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Aims and Scope

Clinics in Shoulder and Elbow (Clin Shoulder Elbow, CiSE; eISSN: 2288-8721) (pISSN: 2383-8337 till 2018) is an international, peer-reviewed journal and the official journal of Korean Shoulder and Elbow Society. It was first launched in 1998 (from March 1998 to June 2010: Journal of the Korean Shoulder and Elbow Society). It is published quarterly in the first day of March, June, September, and December, with articles in English, and has been published as an online-only journal since 2019.
The purposes of CiSE are: first, to contribute in the management and education of shoulder and elbow topics; second, to share latest scientific informations among international societies; and finally, to promote communications on shoulder/elbow problems and patient care. It can cover all fields of clinical and basic researches in shoulder and elbow.
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Editorial Board

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CiSE
Clinics in Shoulder and Elbow

Contents

Volume 24 · Number 4 · December 2021

Editorial

Original Articles

Case Reports

Concise Review

Editorial

Clin Shoulder Elbow 2021;24(4):199-201
https://doi.org/10.5397/cise.2021.00640

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Is bending the hook plate necessary in acromioclavicular joint dislocation?

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Hook plate placement to treat acromioclavicular joint dislocation has been used widely since the 1980s despite the inconvenience of having to remove the plate several months after surgery [1]. The reason for its continued use is that the operation is simple, and the effect is satisfactory [2,3]. However, several complications of this procedure are controversial.

One of them is subacromial erosion/osteolysis due to use of a plate hook [4,5]. The study, "The clinical outcomes of bending versus non-bending of the plate hook in acromioclavicular joint dislocation," by Joo et al. [6] in the issue focuses on subacromial osteolysis of the hook plate and its associated deterioration of clinical outcomes. Several papers have demonstrated that friction pain and osteolysis are caused by compression of the subacromial area of the hook plate [7-10]. There also are reports of other complications, such as postoperative acromial fracture with severe osteolysis [11-15].

In a study by Joo et al. [6], the hook plate was bent with the angle of the plate hook an average of 21°, and patient outcomes were compared with those of the non-bending group. The results showed that the incidence of subacromial osteolysis was significantly reduced, and the clinical outcome prior to plate removal had improved considerably. Since then, several studies have described the effects of the bending of hook plates. Li et al. [16] reported improved clinical results by bending the hook by 15°. They observed that the patients' clinical outcomes were improved by reducing the amount of hook compression applied to the subacromial area by bending the hook plate. Hyun et al. [17] applied hook plate bending that followed the patient's unique acromial arch through a modified fluoroscopic technique (hook view) and obtained better results than those in patients who underwent non-bending procedures.

As reported by Li et al. [16], bending the hook plate reduces the transmission of excessive compressive force from the clavicle to the subacromial area by decreasing the clavicle angle [18,19]. However, according to a finite analysis by Hung et al. [20], increasing the bending angle can shorten the lever arm of the hook and increase the stress applied to the contact surface between the acromion and the plate. Even though the maximum stress was lower than the yield strength of the hook plate, there were no reports of deformity or hook fracture after hook plate bending. However, compared to the small number of clinical studies on bending plates, there is a large number of studies on non-bending plates. This makes it difficult to conclude that there are no problems with bending the hooks because they simply might not have been discovered yet.

Despite these studies, design of the hook plate has not changed much for 30 years. There could be many reasons for this lack of redesign. In most cases, the hook plate is removed within a few

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months, and the induced complications do not worsen after removal, and the clinical results improve in most cases [21,22]. Many studies recommend early removal of the hook plate to prevent complications and aggravation of clinical outcomes [8,19]. In a study of Joo et al. [6], there was a significant difference in osteolysis between the bending and non-bending groups. However, the difference in clinical results was resolved after metal removal. Even if there are only minor complications caused by a non-bending hook plate, it is important not to induce a severe complication by proceeding with early removal [15,23]. In the study of Oh et al. [24], 38% of subacromial erosion cases were confirmed in the group where the hook plate was removed at 5.31 months, but 67% of the group who had the hook plate removed at 9.65 months demonstrated the same type of erosion.

Because a randomized controlled trial or meta-analysis has not been published, a conclusion cannot be made about this issue. The hook plate bending technique is thought to be worth considering in surgeries that use a hook plate. Hook plates can be bent at an appropriate angle to match the patient's unique anatomy or shaped according to the patient's specific acromial curve. The results of additional future studies are needed to determine the best method.

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Clinical outcomes of bending versus non-bending of the plate hook in acromioclavicular joint dislocation

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Background: We aimed to assess the effect of plate hook bending in treatment of acromioclavicular (AC) dislocation by analyzing clinical and radiological results according to the angle of the plate hook (APH).
Methods: This was a retrospective, observational, case-control study including 76 patients with acute AC joint dislocation that were divided into two groups according to treatment with bent or unbent plate hook. The visual analog scale (VAS), the American Shoulder and Elbow Surgeons (ASES) shoulder score, and range of motion (ROM) were evaluated as clinical outcomes. Comparative coracoclavicular distance (CCD) was measured to evaluate radiological outcomes.
Results: While the VAS and ASES of the bending group at 4 months after surgery were significantly higher (p=0.021 and p=0.019), the VAS and ASES of the bending group at other periods and ROM of the bending group showed no significant difference. The initial CCD decreased from 183.2%±25.4% to 114.3%±18.9% at the final follow-up in the bending group and decreased from 188.2%±34.4% to 119.1%±16.7% in the non-bending group, with no statistical difference (p=0.613). The changes between the initial and post-metal removal CCD were 60.2%±11.2% and 57.3%±10.4%, respectively, with no statistical difference (p=0.241). The non-bending group showed greater subacromial osteolysis (odds ratio, 3.87). Pearson's coefficients for the correlation between APH and VAS at 4 months after surgery and for that between APH and ASES at 4 months after surgery were 0.74 and –0.63 (p=0.027 and p=0.032), respectively.
Conclusions: The APH was associated with improved postoperative pain and clinical outcomes before implant removal and with reduced complications; therefore, plate hook bending is more useful clinically during plate implantation.

Keywords: Acromioclavicular joint; Acromioclavicular injury; Plate hook bending

INTRODUCTION

Acromioclavicular (AC) joint injury accounts for 9%–12% of shoulder injuries that are caused by falling on outstretched hands [1]. Recently, as the frequency of traffic, industrial, and falling accidents has increased, the frequency of AC joint injuries also has increased. AC joint dislocations are classified according to the Rockwood classification [2]. Despite controversies, surgical treatment is considered in injuries more severe than type 3 [3-5]. Among the previously introduced treatment options, such as pinning, tension band wiring, washer screw, and clavicular hook plate, the best option remains controversial [6-8].

After being introduced by Hackenbruch, open reduction and internal fixation (ORIF) with a hook plate gradually grew to be

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considered the ideal method as it could easily maintain reduction without affecting the injury to the AC joint space, and it allows normal biomechanical rotation between the clavicle and scapula with non-rigid fixation. This allows long-term retention of the plates, which can help in appropriate recovery of the coracoclavicular (CC) ligament [9-12].

As the use of hook plates increased, complications related to internal fixation also increased. Complications such as subacromial impingement syndrome, subacromial erosion, metal failure, need for secondary surgery for metal removal, wide skin incision, widening of the hook hole, and pain due to metal irritation when retained for long-term and stress fractures have been reported [7,13,14]. In particular, postoperative pain was reported as a comprehensive sign of various complications that affected the shoulder. According to a report, 14% of subjects who underwent surgery with hook plates for distal clavicular fracture experienced postoperative pain [15].

Studying the cause of postoperative pain and its prevention methods has become an important task. Many studies have reported that these are related to the position of the hook plate, subacromial impingement syndrome, and functional exercise [11,12].

According to Ko [14], if the tip of the plate hook was pointing upward to the subacromion, such as in Wolter's crook plates, the pain resulting from impingement and metal irritation could not be overlooked, as three of 11 patients in that study complained of persistent pain before metal removal. In this study, we aimed to determine the effect of plate hook bending by analyzing clinical and radiological results based on the shape of the plate hook.

METHODS

We conducted this study in compliance with the principles of the Declaration of Helsinki. The study's protocol was reviewed and approved by the Institutional Review Board of Wonkwang University Hospital (IRB No. WKUHIRB 2021-07-032), and agreement of the patient was exempted as it was a retrospective study.

Subjects

This study was retrospectively performed on patients who had acute (less than 2 weeks) Rockwood type III, IV, or V AC joint dislocation and were treated with hook plate fixation at our hospital from 2011 to 2019. Among 103 patients, three who were younger than 18 years, 17 with concomitant injury, four with abnormal range of motion (ROM) before injury, and three who could not be followed up after metal removal were excluded from the study according to exclusion criteria. A total of 76 patients was included in the study. Most of the injuries were low energy, such as slipping and sports injuries, or high energy, such as falls and traffic accidents. As a result of the retrospective analysis, 31 cases underwent surgery without bending of the plates prior to and in the year 2014. As patients complained of complications such as postoperative pain, we performed downward plate bending in 45 cases from the year 2015 onward.

Surgical Technique

Surgery was performed under general anesthesia in the supine position. A senior surgeon (JWK) performed all the surgeries. The incision was made from the lateral tip of the acromion to the medial side of the coracoid process. After subcutaneous dissection, the AC joint and CC ligament were exposed. The site for the insertion of the hook plate (Arbeitsgemeinschaft für osteosynthesefragen hook locking compression plate [LCP]; Synthes, Solothurn, Switzerland; LCP clavicle hook plate, Taeyeon Medical, Seoul, Korea) was determined to be on the soft tissue posteri-

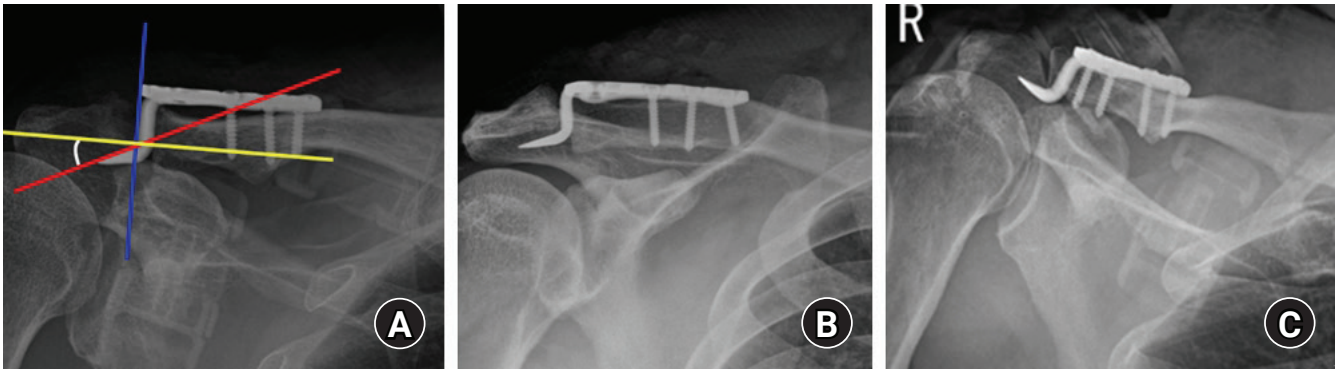

Fig. 1. (A) Plate inclined 15° downward. Angle of plate hook is the angle between the tip and longitudinal post, determined as the angle (white curved line) between the perpendicular line (yellow line) of the lateral edge of the plate (blue line) and the superior edge of the tip of the hook (red line). (B) Anteroposterior view of the shoulder radiograph with a bent plate hook. (C) Anteroposterior view of the shoulder radiograph with an unbent plate hook.

or to the AC joint. From 2015, a bending iron and flier were used to bend the plate hook approximately 15° downward by bending the tip and longitudinal post of the plate hook (Fig. 1). The plate was inserted to reach the lower part of the acromion. Downside pressure on the clavicular part of the plate was used for reduction. Furthermore, the acromion helped the reduction, as it worked as a lever. Before inserting the screws, the authors used a radiographic image intensifier to confirm the adequacy of reduction by evaluating the positions of the acromion, clavicle, and the hook fixed on the acromion.

The hook plates were removed 4 months after ORIF [16,17]. The patients performed passive forward elevation and pendulum exercises using Kenny-Howard braces from postoperative day 1 (POD 1) and then active exercise with the braces from POD 3 weeks. They were allowed to return to their everyday lives without strenuous exercise and without the braces starting at POD 6 weeks.

Hook Plate Factors

We performed a retrospective analysis by dividing the subjects into bending and non-bending groups. The angle of the plate hook (APH), that of the tip and longitudinal post of the hook plate, determined as the angle between the perpendicular line of the lateral edge of the plate and the superior edge of the tip of the hook, was evaluated in the two groups.

Clinical Evaluation

The visual analog scale (VAS) was evaluated before surgery, 4 months after the surgery (just before metal removal), 6 months after metal removal, and at the final follow-up (1 year after metal removal).

Radiological Evaluation

To evaluate AC joint reduction after the surgery, the CC distance (the height between the upper border of the coracoid process and the inferior cortex of the clavicle) was measured before ORIF and at 6 months to 1 year after metal removal. The percentage increase of the affected side compared to that of the unaffected side was calculated (comparative coracoclavicular distance [CCD]). Subluxation, re-dislocation, subacromial osteolysis, metal displacement, or peri-implant fractures were evaluated as postoperative radiological complications. Subluxation was defined as the clavicle being less than 50% displaced compared to the height of the acromion; displacement greater than 50% was defined as dislocation [18].

Statistical Analysis

The paired t-test was used to assess differences between the preoperative and postoperative outcomes in each group, while an independent t-test was used to compare results between the groups. The chi-square test and Fisher's exact test were used to assess categorical data of the injury type. Pearson's coefficient was used to describe the correlations of APH and other outcomes with statistically significant difference between the two groups. The SPSS ver. 12.0 (SPSS Inc., Chicago, IL, USA) was used for all statistical analyses. The significance level for all analyses was set at $p < 0.05$.

RESULTS

The mean age of the subjects was 52.9 years (range, 24–82 years) for the bending group and 56.4 years (range, 29–81 years) for the non-bending group. The American Shoulder and Elbow Surgeons (ASES) shoulder score and ROM were used to evaluate

Table 1. Demographics of the subgroups

Variable	Bending group	Non-bending group	p-value
Case	45	31	-
Type of hook plate (AO/Taeyeon)	14:31	13:18	0.333
Sex (male:female)	26:19	17:14	0.799
Age (yr)	52.9 (24–82)	56.4 (29–81)	0.254
Angle of plate hook (°)	2.8 ± 1.2	21.2 ± 6.9	0.031
Follow-up period after metal removal (mo)	16.1 ± 1.4	15.7 ± 1.1	0.352
Injury type			0.862
High-energy (fall down, traffic accident)	37	25	
Low-energy (slip down)	8	6	
Classification			0.976
Rockwood III	14	9	
Rockwood IV	6	4	
Rockwood V	25	18	

Values are presented as number, median (range), or mean±standard deviation. A p-value <0.05 was considered significant.

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functional outcomes at every regular follow-up. Metal removal was performed 4.1 ± 0.4 months after surgery. The mean follow-up periods were 16.1 ± 1.4 and 15.7 ± 1.1 months for the bending and non-bending groups, respectively. The demographic data are shown in Table 1. The number of low-energy injuries was 14, while that of high-energy injuries was 62. The mean APH of the bending group was 21.2° ± 6.9°, while that of the non-bending group was 2.8° ± 1.2° (p = 0.031).

In the clinical outcomes, the VAS of the bending group improved from 3.8 ± 0.9 before surgery to 2.2 ± 0.4, 1.2 ± 0.2, and 1.1 ± 0.1 at 4 months after surgery (just before metal removal), 6 months after metal removal, and at the final follow-up (1 year after metal removal), respectively; while that for the non-bending group improved from 3.7 ± 0.6 to 3.5 ± 0.3, 1.4 ± 0.3, and 1.2 ± 0.2, respectively. In particular, the VAS at 4 months after surgery was better in the bending group than in the non-bending group with statistical significance (p = 0.021) but did not show a statistically significant difference at 6 months after metal removal or at the final follow-up (Table 2).

The ASES score in the bending group improved from 66.2 ± 49.1 at 4 months after the surgery to 83.2 ± 44.8 at 6 months after metal removal and 85.1 ± 42.3 at the final follow-up; in the non-bending group, it improved from 56.2 ± 39.8 at 4 months after the surgery to 79.2 ± 9.8 and 82.1 ± 30.1. The ASES at 4 months after surgery was better in the bending group than in the non-bending group with statistical significance (p = 0.019) but did not show a statistically significant difference at 6 months after metal removal or at the final follow-up (Table 2).

In ROM, active forward elevation angles at 4 months after surgery were 121.1° ± 13.8° and 105.1° ± 16.4° in the bending and non-bending groups, respectively. At 6 months after metal removal, they improved to 141.1° ± 16.4° and 139.3° ± 15.5°, respectively. At the final follow-up, they were 151.1° ± 12.3° and 148.7° ± 10.1°, respectively. There was no statistically significant difference at any time point. External rotation, internal rotation, and abduction showed the same tendencies (Table 2).

CCD measurement for evaluation of radiological outcomes was 183.2% ± 25.4% preoperatively and 114.3% ± 18.9% at 4 months after surgery in the bending group and 188.2% ± 34.4% and 119.1% ± 16.7%, respectively, in the non-bending group. The changes in CCD between the initial measurement and the post-metal removal measurement were 60.2% ± 11.2% in the bending group and 57.3% ± 10.4% in the non-bending group, with no statistical significance (p = 0.241). The two groups showed decreased post-

Table 2. Comparison of clinical outcomes between the subgroups

Variable	Bending group	Non-bending group	p-value
Initial outcome			
VAS score	3.8 ± 0.9	3.7 ± 0.6	0.361
POD 4-month outcome			
VAS score	2.2 ± 0.4	3.5 ± 0.3	0.021
ASES score	66.2 ± 49.1	56.2 ± 39.8	0.019
Post-metal removal outcome			
VAS score	1.2 ± 0.2	1.4 ± 0.3	0.235
ASES score	83.2 ± 44.8	79.2 ± 9.8	0.247
Last FU outcome			
VAS score	1.1 ± 0.1	1.2 ± 0.2	0.317
ASES score	85.1 ± 42.3	82.1 ± 30.1	0.251
Range of motion (POD 4 mo, °)			
Active FE	121.1 ± 13.8	101.5 ± 14.7	0.341
ER	55.2 ± 8.3	54.3 ± 11.3	0.237
IR	24.5 ± 6.9	25.1 ± 3.8	0.155
Abduction	75.1 ± 4.9	64.0 ± 8.5	0.148
Range of motion (last FU, °)			
Active FE	151.1 ± 12.3	148.7 ± 10.1	0.982
ER	74.2 ± 12.3	73.8 ± 11.7	0.754
IR	33.2 ± 5.8	32.7 ± 6.3	0.894
Abduction	85.2 ± 10.4	84.9 ± 7.4	1.014

Values are presented as mean±standard deviation. A p-value <0.05 was considered significant.
VAS: visual analog scale, POD: postoperative day, ASES: American Shoulder and Elbow Surgeons, FU: follow-up, FE: forward elevation, ER: external rotation, IR: internal rotation.

Table 3. Comparison of CCD measurement and complications between the subgroups

Variable	Bending group (n = 45)	Non-bending group (n = 31)	p-value
Initial CCD (affected:unaffected, %)	183.2 ± 25.4	188.2 ± 34.4	0.214
Postoperative CCD (%)	97.3 ± 16.2	97.8 ± 12.7	0.857
Post-metal removal CCD (%)	114.3 ± 18.9	119.1 ± 16.7	0.613
Change between initial and post-metal removal CCD (%)	60.2 ± 11.2	57.3 ± 10.4	0.241
Pathology of AC joint (intact:subluxation:re-dislocation)	35:9:1	25:6:0	0.701
Subacromial osteolysis	3	8	0.020

Values are presented as mean±standard deviation or number. A p-value <0.05 was considered significant.
CCD: comparative coracoclavicular distance, AC: acromioclavicular.

operative CCD compared to the preoperative states and showed no significant difference between the two groups (Table 3).

After metal removal, nine cases in the bending group and six in the non-bending group showed subluxation, and there was an increasing tendency according to the increase in severity of the injury subtype. Asymptomatic patients underwent conservative treatment. One patient showed symptoms of pain and discomfort and underwent the Weaver-Dunn procedure. One case in the bending group showed re-dislocation, which required refixation with another hook plate (Table 3).

A total of 11 cases showed subacromial osteolysis during the final radiological follow-up with X-rays, with most of these cases (n = 8) being in the non-bending group. The odds ratio between the two groups was 3.87 (8/31:3/45), showing significantly increased subacromial osteolysis in the non-bending group (p = 0.020) (Table 3).

Among the outcomes, VAS and ASES at 4 months after surgery and the proportion of the number of patients with subacromial osteolysis showed statistically significant difference between the two groups. The amount of subacromial osteolysis was not quantifiable, thus the odds ratio between the groups were not evaluated. Therefore, we used Pearson's coefficient for the correlation between APH and VAS at 4 months after surgery, along with the correlation between APH and ASES at 4 months after surgery. Pearson's coefficient of the former was 0.74 (p = 0.027), while that of the latter was −0.63 (p = 0.032) (Table 4).

Other complications, such as deep infection or nerve injury, were not observed in this study. According to the results of this study, the mean APH of the two groups was different (2.8° ± 1.2° in the bending group and 21.2° ± 6.9° in the non-bending group), and this difference in APH was a factor of significant differences in VAS and ASES at 4 months after surgery (Table 2).

Table 4. Correlations of APH with other outcomes

Variable	Pearson's coefficient	p-value
APH and VAS score at 4 months after surgery	0.74	0.027
APH and ASES score at 4 months after surgery	−0.63	0.032

A p-value <0.05 was considered significant.
APH: angle of plate hook, VAS: visual analog scale, ASES: American Shoulder and Elbow Surgeons.

DISCUSSION

In this study, while APH according to bending of the plate hook did not affect postoperative CCD, it was an associated with postoperative pain and clinical outcomes before implant removal and reduced complications such as subacromial osteolysis and impingement.

Postoperative shoulder pain is the most common complication associated with hook plate fixation, which adversely affects postoperative rehabilitation. This suggests the need to study the cause of pain and its prevention. The main cause was suggested to be related to the plate itself, such as impingement between the clavicle and hook, length of the hook tail, and position. Therefore, early metal removal is recommended for fast rehabilitation [1,19].

According to ElMaraghy et al. [20], the hook can injure the subacromial bursa, narrowing the space and decreasing ROM. In this study, patients showed restricted ROM at 4 months after surgery. At the time of the last follow-up after metal removal, compared to at 4 months after surgery, most patients recovered to normal ROM. In contrast, the non-bending group showed significantly inferior results compared to the bending group in VAS and clinical scores at 4 months after ORIF, which was before metal removal. This is suspected to be due to the sharp tip of the hook plate, which irritates the subacromial space. Without bending, the tip of the hook has a high possibility of being upturned, which can increase the stress on the tip of the hook in the subacromial space due to point contact rather than surface contact, leading to aggravation of the bony erosion and shoulder pain. According to a report by Xu et al. [21], as a mechanical factor,

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APH independently affected the outcome, showing better outcomes in a group with a higher angle. The bending and non-bending groups had differences in APH, which led to significant differences in pain and clinical scores at 4 months after ORIF, with the bending group showing better clinical outcomes.

When hook plates are used without modification, the risk of complications such as subacromial osteolysis, which can lead to pain, increases due to the concentration of stress on both tips of the plate [21,22]. In this study, CCD according to hook plate bending did not show a statistically significant difference between the two groups (postop CCD, p=0.857) (Table 3), indicating that bending the plate had no effect on postoperative CCD (post-metal removal CCD, p=0.613) (Table 3). Even though there was no significant difference between the groups according to bending itself, the non-bending group showed more severe subacromial osteolysis (8/31) compared to the bending group (3/45) (odds ratio, 3.87).

ORIF with a hook plate can maintain shoulder function based on leverage [16] but can cause complications such as postoperative pain. In particular, decreased APH, caused by not bending the plate, acted as a factor of pain at 4 months after ORIF. However, this can be managed by metal removal, as evidenced by the lack of significant difference in VAS, which was better in the bending group at 4 months after surgery, between the two groups at the last follow-up.

This study has certain limitations as it was performed retrospectively in a single center with a small number of subjects. In addition, two types of implants were used, but analysis between the implants could not be performed due to the small number of samples. Also, the native acromial slope was not considered as a factor. This study, however, is meaningful for evaluating the factors that affect clinical outcomes and complications before and after metal removal.

The APH was associated with improved postoperative pain and clinical outcomes before implant removal and with reduced complications; therefore, plate hook bending is considered useful clinically during plate implantation.

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Anatomic reconstruction for acromioclavicular joint injuries: a pilot study of a cost-effective new technique

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Background: The treatment for acromioclavicular joint injuries (ACJI) ranges from a conservative approach to extensive surgical reconstruction, and the decision on how to manage these injuries depends on the grade of acromioclavicular (AC) joint separation, resources, and skill availability. After a thorough review of the literature, the researchers adopted a simple cost-effective technique of AC joint reconstruction for acute ACJI requiring surgery.

Methods: This was a prospective single-center study conducted between April 2017 and April 2018. For patients with acute ACJI more than Rockwood grade 3, the researchers performed open coracoclavicular ligament reconstruction using synthetic sutures along with an Endobutton and a figure of 8 button plate. This was followed by AC ligament repair augmenting it with temporary percutaneous AC K-wires. Clinical outcomes were evaluated using the Constant Murley shoulder score.

Results: Seventeen patients underwent surgery. The immediate postoperative radiograph showed an anatomical reduction of the AC joint dislocation in all patients. During follow-up, one patient developed subluxation but was asymptomatic. The mean follow-up period was 30 months (range, 24–35 months). The mean Constant score at 24 months was 95. No AC joint degeneration was noted in follow-up X-rays. The follow-up X-rays showed significant infra-clavicular calcification in 11 of the 17 patients, which was an evidence of a healed coracoclavicular ligament post-surgery.

Conclusions: This study presents a simple cost-effective technique with a short learning curve for anatomic reconstruction of acute ACJI. The preliminary results have been very encouraging.

Keywords: Acromioclavicular joint; Coracoclavicular reconstruction; Open technique; Anatomical reconstruction; Shoulder

INTRODUCTION

Acromioclavicular joint injuries (ACJI) are commonly seen in orthopedic surgery and sports medicine [1]. They often occur in athletes and youth after blunt force to the shoulder. The true incidence of ACJI has not been accurately reported, as many minor cases are missed [1]. The injured AC joint can cause persistent pain and compromise the function of the shoulder joint. The treatment of ACJI is controversial and ranges from a conservative approach to extensive surgical reconstruction. The decision on the best way to manage these dislocations depends on the grade of AC joint separation, availability of appropriate skills, and resources.

A wide variety of operative techniques using K-wires, hook

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plates, button plates, suture anchor fixation, and ligament reconstruction have been reported with different success rates [2,3]. After a thorough review of the literature, the authors decided to adopt a simple, cost-effective technique of AC joint reconstruction for acute ACJI requiring surgery. They performed coracoclavicular (CC) ligament reconstruction using synthetic sutures and AC ligament repair augmenting it with temporary percutaneous AC K-wires.

In this study, the authors intended to detail their technique, explain the rationale and merits behind such a technique, and report on the functional outcomes with a 2-year follow-up. To their best knowledge, such a technique has not yet been reported in the literature.

METHODS

This was a prospective single-center study conducted between April 2017 and April 2018. The approval of Institutional Ethical Committee of Government Mohan Kumaramangalam Medical College Hospital was obtained (No. 76/LE/18221). Detailed consent was obtained from the patients. The study excluded patients with chronic ACJI (of more than 2 weeks duration), Acute ACJI-Rockwood grade ≤III, previous history of clavicle and acromion fractures, patients more than 60 years of age or less than 20 years of age, and those with a history of chronic shoulder pain. Diagnosis and grading of AC injury was conducted based on a standard anteroposterior stress radiograph of the involved shoulder. The radiological examination included anteroposterior, axillary, and Zanca radiographic views [4]. Clinical outcomes were evaluated using the Constant score [5].

Operative Technique

Under general anesthesia, the patient was placed in the supine position with a sandbag under the ipsilateral scapula. The shoulder and upper extremity were prepped and draped. A 5-cm sabercut incision was made along the Langer's line, starting 1 cm posterior to the clavicle and extending anterior to the clavicle (Fig. 1), 2.5 cm medial to the AC joint. The deltoid and trapezius muscles were elevated subperiosteally from the distal clavicle and anterior acromion.

The base of the coracoid was prepared. The medial and the lateral ends of the coracoid were visualized. The center of the coracoid was marked. The entire length of the coracoid was then drilled with a 4-mm endoscopic reamer directing it slightly anteriorly, respecting neurovascular structures below. The titanium endo button (Onbutton; Biotek, Vadodara, Gujarat, India) was loaded with three size-2 fiber wires (BioFiber; Biotek, Vadodara, Gujarat, India) manually and was pushed through the coracoid using a 3.2-mm plunger. The Endobutton flipped under the coracoid (Fig. 2). A 3.2-mm drill bit was used to create two tunnels through the superior cortex of the clavicle over the footprint of the two parts of the CC ligament—the trapezoid and the conoid respectively—about 1 cm apart and 2 to 5 cm from the lateral end of the clavicle, one anterolaterally and the other posteromedially. A large, curved cutting needle was passed through these tunnels to retrieve three strands of the fiber wire through each hole. The strands were then passed through the two holes of an eight plate or a two-holed reconstruction plate (Universal Co., Salem, India) placed over the top of the clavicle. The AC joint was reduced to a small degree below its normal anatomical position, and the ends of fiber wires were tied and tightened over the plate (Fig. 3). The AC ligaments were now repaired if both the ends of torn ligaments were identifiable. If not, the acromial part was tied to the button plate using size 2 ethibond (Fig. 3). Then, 1.8-mm K-wires were passed across the AC joint from outside without exploring the joint to augment the repaired AC ligaments. The delto-trapezial aponeurosis and fascia were meticu-

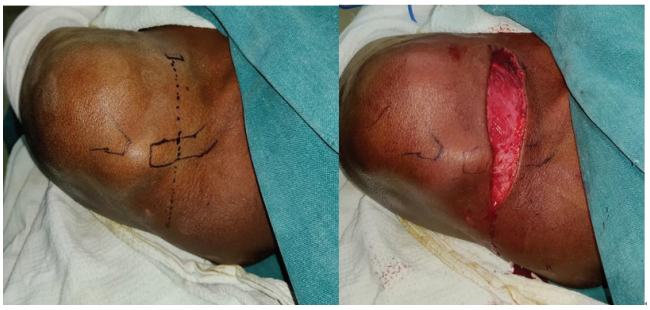

Fig. 1. Sabercut incision.

