The shoulder ROM was measured by 1 senior investigator (S.W.C.), various functional outcome scores were measured; data from the preoperative and final follow-up assessments were analyzed. For the evaluation of shoulder ROM, forward flexion (FF) was measured in degrees between the arm and thorax with the elbow held straight, and external rotation (ER) at the side was measured in degrees between the thorax and forearm with the arm held in an adducted position with the elbow in 90° of flexion. Internal rotation (IR) across the back was measured according to the vertebral level that the patient could reach with the tip of their thumb.[7] The pain VAS was scored on a scale of 0–10, with 10 indicating the highest level of pain, and

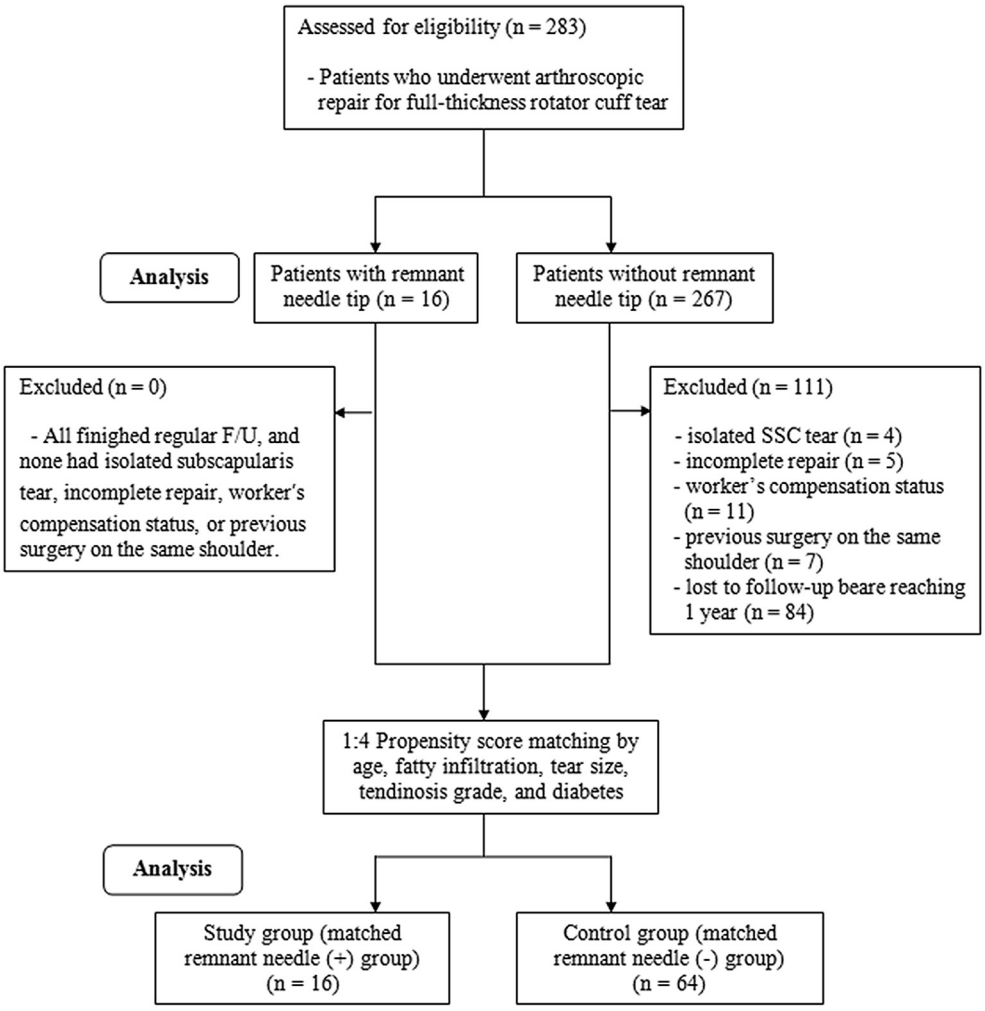

Fig. 3. The flowchart is shown.

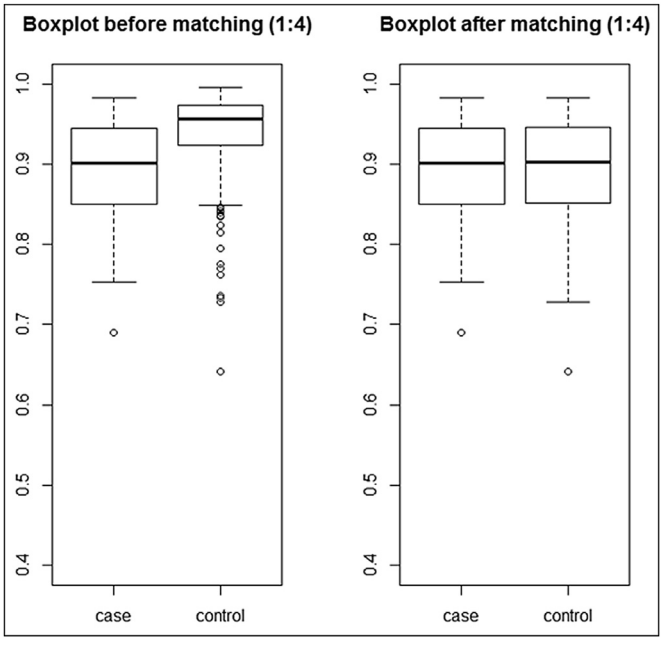

Fig. 4. Shows boxplots before and after propensity score matching.

the ASES score consisted of a summation score using a 100-point system (50 points for daily function and 50 points for pain).

Surgical procedures and rehabilitation

All surgical procedures were performed arthroscopically with the patient in a beach chair position by a single surgeon. Subacromial decompression and acromioplasty were performed in all patients. Biceps tenotomy (n = 102) or tenodesis (n = 62) was performed in cases of long head of the biceps tendon problem. The margin of the tear was debrided to obtain better quality tendon tissues, however this was believed not to affect the thickness of tendon we measured in preoperative MRI. Suture bridge repair was performed in all patients. Sutures were passed through the tendon in a mattress fashion for suture-bridge repair by using an antegrade suture-passing device (Arthrex Scorpion, Arthrex, Naples, FL, USA) in all patients. The needle of suture-passing device was not re-used to minimize the possibility of needle breakage by blunted-tip.

Immobilization after cuff repair was maintained with an abduction brace, and the duration of immobilization ranged from 4 to 6 weeks and was based on tear size measured at the time of surgery. Active-assisted range of motion exercise was allowed after weaning off the brace. Muscle strengthening exercises were initiated at 9–12 weeks postoperatively. Sports activities and

Table 1
Characteristics of the patients with remnant needle tip compared with those without remnant needle tip.

	Remnant needle (+) group (n = 16)	Remnant needle (−) group (n = 267)	p-value
Age (years)	60.4 ± 7.4	59.4 ± 9.2	0.686
Gender (M:F, n)	8:8	130:137	0.975
Duration of symptoms (months)	16.8 ± 21.7	18.9 ± 23.1	0.778
Side of involvement (D:ND, n)	13:3	184:83	0.793
Steroid injection history (n)	8 (50.0%)	89 (33.3%)	0.211
Traumatic onset (n)	5 (31.3%)	87 (32.6%)	0.895
Preoperative stiffness (n)	3 (18.8%)	48 (18.0%)	0.823
Smoking (n)	3 (18.8%)	38 (14.2%)	0.472
Diabetes mellitus (n)	5 (31.3%)	47 (17.6%)	0.125
Hypercholesterolemia (n)	6 (37.5%)	57 (21.3%)	0.124
Sports level (Low:Middle:High)	9: 5: 2	134: 81: 52	0.173
Work level (Low:Middle:High)	5: 3: 8	106: 97: 64	0.465
[a]Tear size (Small:Medium:Large:Massive)	3:6:5:2	49:115:54:49	0.360
[a]Tear size of AP dimension (mm)	21.92 ± 9.94	26.05 ± 14.58	0.315
[a]Tear size of retraction (mm)	18.66 ± 9.93	20.89 ± 13.12	0.542
Number of medial anchors	2.31 ± 0.70 (1–3)	2.07 ± 0.71 (1–3)	0.184
Times of suture passing from medial anchors	8.31 ± 2.25 (4–16)	8.09 ± 2.34 (4–16)	0.631
[b]FI of the supraspinatus	1.31 ± 0.94	1.74 ± 0.94	0.109
[b]FI of the infraspinatus	1.31 ± 1.01	1.51 ± 1.11	0.423
[b]FI of the subscapularis	1.06 ± 1.06	1.02 ± 1.15	0.905
Delamination tear (n)	9 (56.3%)	86 (32.2%)	**0.035**
Biceps procedure (To:Td:no, n)	6:3:7	96:59:112	0.785
[c]Tendon thickness	6.72 ± 1.05	5.33 ± 1.34	**0.047**
[d]Tendinosis grade (mean, mm)	1.88 ± 0.84	1.43 ± 0.82	**0.029**
(G0:G1:G2:G3)	0:5:6:5	34:116:88:29	(G0:G1:G2:G3)