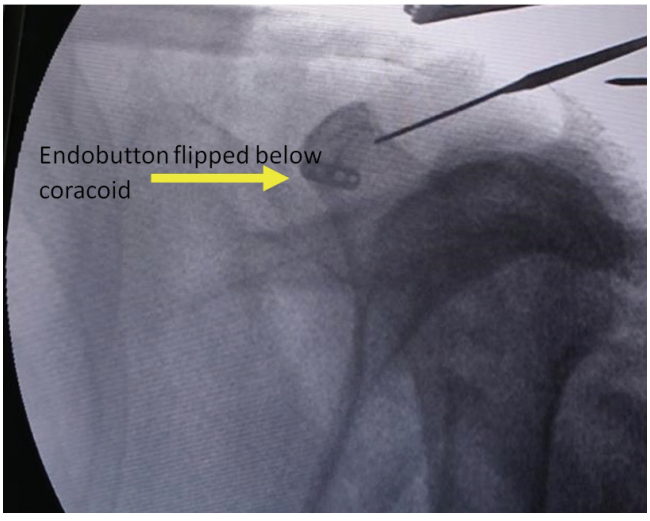

Fig. 2. C arm image after flipping the Endobutton.

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lously closed. Skin closure was performed. The important steps of the surgical technique are illustrated in the form of a line diagram in Fig. 4.

Postoperatively, the shoulder was protected in a sling for 3 weeks. Pendulum exercises were started 2 weeks after surgery. After the third week, K-wires were removed and the patients were taught progressive range of motion exercises. Heavy weight-lifting and resistance exercises were allowed after 3 months of surgery.

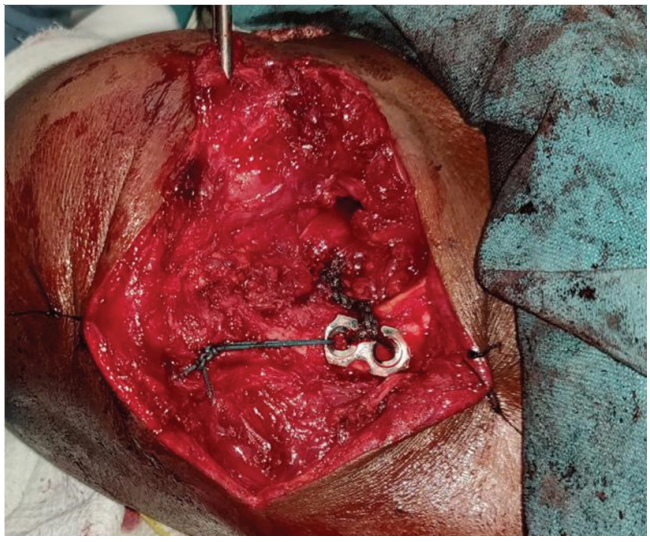

Fig. 3. Acromioclavicular ligament being repaired to the 8 plate. Note the oblique position of the plate indicating an anterolateral and a posteromedial position of drill holes on the clavicle, replicating the natural anatomy.

RESULTS

Seventeen patients (4 females and 13 males) with acute ACJI who met study criteria received surgical intervention and were followed for an average of 2 years. The average age of presentation was 37 years (standard deviation [SD], 7.6). Average time of presentation since injury was 4.6 days (SD, 2.6). All cases were Rockwood grade 5 injuries. The immediate postoperative radiograph showed an anatomical reduction of the AC joint dislocation in all patients (Fig. 3). No neurovascular complications were noted postoperatively. No implant-related and soft tissue complications were encountered.

During follow-up, one patient developed subluxation but was asymptomatic. The mean follow-up period was 30 months (range, 24–35 months). All patients had a clinically good range of movements and pain-free joints by an average of 10 weeks post-procedure. The mean Constant score at 24 months was 95 (SD, 3.5). No AC joint degeneration was noted in follow-up X-rays (Fig. 5). Follow-up x-rays showed significant infra-clavicular calcification (Fig. 6) in 11 of the 17 patients, which is an evidence of a healed CC ligament [6].

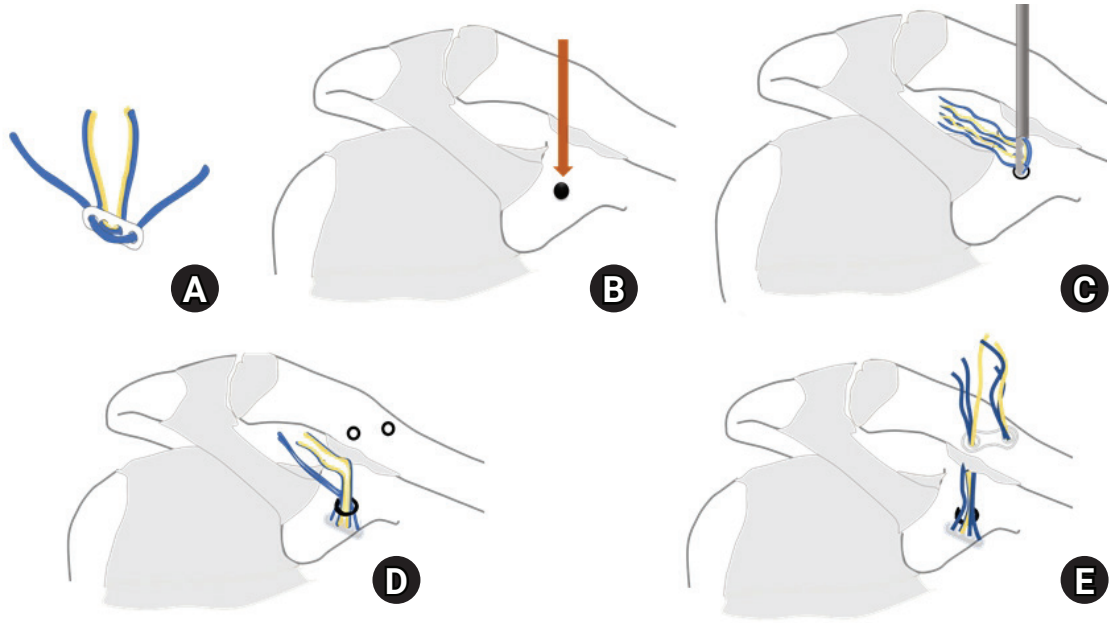

Fig. 4. Line diagram illustrating important steps of surgery. (A) Free Endobutton mounted on 3 fiber wires. (B) Point marked on the center of the coracoid near its base for coracoid tunnel. (C) Using 3.2-mm plunger the Endobutton is passed through the tunnel. (D) Endobutton is flipped below the coracoid. Drill holes over the clavicle are marked over the conoid and trapezoid footprints. (E) Fiber wires shuttled over the clavicle over the 8 plate.

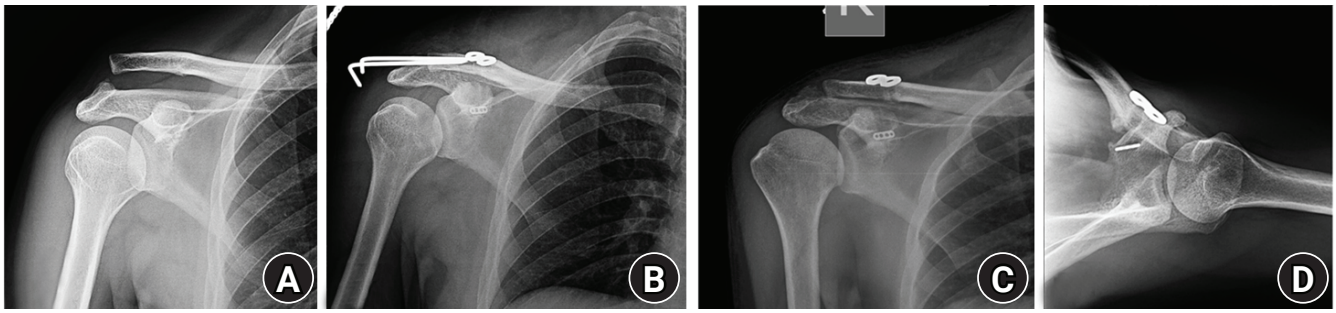

Fig. 5. Case example. (A) Preoperative X-ray showing type 5 acromioclavicular joint disruption. (B) Immediate postoperative X-ray with K-wires (C) *in situ* and (D) follow-up anteroposterior and axillary views after 25 months.

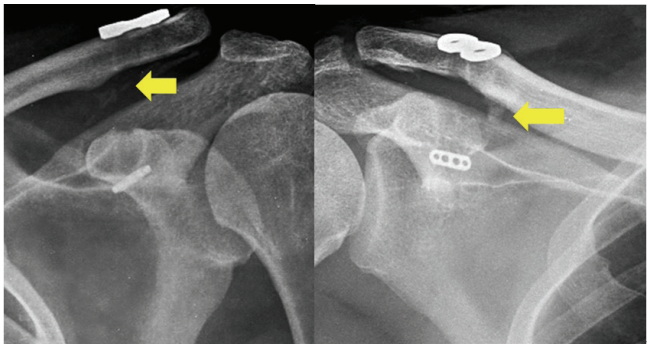

Fig. 6. Infraclavicular calcifications (arrows) in the follow-up X-rays of the patients.

DISCUSSION

Understanding the pathoanatomy and mechanism of injury is important for adopting an appropriate surgical technique. The joint capsule or AC ligament (i.e., thickenings in the capsule) and the extracapsular CC ligaments provide static stability to the AC joint [7,8]. Physiologic forces and the weight of the arms place significant translational forces in the vertical, anteroposterior, and axial planes of the AC joint. AC ligaments are the primary restraints of anterior translation [8]. The CC ligaments are formed by the conoid medially and the trapezoid laterally. They are the primary restraint to the inferior and medial translation of the scapulohumeral complex in relation to the clavicle [9]. The conoid ligament is attached proximally on the posteromedial aspect under the surface of the clavicle, typically 4.5 cm from the AC joint (47.2 mm in men and 42.8 mm in women) [7]. It tenses under loads that force the clavicle superiorly (or the scapula inferiorly). The trapezoid attaches proximally to the anterolateral aspect of the inferior clavicle, approximately 2.5 cm from the joint (25.4 mm in men and 22.9 mm in women) [8]. It tenses when there is medialization of the scapulohumeral complex, i.e., compression of the AC joint. The delto-trapezial aponeurosis and fascia provide dynamic stabilization to the AC joint, especially the anterolateral deltoid insertion [10].

The typical trauma mechanism is a force that depresses the shoulder girdle, such as that occurring in a fall from a two-wheeler on the shoulder or during a collision in contact sports. The force depresses the scapulohumeral complex resulting in tears of the AC and the CC ligaments [10]. The authors used the Rockwood classification [11] to grade ACJI. Surgery is generally indicated for types 4, 5, and 6 injuries. Conservative treatment is advised for types 1 and 2. Type 3 injuries are initially treated conservatively. Surgical intervention is done if needed later on [12-14].

Numerous surgical repair or reconstruction techniques have been published. In 2013, the number of different surgical techniques described was 162 [15]. Surgical procedures have gradually evolved from hardware fixation of the AC and CC joints through the reconstruction of ligaments by an array of methods such as utilization of the coracoacromial ligament, use of autologous or allografts, suture anchors, and flipped buttons to mini-open, arthroscopy assisted, and all arthroscopic techniques [16].

With increased understanding of the biomechanics of the AC joint, there is a greater inclination towards the use of anatomic ligament reconstruction techniques such as the use of synthetic sutures in the form of anchors or buttons, synthetic tapes, or auto or allografts, as they help in regaining pre-trauma biomechanics and function of the joint [15].

Beitzel et al. [15], in their systematic review, have described anatomic reconstruction as "the one that respects the bony anatomy of the clavicle and the acromion and reconstructs both the conoid and the trapezoid ligaments respecting their anatomy and individual function." They emphasized that the reconstruction should allow the complex three-dimensional motion pattern of the shoulder joint complex without compromising the stability of the construct. They preferred reinforcement of AC ligaments in the form of reefing of the overlying fascia.

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Among the various methods of anatomic reconstructions, use of synthetic suture materials is one of the simplest methods available. Walz et al. [6], in a cadaveric study of 40 shoulders, did a load test on native and reconstructed AC joints. They used two tight ropes for the reconstruction of CC ligaments and concluded that the technique is a stable and functional anatomic reconstruction procedure. In their cadaver study of Jerosch et al. [17] also emphasized a similar model. Synthetic suture reconstruction is recommended for acute injuries (< 2 weeks) [15] as there is a high chance of healing natural ligaments post-reconstruction. In chronic injuries, it is recommended to use grafts for ligament reconstruction as chances of healing are minimal [15].

Though studies support the reconstruction of the CC ligament alone, it does not restore the complete natural anatomy as the additional anteroposterior stability provided by the AC ligaments is lacking [8,18]. Lädermann et al. [19] used nonabsorbable sutures in the form of cerclage wires to reconstruct AC ligaments. Jerosch et al. [17] pointed out that anterior dislocation of the clavicle may result after some forms of CC reconstruction. Reconstruction of the AC ligament not only provides AP stability but also reduces the stress on the reconstructed CC ligament. Persistent AP instability has been described as a cause of chronic shoulder pain after AC joint reconstruction [19].

The authors have addressed acute ACJI considering all the inputs from the literature. Respecting the natural anatomy of conoid and trapezoid, they used synthetic sutures to reconstruct the ligaments. They restored anteroposterior stability by repairing the AC ligaments, closing the delto-trapezial aponeurosis and fascia, and temporarily augmenting this with K-wires until the ligaments healed. The load to failure of CC ligaments was 500 ± 134 N, which was much less when compared to the material properties of the synthetic sutures that they have used [8,20]. The appearance of infraclavicular calcifications show healed CC ligaments which will provide permanent AC joint stability [6].

The advantages of this procedure include that this is a simple cost-effective procedure with a short learning curve when compared to similar all-arthroscopic and arthroscopy-assisted procedures. The authors used fiber wires, a free endo button, and button plates. This significantly brought down the cost when compared to implants such as suture anchors or sutures tapes and allografts. The other advantage compared to the arthroscopic technique is the ability to repair AC ligament and delto-trapezial aponeurosis and fascia.

However, this was a pilot study with a small sample size. Since significant complications were not experienced, further randomized controlled trials involving this technique will provide guidance in the right direction.

The authors have presented a simple cost-effective technique with a short learning curve for anatomic reconstruction of acute ACJI. Preliminary results have been very encouraging. Further large studies are needed to validate the technique.

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The benefit of platelet-rich plasma injection over institution-based physical therapy program in adhesive capsulitis patients with diabetes mellitus: prospective observational cohort study

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Background: The objective of this study was to compare the efficacy of platelet-rich plasma (PRP) injection with an institution-based physical therapy (PT) program for adhesive capsulitis (AC) of the shoulder in patients with diabetes mellitus (DM).
Methods: A total of seventy diabetic patients with AC of the shoulder for <6 months were assigned to two groups: PRP group and PT group. In the PRP group, 35 patients were administered a single shot of PRP (4 mL) into the glenohumeral joint. In the PT group, 35 patients were given institution-based PT that included 10 30-minute sessions of planned PT over a 2-week period. After the interventions, all patients were prospectively followed for 12 weeks. Intensity of shoulder pain, function, and range of motion were assessed at baseline and then at 3, 6, and 12 weeks.
Results: Thirty-three patients in the PRP group and 32 in the PT group completed the 12-week study. At 12 weeks, patients who received PRP injections showed greater improvement in shoulder pain ($p<0.001$) than those recruited to the PT group. In the range of motion and shoulder function activities, patients in the PRP group showed significant improvement compared with the institution-based PT group ($p<0.001$). No significant complications were reported from any groups.
Conclusions: In a diabetic population, PRP injections significantly improved shoulder pain and function compared with an institution-based PT program for shoulder AC. Additionally, it is a safe and well-tolerated method for AC management for diabetic patients.

Keywords: Shoulder; Diabetes mellitus; Platelet-rich plasma; Physical therapy; Ultrasound therapy

INTRODUCTION

Adhesive capsulitis (AC), one of the common painful musculoskeletal conditions, presents with impaired shoulder function and movement restrictions of the glenohumeral joint [1,2]. The incidence of primary AC is approximately 2%–5% in the general population, and can be as high as 20% among diabetic people [3]. Diabetes mellitus (DM) has been reported as the most common cause of secondary AC [3]. Patients with DM and AC have been reported as having worse functional outcomes, including disabil-

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ity, compared with patients without DM [4].

Therapeutic exercises, particularly joint mobilization and stretching, are the mainstay of conservative AC treatment [5]. However, these therapeutic exercises may aggravate pre-existing shoulder pain during mobilization. Therefore, these exercises are frequently advised along with various pain-relieving agents, such as oral/injectable medications or pain-relieving physical modalities.

Several injections, including intra-articular corticosteroid (CS) injection [2], sodium hyaluronate injection [3,6], and hydraulic distension (hydrodilatation) [7], have been advocated to reduce shoulder pain. However, patients with DM often express concern about the side effects from these injections, which include hyperglycemia, subcutaneous tissue atrophy, and tendon rupture) of CS injection [8]. Furthermore, sodium hyaluronate injection is expensive. Therefore, many patients with DM and AC prefer to receive ultrasound therapy (UST) or transcutaneous electrical nerve stimulation (TENS), or to continue to undergo various combinations of physical modalities, especially from physical therapy (PT) centers or hospitals, for short-term and long-term care.

A recent new innovative treatment method, platelet-rich plasma (PRP) injection, has received attention for treating musculoskeletal conditions because of its safety and effectiveness across many populations [9-15]. Additionally, many studies have shown its effectiveness for managing shoulder pathologies [15-18]. However, its effectiveness compared with an institution-based PT program has not been evaluated yet, especially for patients with AC and DM.

The objective of this study was to assess the effectiveness of PRP injections with institution-based PT programs for treating shoulder AC among diabetic patients. We hypothesized that a single shot of intra-articular PRP injection would be superior to an institution-based PT program.

METHODS

The study was approved by approved by the Institutional Review Board of All India Institute of Medical Sciences, Bhubaneswar, India. Written informed consents were obtained from all participants.

Participants

Patients with DM and shoulder pain who visited the Physical Medicine and Rehabilitation Out-Patient Department at All India Institute of Medical Sciences between March 2018 to March 2020 were recruited. DM was diagnosed based on either fasting- and 2-hour postprandial-plasma glucose value (75-g oral glucose tolerance test) or glycosylated haemoglobin (HbA1c) values [19]. Patients who were on hypoglycemic agents were considered diabetic. Patients ≥18 years old presenting with shoulder pain and stiffness for less than six months and with >25% restriction in passive movement of the shoulder joint in at least two directions (out of shoulder-abduction, -flexion, -internal and -external rotations) compared with the opposite shoulder were included in this study. The inclusion criteria for AC were set according to previous reports [15,20].

Patients with secondary AC were excluded if they had (1) low hemoglobin ≤9.9 gm/dL (moderate to severe anemia), (2) inflammatory arthritis, (3) bony deformities or pre-existing musculoskeletal disorders of the shoulder joint, (4) weakness of the shoulder girdle muscles associated with neurological deficits, (5) cognitive deficits that made them unable to correctly adhere to exercise programs, (6) received an injection for shoulder pain, or (7) undergone any surgeries or invasive procedures in the affected shoulder.

Study Design

This prospective observational cohort study was conducted at a tertiary care teaching hospital in India. Institutional ethics committee permission was obtained before starting the project. After obtaining written informed consent, patients with DM and AC who fulfilled the inclusion criteria were included in the study. Patients were given the option to undergo either PRP injection or an institution-based PT program. After an initial assessment, patients who were willing to receive a PRP injection were included in the PRP group (n=35). Patients who were not willing to receive the injection (immediately after assessment) but still wanted to participate in the study were included in the PT group (n=35). Patients in the PRP group were given a single intra-articular injection of PRP. Patients in the PT group were administered ten sessions of UST and TENS for 30 minutes/day over a 2-week period. Based on previously published reports [16], ten sessions of PT over a 2-week period is considered the optimal duration for AC treatment.

PRP solution was prepared using the Eppendorf AG Centrifuge 5702 (Eppendorf Hamburg, Germany; Platelet Separation System). Using an 18-g needle, 25 mL of venous blood was obtained from each patient, and 24 mL of venous blood was transferred into two disposable bio-kit tubes (12 mL each) with 1.5 mL of ACD-A anticoagulant. The remaining 1-mL blood sample was sent for platelet count. Bio-kit tubes were then centrifuged for 14 minutes at 1,800 rpm. A total of 5 mL of PRP was obtained from the tubes. Out of 5 mL of PRP, 1 mL was sent for total plate-

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let count, and 4 mL was held for injection into the target joint. The entire preparation procedure was conducted inside a class-IIA biosafety cabinet and under the supervision of a transfusion medicine physician in the clinical laboratory of the Department of Transfusion Medicine. Mean platelet & leukocyte count (in PRP solution) yields were 694 $\times 10^3$/μL and 0.3 $\times 10^3$/μL (range, 0.1–1.5 $\times 10^3$/μL), respectively. Both platelet count times (from whole blood and PRP) were conducted using the same automated cell counter (Sysmex XP-100; Sysmex, Kobe, Japan). The injection was then administered into the target shoulder joint within 30 minutes of PRP preparation.

Interventions

PRP injections (4 mL) were given intra-articularly through a posterior approach under proper aseptic conditions. One experienced physician performed all injections under ultrasound guidance. An ultrasound machine, SonoSite M-Turbo, and a linear array transducer (13–6 MHz) were used during this intervention. The institution-based PT program consisted of TENS and UST, followed by passive joint mobilization of the affected shoulder. A total of 10 sessions, 30 minutes/day, over 2 weeks (5 days/wk) were administered at our institution. The same physical therapist applied TENS and UST and performed mobilization exercises for all the patients. TENS was applied for 20 minutes and UST for 7 minutes in each session. TENS and UST were administered from the same Intelect Transport Combination Therapy Unit (Chattanooga Chattanooga Intelect Transport, USA) on the anterior and posterior sides of the target shoulder joint. TENS was applied at a 100-Hz frequency and a 15-mA amplitude for 100 milliseconds. UST was given using a transducer head 5 cm^2 in area, at a 1-MHz frequency and 1.5-W/cm^2 intensity.

The home exercise program, advised to both groups, was demonstrated by the same physical therapist. Each participant was instructed to complete the 20-minute home exercise program daily. The home exercise program included Codman exercises, stretching, and isometric strengthening exercises for the primary shoulder muscles. Non-steroidal anti-inflammatory drugs were not provided to any patient. However, patients were permitted to consume oral acetaminophen (1 g) up to a maximum of 2 g/day and to apply a hot water bag to the affected shoulder joint when experiencing severe pain or discomfort. After injection, patients were instructed to rest the intervention arm for 2 days from any overhead activities and rotational movements of the shoulder joint. After 2 days, patients were advised to start home exercises as demonstrated. Participants were called at frequent intervals to encourage home exercises and were advised not to take any pain-relieving medication or any physical agents (pain-relieving modalities).

Outcome Assessment

The visual analog scale (VAS; 100 mm) pain score [16] was used as the primary outcome measure (0, no pain; 100, worst pain possible). The shoulder pain and disability index (SPADI) and range of motion (ROM) score (both active- and passive-ROM) were used for secondary outcomes [16]. Baseline and outcome assessments at all follow-up visits were performed by one physician who was not associated with the study. Follow-up visits were done at 3 weeks, 6 weeks, and 12 weeks. During their evaluation, all patients were asked to complete the SPADI questionnaire. Additionally, active and passive ROMs (shoulder—flexion, extension, abduction, internal and external rotation) were measured by goniometry.

The SPADI questionnaire [7] consisted of two divisions (pain and disability), with five questions in one division (pain) and eight questions in the second division (disability), for a total of 13 questions (total SPADI). The two division scores were expressed as percentages, and their means were averaged to get a total SPADI score that ranged from 0–100.

Statistical Analysis

A sample size calculation was done considering VAS pain score as the primary outcome. To achieve 80% study power, a 10-point difference in VAS improvement between the two groups would need to be detected (pooled standard deviation, 14; two-sided t-test α, 0.05). Thirty participants in each group were required to achieve this target.

Categorical variables are presented as percentages or proportions. Continuous variables were presented as the mean (standard deviation). Statistical analyses included intention-to-treat (ITT) analysis [21], and repeated measure analysis of variance and the post-hoc Bonferroni test were used to identify differences in parameter changes at different time points and compare the parameter changes from baseline and 2nd, 3rd, and 4th visits among the two groups. A p-value <0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS ver. 22.0 (IBM Corp., Armonk, NY, USA).

RESULTS

A total of 70 patients were recruited for this study, 35 patients in each group. Thirty-three patients in the PRP group and 32 in the PT group finished the 12-week study period. Two patients from the PRP group and three from the PT group did not complete all follow-up. A schematic diagram of the study is present-

ed in Fig. 1. Study participants' demographic and clinical characteristics are reported in Table 1. Figs. 2 and 3 show the distribution of patients' diabetic medications in the PRP and PT groups, respectively.

There were no disparities in baseline characteristics—age, body-mass index, shoulder pain duration, DM duration, blood sugar level, VAS pain score, shoulder ROM, and SPADI score (total)—between the two groups (Table 1). The right shoulder was predominantly affected in both groups.

Both groups showed a decrease in VAS pain scores at every follow-up visit (Table 2). The differences in mean VAS pain scores within the groups from 1st (baseline visit) to 2nd visit (3 weeks), 1st to 3rd visit (6 weeks), and 1st to 4th visit (12 weeks) were statistically significant (Table 3). In inter-group comparisons, the improvements in mean VAS pain scores between 1st to 2nd visit, 1st to 3rd visit, and 1st to 4th visit were greater in the PRP group (Table 3). At the end of 12 weeks, significant differences were observed between the change of the mean VAS pain scores between the PRP and PT groups ($p \leq 0.001$) (Table 4).

With progression of the study, active and passive ROM improved in each group (Table 2). The differences in changes of ROM (flexion, extension, abduction, internal rotation, and external rotation) within the groups from 1st to 2nd, 1st to 3rd, and

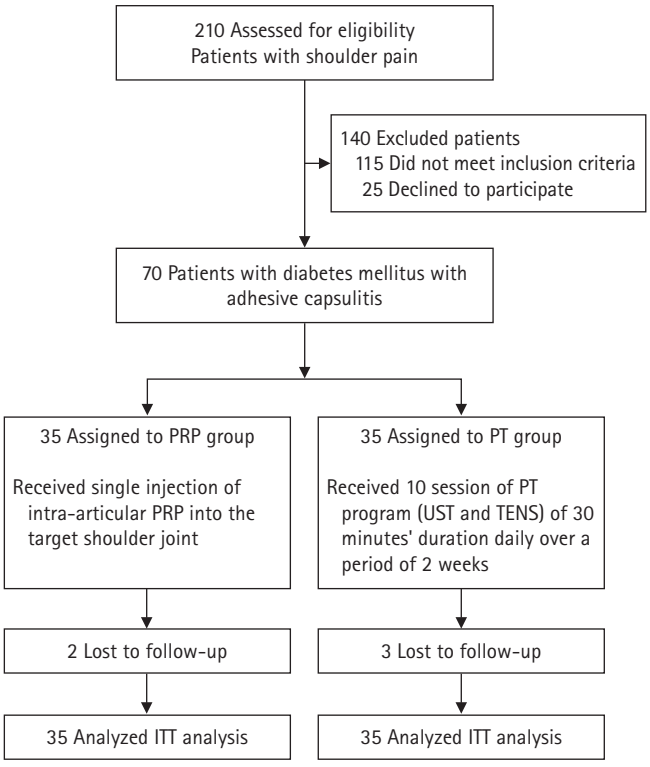

Fig. 1. Flowchart of patient enrollment. PRP: platelet-rich plasma, PT: physical therapy, UST: ultrasound therapy, TENS: transcutaneous electrical nerve stimulation, ITT: intention-to-treat.

Table 1. Baseline demographics and clinical characteristics

Parameter	PRP group (n = 35)*	PT group (n = 35)*	p-value†
Total number of patients recruited	35	35	
Patients completed all follow-up	30	29	
Male:female	14:21	15:20	0.90
Age (yr)	48.8 ± 5.9	49.6 ± 5.7	0.55
Body mass index (kg/m^2)	24.9 ± 2.9	25.4 ± 3.4	0.57
Duration of disease (mo)	4.1 ± 0.9	4.0 ± 1.0	0.28
VAS	73.14 ± 8.5	74.4 ± 7.5	0.51
Active ROM (°)			
Flexion	80.6 ± 12.0	78.4 ± 11.7	0.43
Extension	22.3 ± 6.2	21.4 ± 2.9	0.47
Abduction	68.0 ± 8.3	64.8 ± 9.1	0.12
Internal rotation	16.8 ± 6.2	18.0 ± 5.3	0.39
External rotation	17.8 ± 3.8	19.1 ± 5.4	0.21
Passive ROM (°)			
Flexion	97.9 ± 13.5	95.0 ± 10.6	0.33
Extension	29.0 ± 4.5	28.4 ± 3.7	0.52
Abduction	88.2 ± 10.9	86.1 ± 9.8	0.40
Internal rotation	25.4 ± 5.4	26.6 ± 5.4	0.34
External rotation	25.0 ± 6.2	26.2 ± 4.6	0.35
SPADI	71.1 ± 12.0	69.3 ± 10.3	0.51

Values are presented as mean±standard deviation. The p-values correspond to the mean difference between two groups.
PRP: platelet-rich plasma, PT: physical therapy, VAS: visual analog scale, ROM: range of motion, SPADI: shoulder pain and disability index.
*Intention-to-treat analysis; †Unpaired t-test/Fischer's exact test for two group comparisons ($p<0.05$).