M, male; F, female; D, dominant; ND, nondominant; AP, anteroposterior; FI, fatty infiltration; To, tenotomy; Td, tenodesis.
[a] The tear size was measured arthroscopically using a calibrated probe at the time of surgery, and classified according to the rating system of DeOrio and Cofield.[7]
[b] Fatty infiltration was graded according to the criteria established by Goutallier et al.[8]
[c] Tendon thickness was defined as the width of the thickest tendon portion in the MR T2-weighted oblique coronal image where the retraction of the torn cuff tendon is the most prominent.
[d] Tendinosis was graded according to the criteria established by Sein et al.[11]

Table 2
Comparison between matched remnant needle tip (+) group and matched remnant needle tip (−) group.

	Matched remnant needle (+) group (n = 16)	Matched remnant needle (−) group (n = 64)	p-value
Age (years)	60.4 ± 7.4	60.9 ± 8.4	0.814
Gender (M:F, n)	8:8	35:29	0.785
Duration of symptoms (months)	16.8 ± 21.7	16.6 ± 19.8	0.990
Side of involvement (D:ND, n)	13:3	44:20	0.520
Steroid injection history (n)	8 (50.0%)	23 (36.5%)	0.394
Traumatic onset (n)	5 (31.3%)	15 (23.4%)	0.530
Preoperative stiffness (n)	3 (18.8%)	11 (17.2%)	>0.999
Smoking (n)	3 (18.8%)	11 (17.2%)	>0.999
Diabetes mellitus (n)	5 (31.3%)	20 (31.3%)	>0.999
Hypercholesterolemia (n)	6 (37.5%)	12 (18.7%)	0.360
Sports level (Low:Middle:High)	9: 5: 2	30: 19: 15	0.892
Work level (Low:Middle:High)	5: 3: 8	22: 28: 14	0.162
[a]Tear size (Small:Medium:Large:Massive)	3:6:5:2	7:30:16:11	0.744
[a]Tear size of AP dimension (mm)	21.92 ± 9.94	25.08 ± 12.44	0.254
[a]Tear size of retraction (mm)	18.66 ± 9.93	18.76 ± 13.69	0.979
Number of medial anchors	2.31 ± 0.70 (1–3)	2.08 ± 0.72 (1–3)	0.252
Times of suture passing from medial anchors	8.31 ± 2.25 (4–16)	8.11 ± 2.48 (4–16)	0.719
[b]FI of the supraspinatus	1.31 ± 0.94	1.60 ± 0.86	0.217
[b]FI of the infraspinatus	1.31 ± 1.01	1.39 ± 1.12	0.800
[b]FI of the subscapularis	1.06 ± 1.06	0.87 ± 1.03	0.520
Delamination tear (n)	7 (43.7%)	18 (28.1%)	0.261
Biceps procedure (To:Td:no, n)	6:3:7	20:27:17	0.460
[c]Tendon thickness	6.72 ± 1.05	6.28 ± 1.27	0.307
[d]Tendinosis grade (mean, mm)	1.88 ± 0.84	1.82 ± 0.80	0.850
(G0:G1:G2:G3)	0:5:6:5	2:17:29:16	(G0:G1:G2:G3)

M, male; F, female; D, dominant; ND, nondominant; AP, anteroposterior; FI, fatty infiltration; To, tenotomy; Td, tenodesis.
[a] The tear size was measured arthroscopically using a calibrated probe at the time of surgery, and classified according to the rating system of DeOrio and Cofield.[7]
[b] Fatty infiltration was graded according to the criteria established by Goutallier et al.[8]
[c] Tendon thickness was defined as the width of the thickest tendon portion in the MR T2-weighted oblique coronal image where the retraction of the torn cuff tendon is the most prominent.
[d] Tendinosis was graded according to the criteria established by Sein et al.[11]

Table 3
Functional outcomes after surgery: comparison between those with and without remnant needle tip after propensity score matching.

Evaluation tool		Preoperative			Postoperative (>1yr)		
		Matched remnant needle (+) group	Matched remnant needle (−) group	p value	Matched remnant needle (+) group	Matched remnant needle (−) group	p value
ROM	FF	157.81 ± 19.05	157.81 ± 22.58	>0.999	163.33 ± 37.85	172.50 ± 10.83	0.578
	ER	50.01 ± 19.27	50.31 ± 16.27	0.961	55.10 ± 18.02	60.33 ± 7.52	0.496
	IR	11.56 ± 3.70	10.12 ± 2.91	0.532	10.33 ± 4.16	9.40 ± 3.13	0.451
Pain VAS		6.50 ± 2.16	6.74 ± 2.02	0.780	1.21 ± 3.16	0.82 ± 3.06	0.639
ASES		50.62 ± 17.56	48.58 ± 16.54	0.754	86.66 ± 32.99	93.12 ± 11.57	0.741
Constant		52.11 ± 15.39	54.11 ± 10.56	0.400	87.04 ± 2.82	89.85 ± 17.12	0.892
SST		4.05 ± 2.73	4.74 ± 3.04	0.760	9.66 ± 2.51	10.60 ± 2.30	0.610
UCLA		19.33 ± 3.50	18.45 ± 5.35	0.668	30.10 ± 6.51	29.83 ± 6.49	0.982

ROM, range of motion; FF, forward flexion; ER, external rotation at the side; IR, internal rotation at the back; VAS, visual analogue scale; ASES, American Shoulder and Elbow Surgeon's score; SST, Simple Shoulder Test score; UCLA, University of California–Los Angeles score.

heavy labor were allowed after 6 months. The rehabilitation protocol was home-based and did not change during the study period.

Statistical analysis

The Mann–Whitney U test for continuous variables and Fisher exact test and the chi-square test for categorical variables were used to identify differences between the remnant needle (+) group and the remnant needle (−) group in terms of various demographic, clinical and radiologic factors. The propensity score matching was used to match age, fatty infiltration, tear size, tendinosis grade, and presence of diabetes, which are known to be prognostic factors to outcomes after rotator cuff repair. The results of propensity score matching were evaluated by the value of the c-statistic and the p value of the Hosmer lemeshow goodness-of-fit test derived from the logistic regression model. PSM is considered to be appropriate when the value of c-statistics is above 0.7 and p-value of Goodness of Fit is above 0.05. Characteristics between the matched groups were compared with use of the McNemar test for binary variables, the marginal homogeneity test for multinomial variables, and Wilcoxon's signed rank test for continuous variables. The intraclass correlation coefficient (ICC), a 2-way random model with absolute agreement, was used to evaluate interrater reliabilities of the fatty infiltration of each rotator cuff muscle, tendon thickness, and tendinosis grade. The software IBM SPSS statistics 23.0 (SPSS Inc., Chicago, IL) was used for all statistical analyses, and $p < 0.05$ was considered statistically significant.

Results

The mean final follow-up period was 21.16 ± 5.15 months (range, 12–40 months). All needle of the antegrade suture passer were broken at the groove site for the suture to be put in there (this was inspected at the time of surgery, around 2 mm in length), and all broken needle tips were embedded in the medial tendon portion by the breakage occurred during the suture passing from the medial anchors (if we say the most anterior knot as 1st knot, two cases showed the broken needle tips at the 2nd knot area, 5 cases at the 3rd knot area, 7 cases at the 4th knot area, and 2 cases at the 5th knot area.). All patients accepted the broken needle tips inside the shoulder, and none of them wanted additional surgery for the removal. All these embedded needle tips did not migrate from the original locations, which were confirmed by serial X-rays until final follow-ups of 2, 5 weeks, 3, 6 months, and at least 1 year after surgery.

Patients with broken needle tips embedded inside the tendon showed preoperative thicker tendon ($p = 0.047$), worse tendinosis grade ($p = 0.029$), and higher incidence of the delamination tears ($p = 0.035$), compared with those without remnant needle tip inside the tendon. The characteristics of the remnant needle tip (+) group compared with the remainders were listed in Table 1.