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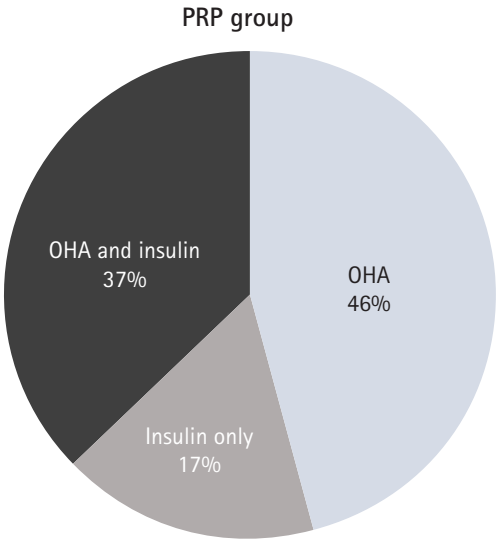

Fig. 2. Diabetic medications in people with adhesive capsulitis who received intra-articular platelet-rich plasma (PRP) injections. OHA: oral hypoglycaemic agents.

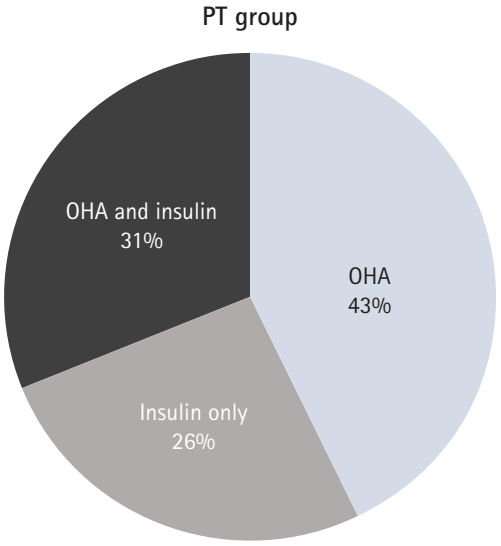

Fig. 3. Diabetic medications in people with adhesive capsulitis who received institution-based physical therapy (PT). OHA: oral hypoglycaemic agents.

Table 2. Study outcome data for the PRP and PT groups

Variable	PRP group (n=35)*					PT Group (n=35)*	
	Baseline visit	2nd visit	3rd visit	4th visit	p-value (RMA)†	Baseline visit	2nd visit
VAS	73.1±8.5	39.3±11.2	24.2±8.7	15.9±7.5	<0.001	74.4±7.5	52.1±11.3
Active ROM (°)							
Flexion	80.6±12.0	98.6±11.8	115.6±11.5	129.9±11.5	<0.001	78.4±11.7	88.9±14.3
Extension	22.3±6.2	29.5±5.9	35.5±5.8	39.2±6.3	<0.001	21.4±2.9	26.6±3.4
Abduction	68.0±8.3	86.5±10.7	101.7±12.4	119.2±10.3	<0.001	64.8±9.1	73.8±11.4
Internal rotation	16.8±6.2	27.1±6.5	37.1±7.7	48.1±7.5	<0.001	18.0±5.3	24.1±6.4
External rotation	17.8±3.8	28.2±5.0	38.8±8.1	50.3±8.9	<0.001	19.1±4.5	26.4±5.3
Passive ROM (°)							
Flexion	97.9±13.5	116.5±13.5	137.0±12.5	148.0±10.7	<0.001	95.0±10.6	106.3±12.3
Extension	29.0±4.5	37.9±6.6	43.1±5.1	45.8±3.7	<0.001	28.4±3.7	33.1±4.7
Abduction	88.2±10.9	104.2±11.0	123.1±10.4	138.3±9.4	<0.001	86.1±9.3	96.6±11.7
Internal rotation	25.4±5.4	39.3±6.1	52.7±8.1	62.1±9.0	<0.001	26.6±5.4	34.6±5.9
External rotation	25.0±6.2	39.1±7.7	53.1±9.2	61.7±10.1	<0.001	26.2±4.6	34.5±6.0
SPADI							
Pain	81.3±11.2	47.1±9.6	28.6±7.6	17.0±7.2	<0.001	78.8±9.6	65.2±10.7
Disability	64.3±13.4	37.4±7.2	25.2±8.0	14.2±5.2	<0.001	63.1±11.2	51.5±8.5
Total	71.1±122.0	41.4±7.3	26.4±6.4	14.9±5.2	<0.001	69.3±10.3	56.8±8.8

Values are presented as mean±standard deviation.
PRP: platelet-rich plasma, PT: physical therapy, RMA: repeated measures analysis, VAS: visual analog scale, ROM: range of motion, SPADI: shoulder pain and disability index.
*Intention-to-treat analysis (35 patients in each group); †RMA of variance.

1st to 4th visits were statistically significant (Table 3). The improvements in mean ROM from 1st to 2nd, 1st to 3rd, and 1st to 4th assessments were greater in the PRP group (Table 3). At the conclusion of the study, there were significant differences ($p<0.001$) in ROM between the two groups (Table 4). A significant decrease in SPADI scores was seen (Tables 2 and 3) in the PRP and PT groups. However, inter-group comparison revealed that the improvement was greater in the PRP group at the 4th visit (Table 4).

During the study period, 17 patients (51.5%) in the PRP group and six patients (18.7%) in the PT group did not receive any acetaminophen tablets. During the entire study period, 11 patients

Table 3. Comparison of mean changes from baseline visit over time (2nd, 3rd, and 4th visit)

Variable	PRP group (n = 35)*			p-value (RMA)†	PT group (n = 35)*			p-value (RMA)†
	Change between baseline & 2nd visit‡	Change between baseline & 3rd visit‡	Change between baseline & 4th visit‡		Change between baseline & 2nd visit‡	Change between baseline & 3rd visit‡	Change between baseline & 4th visit‡	
VAS	33.86 (29.60 to 38.12)	48.94 (45.09 to 52.79)	57.29 (52.90 to 61.67)	< 0.001	22.35 (17.99 to 26.72)	31.18 (26.55 to 35.81)	41.76 (36.99 to 46.54)	< 0.001
Active ROM (°)								
Flexion	−18.00 (−21.57 to −14.43)	−35.00 (−40.10 to −29.90)	−49.34 (−54.26 to −44.42)	< 0.001	−10.53 (−13.33 to −7.73)	−19.79 (−23.78 to −15.81)	−27.94 (−32.18 to −23.70)	< 0.001
Extension	−7.26 (−8.90 to −5.61)	−13.23 (−15.66 to −10.80)	−16.97 (−19.23 to −14.71)	< 0.001	−5.26 (−6.44 to −4.49)	−8.97 (−10.58 to −7.36)	−13.23 (−14.78 to −11.69)	< 0.001
Abduction	−18.43 (−21.43 to −15.43)	−33.69 (−38.91 to −28.46)	−51.14 (−56.03 to −46.25)	< 0.001	−9.09 (−11.10 to −6.18)	−17.17 (−21.10 to −13.20)	−26.18 (−30.28 to −22.07)	< 0.001
Internal rotation	−10.26 (−12.59 to −7.92)	−20.30 (−23.56 to −17.02)	−31.23 (−34.75 to −27.71)	< 0.001	−6.03 (−7.69 to −4.36)	−12.32 (−15.13 to −9.51)	−17.47 (−20.47 to −14.47)	< 0.001
External rotation	−10.43 (−12.56 to −8.29)	−21.00 (−24.57 to −17.43)	−32.54 (−36.42 to −28.67)	< 0.001	−7.32 (−9.24 to −5.40)	−15.00 (−18.59 to −11.41)	−20.03 (−23.6 to −16.40)	< 0.001
Passive ROM (°)								
Flexion	−18.60 (−20.86 to −16.34)	−39.14 (−43.14 to −35.14)	−50.14 (−54.26 to −46.02)	< 0.001	−11.82 (−15.21 to −8.44)	−21.82 (−25.75 to −17.90)	−30.12 (−33.84 to −26.40)	< 0.001
Extension	−8.83 (−10.94 to −6.72)	−14.11 (−16.30 to −11.93)	−16.77 (−19.17 to −14.38)	< 0.001	−4.76 (−6.26 to −3.26)	−9.29 (−10.73 to −7.86)	−13.06 (−14.88 to −11.23)	< 0.001
Abduction	−16.06 (−18.59 to −13.52)	−34.97 (−38.68 to −31.27)	−50.17 (−53.91 to −46.43)	< 0.001	−10.50 (−12.68 to −8.32)	−19.56 (−22.77 to 16.35)	−28.38 (32.50 to −24.26)	< 0.001
Internal rotation	−13.91 (−15.40 to −12.43)	−27.37 (−30.32 to −24.42)	−36.77 (−40.44 to −33.10)	< 0.001	−8.00 (−9.38 to −6.62)	−15.03 (−17.34 to −12.72)	−20.73 (−23.54 to −17.93)	< 0.001
External rotation	−14.09 (−15.91 to −12.26)	−28.14 (−30.96 to −25.33)	−36.71 (−40.20 to −33.23)	< 0.001	−8.26 (−10.25 to −6.28)	−15.71 (−18.64 to −12.77)	−20.76 (−24.37 to −17.16)	< 0.001
SPADI								
Pain	34.26 (30.24 to 38.28)	52.69 (48.42 to 56.95)	64.29 (59.20 to 69.37)	< 0.001	13.53 (8.14 to 18.92)	27.82 (20.49 to 35.15)	39.65 (32.45 to 46.84)	< 0.001
Disability	26.83 (21.40 to 32.25)	39.11 (32.01 to 46.20)	50.09 (44.14 to 56.04)	< 0.001	11.60 (6.278 to 16.92)	22.33 (15.96 to 28.70)	29.60 (21.96 to 31.24)	< 0.001
Total	29.68 (25.19 to 34.17)	44.683 (39.11 to 50.26)	56.19 (51.07 to 61.32)	< 0.001	12.46 (7.47 to 17.45)	24.23 (17.78 to 30.68)	33.69 (26.40 to 40.98)	< 0.001

Values are presented as mean (95% confidence interval).
PRP: platelet-rich plasma, PT: physical therapy, RMA: repeated measures analysis, VAS: visual analog scale, ROM: range of motion, SPADI: shoulder pain and disability index.
*Intention-to-treat analysis (35 patients in each group); †Repeated RMA with ‡post-hoc Bonferroni test within the groups.

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Table 4. Comparison of changes in outcome assessment scores (from baseline visit to 4th visit) at 12 weeks, between the two groups

Variable	Change in PRP group (n = 35)	Change in PT group (n = 35)	Difference in change between groups	p-value
VAS	57.28 ± 9.26	41.76 ± 9.91	−15.52 (−20.13 to −10.91)	< 0.001
Active ROM (°)				
Flexion	−49.34 ± 10.38	−27.94 ± 8.80	21.40 (16.77 to 26.03)	< 0.001
Extension	−16.97 ± 4.78	−13.24 ± 3.21	3.73 (1.77 to 5.69)	< 0.001
Abduction	−51.14 ± 10.32	−26.17 ± 8.53	24.97 (20.41 to 29.51)	< 0.001
Internal rotation	−31.22 ± 7.42	−17.47 ± 6.22	13.76 (10.46 to 17.05)	< 0.001
External rotation	−32.45 ± 8.18	−20.03 ± 7.52	12.51 (8.73 to 16.29)	< 0.001
Passive ROM (°)				
Flexion	−50.14 ± 8.70	−30.12 ± 7.72	20.02 (16.07 to 23.98)	< 0.001
Extension	−16.77 ± 5.06	−13.06 ± 3.79	3.71 (1.56 to 5.86)	< 0.001
Abduction	−50.17 ± 7.90	−28.38 ± 8.55	21.79 (17.83 to 25.74)	< 0.001
Internal rotation	−36.77 ± 7.75	−20.74 ± 5.82	16.04 (12.73 to 19.34)	< 0.001
External rotation	−36.71 ± 7.35	−20.76 ± 7.49	15.95 (12.38 to 19.52)	< 0.001
SPADI				
Pain	64.28 ± 10.73	39.64 ± 14.94	−24.64 (−30.88 to −18.40)	< 0.001
Disability	50.09 ± 12.56	29.60 ± 15.87	−20.49 (−27.36 to −13.62)	< 0.001
total	56.19 ± 10.82	33.69 ± 15.14	−22.50 (−28.82 to −16.19)	< 0.001

Values are presented as mean±standard deviation or mean (95% confidence interval). The p-values correspond to the mean difference between two groups.
PRP: platelet-rich plasma, PT: physical therapy, VAS: visual analog scale, ROM: range of motion, SPADI: shoulder pain and disability index.

in the PRP group (33.3%) received 1–2-g acetaminophen tablets and five PRP patients (15.1%) received 3–4-g tablets. Whereas, in the PT group, three patients (9.4%) received 1–2-g acetaminophen tablets, 10 (31.2%) received 3–4-g tablets, and 13 (40.6%) received >4-g tablets. Four patients in the PRP group reported mild pain and discomfort at the puncture site (immediately after injection). No significant complications (inflammation, infection, or other adverse events), either during the treatment or follow-up period, were reported in either group over the study period.

DISCUSSION

This study compared the effectiveness of a single PRP injection with an institution-based PT program for treating AC in diabetic patients. After receiving full treatment, both groups showed significant pain relief and functional improvement. However, compared with the institution-based PT programs, patients who received PRP injection showed rapid pain reduction, increased active and passive ROM, and improved shoulder function at all follow-up visits. At 12 weeks, the PRP group demonstrated clinically significant improvement in all parameters (pain relief, ROM, and shoulder function). Additionally, patients who received PRP injections consumed fewer acetaminophen tablets for pain relief than patients who received a PT program. Finally, none of the patients reported any significant complications after the intervention.

In terms of PRP injection efficacy for AC, this study's results were consistent with the majority of previously published studies [15-18,22,23]. However, most previous studies were conducted among patients with rotator cuff tendinopathy [17,22,23], where, in most cases, injections were given extra-articularly in the sub-acromial bursa [17,22,23]. Supra-scapular nerve block [24], sub-acromial bursa or intra-articular CS [2], or hyaluronic acid [3] injections have been studied extensively for shoulder AC in the general population. However, PRP injection efficacy for AC, especially in patients with DM, has not been demonstrated. To the best of our knowledge, this is the first study to confirm the beneficial effect of intra-articular PRP injection over institution-based PT programs for treatment of AC among diabetic patients.

It is already well established that PRP injection has anti-inflammatory, anti-nociceptive, and regenerative properties [15,22,25]. Hepatocyte growth factor and tumor necrosis factor-α, released from α-granules in platelets, have potent anti-inflammatory properties [15,22]. Additionally, chemokines, released from platelets, regulate leucocyte recruitment at the inflammation site, which ultimately helps to reduce inflammatory and nociceptive reactions [15,20,22,25].

On the other hand, few physical modalities have been reported

as having pain relieving properties [16,26,27]. Though there is no clear consensus in the literature, UST and TENS are used in increased numbers for pain relief, and both have shown effectiveness [24]. PT sessions consisting of UST and TENS have been used to treat AC [16,24]. Exercise programs, including ROM and stretching exercises, are used to prevent further restriction and increase the ROM of the affected joint [28].

Strength training of the prime movers (shoulder joints) may prevent weakness and atrophy of the shoulder girdle muscles. Therefore, home self-guided exercise therapy, consisting of Codman exercises, stretching, and isometric strengthening exercise, was suggested to all study participants.

AC pathophysiology remains largely unknown, but most researchers believe that inflammation (followed by fibrosis of the joint capsule) is mainly responsible for AC [15,16]. Patients with DM report a higher incidence of AC, probably due to poor circulation to the shoulder joint, abnormal collagen repair, and degenerative changes following tissue injury [4]. In this study, early treatment with intra-articular injection of PRP into the affected shoulder joint most probably reduced synovial proliferation, restricted capsular fibrosis, and altered the natural history of the disease. PRP is a reservoir of growth factors [12,15,22], including transforming growth factor-β, platelet-derived growth factor, a platelet-derived angiogenic factor, vascular endothelial growth factor, and fibroblast growth factor. These growth factors play a central role in tissue repair. However, additional clinical and basic science research is needed before recommending and/or framing clinical guidelines for PRP application in AC.

PRP quality was determined by the concentration of platelets in the PRP solution [15,22]. A four-fold increase in PRP platelets was achieved in this study, which is considered standard and adequate for PRP solutions for musculoskeletal intervention [11,15,22]. There is strong evidence that the higher the platelet count in the PRP, the greater the clinical response [29]. Blajchman [30] reported that storing platelets in freezing conditions might decrease their functional properties. In this study, PRP injection was administered within 30 minutes of its preparation. To date, there are no definite guidelines for using platelet-activating agents for intra-articular PRP injection.

The strengths of this study are that it focuses on diabetic patients, who are the most vulnerable to developing shoulder AC, and these patients usually refuse CS injection (the most common treatment). All PRP injections were administered under ultrasound guidance. ITT analysis was done, and outcomes were assessed at frequent intervals.

This study also has several limitations. Randomization was not done for participant recruitment. Participants decided for themselves what treatment intervention they wanted (PRP injection vs. PT). The study was limited to a very short duration, 12 weeks, and an adequate control group was lacking, thus, the possibility of a placebo effect among the PRP injection patients cannot be excluded. A cost-benefit analysis of treatments was conducted but growth factor levels were not assessed in the prepared PRP solution. Randomized multicenter controlled trials with a longer follow-up duration are needed to confirm these results and reassess improvements from PRP injection, especially among diabetic patients.

In a diabetic population, PRP injection significantly improved shoulder pain and function compared with the institution-based PT program for shoulder AC. Furthermore, it is a safe and well-tolerated method for AC management in diabetic populations.

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Neurotropin protects rotator cuff tendon cells from lidocaine-induced cell death

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Background: Local anesthetics often are used in rotator cuff tears as therapeutic tools, although some cases have reported that they have detrimental effects. Neurotropin (NTP) is used widely in Japan as a treatment for various chronic pain conditions and is shown to have protective effects on cartilage and nerve cells. In this study, we investigated the protective effect of NTP against lidocaine-induced cytotoxicity.
Methods: Tenocytes from rotator cuff tendons were incubated with lidocaine, NTP, lidocaine with NTP, and a control medium. Cell viability was evaluated using the WST-8 assay. Cell apoptosis was detected via annexin V staining using flow cytometry. The expression of BCL-2 and cytochrome c, which are involved in the intrinsic mitochondrial pathway of apoptosis, was evaluated via Western blotting and immunohistochemical staining.
Results: In the cell viability assay, lidocaine decreased cell viability in a dose-dependent manner, and NTP did not affect cell viability. Moreover, NTP significantly inhibited the cytotoxic effect of lidocaine. The flow cytometry analysis showed that lidocaine significantly induced apoptosis in tenocytes, and NTP considerably inhibited this lidocaine-induced apoptosis. Western blotting experiments showed that lidocaine decreased the protein expression of BCL-2, and that NTP conserved the expression of BCL-2, even when used with lidocaine. Immunohistochemical staining for cytochrome c showed that 0.1% lidocaine increased cytochrome c-positive cells, and NTP suppressed lidocaine-induced cytochrome c expression.
Conclusions: NTP suppresses lidocaine-induced apoptosis of tenocytes by inhibiting the mitochondrial apoptotic pathway. Intra-articular/bursal injection of NTP with lidocaine could protect tenocytes in rotator cuff tendons against lidocaine-induced apoptosis.

Keywords: Apoptosis; Lidocaine; Rotator cuff injuries; Tenocytes

INTRODUCTION

Local anesthetics are used for analgesic control in various diseases, including lateral and medial epicondylitis of the elbow, De Quervain's disease, patellar and pes anserine tendinopathies, and Achilles tendinopathy [1-9]. Similarly, subacromial injections of local anesthetics are used in rotator cuff tears as therapeutic and diagnostic agents [8]. However, deleterious effects of these agents have been reported [9-12], especially damaging effects on chondrocytes, fibroblasts, tenocytes, and human mesenchymal stem cells [1,13-15]. Lehner et al. [9] showed that 0.5% bupivacaine inflicted temporary functional damage after a single peritendi-

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nous injection in the Achilles tendons of rats and caused cell apoptosis at the injection site. In our previous study, we reported that lidocaine was not only cytotoxic to tenocytes in a rotator cuff tear model, but also decreased biomechanical properties and induced apoptosis and collagen organization delay [1]. Hence, alternate therapeutic drugs for treating rotator cuff tears should be explored.

Neurotropin (NTP) is a drug derived from the non-protein fraction extracted from the inflamed skin of rabbits after vaccinia virus administration [1,16-22]. NTP has been safely used in Japan for more than 50 years to treat various chronic pain conditions, such as lower back pain, cervico-omo-brachial syndrome, postherpetic neuralgia, hyperesthesia of subacute myelo-optic neuropathy, and other painful conditions [23]. Thus, NTP has been demonstrated to suppress chronic pain in various diseases, possibly through the descending pain inhibitory system [23].

Recent reports have suggested that NTP has not only analgesic, but also protective effects on cartilage and nerve cells [16,18]. NTP significantly reduced bidirectional axonal transport in time- and concentration-dependent manners without affecting the neurite diameter [16]. NTP alleviated oxaliplatin-induced apoptosis via the apoptosis signal regulating kinase 1 (ASK1)-p38 signaling pathway in dorsal root ganglion neurons by inducing thioredoxin [19]. A T-2 mapping study demonstrated that NTP administration improved knee pain in osteoarthritis without affecting the intra-articular proteoglycan concentration [18]. Based on these reports, we hypothesized that NTP inhibits the cytotoxic effects of lidocaine on tenocytes. Thus, we examined the effect of NTP against the cytotoxicity induced by lidocaine on tenocytes isolated from human and rat rotator cuff tendons.

METHODS

Ethics Approval

The use of human samples was approved by the Institutional Review Board of Kurume University Hospital (No. 2456), and the animal study was approved by our Institutional Animal Care and Use Committee (No. 2014-189-2).

Materials

NTP was provided by the Nippon Zoki Pharmaceutical Co., Ltd. (Osaka, Japan). The biological activity of NTP was expressed in NTP units (U). Lidocaine was purchased from Aspen (Xylocaine Injection Polyamp 1%; Aspen, Tokyo, Japan).

Tissue Collection

Human rotator cuff tendons were obtained from 12 patients (six males and six females) who underwent arthroscopic rotator cuff repair for small or medium tear; the patients had a mean age of 63.4 years, and the approximate size of the specimens were 5 mm in width. The rotator cuff was repaired without excessive tension at the sides, and only trimmed and redundant tissues were harvested before or after the repair. Rat rotator cuff tendons were obtained from 12 adult Sprague-Dawley rats (20–25 weeks old).

Cell Culture

Both human and rat rotator cuff tissues were rinsed twice with phosphate-buffered saline, cut into small pieces, and incubated in Dulbecco's modified Eagle's medium with 10% fetal bovine serum at 37°C in a humidified atmosphere that contained 5% CO_2 in T-75 flasks. Twenty-four hours after incubation, tenocytes that were attached to the plastic bottom were maintained in the same condition, and tissues that were not attached to the plastic bottom were discarded. Semi-confluent tenocytes from passages 4 to 6 were used in all experiments.

Cell Viability Assay

Human and rat tenocytes from six donors were seeded in 96-well plates at 5,000 cells/well and incubated for 24 hours. The cells were exposed to lidocaine (0.01%, 0.05%, 0.1%, 0.2%), NTP (0.1, 0.25, 0.5, 1.0 U/mL), 0.1% lidocaine with NTP (0.1, 0.25, 0.5, 1.0 U), or control medium for the next 24 hours. Cell viability was examined using the WST-8 cell proliferation assay kit (Nakarai, Kyoto, Japan). Briefly, 20 μL of WST-8 reagent was added to each well, and the plates were incubated for 4 hours. The absorbance of each well, which represented its cell viability, was measured at 450 nm using a microplate reader (Bio-Rad Model 550; Bio-Rad Laboratories, Hercules, CA, USA).

Flow Cytometry Analysis

Semi-confluent human and rat tenocytes from 10 donors were exposed to 0.1% lidocaine, 0.1 U/mL NTP, 0.1% lidocaine with 0.1 U/mL NTP, or a control medium in T-75 flasks for 24 hours. The tenocytes were trypsinized, collected by centrifugation, washed with phosphate-buffered saline, and labelled with annexin V-FITC and propidium iodide (PI) for 15 min according to the manufacturer's protocol (ApoScreen Annexin V Apoptosis Kit; Southern Biotech, Birmingham, AL, USA). The cells were analyzed using a FACSDiva flow cytometer (Becton Dickinson, Franklin Lakes, NJ, USA) to count apoptotic (annexin V-positive and PI-negative), necrotic (PI-positive), and viable (annexin V- and PI-negative) cells.

Western Blotting Analysis

Rat tenocytes from two donors were exposed to 0.1% lidocaine, 0.1 U/mL NTP, or 0.1% lidocaine with 0.1 U/mL NTP for 24 hours, switched to normal medium, and incubated for an additional 72 hours. Whole cell extracts were lysed with radioimmunoprecipitation assay buffer containing Protease Inhibitor Cocktail (Nacalai, Kyoto, Japan) and a Halt Phosphatase Inhibitor Cocktail (Pierce Biotechnology, Waltham, MA, USA), separated using a 10% SDS-polyacrylamide gel, and transferred onto equilibrated polyvinylidene difluoride membranes (Bio-Rad). The membranes were blocked with 5% bovine serum albumin in tris-buffered saline-Tween (TBS-Tween) for 1 hour and incubated overnight at 4°C with primary antibodies specific for glyceraldehyde 3-phosphate dehydrogenase (GAPDH; 1:1000; AB_2536381; Invitrogen, Waltham, MA, USA) and BCL-2 (1:1000; ab196495; Abcam, Cambridge, UK). The membranes were incubated with secondary antibodies labelled with horseradish peroxidase, and positive signals were visualized using an image analyzer (LAS-4000; Fujifilm, Tokyo, Japan). GAPDH was used as an internal reference control. BCL-2 band intensities were measured with ImageJ software 1.52k (National Institutes of Health, Bethesda, MD, USA) and normalized to GAPDH band intensity.

Immunohistochemistry

Semi-confluent rat tenocytes that were incubated on glass cover slips were exposed to 0.1% lidocaine, 0.1 U/mL NTP, 0.1% lidocaine with 0.1 U/mL NTP, or a control medium for 24 hours and incubated with normal medium for an additional 72 hours. The cells were fixed with 4% formaldehyde at room temperature, rinsed with TBS, treated with 1% hydrogen peroxidase in methanol to deplete endogenous peroxidase activity, and blocked with 5% skim milk powder in TBS for 60 minutes. They were incubated overnight at 4°C with the primary antibody specific for cytochrome c (1: 200; 11940S; Cell Signaling Technology, Danvers, MA, USA), rinsed thrice with TBS, incubated with biotinylated anti-rabbit IgG (Histofine Simple Stain PO (R), Nichirei Corp., Tokyo, Japan) for 30 minutes, stained using a DAB kit, and counterstained with Mayer's hematoxylin. Cytochrome c-positive cells were counted in 10 randomly selected high-power fields (HPF) in each condition, and a mean positive cell count per HPF was calculated.

Statistical Analysis

Statistical analysis was performed using JMP ver. 12 (SAS Institute Inc., Cary, NC, USA). The Kruskal-Wallis test with the Wilcoxon test as a post-hoc analysis was used to evaluate statistical differences between groups. Values are shown as the mean ± standard deviation. Differences with a p-value < 0.05 were considered significant.

RESULTS

Cell Viability Assay

Cell viability was significantly decreased by 0.01%–0.1% lidocaine in both human and rat tenocytes compared to that in the control group cells. The values ranged from 88.6% in 0.01% lidocaine to 15.6% in 0.2% lidocaine in human tenocytes (all $p < 0.001$) and from 89.5% in 0.01% lidocaine to 10.7% in 0.2% lidocaine in rat tenocytes which indicated a dose-dependent manner (all $p < 0.001$). However, NTP alone did not affect cell viability at any dose in either human or rat tenocytes (Fig. 1A). In human tenocytes, the cell viability in the lidocaine alone group was 51.5%, and that in the lidocaine with 0.1–1 U/mL NTP group was 71.0%–74.1% ($p = 0.0253$–$p = 0.05$) (Fig. 1B). Similarly, in rat tenocytes, the cell viability in the lidocaine alone group was 58.7%, and that in the lidocaine with 0.1–1 U/mL NTP group was 88.5%–102% ($p = 0.0011$–$p = 0.0017$) (Fig. 1B). These results show that NTP significantly inhibited the cytotoxic effect of lidocaine in both human and rat tenocytes.

Flow Cytometric Analysis to Detect Apoptotic Cells

The flow cytometry results showed that, in human tenocytes, 0.1% lidocaine-induced significant apoptosis with the apoptotic cells, with the values increasing from 2.0% ± 0.77% in the control group to 11.7% ± 6.58% in lidocaine-treated cells ($p < 0.001$). Similarly, in rat tenocytes, 0.1% lidocaine-induced significant apoptosis, with the apoptotic cell proportion increasing from 1.6% ± 0.94% in the control group to 12.7% ± 8.16% in the lidocaine-treated cells ($p < 0.001$). The results indicated that 0.1 U/mL NTP/mL considerably inhibited this lidocaine-induced apoptotic effect when it was administered in combination with 0.1% lidocaine, reducing the apoptotic cell population to 4.51% ± 2.01% in human tenocytes and to 2.87% ± 2.05% in rat tenocytes (both $p < 0.001$) (Figs. 2 and 3).

Western Blotting Analysis of BCL-2

The Western blotting experiments demonstrated that exposure of rat tenocytes to 0.1% lidocaine decreased BCL-2 protein expression, and administration of 0.1 U/mL NTP inhibited this BCL-2 reduction from 41.0% in 0.1% lidocaine alone to 78.1% when used in combination with 0.1% lidocaine (Fig. 4).

Cytochrome C Protein-Positive Cells

The immunohistochemical staining of rat tenocytes showed that only a few cells (mean, 0.2 cells/HPF) in the control group were

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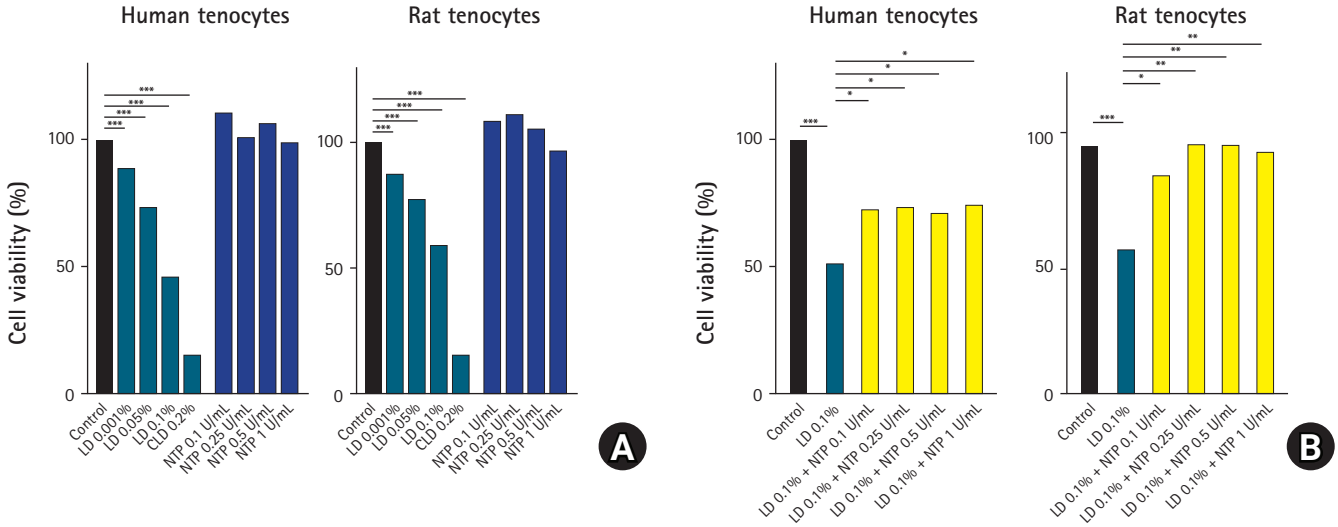

Fig. 1. Effects of lidocaine and neurotropin (NTP) on viability of human and rat tenocytes. Human and rat tenocytes from six donors were incubated with the indicated concentrations of lidocaine (LD), NTP, or LD with NTP for 24 hours, and cell viability was analyzed using a WST-8 assay. In both human and rat tenocytes, (A) LD significantly decreased cell viability in a dose-dependent manner, and (B) the reduction of cell viability by 0.1% LD was significantly rescued with administration of 0.1-1U/mL NTP. *p<0.05; **p<0.01; ***p<0.001.

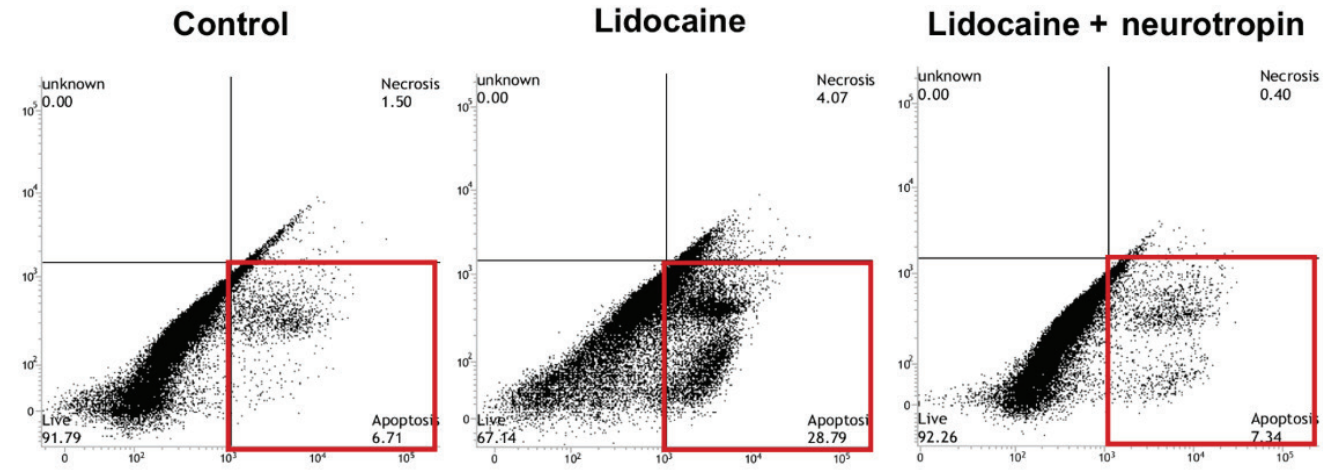

Fig. 2. Representative plot of flow cytometric analysis of 10 donors. Human tenocytes were incubated for 24 hours with control medium, 0.1% lidocaine, and 0.1% lidocaine with 0.1 U/mL neurotropin. The cells were analyzed via flow cytometry after staining with annexin V and propidium iodide (PI). The population in the lower right quadrant (red rectangle) represents apoptotic cells (annexin V-positive and PI-negative).

cytochrome c-positive. Cells treated with 0.1% lidocaine showed an increased number of cytochrome c-positive cells (mean, 0.9 cells/HPF) compared to that in the control group, and treatment with NTP resulted in a reduced number of cytochrome c-positive cells (mean, 0.3 cells/HPF) upon co-administration with lidocaine (Fig. 5).

DISCUSSION

In vitro studies [1,24-27] have reported notable local anesthetic toxicity in various cell types, including tendon fibroblasts derived from bovine tendons [1,4] and torn human rotator cuff tendons [1,6]. Recently, an *in vitro* study revealed the cytotoxic mechanism of amino amide local anesthetics that act on human rotator cuff tendon fibroblasts [1,6]. This study evaluated the response of tendon fibroblasts to ropivacaine, bupivacaine, and lidocaine and found that these anesthetics caused cell death that was mediated by increased production of reactive oxygen species. In a rat rotator cuff tear model, lidocaine significantly inhibited cell proliferation and caused cell death in tenocytes from torn human rotator

cuffs, along with inducing apoptosis and collagen necrosis and decreasing the biomechanical strength at the tear site [1].

In the present study, lidocaine decreased the viability of tenocytes from rat and human rotator cuff tendons and induced cell apoptosis, and these cytotoxic effects were inhibited by administration of NTP. Additionally, NTP inhibited apoptosis by upregulating BCL-2 expression and decreasing the immunohistochemical reactivity of cytochrome c, which is associated with induction of apoptosis. Thus, this study demonstrated that NTP protects tenocytes in torn rotator cuff tendons against the cytotoxic effects of lidocaine.

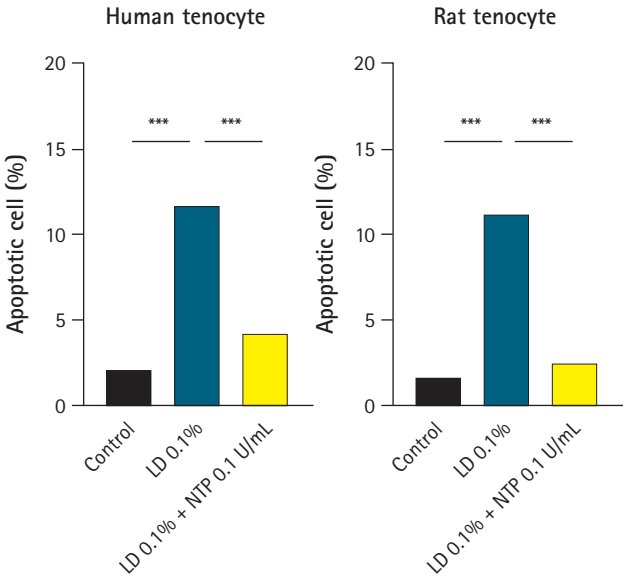

Fig. 3. Apoptotic cell flow cytometric analysis. Human and rat tenocytes from 10 donors were incubated for 24 hours with control medium, 0.1% lidocaine (LD), and 0.1% lidocaine with 0.1 U/mL neurotropin (NTP). The cells were stained with annexin V and propidium iodide and analyzed via flow cytometry. The graphs show the average percentage of apoptotic cells from the 10 donors. In both human and rat tenocytes, 0.1% LD significantly increased apoptotic cell levels, and 0.1U/mL NTP significantly rescued the increase of apoptotic cells. ***p<0.001.

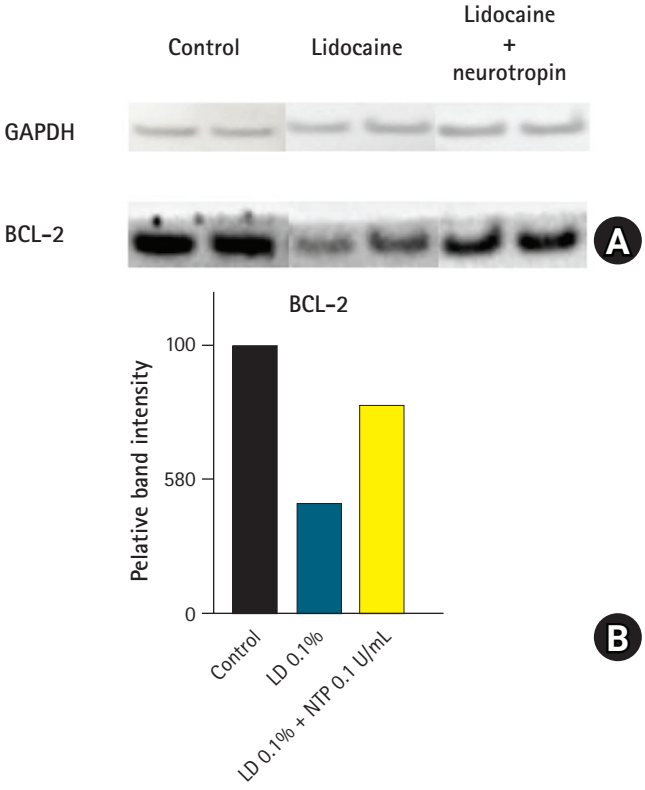

Fig. 4. (A) Western blotting of glyceraldehyde 3-phosphate dehydrogenase (GAPDH) and BCL-2 protein. (B) Rat tenocytes from two donors were incubated for 24 hours with control medium, 0.1% lidocaine (LD), and 0.1% LD with 0.1 U/mL neurotropin (NTP). LD alone reduced BCL-2 protein level, and NTP rescued this reduction of BCL-2 when used in conjunction with LD.

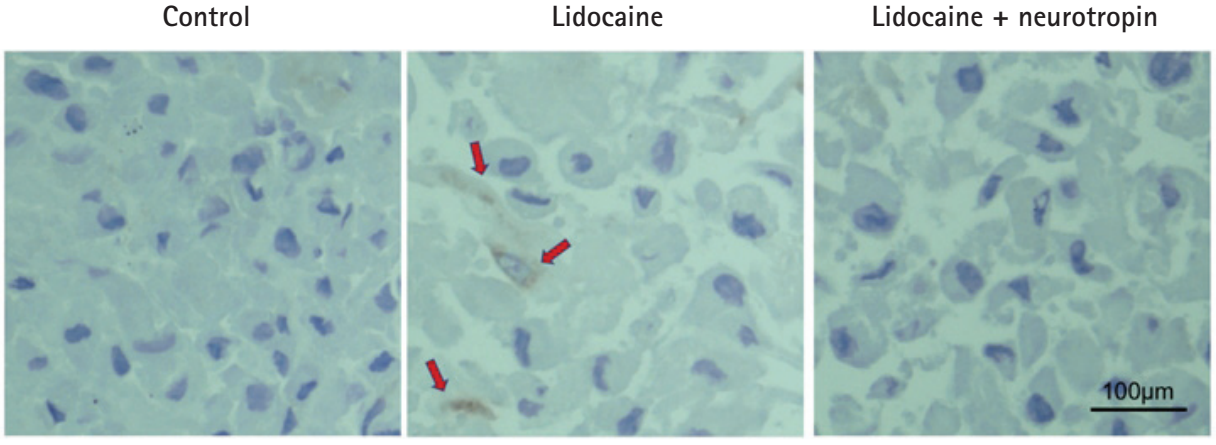

Fig. 5. Immunohistochemistry for cytochrome c. Rat tenocytes were incubated for 24 hours with control medium, 0.1% lidocaine, 0.1 U/mL neurotropin, and 0.1% lidocaine with 0.1 U/mL neurotropin. The red arrows show the cytochrome c-positive area.

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The loss of plasma membrane asymmetry is an early event associated with apoptosis, independent of cell type, and results in exposure of phosphatidylserine residues at the outer plasma membrane leaflet. Annexin V interacts strongly and specifically with phosphatidylserine and can be used to detect apoptosis by targeting the loss of plasma membrane asymmetry [28]. Using these systems, we showed that NTP inhibited lidocaine-induced apoptosis and protected human and rat tenocytes.

The extrinsic and intrinsic pathways of apoptosis induction are the two major apoptotic processes. The extrinsic pathway is mediated by a death receptor, such as the tumor necrosis factor receptor, and the intrinsic pathway is regulated largely by the mitochondria. The intrinsic pathway is activated by a variety of extracellular and intracellular stresses. Further, BCL-2 expression is inhibited following activation of the intrinsic pathway by cellular stress. The subsequent activation of the pro-apoptotic proteins BCL-2 antagonist killer 1 (BAK) and BCL-2 associated X protein (BAX) results in mitochondrial outer membrane permeabilization. This results in release of cytochrome c from the mitochondria to form a complex with procaspase 9 and apoptosis protease-activating factor 1 (APAF1), leading to activation of caspase-9. Caspase-9 then activates procaspase 3 and procaspase 7, ultimately resulting in cell death (Fig. 6) [28,29].

In the present study, BCL-2 expression was inhibited by lidocaine, but this expression was sustained in the presence of lidocaine and NTP. During immunohistological analysis, cytochrome c-positive cells were observed in a greater number in the lidocaine group compared with the other three groups (NTP, lidocaine+NTP, and control groups). Based on these findings, we hypothesize that lidocaine induces apoptosis via the intrinsic pathway, and NTP inhibits this pathway, protecting the tendon cells from apoptosis.

In this study, we used cells not only from rat rotator cuff tendons, but also from human rotator cuff tendons, which was advantageous for exploring the effects of NTP in human models. However, we only conducted *in vitro* experiments, and it would be beneficial to test this hypothesis further in *in vivo* studies.

The present study evaluated the effects of NTP on rotator cuff tendon cells from both rats and humans and demonstrated the protective effects of this agent against cell death by lidocaine-induced apoptosis. Thus, NTP can be a useful approach to consider when lidocaine is administered in clinical settings.

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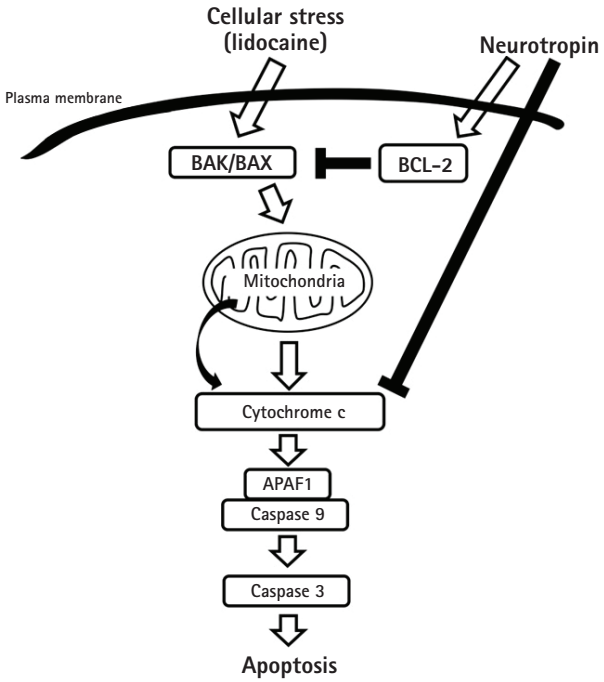

Fig. 6. Effects of neurotropin on the intrinsic pathway of apoptosis. Neurotropin could inhibit lidocaine-induced BCL-2 reduction and cytochrome c upregulation, resulting in suppression of apoptosis. BAK: BCL-2 antagonist killer, BAX: BCL-2 associated X protein, APAF1: apoptosis protease-activating factor 1.

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Original Article

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Comparison of the effectiveness of extensor muscle strengthening exercise by itself, exercise with polydeoxyribonucleotide injection, and exercise with extracorporeal shockwave therapy in lateral epicondylitis: a randomized controlled trial

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Background: Extensor muscle strengthening exercises with counterforce braces (EX) is a conventional conservative treatment for lateral epicondylitis (LE) of the elbow. In addition, polydeoxyribonucleotide (PDRN) or extracorporeal shockwave therapy (ESWT) has been recently used for LE.
Methods: Sixty-three patients with chronic LE participated in this study and randomly allocated in three groups (G1: EX, G2: EX+PDRN injection, and G3: EX+ESWT). All of the three groups were taught to perform EX at the first out-patient department (OPD) visit. Group 2 was injected with 3 mL PDRN (5.625 mg/3 mL), while group 3 received ESWT at the first OPD visit. Visual analog scale pain score, Mayo elbow performance score (MEPS), and ultrasonographic examination were checked before, 6 weeks, and 12 weeks after the treatments.
Results: Overall functional scores and ultrasonographic findings in all three groups improved after treatment. The mean MEPS in group 2 improved more than groups 1 and 3 at 6 weeks (G1, 56.9>62.4; G2, 54.3>65.0; G3, 55.7>62.6), and more than group 1 at 12 weeks (G1, 56.9>67.9; G2, 54.3>73.6). The mean common extensor tendon depth (CETD) on ultrasonography in group 2 increased more than groups 1 and 3 at 6 and 12 weeks (6 weeks: G1, 0.385>0.386; G2, 0.332>0.392; G3, 0.334>0.357; 12 weeks: G1, 0.385>0.409; G2, 0.332>0.438; G3, 0.334>0.405 [cm]).
Conclusions: PDRN injections combined with EX exhibited a greater improvement in mean MEPS and mean CETD compared to EX only or EX combined with ESWT for LE within the 12 weeks follow-up.

Keywords: Lateral epicondylitis; Extensor muscle strengthening exercise; Counterforce brace; Polydeoxyribonucleotide; Extracorporeal shockwave therapy

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INTRODUCTION

Lateral epicondylitis (LE), also known as tennis elbow, is the most common cause of elbow pain in the adult population [1]. The incidence rate of LE is estimated to be four to seven per 1,000 patients per year. The majority of cases are believed to be caused by musculotendinous lesions of the common extensor tendon originating at or near the attachment to the lateral epicondyle, often as a result of overload injury and typically after minor and often unrecognized microtrauma [2]. The diagnosis is generally clinical, but in patients with persistent findings despite treatment or in patients who plan to undergo surgery, imaging may be necessary [1]. Therefore, ultrasonographic evaluation for injuries of the common extensor tendon, the cortex of the lateral epicondyle, or nearby soft tissues could be helpful [1,2].

The treatment of LE varies from "wait and see," nonsteroidal anti-inflammatory drugs, physical therapies, extensor muscle strengthening exercises with counterforce braces (EX), injection therapy including glucocorticoid, polydeoxyribonucleotide (PDRN) or platelet rich plasma (PRP), and extracorporeal shockwave therapy (ESWT), and uncommonly as a last option, surgery [1-4]. Recently, PDRN injections have also been used for LE. PDRN is a tissue regeneration activator that is composed of a mixture of nucleotides and activates adenosine A2A receptors, stimulating vascular endothelial growth factor (VEGF) and the activity of fibroblasts [4-7]. ESWT, in orthopedic cases, is used to induce neovascularization at the junction of the tendon-bone, and to release growth factors. Subsequently, tissue repair is achieved through the improvement of the blood supply and increase in cell proliferation, leading to tissue regeneration of the tendon and bones [8].

Although few in number, comparisons between treatment alternatives have been studied in the literature with conflicting results and no single intervention has been proven to be the most efficient. Therefore, the object of the present study is to compare the clinical and ultrasonographic results of three treatment options: EX only, EX with PDRN injections, and EX with ESWT.

METHODS

We conducted this study in compliance with the principles of the Declaration of Helsinki. The study's protocol was reviewed and approved by the Institutional Review Board of the Chuncheon Sacred Heart Hospital (IRB no. 2013-35). All patients provided written informed consent to participate in this study.

This study was a randomized controlled trial of 69 patients who visited our out-patient department (OPD) and received a diagnosis of LE from May 2013 to April 2014. Sixty-nine patients with chronic LE were enrolled in this study and allocated in three groups (G1: EX only, G2: EX+PDRN injection, and G3: EX+ESWT) under single-blind randomization. The randomization was performed by an independent nurse using a computerized random-sequence generator. Inclusion criteria were LE symptoms that persisted or increased for more than 3 months in which LE was defined as pain on the lateral side of the elbow and pain at the lateral epicondyle upon direct palpation and during resisted dorsiflexion of the wrist.

Exclusion criteria were ages younger than 20 years, history of ipsilateral elbow surgery, common extensor tendon tears more than 30% in depth, inflammatory diseases (e.g., rheumatoid arthritis, psoriatic arthritis), osteoarthritis with a limitation of range of motion (flexion contracture >30° and further flexion <100°), neurological deficits in the ipsilateral upper limb, and follow-ups less than 12 weeks. The practitioners who participated in the procedure were blinded to the patient's information. According to the above criteria, six patients were excluded and 21 patients remained in each of the three group (Fig. 1). All of the three groups were taught to perform EX at the first visit in the OPD. Group 2 was injected with 3 mL PDRN (5.625 mg/3 mL), while group 3 received ESWT (pressure 1.5 bar, frequency 4.0 Hz, number 500; DolorClast Master; EMS, Nyon, Swiss) on the first visit in the OPD [1]. ESWT was performed by a 7 years-experienced orthopedic nurse after the initial ultrasonographic examination and marking of the lesion. From the first OPD visit, a nonsteroidal anti-inflammatory drug (100 mg of aceclofenac) was given orally with a drug protective of the gastric mucosa (60 mg of eupatilin) twice daily. Visual analog scale (VAS) pain score, Mayo elbow performance score (MEPS), and ultrasonographic examinations were checked before, 6 weeks, and 12 weeks after the treatments. VAS pain score was based on a scale from 0 to 10, where 0 indicated no pain and 10 represented severe pain.

The ultrasonographic evaluations were performed by a musculoskeletal radiologist with 19 years of experience who was blinded to the patient's information on the iU22 machine (Philips Healthcare, Bothell, WA, USA) using a 5- to 12-MHz linear probe at all clinical visits. The patients were examined in a sitting position with the elbow flexed to 90°, the forearm neutral, and the arm resting on a pillow on the patient's thighs. A linear probe was prepared with 70% alcohol and a thin layer of sterile ultrasonographic transmission gel (Sung Heung, Bucheon, Korea). The transducer was aligned with the long axis of the radius over the common extensor tendon origin. The common extensor tendon origin was examined with color Doppler ultrasonography in the longitudinal plane by moving the transducer from side to side,

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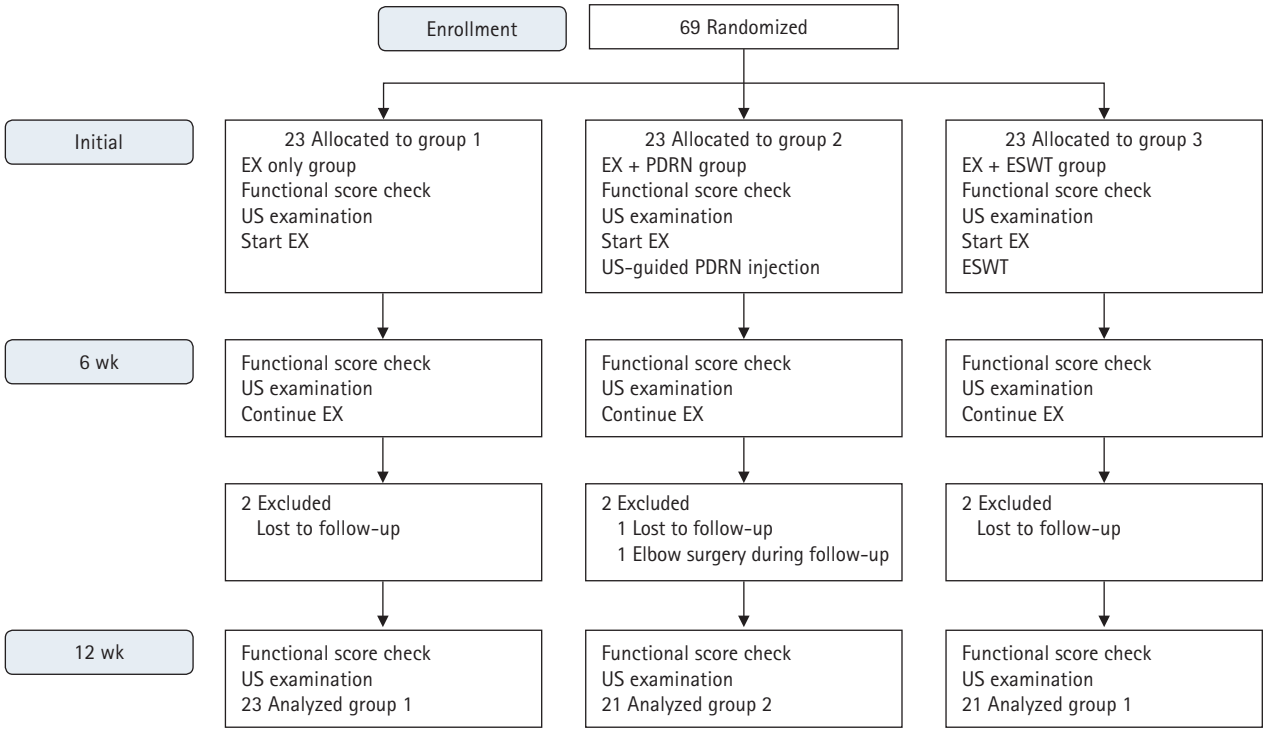

Fig. 1. Flow diagram of this study. EX: extensor muscle strengthening exercises with counterforce braces, US: ultrasound, PDRN: polydeoxyribonucleotide, ESWT: extracorporeal shockwave therapy.

locating the part with the most Doppler activity. The color Doppler activity (CDA) was observed in an area limited proximally by the tip of the lateral epicondyle and distally by the humeroradial joint space [2]. The superficial border involved the most superficial fibers, while the deep border was the bone. The CDA in the present study was ranked in a scale from 0 to 4. The grading was estimated in a 0.5-cm longitudinal part of the tendon with maximal Doppler activity (grade 0, no activity; grade 1, single vessel in the region of interest [ROI]; grade 2, <25%; grade 3, 25%–50%; grade 4, >50% of the ROI [2]) (Fig. 2). Color velocity scale was set at 11.3 cm/sec. The common extensor tendon depth (CETD) was measured at an anatomic landmark at the bony surface of the lateral epicondyle, labelled the "plateau" [2]. This plateau is located at the capitellum between the insertion of the tendon and the humeroradial joint [2]. Common extensor tendon tear thickness (CETTT) was measured in a similar manner to the CETD (Fig. 3).

The ultrasound-guided PDRN injections were performed by an orthopedic surgeon blinded from the patient's information using 5- to 13-MHz linear ultrasonography transducer (Logiq p6 pro; GE Healthcare, Chicago, IL, USA) in the same position using a 5-mL syringe with 21-G needle filled with the drug. The injection was performed with one skin portal, and the content was injected at the middle aspect, partial thickness tear site of the common extensor tendon origin, or tendon sheath if there was too much resistance [4].

The strengthening exercise of the extensor muscle with a counterforce brace was taught in all three groups. The counterforce brace was applied on the patient's forearm 2 cm below the lateral epicondyle, and the patient's arm was positioned on the table with the elbow flexed to 30°. The exercise was initiated with all the ipsilateral fingers and the ipsilateral wrist fully extended, the position maintained, and isometric force applied for 10 seconds, followed by a 10-second rest with all the fingers slightly flexed and the wrist neutral. This was performed ten times for one set, and three sets were completed just after eating (Fig. 4) [9].