When we compare the surgical outcomes between these matched groups, after securing the comparability with reducing the selection bias by propensity score matching, there was no difference in the healing failure rate (18.8% (3/16) in the matched remnant needle tip (+) group and 21.9% (14/64) in the matched remnant needle tip (−) group, $p = 0.827$). In addition, the functional outcomes evaluated at least 1 year after surgery did not reveal any differences between matched groups (Table 3 and Fig. 5).

However, the patients with the matched remnant needle tip (+) group showed higher pain VAS at the earlier postoperative period (pain VAS: 4.13 ± 2.07 vs. 2.48 ± 1.61 ($p = 0.032$) at 5 weeks and 3.79 ± 2.12 vs. 2.25 ± 1.76 ($p = 0.044$) at 3 months), but the differences were disappeared after 6 months (Fig. 6). In addition, there was not any significant correlations between preoperative tendon thickness and pain VAS at any postoperative period (all $p > 0.05$) in remnant needle tip (−) group.

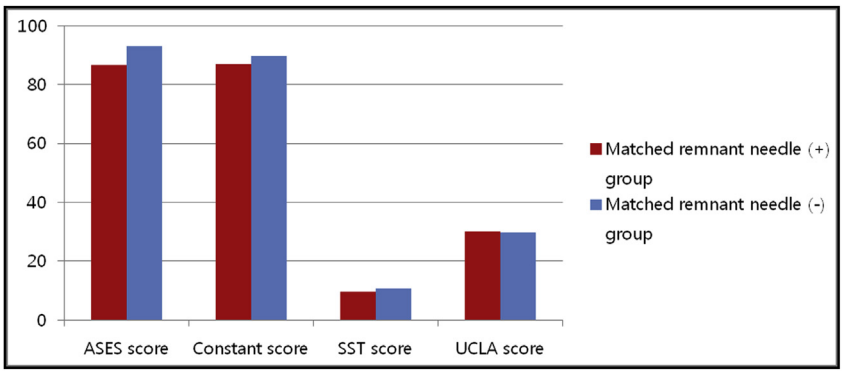

Fig. 5. Shows the functional outcomes evaluated at final follow-up (>1yr) between matched groups.

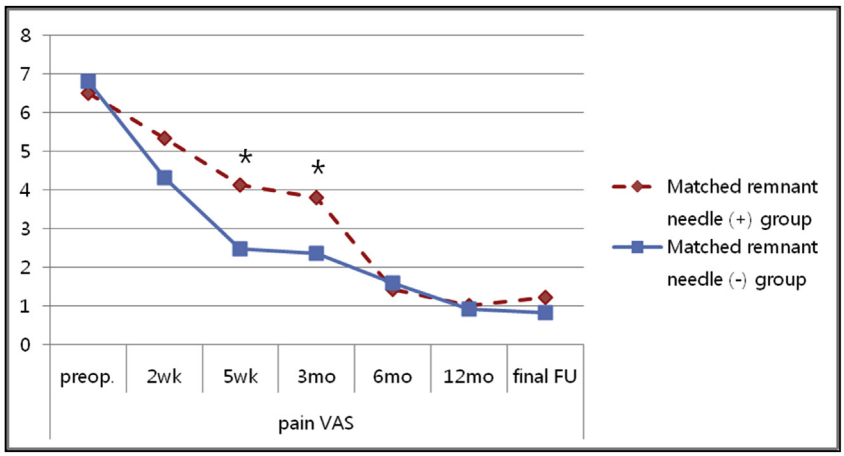

Fig. 6. Shows the comparison of the pain VAS between matched groups, *statistically significant.

The range of motion of shoulder (forward flexion, external rotation, and internal rotation) did not show any differences in any measured postoperative period (all $p > 0.05$, Fig. 7).

Discussion

The present study revealed that patients with thicker tendon, higher tendinosis, and delamination tears were related with higher incidence of needle breakage of the antegrade suture passer and embedding inside the tendon, and the needle breakage seemed to be associated with higher pain VAS scores in the early post-operative period.