A power analysis indicated that a sample size of 54 patients (18 per group) would provide a statistical power of 80% with a two-sided alpha level of 0.05 to detect a significant difference in the improvement of VAS pain score between the initial visit and 12 weeks after treatment, assuming an effect size of 0.85 (mean difference, 1.10; standard deviation [SD], 1.29]). This was based on the mean and SD of improvement of the VAS pain score between the initial visit and 12 weeks after treatment observed in a pilot study of 20 patients. Wilcoxon signed-rank test or paired t-test according to the normality of data were completed to evaluate the differences between the initial visit and 12 weeks after treatment. One-way analysis of variance, followed by Bonferroni

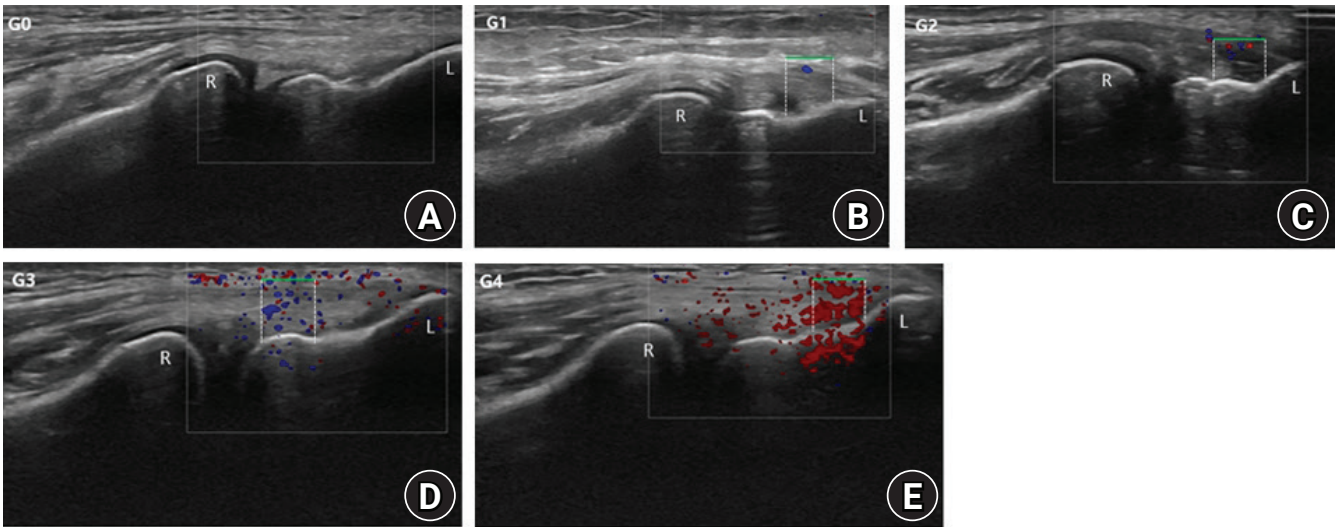

Fig. 2. The grading of the color Doppler activity (CDA) on longitudinal ultrasonographic examinations of the common extensor tendon origin. The grading was performed in the region of interest (ROI) defined as a 0.5 cm longitudinal part of the tendon with maximum CDA. A horizontal green line measuring 0.5 cm marks the superficial border of the ROI, white dotted lines mark the proximal and distal borders, and the bone marks the deep border. Flow towards the transducer is depicted in red while flow away from the transducer is shown in blue. (A) G0, no activity. (B) G1, single vessel in the ROI. (C) G2, CDA in <25% of the ROI. (D) G3, CDA in 25%–50% of the ROI. (E) G4, CDA in >50% of the ROI. R: radial head, L: lateral epicondyle.

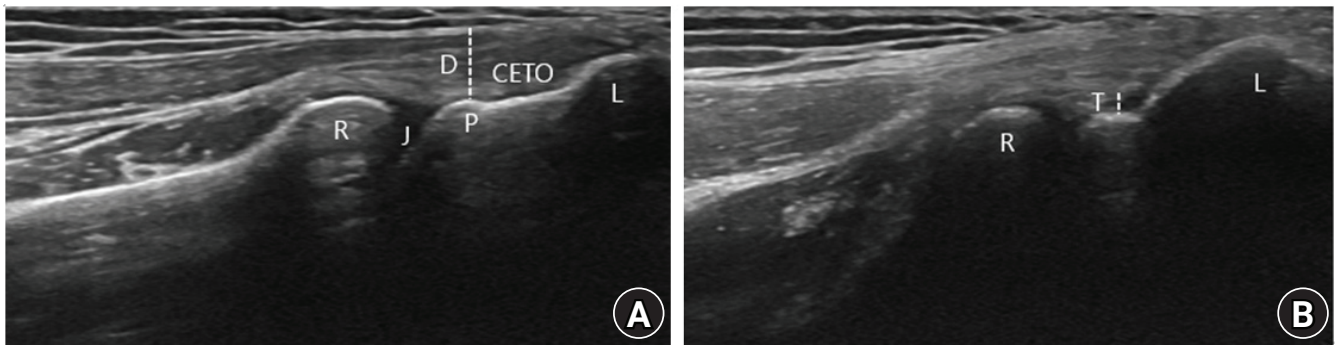

Fig. 3. The common extensor tendon depth (CETD) and the common extensor tendon tear thickness (CETTT) on longitudinal ultrasonographic examinations. (A) CETD. (B) CETTT. R: radial head, J: radiohumeral joint, D: dotted line indicates tendon depth, P: plateau, L: lateral epicondyle, CETO: common extensor tendon origin, T: CETTT.

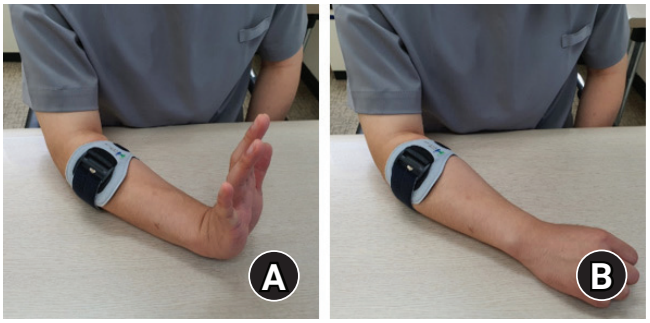

Fig. 4. Strengthening exercise of the extensor muscle of the elbow. (A) All the fingers and wrist were fully extended, and isometric force was applied for 10 seconds. (B) A period of rest was followed for 10 seconds with all the fingers slightly flexed and the wrist neutral.

post hoc testing or Kruskal-Wallis analysis, followed by Mann-Whitney post hoc testing were used to analyze the values between the groups according to normality. The Mann-Whitney U-test or independent t-test was performed to compare the values between the two groups according to normality. Statistical analysis was performed using IBM SPSS ver. 22 (IBM Corp., Armonk, NY, USA). A $p < 0.05$ was considered statistically significant.

RESULTS

There are no significant differences in the demographic data of the three groups (Table 1). The overall functional scores and ul-

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Table 1. Demographic data (initial)

Variable	Group I (n = 21)	Group II (n = 21)	Group III (n = 21)	p-value
Age (yr)	52.3 ± 10.2 (25–71)	52.2 ± 8.2 (41–70)	48.7 ± 7.1 (34–64)	0.304
Sex (male:female)	11:10	13:8	9:12	0.472
Dominant:nondominant	14:7	16:5	14:7	0.743
Symptom duration (wk)	53.9 ± 129.2 (12–600)	55.8 ± 83.9 (12–364)	52.6 ± 70.9 (12–260)	0.416
No. of CS injections	1.0 ± 1.2 (0–4)	1.1 ± 1.6 (0–4)	1.1 ± 1.6 (0–5)	0.937
VAS pain score (0–10)	6.3 ± 1.8 (3.0–9.0)	6.3 ± 1.5 (4.0–9.0)	6.6 ± 1.5 (4.0–9.0)	0.839
MEPS (0–100)	56.9 ± 12.1 (30.0–75.0)	54.3 ± 10.5 (30.0–70.0)	55.7 ± 11.5 (30.0–70.0)	0.723
CETD (cm)	0.39 ± 0.17 (0.19–0.69)	0.33 ± 0.17 (0.16–0.64)	0.33 ± 0.11 (0.19–0.53)	0.469
CDA (grade, 0–4)	1.9 ± 0.7 (1–4)	1.6 ± 0.8 (1–4)	1.7 ± 0.8 (1–4)	0.336
CETPTT (tear:no tear)	11:10	11:10	9:12	0.779
CETTT (cm)	0.03 ± 0.04 (0.00–0.14)	0.03 ± 0.04 (0.00–0.13)	0.02 ± 0.04 (0.00–0.15)	0.788

Values are presented as mean ± standard deviation (range). One-way analysis of variance or Kruskal-Wallis analysis was used to analyze the values among the three groups, $p < 0.05$.
CS: corticosteroid, VAS: visual analog scale, MEPS: Mayo elbow performance score, CETD: common extensor tendon depth measured at the "plateau" which is located at the origin of common extensor tendon and the humeroradial joint, CDA: color Doppler activity, CETPTT: common extensor tendon partial thickness tear, CETTT: common extensor tendon tear thickness.

Table 2. Overall functional and ultrasonographic outcome according to the three groups

Variable	Initial	12 wk	p-value
Group 1			
VAS score (0–10)	6.3 ± 1.8 (3.0–9.0)	3.6 ± 1.9 (0.0–7.0)	< 0.001
MEPS (0–100)	56.89 ± 12.1 (30.0–75.0)	67.9 ± 12.7 (45.0–90.0)	0.001
CETD (cm)	0.39 ± 0.17 (0.19–0.69)	0.41 ± 0.15 (0.23–0.71)	0.029
CDA (grade, 0–4)	1.9 ± 0.7 (1–4)	0.9 ± 0.7 (0–2)	0.001
CETPTT (tear:no tear)	11:10	11:10	1.000
CETTT (cm)	0.03 ± 0.04 (0.00–0.14)	0.03 ± 0.04 (0.00–0.14)	0.005
Group 2			
VAS score (0–10)	6.3 ± 1.5 (4.0–9.0)	2.3 ± 2.0 (0.0–6.0)	< 0.001
MEPS (0–100)	54.3 ± 10.5 (30.0–70.0)	73.6 ± 7.9 (55.0–90.0)	< 0.001
CETD (cm)	0.33 ± 0.17 (0.16–0.64)	0.44 ± 0.16 (0.25–0.71)	< 0.001
CDA (grade, 0–4)	1.6 ± 0.8 (1–4)	0.57 ± 0.60 (0–2)	0.001
CETPTT (tear:no tear)	11:10	9:12	0.157
CETTT (cm)	0.03 ± 0.04 (0.00–0.13)	0.01 ± 0.02 (0.00–0.06)	0.003
Group 3			
VAS score (0–10)	6.6 ± 1.5 (4.0–9.0)	3.2 ± 2.0 (1.0–8.0)	< 0.001
MEPS (0–100)	55.7 ± 11.5 (30.0–70.0)	71.4 ± 12.5 (30.0–90.0)	< 0.001
CETD (cm)	0.33 ± 0.11 (0.19–0.53)	0.41 ± 0.10 (0.25–0.55)	< 0.001
CDA (grade, 0–4)	1.7 ± 0.8 (1–4)	0.7 ± 0.8 (0–3)	< 0.001
CETPTT (tear:no tear)	9:12	7:14	0.157
CETTT (cm)	0.02 ± 0.04 (0.00–0.15)	0.02 ± 0.03 (0.00–0.09)	0.012

Values are presented as mean ± standard deviation (range). The above analysis was performed using Wilcoxon signed-rank test or paired t-test according to the normality of data to evaluate the differences between initial and 12 weeks after treatment, $p < 0.05$.
VAS: visual analog scale score, MEPS: Mayo elbow performance score, CETD: common extensor tendon depth measured at the "plateau", CDA: color Doppler activity, CETPTT: common extensor tendon partial thickness tear, CETTT: common extensor tendon tear thickness.

trasonographic findings in all three groups except for the number of common extensor tendon partial tears improved after treatment (Table 2, Fig. 5). There are significant differences in the improvement of mean MEPS and CETD at 6 and 12 weeks among the three groups (MEPS: 6 weeks, $p = 0.039$; 12 weeks, $p = 0.022$; CETD: 6 weeks, $p < 0.001$; 12 weeks, $p < 0.001$). The mean MEPS in group 2 significantly improved more than groups 1 and 3 at 6 weeks (G1, 56.9 > 62.4; G2, 54.3 > 65.0; G3, 55.7 >

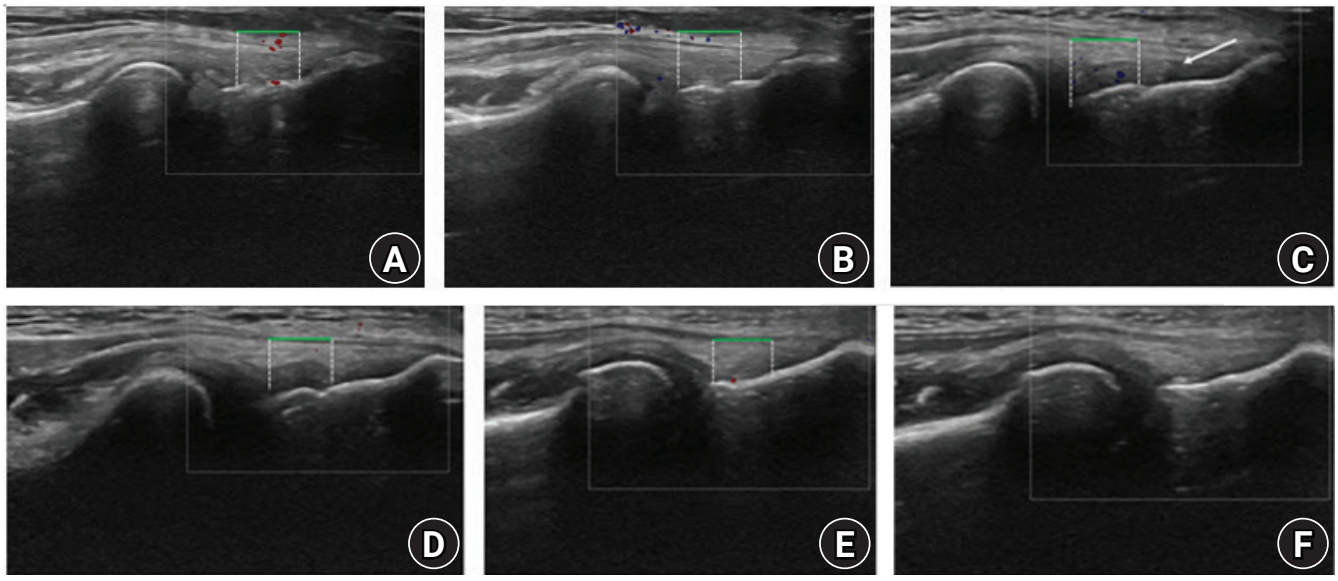

Fig. 5. The ultrasonographic follow-up of the three groups. (A) Group 1 at initial. Color Doppler activity (CDA), grade 2; common extensor tendon depth (CETD), 4.3. (B) Group 1 at 12 weeks. CDA, grade 2; CETD, 4.4 mm. (C) Group 2 at initial. CDA, grade 2; CETD, 4.2 mm. White arrow indicates a suspicion of a partial thickness tear of the common extensor tendon. (D) Group 2 at 12 weeks. CDA, grade 1; CETD, 4.5 mm. (E) Group 3 at initial. CDA, grade 1; CETD, 3.8 mm. (F) Group 3 at 12 weeks. CDA, grade 0; CETD, 4.0 mm.

62.6; G1 vs. G2, $p=0.036$; G2 vs. G3, $p=0.039$), and more than group 1 at 12 weeks (G1, 56.9 > 67.9; G2, 54.3 > 73.6; G1 vs. G2, $p=0.018$). The mean CETD on ultrasonography in group 2 significantly increased more than groups 1 and 3 at 6 weeks (G1, 0.385 > 0.386; G2, 0.332 > 0.392; G3, 0.334 > 0.357; G1 vs. G2, $p<0.001$; G2 vs. G3, $p<0.001$) and those in groups 2 and 3 increased more than group 1 at 12 weeks (G1, 0.385 > 0.409; G2, 0.332 > 0.438; G3, 0.334 > 0.405 [cm]; G1 vs. G2, $p<0.001$; G1 vs. G3, $p=0.031$) (Table 3).

DISCUSSION

Our results have shown that the mean VAS and MEPS of LE patients improved after EX only or combined with PDRN injections and ESWT. Ultrasonographic findings of LE patients including the mean CETD, CDA, and CETTT also improved after the treatments. Among the three groups, the mean MEPS in group 2 significantly improved more than groups 1 and 3 at 6 weeks, and more than group 1 at 12 weeks. The mean CETD on ultrasonography in group 2 significantly increased more than groups 1 and 3 at 6 weeks, and those in groups 2 and 3 increased more than group 1 at 12 weeks.

The treatment of LE is mainly conservative and encompasses physiotherapy, stretching or strengthening exercises, local injections (corticosteroid, PDRN, and PRP, etc.), and ESWT [1-3]. Although physical treatment modalities have been mentioned to be effective in the early period of treatment, their long-term effects are not definite [3]. Corticosteroid injections have been a frequently used treatment option, but its anti-inflammatory nature is reported to have only short-term to intermediate-term efficacies for pain relief. Therefore, the repetitive use of corticosteroids in LE is discouraged due to its adverse effects after the long-term use of steroid injections including tissue atrophy, tendon weakness, or tearing [10]. PRP is blood plasma with an increased concentration of autologous platelets, which is now being used as a part of wound treatment, bone healing, and muscle or tendon damage. It could potentially enhance tendon healing and tissue regeneration by delivering various growth factors and cytokines, thereby affecting cell proliferation, chemotaxis, cell differentiation, and angiogenesis [2,11,12]. There remains some debate about the efficacy of PRP for LE [12]. Systemic reviews that evaluated the effectiveness and safety of ESWT for the treatment of LE exist with conflicting results [13-16]. While the effects of ESWT in LE treatment have been found to be favorable in some studies [13,14], other studies have mentioned certain local side effects like erythema, pain, and small hematomas [15,16]. PDRN is a tissue regeneration activator that is composed of a mixture of nucleotides and activates adenosine A2A receptors, stimulating VEGF and the activity of fibroblasts. PDRN has recently been used for the treatment of LE [5,6].

In the present study, CDA decreased in all three group after treatment because the inflammatory reactions gradually decreased. EX could strengthen the extensor muscle and tendon and stimulate its regeneration. Therefore, CETD significantly in-

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Table 3. Comparison of functional and ultrasonographic outcome among the three groups

Group	VAS score	MEPS	CETD	CDA	CETPTT	CETTT
6 wk						
G1 vs. G2	0.835	0.036	< 0.001	0.893	0.152	0.054
G1 vs. G3	0.561	0.429	0.282	0.051	0.152	0.531
G2 vs. G3	0.768	0.039	< 0.001	0.048	1.000	0.721
One-way ANOVA or Kruskal-Wallis testing	0.855	0.049	< 0.001	0.080	0.350	0.289
12 wk						
G1 vs. G2	0.044	0.018	< 0.001	0.864	0.152	0.192
G1 vs. G3	0.251	0.328	0.031	0.638	0.152	1.000
G2 vs. G3	0.452	0.683	0.168	0.815	1.000	0.289
One-way ANOVA or Kruskal-Wallis testing	0.138	0.022	< 0.001	0.906	0.350	0.383

One-way analysis of variance (ANOVA), followed by Bonferroni post hoc testing or Kruskal-Wallis analysis, followed by Mann-Whitney post hoc testing was used to analyze the values between the groups according to normality, $p < 0.05$.
VAS: visual analog scale, MEPS: Mayo elbow performance score, CETD: common extensor tendon depth measured at the "plateau", CDA: color doppler activity, CETPTT: common extensor tendon partial thickness tear, CETTT: common extensor tendon tear thickness.

creased in all three groups after treatment. The effect of EX combined with PDRN injections or ESWT could increase compared to that of EX only. Compared to EX only or EX combined with ESWT, EX combined with PDRN exhibited a greater improvement in mean MEPS and CETD within the 12 weeks follow-up. The increase in the mean MEPS and CETD could be closely related to the aspect of tendon regeneration. The decrease in the mean CETTT in all three groups after treatment is also related with the tendon regeneration process. Although there is no significant difference among the three groups, two partial thickness tears of the common extensor tendon each in groups 2 and 3 were healed after the treatments.

EX is a conventional conservative treatment with a long history for LE. A combination therapy of several conservative treatments of LE could be more effective than a single therapy. There have been several attempts for combination therapy [17,18]. A single blinded randomized controlled trial reported that there were no significant differences amongst the physiotherapy, prolotherapy, and combined groups in the patient-related tennis elbow evaluation [17]. Another randomized controlled trial about braces versus physical therapy or a combination of both indicated that brace treatment may be useful as an initial therapy, and that combination therapy has no additional advantages compared to physical therapy, but is superior to braces only for the short term [18]. There are only a few studies about combination therapy, and further studies are necessary.

The present study has some limitations. First, there is no untreated control group, but this study is a randomized controlled trial about combination therapy. Combination therapy could be compared to single EX therapy. Second, the follow-up period is short-term. Since the follow-up is 12 weeks, this study cannot provide long-term results, but the functional and ultrasonographic parameters in this study could provide a definite comparison among the treated groups. Third, this study is single-blinded. Due to the nature of this study using injections and ESWT, this study was designed as a single-blinded randomized controlled trial. Fourth, the sample number is small, but the study satisfied a power analysis. Further considerations are necessary in the aspect of clinical significance. PDRN injections combined with EX exhibited a greater improvement in mean MEPS and mean CETD compared to EX only or EX combined with ESWT for LE within the 12 weeks follow-up.

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Original Article

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Outcome of open reduction and Kirschner wire fixation in pediatric radial neck fracture

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Background: Radial neck fracture in children is rare. This study attempted to evaluate the outcome of surgically treated patients and any associated complications.
Methods: This study evaluated 23 children under 15 years of age with radial neck fracture who were treated with open reduction between 2006 and 2016 to determine their range of motion, postoperative complications, and radiographic outcomes. The results were assessed clinically using the Mayo clinic elbow performance score.
Results: The mean follow-up duration for patients was 34.6 months. The average postoperative angulation was 3.6°. Hypoesthesia was reported in only 9% of patients, and none of the patients complained of postoperative pain. The postoperative X-ray results were excellent in 60% and good in 40%. No radiographic complications were identified. The elbow score was excellent in 87% and good in 13% (mean score, 96.74). There was a statistical relationship between range of motion limitations and age, degree of fracture, initial displacement, and surgical pin removal time.
Conclusions: Although most patients accept the closed reduction method as a primary treatment, the present study suggests that an open-reduction approach has been associated with optimal therapeutic outcomes for patients in whom closed reduction was not satisfactory or indicated.

Keywords: Radius; Open fracture reduction; Radius fractures; Pediatrics; Treatment outcome

INTRODUCTION

Radial neck fracture in children is a relatively rare injury and comprises up to 10% of elbow fractures and 5% of all pediatric fractures [1,2]. In most cases, the mechanism of fracture is falling on the arm while the elbow is in extension [3,4]. The presence of radial head blood supply impairment after fracture can lead to avascular necrosis of the radial head and some other complica-

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tions, such as closure of the epiphyseal plate, nonunion, synostosis, infection, and limited range of motion (ROM) [5-7]. The median age of children who sustain this type of injury is 9–10 years, and no difference in sex prevalence was seen [1,3,5] .

Controversies about the best treatment of these fractures (especially in angulated or displaced fractures) remain [8]. Recent studies have relied on the closed reduction technique as a cornerstone of treatment because of the high rate of side effects reported for open reduction methods [1,3,5,6]. However, open reduction is unavoidable in some cases. Generally, open reduction techniques are used in patients with severe angulation or displacement, multiple fractures of the elbow, and failure of closed reduction [3,7,9]. Although previous studies have emphasized the high rate of complications that occur with open reduction techniques, our experiments showed the opposite. This study attempted to evaluate the outcome of surgically treated patients and determine the prevalence of complications with this treatment.

METHODS

The study was approved by the research ethics committee of Tabriz University of Medical Sciences (No. IR.TBZMED.VCR.REC.1397.143). Written informed consent was obtained from the patients' parents for their anonymized information to be published in this article.

This was a cross-sectional study conducted through evaluation of the medical records and follow-up visit summaries of patients who were admitted with a confirmed diagnosis of radial neck fracture to an orthopedic center between March 2006 and September 2016. Data for all patients with a definite diagnosis of radial neck fracture and who were younger than 15 years at the time of fracture were extracted. The diagnosis of radial neck fracture was confirmed by conventional radiography or computed tomography scanning of the elbow, and these images were interpreted by two orthopedic surgeons (a pediatric orthopedic surgeon and a shoulder and elbow orthopedic surgeon). All cases treated with nonoperative methods, closed reduction, or closed reduction and percutaneous fixation were excluded from the study, and only patients who needed open reduction and internal fixation were included in this investigation. Furthermore, patients were excluded if the diagnosis was uncertain, the patient was older than 15 years, medical records were missing, or if follow-up was not possible. Data regarding age at fracture, type of fracture according to Judet's classification, angular displacement, associated fracture, mechanism of injury, duration of immobilization, pin removal time after surgery, postoperative clinical examination (including ROM, neural examination, and postsurgical complications), and postsurgical radiographic results were extracted from the patient medical records. After collecting the data, all included patients were asked to participate in an in-person examination, which was carried out with all except one participant who was not able to come to the orthopedic clinic due to the great distance. The data for this patient were obtained via a telephone interview; to assess elbow motions, this patient was asked to take directed photos of his elbow. Among 251 patients, 184 were treated nonoperatively, 45 were treated using closed methods, and 22 (11 females and 11 males) fulfilled the inclusion criteria and entered the study. One of the female patients had bilateral fractures, so we considered her as two cases.

All cases were operated on by two orthopedic surgeons (a pediatric orthopedic surgeon and a shoulder and elbow orthopedic surgeon) at an orthopedic referral hospital with one technique. The average duration of the follow-up period was 34.6 ± 5.6 months (range, 6–96 months).

The Mayo clinic elbow performance score was used to evaluate the function of the elbow [10]. Post-surgical radiographs were classified using the Metaizeau classification [11]. Our cutoff for a normal ROM was based on the study of the American Academy of Orthopedic Surgeons (flexion, 146; supination, 84; extension, 0; pronation, 71). After induction of general anesthesia, closed reduction or closed percutaneous reduction was attempted under control of an image intensifier. If there was $>30^{o}$ of angulation, >3 mm translation, or an associated fracture, we continued with open reduction.

The Kocher approach was used in all cases. Under tourniquet control, the incision was centered over the lateral epicondyle and extended proximally over the lateral ridge and distally parallel to the ulna. Dissection was continued between the anconeus and extensor carpi ulnaris muscles; when the proximal end of the radius was visible, the radial head was manipulated, and the forearm was rotated to reduce the fracture and was pinned with two 1.5-mm cross or parallel pins. After surgery, the elbow was immobilized for 4 weeks with a splint that was removed once a day for elbow motion. No forearm rotation was allowed until pin removal. Pins were removed 4–16 weeks after surgery depending on the postoperative radiographs.

The recorded information was imported to the IBM SPSS ver. 22.0 (IBM Corp., Armonk, NY, USA). A normal distribution of the quantitative data was assessed using the Shapiro-Wilk test, and if the normality was rejected, a Mann-Whitney U-test (nonparametric) was used. The data are expressed as mean ± standard deviation or median (interquartile range), as appropriate. A multivariate analysis was designed to predict the risk factors related

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to the quantitative data. A Spearman test was used for continuous variables with a normal distribution. Binomial variables were analyzed with a chi-square analysis. The null hypotheses were rejected if the p-value was <0.05.

RESULTS

The mean age of the patients was 9.09±0.46 years (range, 1–12 years). The mean age of girls was 9.08±0.63 years, while the average age of boys was 9.09±0.69 years. Fifteen fractures (65.2%) were located on the right side, and eight (34.8%) were found on the left side. In 21 patients (95.7%), the mechanism of the fracture was fall onto the outstretched arm, and only one fracture (4.3%) was due to a car accident. The average angulation at admission was 54.4°±3.3°. Based on the Judet classification, two patients (8.7%) had <30° angulation (type 2), 20 (87%) demonstrated 30°–60° angulation (type 3), and one (4.3%) had >60° angulation (type 4). Both patients with Judet type 2 fracture also had an associated ulnar fracture (Fig. 1). No patient was diagnosed with a type 1 fracture. Eleven patients (47.8%) had an associated fracture (ulnar shaft, 5; radial head, 3; monteggia, 2; distal radius, 2; olecranon, 1).

Among these 11 patients, 8 had a type 3 radial neck fracture, 2 had a type 2 radial neck fracture, and 1 patient's fracture was type 4. The average length of immobilization after surgery was 5.5±1 days (range, 0–10 days). The mean time until pin removal after surgery was 6.5 weeks (range, 4–16 weeks). The average length of treatment (from the first day of admission until pin removal) was 51.2 days. Postsurgical radiographs were interpreted based on the Metaizeau classification; in 14 patients (60%), the result was excellent, while 9 patients (40%) experienced good results. The mean angulation after surgery was 3.6°±1.1°. Postsurgical radiographs were examined for complications, including avascular necrosis of the radial head, non-union, radioulnar synostosis, degenerative changes in the elbow, heterotopic ossification, and premature epiphyseal closure. No complications were seen on radiographic evaluation. During follow-up examinations, only two patients (9%) complained of hypoesthesia in the radial nerve area, and both improved after 2 weeks without medical intervention. One patient complained of muscle weakness that improved after physiotherapy. Pain with motion after surgery was not reported by any of the patients (Table 1). Upon clinical examination, 16 patients (69.9%) had limitation in supination/pronation, and five (21.7%) demonstrated limitation in flexion/extension. The limitations in pronation in five patients (22%) and in supination in 10 patients (44%) were >20°.

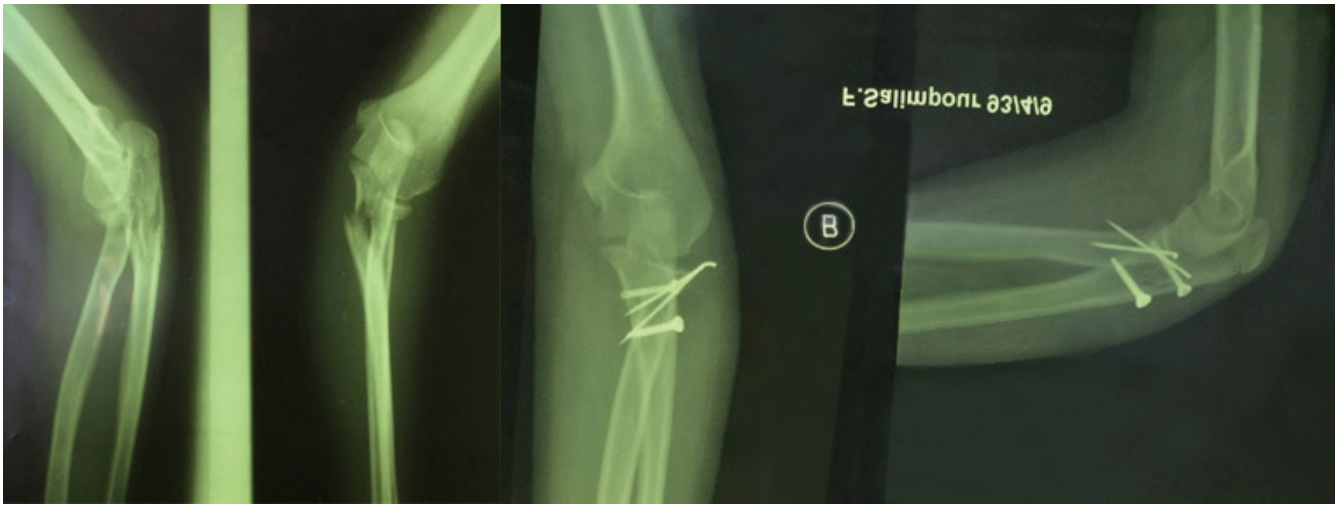

Fig. 1. After surgery.

Table 1. Postoperative forearm range of motion

Variable	Flexion (°)	Extension (°)	Supination (°)	Pronation (°)
Mean	141.30	2.39	65.43	61.74
Median	145	0.00	70	65
Max	145	20	80	85
Min	130	–10	40	40

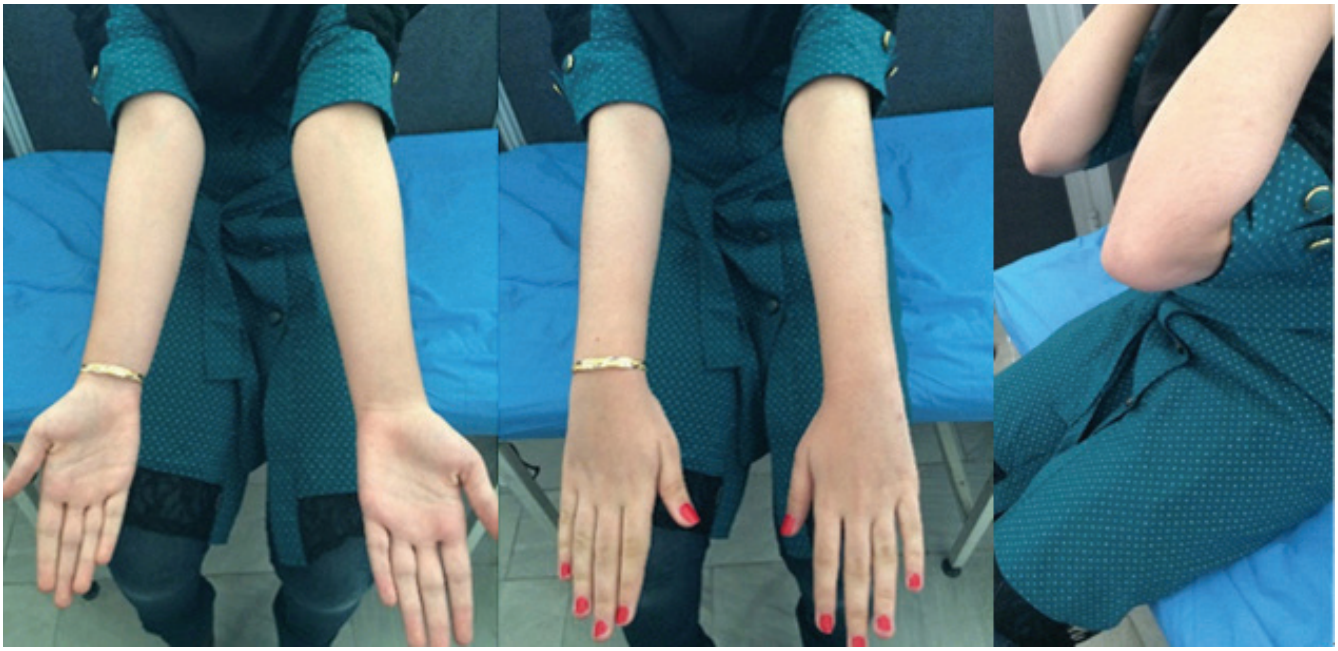

Fig. 2. Range of motion after pin removal.

Table 2. Spearman correlations between variables and elbow movements

Variable	Spearman correlation (p-value)			
	Flexion	Extension	Supination	Pronation
Post-surgery angulation	–0.62 (0.002)	0.64 (0.001)	–0.56 (0.005)	–0.61 (0.002)
Immobilization	0.21 (0.34)	–0.16 (0.94)	–0.45 (0.03)	–0.20 (0.35)
Pin removal	–0.42 (0.045)	0.44 (0.035)	–0.57 (0.005)	–0.56 (0.005)
Age	–0.54 (0.01)	0.68 (0.00)	–0.57 (0.004)	–0.49 (0.017)
First angulation	–0.05 (0.82)	0.09 (0.68)	–0.70 (0.00)	–0.61 (0.002)
Displacement	0.12 (0.58)	0.19 (0.39)	–0.48 (0.02)	–0.36 (0.095)

According to the Mayo elbow performance score, 20 patients (87%) received excellent and three (13%) received a good score (mean score, 96.74). According to the Spearman correlation between different variables and ROM of each elbow movement, there was a strong negative correlation between age and ROM ($p < 0.05$) (Fig.2). A negative correlation was seen between pin removal and ROM. In addition, our findings indicated a negative correlation between first angular displacement and ROM ($p < 0.05$). A negative correlation also existed between duration of immobilization and supination ($r_s = -0.45$, $p < 0.05$) (Table 2).

A chi-square test of independence was performed to examine the relationship between associated fracture and limited ROM with supination/pronation and flexion/extension. The relationship between these variables was not significant; [χ^2 (2, N = 11) = 0.1, p = 0.75 and χ^2 (2, N = 11) = 0.1, p = 0.69, respectively]. There was no significant association between sex and limited ROM in supination/pronation and flexion/extension [χ^2 (2, N = 23) = 1.5, p = 0.22 and χ^2 (2, N = 23) = 0.1, p = 0.69, respectively].

DISCUSSION

Although pediatric radial neck fracture is uncommon, this injury can cause serious complications due to its effect on forearm rotation and elbow motion. The reported average age of patients is 9–10 years [6]. In our study, the average age was 9 years, and there was no age difference between boys and girls.

Due to the high rate of bone remodeling in children, the standard method of treatment for radial neck fracture with angulation < 30° and displacement < 2 mm is closed reduction [12-17]. Some articles have suggested that closed reduction can be the only therapy for angulations up to 45° [1,3,5,6]. However, in a study published in 1998, Vocke and Von Laer [12] proposed that multiple tries at closed reduction cause muscular stiffness, bleeding, and additional injury to the joint. Another study from 1993

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by Metaizeau et al. [11] revealed that treatment of fracture only with closed reduction can increase the risk of secondary displacement. Closed reduction was considered for all patients in this study. If the result was not satisfactory, if the angulation was >30°, or if there was >3 mm translation, closed reduction was not a suitable choice, so the patient underwent open reduction.

One of the most important complications of therapy in pediatric radial neck fracture that is considered in almost all studies is limited ROM. Some studies have mentioned the high incidence of limited ROM with the open reduction technique [18]. In 1993, Metaizeau et al. [11] proposed that 40%–45% of type 3 and 4 fractures had a poor to moderate outcome or ROM after surgery. A newer study from 2016 compared the results of open vs. closed reduction. Of the 68 patients who underwent surgery, 14 (21%) experienced limited ROM [8]. In contrast, Steinberg et al. [6] showed that better treatment results were seen in surgically treated patients instead of in the non-surgically treated group. In a study published in 2011 by Tan and Mahadev [19] in Singapore, the age of the patient was important in treatment outcome, and older ages caused poorer outcomes. Other studies have mentioned poorer outcomes in older children [3,20,21]. Similarly, our study found that increasing patient age increased the risk of limited ROM. This result can be attributed to the higher rate of remodeling at younger ages.

In our study, 69.6% of patients had a few degrees of ROM limitation. Except for age, this limitation was related to other matters, like initial angulation degree, post-surgical angulation, and pin removal time, while variables like sex, associated fracture, duration of immobilization after surgery, and initial displacement had no significant correlation. As shown in other studies [20,21], we found that the initial angulation of the bone played an important negative role in the outcome of treatment. One interesting point was that, in our study, this correlation was seen only for supination/pronation; the range of flexion/extension was not affected. Previous studies have mentioned that the rate of the displacement can influence the outcome and ROM [6,11]. Although none of them specifically mentioned the most affected movement of the elbow, our study showed a weak correlation only for supination ($p = 0.2$, $r_s = -0.48$).

Although not mentioned in previous studies, we noted a relatively strong correlation between postsurgical ROM and pin removal time. When the pin removal time was increased, all four movements of the elbow and forearm were limited, indicating that early removal allows earlier joint movements and could reduce the rate of postsurgical complications. However, pin removal time can influence the stability of the bone after reduction. Since this variable was varied in other studies, additional study should focus on this issue to determine the optimal time for pin removal. Radial head deformity is a complication that results from both closed and open reduction methods [3,13,22]. In previous studies, the prevalence of this complication has ranged from 12% [13] to 83% [12]; in our study, there was only one case (4%) with this complication. Early closure of the epiphyseal plate is another complication that can arise and has a prevalence ranging from 9% [1] to 50% [3], but there was no case in our study. Radioulnar synostosis is another important complication in surgically treated patients, with a prevalence up to 10% [3]. Our sample population did not include any patients with this complication. It seems that the prevalence of these complications is related to both the method of treatment and the surgical technique.

In children and adolescents, the functional ROM for the elbow to carry out contemporary tasks is 51°–139° flexion/extension and 18°–55° supination/pronation [23]. This finding indicates that children do not require full ROM to perform activities. This result is in accordance with our study findings that, while nearly 70% of our patients had limited ROM upon clinical examination, 87% of them obtained an excellent score on the Mayo Elbow Performance Scale, and 13% had a good score. Therefore, to achieve a good practical result of treatment, it is not necessary to fixate on the degree of ROM.

This study was conducted at a single tertiary orthopedic center with 23 patients. The small number of cases and the lack of a control group were the main limitations of this study. Since this was a retrospective study, only patients who had data available and were referred for follow-up examinations were included. In addition, any variation in immobilization period and pin removal time reduced the accuracy of analysis. Different postoperative care techniques between patients might have affected the final results.

In conclusion, despite the high prevalence of complications reported for the open reduction method in previous studies, many of these complications were either not observed in our study or the prevalence was lower. Therefore, although clinical examination might have indicated a limited ROM in many patients, this difference did not lead to significant functional problems.

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Soft-tissue coverage for wound complications following total elbow arthroplasty

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Background: In patients with total elbow arthroplasty (TEA), the soft-tissue around the elbow can be vulnerable to soft-tissue complications. This study aims to assess the outcomes after soft-tissue reconstruction following TEA.
Methods: We retrospectively included nine adult patients who underwent soft-tissue reconstruction following TEA. Demographic data and disease characteristics were collected through medical chart reviews. Additionally, we contacted all four patients that were alive at the time of the study by phone to assess any current elbow complications. Local tissue rearrangement was used for soft-tissue reconstruction in six patients, and a pedicle flap was used in three patients. The median follow-up period was 1.3 years (range, 6 months–14.7 years).
Results: Seven patients (78%) underwent reoperation. Four patients (44%) had a reoperation for soft-tissue complications, including dehiscence or nonhealing of infected wounds. Five patients (56%) had a reoperation for implant-related complications, including three infections and two peri-prosthetic fractures. At the final follow-ups, six patients (67%) achieved successful wound healing and two patients had continued wound healing issues, while two patients had an antibiotic spacer *in situ* and one patient underwent an above-the-elbow amputation.
Conclusions: This study reports a complication rate of 78% for soft-tissue reconstructions after TEA. Successful soft-tissue healing was achieved in 67% of patients, but at the cost of multiple surgeries. Early definitive soft-tissue reconstruction could prove to be preferable to minor interventions such as irrigation, debridement, and local tissue advancement, or smaller soft-tissue reconstructions using local tissue rearrangement or a pedicled flap at a later stage.

Keywords: Arthroplasty; Elbow; Surgical wound dehiscence; Surgical wound infection; Reconstructive surgical procedures

INTRODUCTION

Total elbow arthroplasty (TEA) is a treatment option in patients with advanced rheumatoid arthritis, osteoarthritis, post-traumatic arthritis affecting the elbow, and complex distal humerus fractures [1]. However, the soft-tissue envelope at the elbow can be of poor quality, particularly after prior surgery, increasing the risk of soft-tissue- and implant-associated complications, especially at the olecranon and in patients with systemic inflammatory disease [2,3]. Soft-tissue reconstruction using local tissues, pedicled flaps, or free flaps can be utilized to treat or prevent these complications.

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Conflict of interest: None.

The most common options for soft-tissue reconstruction of the elbow include local tissue rearrangements and pedicled flaps (anconeus, brachioradialis, radial/ulnar forearm, or medial/lateral arm), but free flaps have also been reported (anterolateral thigh, groin, or latissimus dorsi) [3-6]. Infections, wound dehiscence, flap necrosis, seroma formation, and hematomas are potential complications after soft-tissue reconstruction of the elbow, with wound dehiscence being the most common [7,8]. Additionally, wound healing issues may develop due to periprosthetic infections. The implant is generally explanted at the time of soft-tissue reconstruction, but there are many factors involved in such decision making.

Reports on the outcomes of soft-tissue reconstruction in the setting of TEA are limited. Studies with short-term follow-ups have shown the short-term benefits of soft-tissue reconstruction, but longer follow-up complication rates remain high, which is in line with most total elbow arthroplasties [2,3,7,9]. This study aims to assess the soft-tissue related outcomes and the arthroplasty related outcomes after soft-tissue reconstruction following TEA.

METHODS

We conducted this study in compliance with the principles of the Declaration of Helsinki. The study's protocol was reviewed and approved by the Partners Human Research Committee (study number. 1999P008705). Verbal informed consent was obtained in cases of telephonic follow-ups, while informed consent was waived in cases of retrospectively identified patients that were not successfully contacted for follow-ups.

After Institutional Review Board approval, we identified patients that had an International Classification of Diseases 9th edition procedure code, 10th edition procedure code, or current procedural terminology (CPT) code for soft-tissue reconstruction in combination with a CPT code for TEA (Supplementary Material 1). All patients identified with both sets of codes (n = 30) that were treated at a single institutional system including five urban hospitals from the January 1, 2000, to the March 1, 2018, were verified through medical chart reviews. We included all adult patients that underwent soft-tissue reconstructions using local tissue rearrangement or a pedicled flap following TEA. Local tissue rearrangement was defined as adjacent tissue transfers involving rearranging or transferring local areas of the skin along with underlying subcutaneous tissues to cover the defects. Complex wound closure with local tissue advancement was not classified as soft-tissue reconstruction and these patients were not included. Twenty patients were excluded upon manual review because they were miscoded and did not undergo TEA or soft-tissue reconstruction using a flap, while one patient was excluded because a free flap was used for initial soft-tissue coverage, resulting in a final total of nine included patients.

Data regarding patient-, treatment-, and disease characteristics were collected through medical chart reviews. A nonhealing wound was defined as incomplete wound healing per secondary intention requiring additional treatment. Wound dehiscence was defined as the reopening of a previously closed wound requiring additional treatment. A wound infection was defined as an infection of the operated elbow requiring antibiotic treatment and confirmed using microbiological cultures and serologic markers. Serologic markers positive for active infection were defined as a C-reactive protein concentration higher than 13.5 mg/L or an erythrocyte sedimentation rate higher than 22.5 mm/hr, with these data being available in seven patients [10-12]. Differentiation between a wound and implant infection was based on the clinical judgement of the treating physician. Reoperation was defined as any unplanned surgery to the ipsilateral elbow, more specifically, reoperations were subdivided into soft-tissue related (revision surgery for soft-tissue complications) or TEA related (replacement or removal of one or more components of the implant) reoperations. Follow-up time was calculated as the time from soft-tissue reconstruction to final clinical or telephone follow-ups.

The patients that were alive at the time of the study (n = 4) were contacted by letter or phone to complete questionnaires regarding additional treatment at other institutions and the status of wound healing. We were able to contact all four patients. Long-term outcome data were collected and managed through Research Electronic Data Capture (REDCap, Vanderbilt University, Nashville, TN, USA) tools hosted at our institution. This is a secure web-based application designed for data capture and management of research studies [13].

Study Population

The nine patients that were included had a median age of 69 years (range, 21–78 years) at the time of soft-tissue reconstruction and the majority of the patients were female (n = 6). The median follow-up was 1.3 years (range, 6 months–14.7 years). One patient (case 7) did not undergo reoperations, but also had no records of follow-up and was deceased at the time of the study. In total, five patients were deceased at the time of the study. The median follow-up of the remaining patients was 8.0 years (range, 1.1–14.7 years).

Six patients underwent TEA for rheumatoid arthritis, one patient underwent an osteosarcoma resection followed by TEA, one

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patient underwent a TEA for a distal humerus fracture with underlying rheumatoid arthritis, and one patient exhibited a nonunion of a closed distal humerus fracture. Five patients had bilateral total elbow replacements, but no patients underwent bilateral soft-tissue reconstruction. The elbow of the dominant limb was treated in five patients. Prosthesis designs included Discovery (Zimmer Biomet, Warsaw, IN, USA; n=4), Coonrad-Morrey (Zimmer Biomet; n=2), and Capitellar Condylar (Stryker, Kalamazoo, MI, USA; n=1). In two patients, the make of the prosthesis was unknown (Table 1, Figs. 1-3).

After TEA, but prior to soft-tissue reconstruction surgery, all patients had at least one reoperation (range, 1–13), including implant replacement (complete TEA or single component), open reduction and internal fixation, secondary wound closure with local tissue advancement (but no reconstruction requiring soft-tissue rearrangement), triceps repair, radial nerve neurolysis and multiple tendon transfers, elbow scar contracture release, excision of heterotopic ossification, irrigation and debridement (I&D), and ulnar nerve neurolysis and bursectomy (Table 2). Soft-tissue reconstruction was performed at a median of 9.0 months (range, 1 month–27.6 years) following TEA. Indications for soft-tissue reconstruction included an infected nonhealing wound (n=8) and an ischemic nonhealing wound of the soft-tissue covering the olecranon combined with a seroma (n=1). Six out of eight infections were confirmed with microbiological cultures or serologic markers (Table 3). All infections received antibiotic treatment. The implant was exposed in three patients (cases 1, 5, and 7), but was not exchanged at the initial soft-tissue reconstruction. The olecranon was exposed in three patients (cases 2, 4, and 8). Local tissue rearrangement was used in six patients (cases 1, 2, 4–6, and 9), and a pedicled flap was used in three patients (cases 3, 7, and 8). In two patients, soft-tissue reconstruction was performed in multiple stages (cases 4 and 5) with a flap delay in the first surgery and subsequent inset in a second or third surgery. The defect size at the elbow ranged from 2 to144 cm^2 with this information being retrievable from the charts in seven patients (Table 3).

RESULTS

Following soft-tissue reconstruction, seven patients (78%) underwent reoperation and five patients underwent more than one

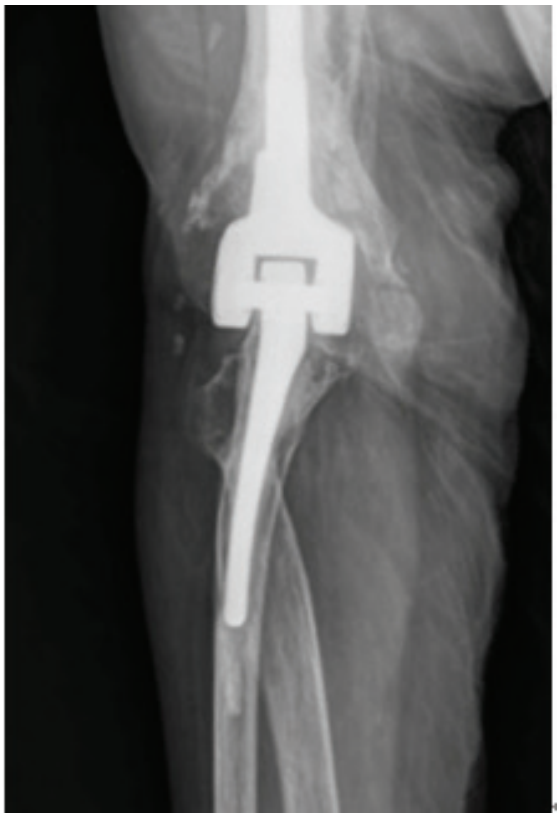

Fig. 1. An anteroposterior radiograph of case 2 showing a total elbow implant in place.

Table 1. Demographics

Case	Sex	Age (yr)	Diagnosis	Implant type	Surgery on dominant limb	Smoker	Diabetes	Workers' compensation
1	Female	61	Rheumatoid arthritis	Unknown	No	Yes	No	No
2	Female	78	Rheumatoid arthritis	Biomet discovery	Yes	No	No	No
3	Female	74	Rheumatoid arthritis	Capitellar condylar	Yes	No	No	No
4	Female	77	Rheumatoid arthritis	Biomet discovery	Yes	No	No	No
5	Male	74	Fracture	Coonrad-Morrey	Yes	No	No	No
6	Female	69	Rheumatoid arthritis	Coonrad-Morrey	No	No	No	No
7	Male	68	Rheumatoid arthritis and fracture	Unknown	Yes	Yes	Yes	No
8	Male	62	Rheumatoid arthritis	Biomet discovery	No	Yes	No	No
9	Female	21	Osteosarcoma	Biomet discovery	Unknown	No	No	No

reoperation (range, 0–4). The median time to reoperation was 4.6 months (range, 1.4 months–1.9 years). Two patients (22%) had successful secondary soft-tissue coverage with a single soft-tissue reconstruction and did not require any further operations (cases 7 and 9) (Table 4).

Four patients (44%) had a reoperation for soft-tissue complications after the primary reconstruction (cases 1–3, and 8), including dehiscence or nonhealing of infected wounds. One patient initially underwent local tissue advancement for wound closure (case 8) and four patients eventually underwent additional soft-tissue reconstruction or skin grafts: local tissue rearrangements (cases 2 and 8), a full-thickness skin graft from the medial arm (case 3), and a radial forearm pedicled flap (case 1) were used for secondary soft-tissue reconstructions. Additional local tissue rearrangement (case 8) and a pedicled muscle flap, covered by a full-thickness skin graft from the lateral arm (case 3), were used for tertiary soft-tissue reconstruction. One patient (case 3) required a fourth operation for soft-tissue reconstruction for which a split-thickness skin graft from the anterolateral thigh was used. A free flap was not used in any of the patients. At the final follow-up, one patient had an above the elbow amputation (case 2), and two patients had persisting nonhealing wounds (cases 1 and 3).

Median implant survival following soft-tissue reconstruction was three years (range, 2 weeks–14.6 years). There was no patient

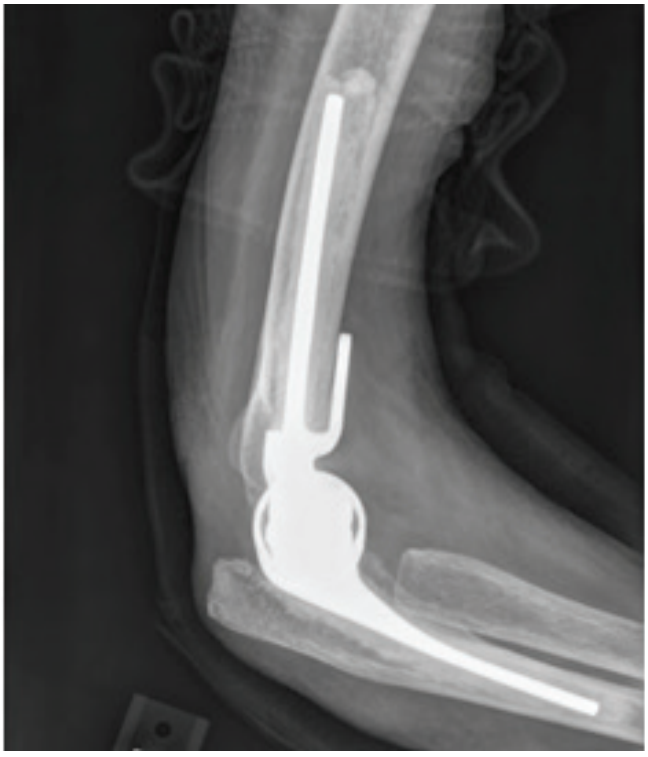

Fig. 2. A lateral radiograph of case 4 showing a total elbow implant in place.

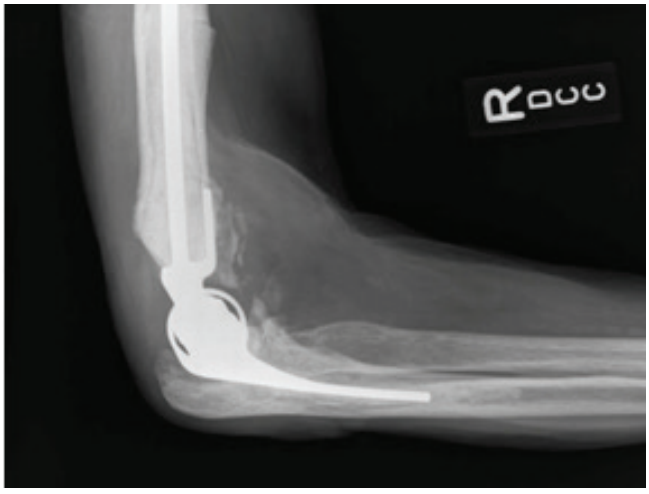

Fig. 3. A lateral radiograph of case 5 showing a total elbow implant in place.

Table 2. Operations before soft-tissue reconstruction

Case	No. of operations	Procedure (n)	Time to reconstruction (yr)
1	13	I&D (5), TEA replacement and triceps repair (2), TEA replacement (2), bushings replacement (1), triceps repair (1), wound closure with local tissue advancement (1), TEA removal and placement of antibiotic spacer (1)	27.60
2	2	I&D (2)	0.13
3	1	Elbow scar contracture release (1)	8.28
4	6	I&D (6)	0.05
5	4	I&D (3), excision of ossification (1)	0.80
6	2	I&D (2)	11.80
7	5	Wound closure with local tissue advancement (3), TEA replacement (1), I&D (1)	0.71
8	2	Ulnar nerve neurolysis and excision of bursitis (1), I&D (1)	0.32
9	2	TEA replacement (1), I&D with placement of antibiotic bead (1)	Unknown

I&D: irrigation and debridement, TEA: total elbow arthroplasty.

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Table 3. Treatment

Case	Indication	Microbial culture	Serologic infection marker	Antibiotic treatment	Bone/implant exposed	Soft-tissue donor	Reconstruction technique	Defect size (cm^2)
1	Nonhealing infected wound	CoNS	Unknown	Yes	Implant	Local	Tissue rearrangement	Unknown
2	Nonhealing infected wound	CoNS	Positive	Yes	Olecranon	Local	Tissue rearrangement	2
3	Nonhealing infected wound	Nocardia farcinica	Positive	Yes	No	Muscle	Pedicle	12
4	Ischemic nonhealing wound	Unknown	Unknown	No	Olecranon	Local	Tissue rearrangement	144
5	Nonhealing infected wound	Unknown	Negative	Yes	Implant	Local	Tissue rearrangement	50*
6	Nonhealing infected wound	MRSA	Positive	Yes	Implant	Local	Tissue rearrangement	60*
7	Nonhealing infected wound	Unknown	Positive	Yes	Unknown	Fasciocutaneous	Pedicle	Unknown
8	Nonhealing infected wound	Negative	Negative	Yes	Olecranon	Fasciocutaneous	Pedicle	48*
9	Nonhealing infected wound	*Staphylococcus epidermidis*	Positive	Yes	No	Local	Tissue rearrangement	32

CoNS: coagulase-negative staphylococci, MRSA: Methicillin-resistant Staphylococcus aureus.
*Covering soft-tissue measured instead of defect.

Table 4. Outcomes

Case	No. of reoperations	Time to reoperation (mo)	Soft tissue complication	Implant revision	Implant survival (mo)	Deceased	Follow-up time (yr)
1	3	2.84	Yes	No	0.51	Yes	0.51
2	2	17.87	Yes	Yes	17.39	Yes	1.54
3	3	2.03	Yes	No	115.64	No	1.10
4	1	23.51	No	Yes	22.88	No	10.65
5	2	4.36	No	Yes	4.24	Yes	0.52
6	1	5.64	No	No	157.47	Yes	0.97
7	0	NA	No	No	Unknown	Yes	-*
8	4	1.35	Yes	Yes	54.14	No	5.27
9	0	NA	No	No	175.20	No	14.72

NA: not applicable.
*No records of reoperations or follow-up.

where the implant was replaced during soft-tissue reconstruction. There were five patients (56%) with a reoperation for implant-related complications, including three infections (cases 2, 5, and 6) and two peri-prosthetic fractures (cases 4 and 8). One patient was successfully treated with an I&D (case 6), while the other four patients required implant revision. Eventually, one patient had the humeral component exchanged (case 4) due to a peri-prosthetic fracture and the entire TEA was removed and replaced with an antibiotic spacer in three patients (cases 2, 5, and 8). At the final follow-ups, six patients still maintained their arthroplasty, of which one was revised after soft-tissue reconstruction (case 4), while two patients had an antibiotic spacer *in situ* (cases 5 and 8) and one patient had an above the elbow amputation (case 2). Other elbow related symptoms at final orthopedic follow-up included pain, weakness, instability, stiffness, and a flail elbow (Fig. 4).