The preoperative higher grade of tendinosis means a more swollen and degenerated tendon due to the overuse or chronic damage to the area, and in this condition, the tendon may be prone to be getting thicker and hardening at the time of surgery because

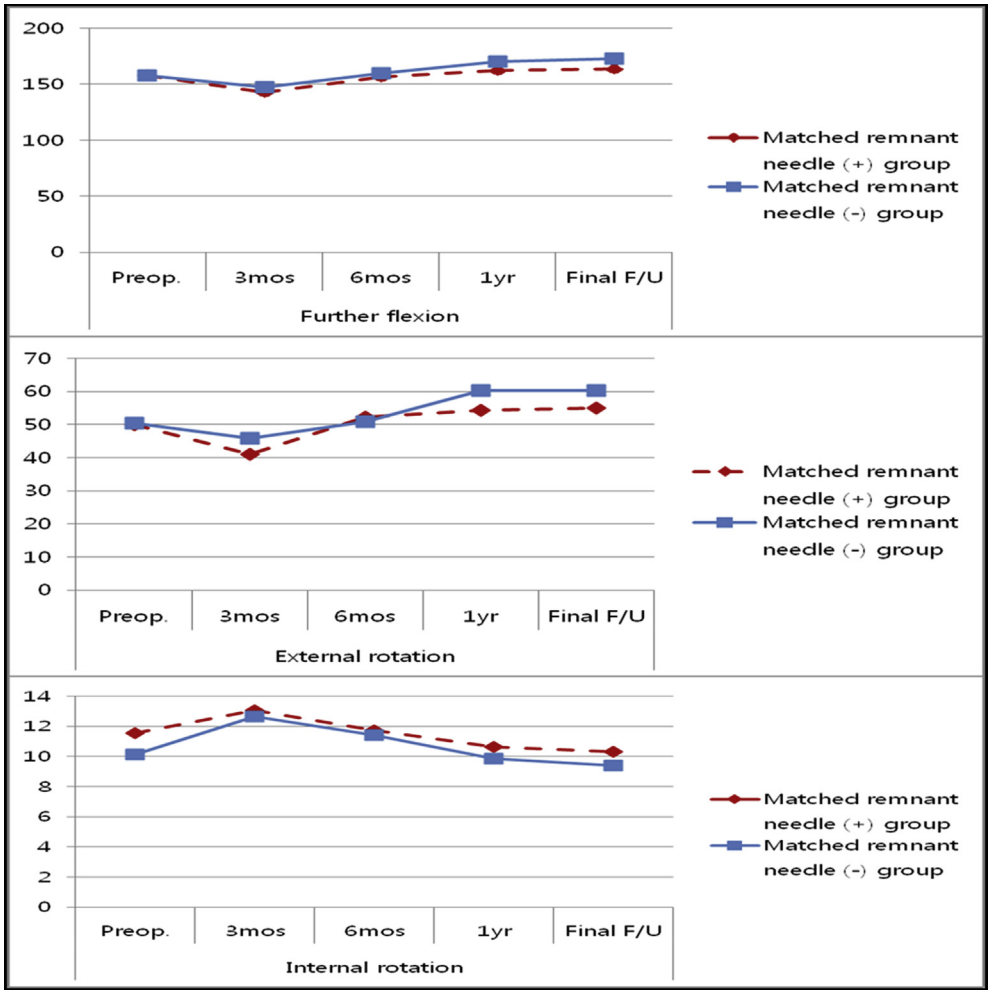

Fig. 7. Shows forward flexion, external rotation at the side, internal rotation at the back. The range of motion of shoulder did not show any differences in all postoperative periods.

of the chronic inflammation.[19] The thicker and harder tendon would have higher resistance to the suture needle passage, and sometimes the needle may be inadvertently broken during the passage.[20]

In addition, delamination tears, which were defined as horizontal cleavage between bursal and articular side of tendon, manifest thickening of the torn tendon.[13] The delaminated surfaces of each bursal and articular side tendon usually form synovial lining and may experience thick fibrotic change.[21] Thus, we think, the delaminated torn tendons which are prone to be thicker than non-delaminated tendons may have higher possibility to cause needle breakage during the needle passage through the tendon.

The needle breakage of antegrade suture passer would be come from the technical problem. There might be a problem within the mechanism of handle which disturbed the antegrade needle passing and there is a possibility of needle tip breakage by hitting on the undersurface of acromion within narrow subacromial space.

In fact, we are now more carefully managing the thick and delaminated tendons, and the incidence of needle breakage seemed to be minimized in our practice since then.

After eliminating the influence of confounding factors by propensity score matching, we demonstrated that the remnant needle tip embedded in the tendon was related with the postoperative pain at early postoperative period up to 3 months, but did not affect final functional and anatomical outcomes. The retained soft tissue foreign body such as remnant needle tip in the tendon causes acute inflammatory reaction dominated by macrophage invasion, and over time, this early inflammatory process transforms into a chronic granulomatous reaction promoting wound healing.[22–24] This acute local inflammatory reaction and neovascularization by retained soft tissue foreign body may cause pain and tenderness by pain-related inflammatory mediators.[25,26] Andrew et al[27] previously reported that the foreign body particularly within a tendon sheath can result in tenosynovitis and pain. We also showed similar result of more postoperative pain at early postoperative period in patients with remnant intratendinous needle tip. In addition, at first, we searched a broken needle tip to pick up using a forceps or probe, even though we did not overdo our strength to remove the embedded needle tip if it is hard to find and remove. Such procedures might cause damage and induce local inflammation of the rotator cuff tendon, and the operation time would take longer than that without needle breakage. This may be another reason of higher pain scores during the early postoperative period.

Over time, the foreign body would experience late foreign body reaction with collagen capsule formation surrounding the foreign body to shield the host from the foreign material, forming granulomas.[28] However, we think, that until final motionless stabilization of intratendinous foreign body, micromotions of the foreign body while moving the shoulder and possible tension mismatch between the layers with and without foreign body, may also a reason for the pain at early postoperative period. The motionless stabilization of the intratendinous foreign body seems to be acquired after 3 months after surgery. Zheng et al[29] described that the acute foreign body reaction with local inflammatory reaction will be diminished by 90 days, then to a late foreign body reaction. In addition, Rodeo et al[30] reported that complete healing between the collagen fibers of the tendon and the surrounding bone was acquired by 26 weeks in a dog model. Thus, we think that the mature healing surrounding the intratendinous remnant needling tip may similarly require at least 3 months and up to 26 weeks. This may explain in part our results which showed more pain up to 3 months after operation in patients with remnant intratendinous needle tip, but no difference in outcomes at final follow-up period at least 1 year after surgery. That is, the stabilized intratendinous remnant needle tip without acute inflammatory reaction at late postoperative period does not seem to irritate adjacent tendon tissue anymore, and does not seem to affect late postoperative functional outcomes and rotator cuff healing. Or, we think that the broken needle tip at the groove site of the antegrade suture passer is very small and this intratendinous remnant needle tip may not be big enough to cause late postoperative symptoms by foreign body.

This is the first comparative study to report the effect of retained soft tissue foreign body, intratendinous remnant needle tip in this study, on outcomes after rotator cuff repair. However, several limitations of this study should be noted. First, this was a retrospective study. Even though we used PSM to sophisticatedly eliminate the influence of confounding factors as much as possible and to overcome the limitation of the retrospective study, we cannot deny the possibility of a selection bias of which we were not aware. Second, the sample size was small, likely attributed to the low frequency of incidence of the needle breakage during rotator cuff repair using the antegrade suture passer. In addition, due to the small sample size, we could not match for all relevant factors to the outcomes in PSM. More studies with larger cohorts, including a multicenter approach, are warranted to exclude the possibility of type-2 error, to more successfully match for every relevant factor to outcomes, and to confirm our results. Third, not all patients who underwent arthroscopic repair for full-thickness rotator cuff tears were included and the dropout rate in the remnant needle tip (−) group was high (84/267, 31.4%) due to the strict inclusion criteria; that is, we limited the patients to those who completed outcome evaluation both anatomically (MRI or ultrasonography) and functionally at least 1 year after surgery. Some patients refused MRI and even ultrasonography because they did not want the rather expensive and time-consuming procedures. This dropout from the cohort might cause the risk of selection bias of which we were not aware. Finally, no further examinations for the gross and histological change of peri-foreign body tissues, such as second-look arthroscopy were performed. Additional studies may be required to confirm the early and late biological and histological changes of the tendon around the remnant needle tip.

Conclusion

Breakage of the needle of the antegrade suture passer occurred more frequently in the thicker tendon, higher tendinosis, and delaminated tears. The retained broken needle tip was associated with higher pain scores during the early postoperative period, but revealed no difference in final outcomes by using PSM.

Conflicts of interest and source of funding

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