DISCUSSION

This study aimed to report the outcomes of soft-tissue reconstruction following TEA. All nine patients in this study had multiple surgeries after TEA (range, 1–13) that were eventually complicated by an infection, wound dehiscence or nonhealing wound, and subsequently treated with soft-tissue reconstructions. However, despite these efforts, initial soft-tissue reconstruction was unsuccessful in seven patients. Four patients underwent additional surgery for soft-tissue complications and five patients had implant-related reoperations. At the final follow-ups, soft-tissue healing was achieved in six patients (67%), while two patients had continued wound healing issues and one patient had an above-the-elbow amputation.

This study was limited by several factors. First, soft-tissue reconstruction is uncommon in patients with TEA. In a large database from five urban hospitals using coding searches followed by

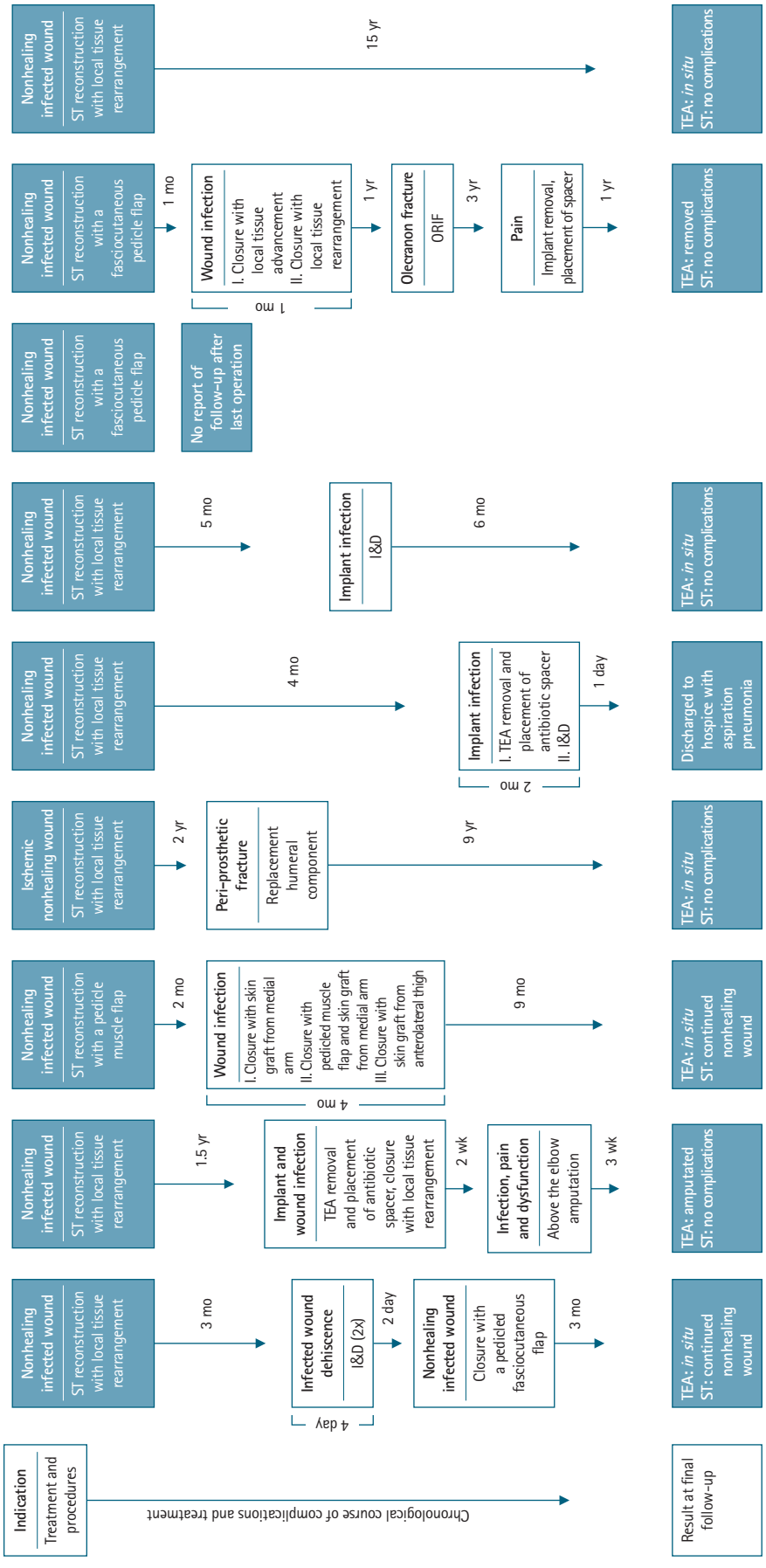

Fig. 4. Treatment timeline. ST: soft-tissue, I&D: irrigation and debridement, TEA: total elbow arthroplasty, ORIF: open reduction and internal fixation.

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manual reviews, we were able to identify nine patients. It is possible that there were cases in which soft-tissue reconstructions were performed at the time of initial TEA, but this was not coded and would not be identified in our searches. Due to the small cohort, we could not perform a meaningful statistical analysis. Second, only four patients were alive at the time of this study and could be contacted for follow-ups. However, for the remaining patients, follow-up data was obtained retrospectively. Therefore, the results were dependent on coding accuracy and completeness of the medical charts. Furthermore, patients were initially treated with TEA between 1977 and 2009 leading to a variation in treatment, especially considering the evolving surgical and rehabilitation techniques (particularly in microsurgery and soft-tissue reconstruction, as well as implant design). There were also notable differences between the patients in our series in the time from initial surgery to soft-tissue reconstruction, the number of operations before soft-tissue reconstruction, the type of reconstruction used, and treatment by different surgeons. Last, we reported implant and soft-tissue related outcomes separately. However, the two are often related and differentiation was based on clinical judgements.

Our data contrasts two case series that report successful soft-tissue reconstructions using pedicle or rotation flaps after TEA in all patients [3,7]. However, their mean follow-up was 6 months and 26 months, compared to 4.4 years in our study. Our data suggests that long-term complication rates after soft-tissue coverage of TEA are likely higher (78%). Two studies reported long-term outcomes after soft-tissue reconstruction for TEA related complications [2,9]. Kim et al. [2] reported reoperations in 60% of the patients (3/5) treated with a pedicled radial forearm flap at a mean follow-up of 88 months. One patient received a free flap from the anterolateral thigh and did not have a complication. The mean age was 41 years and none of the patients had rheumatoid arthritis. In contrast, the reoperation rate after soft-tissue reconstruction in our cohort of older patients with rheumatoid arthritis was higher (78%). Okamoto et al. [9] reported the long-term outcome of one 84-year-old female with rheumatoid arthritis that underwent soft-tissue reconstruction after TEA. At a 3-year follow-up, there were no complications.

The high reoperation rate (78%) in our cohort suggests that soft-tissue coverage using delayed attempts at local tissue rearrangement or a pedicled flap may be insufficient in these patients, particularly if there has been prior failure of soft-tissue closure. In total knee arthroplasty, as well as in severe elbow trauma, soft-tissue coverage using a free flap provides positive results, and it is the practice of the senior author to be increasingly aggressive about providing durable soft-tissue coverage with a definitive flap early on, prior to the development of soft-tissue complications [5,14-17]. We hypothesize that initial soft-tissue coverage of TEA using a free flap may reduce the reoperation rate. Furthermore, in six patients, an initial attempt was made to treat wound dehiscence surgically (I&D or local tissue advancement) without definitive soft-tissue reconstruction, but this was unsuccessful in all patients (cases 1, 2, 4, 5, 7, and 8). Eventually, successful soft-tissue coverage was achieved in four out of six of these patients (cases 4, 5, 7, and 8), but multiple surgeries were needed in all four patients to reach a stable result. In three patients, soft-tissue reconstruction was the primary surgical treatment of wound dehiscence (cases 3, 6, and 9). This was successful in two of the three patients, of which one who had to undergo more than one surgery (case 6). This trend suggests that the early recognition of soft-tissue problems, early consultation with a reconstructive surgeon, and initial, aggressive soft-tissue reconstruction instead of minor interventions may reduce the reoperation rate.

Early flap coverage before or during total joint replacement has been suggested in total knee arthroplasties for patients at a higher risk of soft-tissue complications. In total knee arthroplasty, older age and rheumatoid arthritis have been associated with wound healing complications [18]. Andres et al. [19] found that complications were similar between the patients that underwent "prophylactic" coverage and those who underwent a salvage procedure with flap coverage. However, in the salvage group, three patients eventually had an above-the-knee amputation compared to none in the group with "prophylactic" soft-tissue coverage. In general, poor soft-tissue quality and delayed wound healing have been reported in older patients and patients with rheumatoid arthritis [20-22]. Considering the high complication rate in the setting of soft-tissue compromise, early soft-tissue reconstruction at the time of TEA may be preferable in select patients if preservation of the prosthesis is preferred rather than resection arthroplasty.

This study reports high complication rates after soft-tissue coverage for wound complications following TEA, specifically in older patients with rheumatoid arthritis. Successful soft-tissue healing was achieved in 67% of patients, but at the cost of multiple surgeries. At final follow-up, six out of nine patients had a TEA in place, of which one was revised. Two patients had an antibiotic spacer, and one patient underwent an above-the-elbow amputation. Early soft-tissue reconstruction at the time of TEA may be considered for high-risk patients. When soft-tissue issues occur, early recognition, early consultation with a reconstructive surgeon, and definitive soft-tissue coverage procedures may aid

in the prevention further sequelae. More research is required to further clarify the decision making in complicated cases.

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SUPPLEMENTARY MATERIAL

Supplementary materials can be found via https://doi.org/10.5397/cise.2021.00409.

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Original Article

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Topographical measurement of the attachments of the central band of the interosseous membrane on interosseous crests of the radius and ulna

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Background: To suggest a reasonable isometric point based on the anatomical consistency of interosseous membrane (IOM) attachment in association with topographic characteristics of the interosseous crests, the footprints of the central band (CB) of the IOM on the radial and ulnar interosseous crests (RIC and UIC) were measured.
Methods: We measured the distance from the CB footprints from each apex of both interosseous crests in 14 cadavers and the angles between the forearm axis of rotation (AOR) and the distal slopes of the RIC and UIC in 33 volunteers.
Results: The CB footprints lay on the downslope of both interosseous crests with its upper margin on average 3-mm proximal from the RIC's apex consistently in the radial length, showing normality ($p>0.05$), and on average 16-mm distal from the UIC's apex on the ulna without satisfying normality ($p<0.05$). The average angle between the UIC's distal slope and the AOR was 1.3°, and the RIC's distal slope to the AOR was 14.0°, satisfying the normality tests ($p>0.05$), and there was no side-to-side difference in both forearms ($p<0.05$).
Conclusions: The CB attached to the downslope just distal to the RIC's apex constrains the radius to the UIC that coincides with the AOR of the forearm circumduction, maintaining itself both isometrically and isotonically.

Keywords: Interosseous crest; Radius; Ulna; Interosseous membrane; Central band

INTRODUCTION

The interosseous membrane (IOM) of the forearm is a complex anatomical structure in the form of a strong band connecting the radius and ulna. By constraining the radius relative to the ulna, the IOM acts to maintain a constant radioulnar relationship during rotational movements of the forearm and to transfer and distribute axial loads arising from the hand from the radius to the ulna. The IOM consists of the following five distinctive ligaments: the central band (CB), distal oblique bundle, proximal oblique cord, dorsal oblique accessory cord, and accessory band [1]. Of these, the CB, which originates from the proximal radius and inserts into the distal ulna, is a strong, stable structure responsible for the major functions of the IOM [2,3]. The CB is

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known to maintain a constant length and tension regardless of forearm rotation [1,4]. When comparing the forearm rotation to a simple hinge motion, the radius and ulna may correspond to each leaf of the hinge; the CB may be reduced to the pin joining the leaves; and the radial interosseous crest (RIC) and ulnar interosseous crest (UIC) act as the knuckles holding the pin. However, forearm rotation is not a simple opening and closing of the radio-ulnar hinge complex but instead a circumduction in which the radius traces a cone reciprocating around the ulnar shaft [5,6]. In the setting of such conical motion geometry, we hypothesized that the attachment points of the CB should be uniformly located in accordance with the shapes of the RIC and UIC because the geometric elements of the interosseous crests should maintain the CB both isometrically and isotonically regardless of the degree of the forearm rotation. Such control elements should include a solid axis of rotation (AOR) and topographical aspects of ligament attachment that dynamically tune the tension and relaxation portions depending upon the degree of forearm rotation. Thus, in this study, the authors performed anatomical measurements on cadaveric specimens and volunteers to investigate a coherent structure to the AOR in the forearm and the spatial consistency of the attachments of the CB.

METHODS

This study was approved by the Institutional Review Board of Inje University (IRB No. INJE 2017-03-014-002). Informed consent from patients was waived, and informed consent from the participant in the figure was obtained for publication of the photographs. For the cadaveric investigation, 14 (10 male and four female) fresh frozen upper arm specimens (mean age at death, 72 years; range, 57–83 years) were obtained; after elbow and wrist joint disarticulation, gross observation and radiography were used to exclude any specimens showing lesions related to degenerative change or old trauma as well as specimens where the CB could not be clearly distinguished due to the IOM being too thin. The triangular fibrocartilage complex was retained at the wrist joint to preserve the distal radioulnar joint, and the annular ligament was retained at the elbow joint to preserve the proximal radioulnar joint. An osteoligamentous forearm complex was prepared by removing all soft tissues from the forearm, except for the pronator quadratus, pronator teres, and IOM (Fig. 1). The CB was identified within the IOM using the backlit method [1,7] with a surgical light; the four corners of the CB on the RIC and UIC were marked and drilled with a 1.0-mm K-wire to insert 1.0-mm-thick lead markers for the radiographs. The backlit method has a disadvantage in that the selection range of the IOM may vary somewhat depending upon the illuminance and distance from the light source, but it is regarded as a feasible method by which to distinguish the thickest part of the IOM. We tried to distinguish the CB at around 50 cm from the regular operating room light by referring to the methods of existing researchers [1]. In addition, the isometricity was confirmed by measuring the length changes of the proximal and distal marginal fibers of the selected portion of the IOM in the end-pronation, neutral, and end-supination positions of the forearm. We performed the same measurements on both forearms for data-collection purposes. Still, we chose unilateral data from (six right forearms and eight left forearms) for analysis by random selection to avoid duplication of the data because the measurement values from both forearms tended to be similar for each individual, and the number of cadavers was small.

For the volunteer investigation, 66 forearms from 33 volunteers, including 16 men and 17 women (mean age, 28 years;

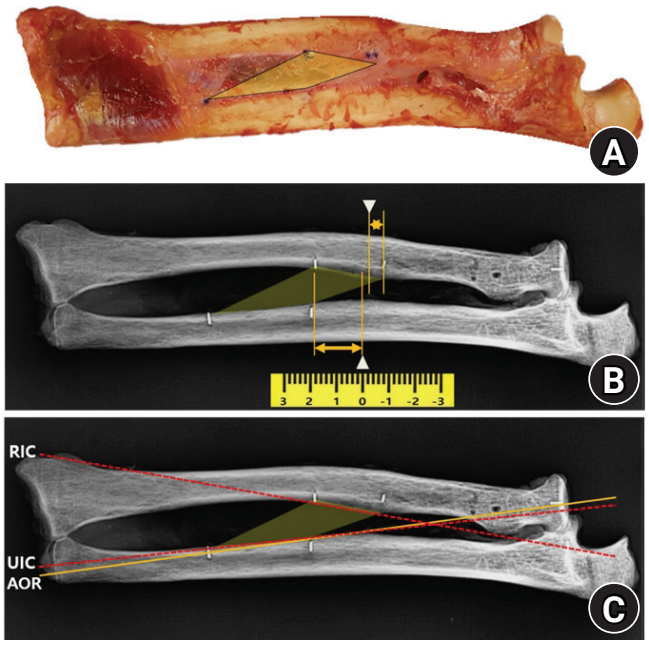

Fig. 1. Measurements from radiographs (palm-up oblique view). When a forearm specimen that has been processed to a forearm osteoligamentous complex is placed naturally on the cassette (A), the ulna becomes externally rotated and the radius becomes internally rotated by itself, aligning both interosseous crests in a single plane (B). The border of the central band (CB) was drawn by joining up the lead markers that had previously been inserted at the four corners of the CB. The distances were measured from each apex (arrowheads) of the interosseous crests on the radius and ulna to the proximal margin of the CB to ascertain the positions of the CB footprints relative to the ulnar interosseous crest (UIC) and radial interosseous crest (RIC) (double arrows). In addition, the angles are measured between the axis of rotation (AOR) of the forearm (solid line) and the lines extrapolated from the downslopes of the RIC and UIC (dotted lines) (C).

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range, 23–44 years), were involved. Since the interosseous crests of both bones project differently, i.e., the RIC anteromedially and the UIC anterolaterally, it is necessary to align them in a single plane. In cadaveric specimens, this forearm configuration could be set simply by placing the osteoligamentous forearm complex naturally on the cassette without manipulation (Fig. 1). In contrast, volunteers rotated their entire forearm externally to turn the ulna externally and rotated only the hand internally to turn the radius internally. We labeled this radiograph a "palm-up oblique view" because only the palm faced upward, yielding a conventional external oblique view of the forearm (Fig. 2). Data from both forearms were used for analysis to investigate the symmetry of the left and right forearms and the consistency of repeated measurements through the measurements of both sides. All statistical analyses were conducted by a statistics expert using the IBM SPSS ver. 21.0 (IBM Corp., Armonk, NY, USA); results with $p < 0.05$ were considered to be statistically significant.

Anatomical Measurements and Confirmation of CB Isometricity

With the cadaveric forearms in end-supination, the distances between the four corners of the CB were measured to discern the lengths of the radial footprint, ulnar footprint, proximal margin, and distal margin. The proximal and distal margins were measured repeatedly in the neutral position and in end-pronation to verify whether the CB maintained isometricity regardless of forearm rotation. All measurements were performed with an accuracy of 0.1 mm by a single orthopedic specialist using Vernier calipers (accuracy, 0.05 mm; Mitutoyo, Kanagawa, Japan); in neutral and end-pronation positions, a divider was used to measure the distances between the points when the measurement point was inaccessible with the caliper. The Shapiro-Wilk test was performed to confirm the normality of the measurements.

Location of the Footprints of the CB and Each Apex of the RIC and UIC

This analysis sought to examine how the geometry of the interos-

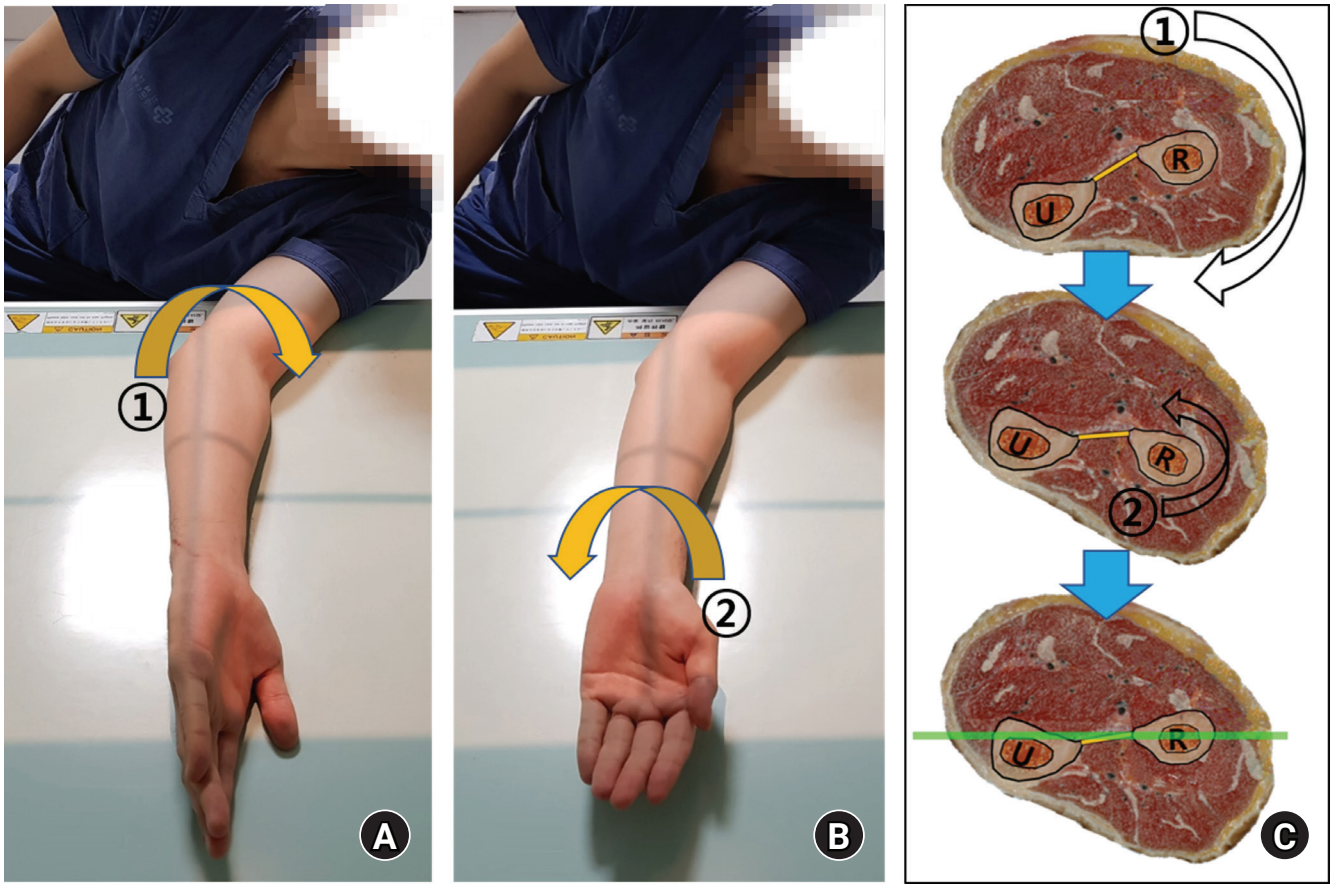


Fig. 2. Palm-up oblique view radiography method. The patient is seated, initially placing the forearm on the cassette in the same position as a conventional 45° external oblique view (A), then asked to rotate only the forearm internally until the palm faces up (B). This method aligns the interosseous crests of both bones with different projections into the same plane for imaging (C). U: ulna, R: radius.

seous crests of both bones could associate with the actions of the CB. On the palm-up oblique view radiographs from the volunteers, each apex of the RIC and UIC was defined as 0; the direction proximal and distal to the apex was defined as positive (+) and negative (–), respectively. The distance from each apex to the upper end of the CB footprint was measured on the RIC and UIC. A normality test was performed for the measurements. The highest point in the outline of each interosseous crest when viewed from the front was defined as the apex, and the slope extending from the apex to the distal part was defined as the downslope.

Angular Configuration of the RIC and UIC to the Forearm AOR

On the palm-up oblique view radiographs from the volunteers, we drew a line from the center of the articular surface of the radial head to the styloid process of the ulna to indicate the AOR [5,8] of the forearm, then measured the angle with lines drawn along the downslopes of the interosseous crests of the radius and ulna. The purpose of this measurement was to examine the coherent anatomy related to the AOR in the conical track of the forearm rotation [6,9]. The Shapiro-Wilk test was performed to confirm the normality of the measurements.

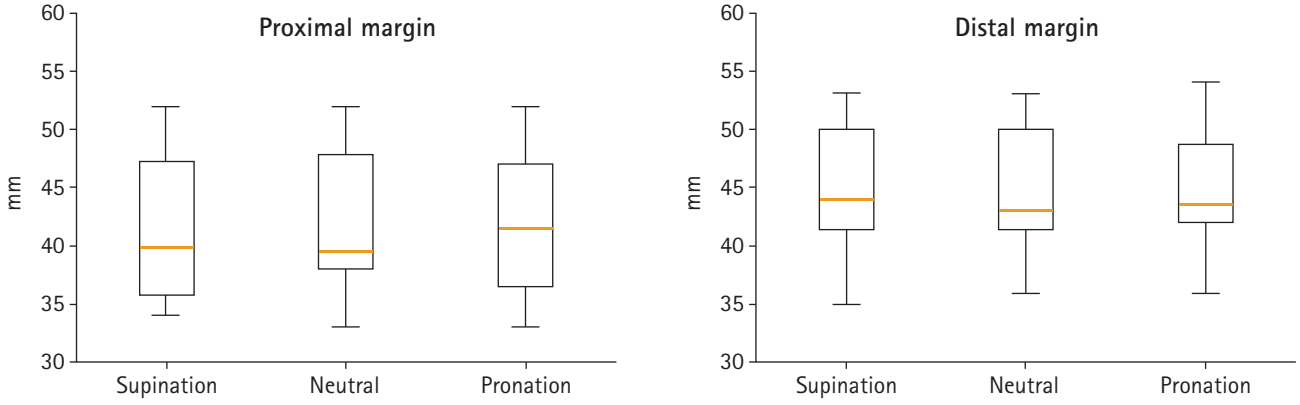
RESULTS

Anatomical Measurements and Confirmation of CB Isometricity

The mean lengths of the radial footprint and ulnar footprint of the CB measured in end-supination were 27.6±4.3 mm (range, 22–43 mm) and 32.8±6.6 mm (range, 25–50 mm), respectively. The mean width in the middle portion measured perpendicular to its fibers was 18.5±3.5 mm (range, 11–26 mm). When measurements of the length of the CB were repeated in different forearm rotations at proximal and distal margins, the results were as follows: proximal margin, 41.7±6.4 mm and distal margin, 45.0±5.5 mm in end-supination; proximal margin, 41.7±6.4 mm and distal margin, 45.1±5.3 mm in neutral rotation; and proximal margin, 41.7±6.5 mm and distal margin, 45.0±4.9 mm in end-pronation. No statistically significant differences were found in CB length at varying degrees of forearm rotation (repeated measures analysis of variance test, p=1.000 and p=0.923, respectively), confirming the isometricity of the CB selected by our method (Fig. 3).

Location of the Footprints of the CB and Each Apex of the RIC and UIC

On the RIC, the proximal margin of the CB inserted into a point 2.9±1.1 mm proximal (+) to the RIC's apex; on the ulna, the proximal margin of the CB inserted into a point 14.7±6.5 mm distal (–) to the UIC's apex. The measured values for the radial footprints satisfied the normality test, but those of the ulnar footprints did not (Shapiro-Wilk test, p=0.13 and p=0.02, respectively) (Fig. 4). Since the proximal margin of the CB attaches adjacent to the apices of the RIC and UIC on both sides, the rest of the footprints of the CB lie distal to these points along the downslopes of both interosseous crests. When the location of the



Variable	Supination	Neutral	Pronation	p-value
Proximal margin	41.71±6.43	41.71±6.46	41.71±6.51	1.000
Distal margin	45.07±5.51	45.07±5.51	45.00±4.87	0.923

Fig. 3. Changes in central band (CB) length based on the extent of forearm rotation. No statistically significant differences were found in the CB length measured in end-supination, neutral rotation, or end-pronation (repeated measures analysis of variance test, p>0.05), confirming CB isometricity. This demonstrates that the portion selected for measurements in the present study is the major bundle of isometric fibers in the CB.

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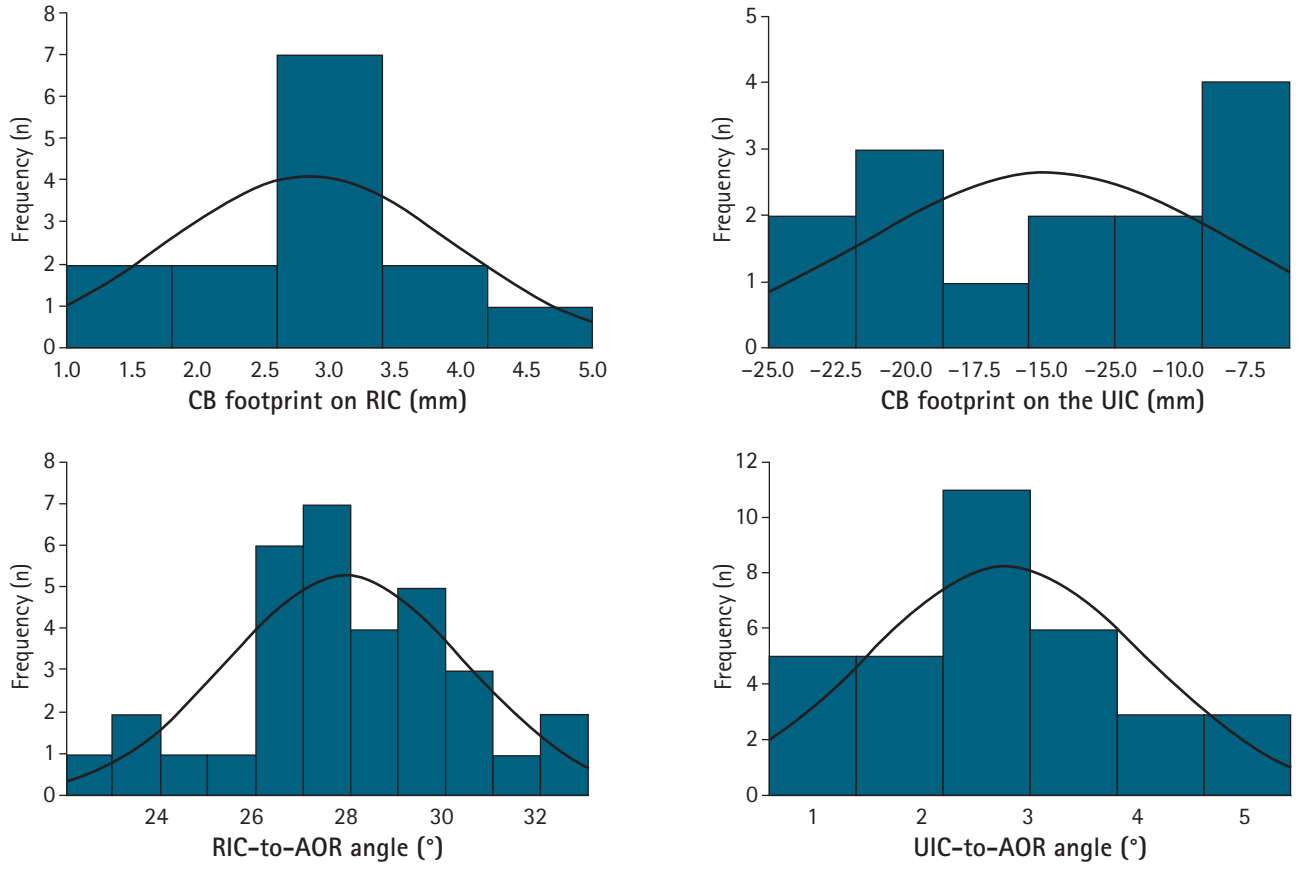

Fig. 4. Location of the central band (CB) footprints and the angular configurations of the forearm axis of rotation (AOR) to the interosseous crest (RIC) and ulnar interosseous crest (UIC). The distance of proximal margin of the CB footprint is approximately 3 mm proximal to the RIC's apex on the radius with normality (Shapiro-Wilk test, $p>0.05$) and 15 mm distal to the UIC's apex on the ulna with no normality (Shapiro-Wilk test, $p<0.05$). This measurement indicates that the CB attaches along the downslopes of both interosseous crests distally to each apex. The UIC coincides with the forearm AOR, and the RIC is at about 15° to this axis with normality (Shapiro-Wilk test, $p>0.05$). n: the number of the specimens or volunteers in the measurement interval.

apex of each interosseous crest was measured by defining the radial length from the radial head top to the radial styloid process and the ulnar length from the olecranon tip to the ulnar styloid process, respectively, the RIC's apex was on average 62.2% (mean, 151 mm/242 mm) and the UIC's apex was on average 51.8% (mean, 135 mm/262 mm) from the distal ends of both bones. The measurements for the location of the RIC's apex satisfied normality (Shapiro-Wilk test, $p=0.120$), but those of the UIC's apex did not (Shapiro-Wilk test, $p=0.007$). There was no statistical difference in the position of each apex on the radial and ulnar lengths in the volunteers (paired t-test, $p=0.09$).

Angular Configuration of the RIC and UIC to the Forearm AOR

After drawing lines to overlap the downslopes of the RIC and UIC (Fig. 1), we measured the angles of these lines with the forearm AOR. On both sides of the forearm, the mean angles of the RIC to AOR and UIC to AOR were 14.0°±1.3° and 1.4° ±0.65°, respectively. Both these measurements satisfied the normality test (Shapiro-Wilk test, $p=0.24$ and $p=0.92$, respectively) (Fig. 4). The line extrapolated from the downslope of the UIC was almost identical to the forearm AOR; this means that the ulnar footprint of the CB inserts precisely along the forearm AOR [8], holding the radius as a firm center of the rotation during forearm circumduction.

In order to test the reliability of repeated measurements for this angular configuration and symmetry between both forearms, we performed an analysis by separating the left and right forearms. The mean angles of the RIC and UIC with the AOR on each side were as follows: right, 14.4±1.3 and left, 13.9±1.3 on the RIC and right, 1.4±0.6 and left, 1.4±0.6 on the UIC, respectively. There was no significant statistical difference between sides (paired t-test, $p=0.19$ and $p=0.08$, respectively).

DISCUSSION

Although there are some different opinions regarding the anatomical structure and components of the IOM in the literature, there seems to be no disagreement that the CB is the most functional element as a stout and constant structure [8,10-13]. The CB works as a restraint on the radius from proximal migration in cooperation with the radial head and works as a load transmitter between the radius and ulna to redistribute load [14-16]. Several authors have demonstrated that the CB is an isometric ligament of the IOM with no change in length or tension occurring during forearm rotation [4,8,11,15,17]. In contrast to the anatomical and functional understanding of the CB, there has been little explanation offered about how this band-shaped structure maintains its isotonicity and isometricity while twisting and fanning during the rotation of the forearm. The authors hypothesized that the morphology of the RIC and UIC would perform a specific function for the CB to restrain the two bones of the forearm without restricting the rotational motion of the forearm in a dynamic environment. This assumption implies a secondary hypothesis of that the RIC and UIC should have predictable shapes and that the attachments of the CB will be distributed with regularity at specific sites in association with such a topographic element. Regarding the attachment point of the CB on the radius and ulna, several researchers have described it as a ratio to the radial and ulnar length or the distance from adjacent structures. Skahen et al. [15] reported that the CB begins 7.7-cm distal to the articular surface of the radial head, inserts 13.7-cm distal to the tip of the olecranon, and is aligned at an angle of 21° from the proximal radius toward the distal ulna. Marcotte and Osterman [3] reported that the ulnar insertion is located at a distance of 33% of the ulnar length from the styloid process, while the radial insertion is located 60% of the radial length from the radial styloid process. Noda et al. [1] investigated the location of the CB insertion point using the distance from the distal part as a proportion of the whole length and reported that the radial insertion is located 53% ± 4% and 64% ± 5% from the distal and proximal ends, respectively, whereas the ulnar insertion is located 29% ± 4% and 44% ± 5% from the distal and proximal ends, respectively. Currently, in clinical practice, these indicators provide rough guidelines for reproducing the isometric point of the CB. Still, due to the lack of explanation for the anatomical or biomechanical necessity of such attachment characteristics, these methodologies might be interpreted differently depending on race and individual.

Forearm motion, which is based on rotation of the radius around the ulna, can be simplified as a hinge or bookbinding [9], wherein the two bones are the leaves, the CB is the pin, and the RIC and UIC are the knuckles. In this simplified model, we make the biomechanical assumption that the CB will show no great change in length throughout the whole range of forearm rotation [1,4,18], while constraining the radius stably and with constant degrees of freedom relative to the ulna. This enables the hypothesis that the bony geometry might play a role in controlling the CB during forearm rotation; hence, we focused on the topography of the RIC and UIC, where the CB footprints are located.

Mori [11] described the forearm AOR as coinciding with the interosseous border of the ulna (UIC), and Hollister et al. [8] showed that all fibers of the IOM crossed the forearm AOR near insertion in the ulna. Their results suggest that the ulnar attachment of the IOM sits consistently aligned in line with the forearm AOR by attaching to the UIC, which is a solid and invariant bony border. We reconfirmed that the forearm AOR and distal slope of the UIC coincided within 1.5°, which is almost equivalent to the measurement error. The agreement between the forearm AOR and UIC might have clinical usefulness as a guide for the ulnar insertion point during IOM reconstruction or an anatomical reference point during the restoration of forearm bones and radial head fractures. We figured out that the proximal margin of the CB almost coincides with the RIC's apex, and the rest of the CB footprint extends from it to the distal slop of the RIC on the radial side. In addition, the anatomical consistency investigation for the location of each apex on the RIC and UIC showed that it appeared at a specific ratio to the total length of the radius and ulna, and there was no statistically significant difference between the right and left forearms. Marcotte and Osterman [3] reported that the ulnar insertion point is located at 33% of the ulnar length from the styloid process and that the radial insertion is located 60% of the radial length from the radial styloid process. Noda et al. [1] reported that the most distal and proximal ends of the radial origin of the CB were 53% and 64% of the total radial length from the tip of the radial styloid, whereas those of the ulnar insertion were 29% and 44% of the total ulnar length from the ulnar head. When we measured the position of each apex of the interosseous crests using a similar method, the results were consistent with those of these previous studies. The result of this study was that the RIC's apex, which the proximal margin of the CB coincides with, is about 40% distal from the top of the radial head. Such findings suggest the anatomical constancy of the topography of the interosseous crests. The observation that both ends of the CB commonly attach to the downslopes of the RIC and UIC will also provide a crucial biomechanical interpretation for understanding forearm rotation. As described by Chao and Morrey [5], forearm rotation follows a conical track with the ver-

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tex at the elbow, the base at the wrist, and the central axis as the AOR, which passes through the fovea of the radial head and the ulnar styloid base. If we look at the spatial configuration of the RIC and UIC from the perspective of the forearm circumduction cone, focusing on the angle of about 15° formed by these two interosseous crests, the UIC's distal slope coincides with the forearm AOR, so it would be the height of this cone, and the RIC's distal slope would move along the slant around it. Therefore, the imaginary cone with a vertex angle of 30° (15°×2) drawn by these two interosseus crests during forearm rotation can be said to be a solid geometric core of the forearm circumduction. In addition to this characteristic motion trajectory of the forearm rotation, it is important to consider that the radius revolves around the ulna, and, at the same time, the axis of the radius rotates in proportion to the revolution angle. In this case of a complex rotatory motion between two long bones in the conical track constrained longitudinally by a broad, non-elastic band like the CB, at the endpoint of rotation, this band structure could become distorted or wound around the shafts of both bones. As a result, disproportional tension in the band constraint would lead to restriction of the forearm rotation [9]. Therefore, some device would be required to offset the conical track of forearm rotation and to overcome the discrepancy between the proximal and distal fibers in the CB at any angle of rotation. We demonstrate that this could be achieved by the downslopes of the interosseous crests tracing two small conical tracks in opposite directions to the conical track of the forearm rotation (Fig. 5). This interpretation suggests that the interosseous crests of the radius and ulna are not simple bone-insertion sites for the CB but also stop distortion of the CB modulating tension and shift of the working segment in the CB during forearm rotation [19,20].

We sought to elucidate clues to the geometric and biomechanical inevitability of the attachment points on the interosseous crests of the radius and ulna. Therefore, in particular, we believe that this study could contribute to the understanding and development of clinical methodologies for determining its isometric points on the osseous ridges when reconstructing the IOM [3,21,22]. Still, the restrictions in the resources and methods, the small number of samples, the paralleled direct measurement from the cadavers and the indirect measurement from the volunteers, and the demarcation of the CB using the backlit method with inherent non-uniformity are noted limitations of this study. Anatomically, most RICs show a clear and conspicuous shape, making it easy to identify their apex. On the other hand, the UICs show a relatively vague and flat tendency, suggesting the possibility of inter-observer differences in their definition. We clearly state that this bias may have impaired normality by causing irregularities in the ulnar side measurements, and we await follow-up studies using larger sample sizes and future validation of the methods used herein.

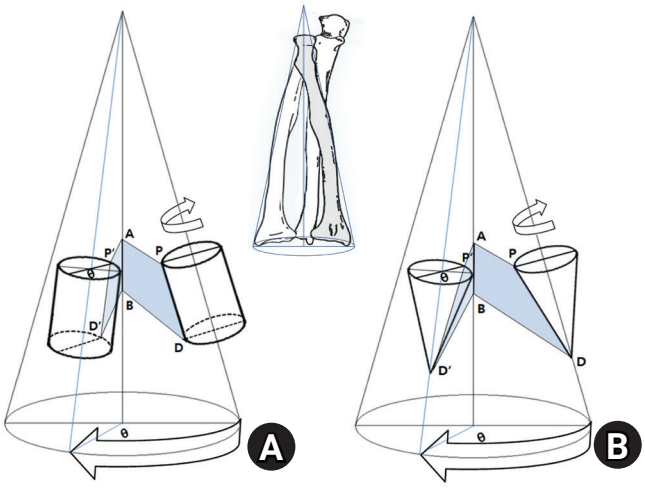

Fig. 5. Role of the longitudinal geometry of the interosseous crests of the radius and ulna. During rotation of the forearm categorized as circumduction, the radius is longitudinally constrained to the ulna by the central band (CB), a band-shaped ligament, and revolves around the forearm axis of rotation, tracing a conical track. One key consideration in this movement is that, when the forearm rotates a given angle, θ (revolution), the shaft of the radius also rotates by the same angle, θ (rotation). In this kinematics, if the interosseous crests where the CB inserts are modeled as cylinders (A), then, as the axis of the radius revolves and rotates along the conical track, distal fibers (line BD) of the CB at the base would move across a longer diameter than proximal fibers (line AP) at the vertex. This disproportional rotation would result in greater tension in distal fibers as the forearm circumduction progresses, eventually restricting the rotation. However, suppose the CB-insertion sites are modeled as slants of a cone in the opposite direction to the slant of the conical track of forearm circumduction (B). In this case, this unfavorable tension will not develop throughout the entire CB, staying isometrically at any angle of forearm circumduction. This interpretation based on the topography might explain why the CB must necessarily insert into the distal downslopes of both interosseous crests.

The UIC coincides with the AOR of the forearm, and the apex of the RIC coincides with the proximal CB footprint. Furthermore, the CB necessarily attaches to the downslope immediately distal to each apex of the interosseous crests of the radius and ulna, offsetting the disproportional conical track of the forearm circumduction to maintain the CB isometrically and isotonically in different degrees of forearm rotation.

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Case Report

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Allograft reconstruction for large parosteal osteoma of the clavicle: a case report

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A large parosteal osteoma arising on the surface of the right clavicle of a 39-year-old male patient was suspected preoperatively as a parosteal osteosarcoma. The lesion was treated with wide resection and allograft reconstruction. In this case report, we discuss the accurate diagnosis and appropriate surgical treatment for unusual clavicular tumors.

Keywords: Clavicle; Osteoma; Allograft; Case report

Primary clavicle tumors are rare. Due to the rarity of clavicle tumors, accurate clinical diagnoses are difficult. Tumors arising from the surface of the clavicle such as parosteal osteomas or osteosarcomas are very rare. In a review of 206 cases published from 1980 to 2011 in East Asia, osteomas and osteosarcomas comprised 3.88% (8 cases) and 8.74% (18 cases) of cases, respectively, which was more than twice the prevalence of parosteal osteoma [1]. The authors report a case of a large parosteal osteoma of the clavicle treated with wide excision and allograft reconstruction due to the possibility of parosteal osteosarcoma based on the preoperative evaluation.

CASE REPORT

A 39-year-old male patient visited our hospital due to the presence of a right medial clavicular mass. A 3×2-cm-sized, fixed, non-tender, hard, bony mass in the medial clavicle area was observed. Upon examination, Tinel's sign was negative with full range of motion in the right shoulder. This lesion had been identified 10 years prior and gradually had grown in size, but the patient had not undergone any treatment. A thorough evaluation was recommended after x-ray examination, but the patient refused and did not return to the hospital. After 11 months, the patient revisited our hospital requesting removal of the mass. The lesion was larger than when it was initially found. His right elbow had a history of injury and exhibited a cubitus varus deformity with limitation of motion (40°–90°) and ulnar nerve symptoms in the right hand. Deterioration in general conditions such as weight loss or lethargy was not observed. On X-ray, computed tomography (CT) scan, and contrast-enhanced magnetic resonance imaging (MRI), the mass measured 6.0 cm mediolaterally and 4.8 cm anteroposteriorly in the medial clavicle area (Fig. 1). The MRI revealed a lesion with low signal intensity on both T1- and T2-weighted images. The lesion was composed of a dense osseous portion, and signal change was observed with suspected involvement of the adjacent subclavius muscle not involving the

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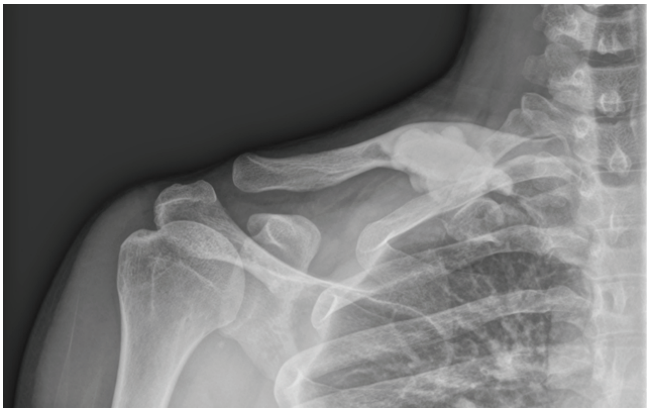

Fig. 1. On plain X-ray, a large dense sclerotic mass was noted in the area of the right medial clavicle.

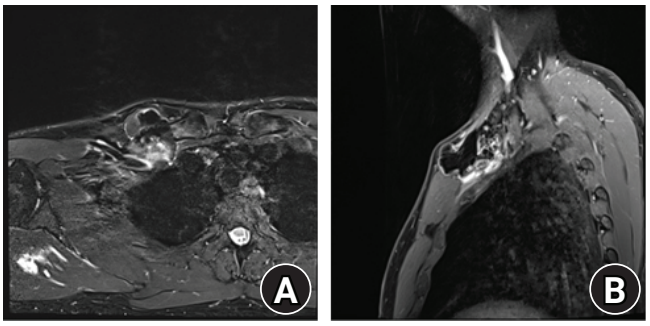

Fig. 2. Magnetic resonance imaging showing a lesion with low signal intensity on both T1- and T2-weighted images with suspected involvement of the adjacent subclavius muscle with enhancing soft tissue portion and deviating subclavian vein. (A) Axial image. (B) Sagittal image.

first rib (Fig. 2). Through a multi-disciplinary approach with our radiology and hemato-oncology departments, the most likely diagnosis was parosteal osteosarcoma, followed by parosteal osteoma. The main reason for suspecting malignancy was involvement of the subscapularis enhancing soft tissue portion and deviating subclavian vein. To rule out malignancy and to determine the stage of tumor, chest CT, bone scan, and positron emission tomography (PET)-CT were performed. On the bone scan, an active lesion was identified on the right medial clavicle. No metastatic lesions were observed on PET-CT. After radiologic interpretation, the patient requested complete removal of the mass. Wide resection with allograft reconstruction was decided upon after extensive communication with the patient due to the large size of the mass, recent rapid growth, fear of recurrence with suspicious malignancy, and possibility of inappropriate diagnosis after inadequate biopsy. Medial resection was performed through the sternoclavicular joint, and lateral resection was created with a margin approximately 3 cm from the most lateral aspect of the clavicular mass (Fig. 3). During resection, soft tissue adhesion was identified between the posterior clavicle and the first rib. Atypical cells were not observed on frozen biopsy that included medial and lateral portions of the fist rib and subclavius muscle. Fibular allograft bone was inserted through the defect site after measuring the exact size. Fixation was performed between the sternum and fibular allograft and between the fibular allograft and remnant lateral clavicle using two plates and screws (Fig. 4). An additional plate was inserted between the two previously inserted plates to prevent stress fracture. Demineralized bone matrix was used to promote bone healing. After the operation, daily teriparatide (Forsteo; Lilly, Seoul, Korea) was injected subcutaneously for eight weeks. Five months after the operation, bony union was observed between the lateral strut and remnant clavicle on the follow-up X-ray. After 11 months, the patient visited

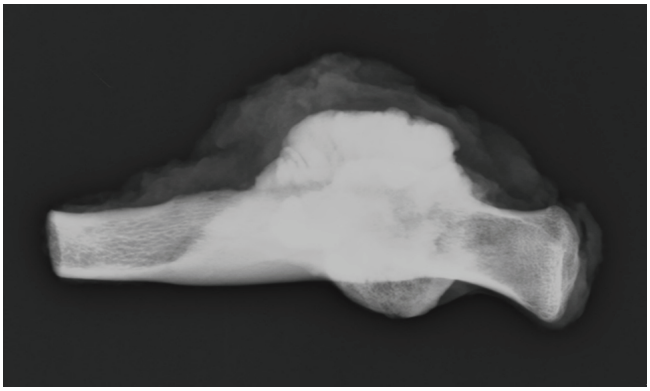

Fig. 3. A photograph of the resected clavicle including the entire mass.

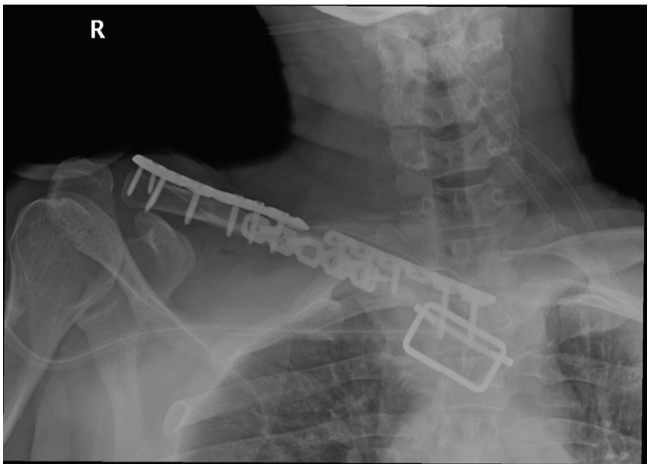

Fig. 4. After wide resection and allograft reconstruction, three plates and screws were fixed.

the hospital after experiencing discomfort at the operation site. The medial plate was fractured, but no further procedures were performed (Fig. 5). The range of motion after 28 months was active forward flexion 160°, abduction 130°, and external rotation

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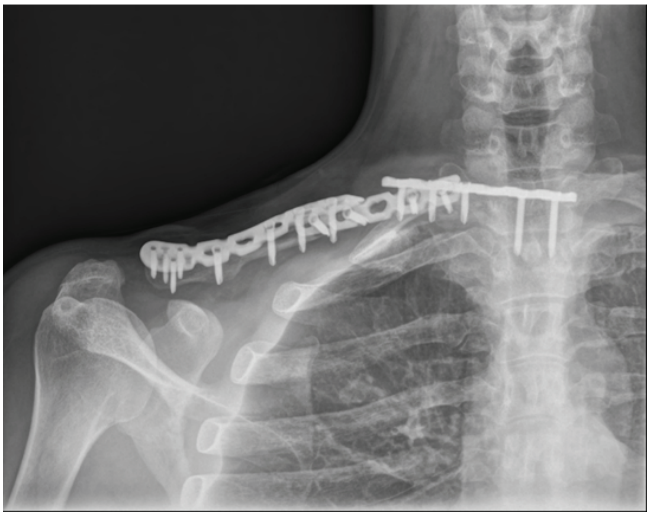

Fig. 5. X-ray taken at 23 months after surgery, showing that the fractured area at 11 months after surgery was well fused. An angular deformity and sternal screw loosening with medial plate pull-out were observed. Since there were no indications of additional pain or discomfort, further observation was performed.

at the side 80°. This was meaningful in that it indicated successful recovery of radiographic and functional outcomes after wide excision with allograft reconstruction for large parosteal osteoma of the clavicle.

DISCUSSION

Primary clavicle tumor and tumorous lesions are rare, and the majority of studies were case reports [2]. Since osteomas are benign lesions, it is important to differentiate them from malignant lesions like parosteal osteosarcoma or parosteal chondrosarcoma [3]. In our case, bone scan revealed an active bone lesion, and the clinical diagnosis of the radiology department was parosteal osteosarcoma due to suspicious involvement of the subscapularis enhancing soft tissue portion and deviating subclavian vein, making it difficult to determine treatment. For evaluation of soft tissue mass or bone tumor, biopsies with various techniques are helpful and important deciding factors. Choosing the appropriate biopsy is important for accurate diagnosis of tumors [4-6]. In our case, we questioned the accuracy of the biopsy since negative predictive values has been shown in the literature. The medial clavicular mass was diagnosed initially as an aneurysmal bone cyst, but due to its rapidly growing nature after diagnosis, open biopsy was performed, revealing a high-grade osteosarcoma [5]. In our case, the patient requested lesion removal regardless of pathology. Careful discussion was performed to determine whether or not a preoperative biopsy would be valuable. It was decided that wide excision be performed with negative margins without preoperative biopsy. In addition, the possibility of tumor seeding or contamination on the biopsy tract could not be ignored. Pressure on the surrounding tissues was an important factor in determining the type of surgery. After wide excision, a mass with a size of 4.9×3.5×3.5 cm with negative resection margins was obtained. Nora's lesion known as bizarre parosteal osteochondromatous proliferation was observed and was supportive of parosteal osteoma, but a clinicopathologic correlation was recommended. The final result was a parosteal osteoma and not a parosteal osteosarcoma as was suspected in preoperative MRI. In summary, the importance of biopsy in diagnosis of a tumor is well known. However, biopsy has the possibility of negative predictive values. Especially for the patient in our case, hoping for operative resection due to the large mass effect, the risk-benefit of biopsy must be considered.

Claviculectomy for clavicular tumor can be inferior functionally due to many issues such as loss of the role as a supporter, muscle weakness, cosmetic problems, and restriction of joint motion as well as loss of the protector effect for important vessels and nerves located in the back of the clavicle [7]. Performing reconstruction using allograft after resecting the clavicle can lead to many complications from the bone graft material. There is a way to re-insert the clavicle after radiation treatment to perform reconstruction [8]. In our case, satisfactory recovery of the radiographic and functional outcomes was obtained after wide excision with allograft reconstruction for large parosteal osteoma of the clavicle.

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A surge in neglected shoulder dislocations and delayed surgical management due to the coronavirus disease 2019 lockdown in India

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Four patients with shoulder problems that were traumatic in etiology presented to us with delays in seeking care ranging from 6 to 12 weeks due to the coronavirus disease 2019 (COVID-19) lockdown. The care of three cases (a 3-month-old neglected anterior shoulder dislocation with a greater tuberosity fracture in a 30-year old man, a 3-month-old neglected anterior shoulder dislocation in a 17-year old boy, and a 2-month-old neglected greater tuberosity fracture in a 31-year old man) was delayed due to the lockdown and the ensuing travel restrictions, while that of one case (a 6-week-old fracture–dislocation of the proximal humerus in a 55-year-old woman) was delayed because the patient was undergoing treatment for COVID-19 at the time of injury. This report intends to present the exceptional circumstances around these cases. The unique treatment challenges and their outcomes are also described to advise the surgeons of the nuances and difficulties in treating these injuries.

Keywords: COVID-19; Shoulder; Neglected disease; Shoulder dislocation; Case report

In February and March 2020, several countries announced a partial or total lockdown in an effort to limit the spread of severe acute respiratory syndrome coronavirus 2, capable of causing coronavirus disease 2019 (COVID-19) [1]. Country-specific guidelines and World Health Organization guidelines specified that non-urgent surgeries should be postponed in view of the prevailing pandemic. To help and guide the scheduling of procedures, orthopedic fracture operations were classified as urgent and surgically necessary procedures [2]. However, for patients with COVID-19, most orthopedic procedures were deferred until the patients subsequently tested negative for infection. During the first 3 months (April–June 2020) of the lockdown in India, there was an overall decrease in the number of orthopedic and trauma surgeries in all hospitals because of the stay-at-home orders and a complete halting of all elective surgeries. Some fractures of the upper limb that could be managed conservatively were preferably treated nonoperatively at our hospital. Elective surgeries, such as rotator cuff repairs, and instability surgeries

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were deferred to a later date. This was done to mobilize resources for the fight against COVID-19. Although fracture surgeries and shoulder trauma decreased in most parts of the world during this period, we started facing challenging shoulder problems due to the social impact of the COVID-19 lockdown. Four patients with shoulder problems that were traumatic in etiology presented to us with care-seeking delays ranging from 6 to 12 weeks due to the COVID-19 lockdown. The care of three patients aged 17 to 31 years was delayed and neglected due to the lockdown and the ensuing travel restrictions; these cases included an (1) anterior shoulder dislocation with a greater tuberosity (GT) fracture in a 30-year-old man (neglected for 3 months), (2) anterior shoulder dislocation in a 17-year-old boy (neglected for 3 months), and (3) GT fracture in a 31-year-old man (neglected for 2 months). Separately, the fourth case was a fracture–dislocation of the proximal humerus in a 55-year-old woman that was managed after a delay of 6 weeks as the patient was undergoing treatment for COVID-19 at the time of her injury. Neglected shoulder problems are not commonly seen in clinical practice, and all four of these cases presented to us after partial lifting of the lockdown. Moreover, these patients' delay in seeking treatment was due to the effects of the COVID-19 lockdown and, as a result, led to unique treatment challenges. This report aims to highlight the etiology and the sudden surge of neglected problems due to COVID-19 lockdown. The unique treatment challenges and their outcomes are also described to apprise surgeons of the nuances and difficulties in treating these injuries.

CASE REPORT

No ethics approval was required in accordance with the local laws for case report submission. All study subjects gave their consent for participation. Ten shoulder trauma-related urgent surgeries were performed by us between June 15 and August 15, 2020, after the lockdown was partially lifted. Amongst the 10 surgeries, four (described herein) were considered to be delayed and neglected, and the rest were acute fractures of the proximal humerus.

Case 1

Neglected (3 months) anterior dislocation of the shoulder with a GT fracture

A 30-year-old man sustained an anterior dislocation of the right shoulder along with a GT fracture (Fig. 1) in the last week of April 2020 after being hit on the shoulder by a stick in a local street fight in a town located 150 kilometers from the main city. This region was served by general primary physicians in primary health services who are only equipped to treat common diseases; as a result, the local doctors provided the patient with a sling, no X-ray imaging or further management for the dislocation was performed. The patient was unable to travel because of the lockdown restrictions and sought our opinion only after a delay of 3 months with symptoms of severe pain with a visual analog scale (VAS) score of 8 points (out of a maximum of 10 points) and restricted use of the affected limb. His functional ability to use the injured limb was limited because he had severe pain and a restricted shoulder range of motion of −10° of external rotation, L4 vertebral level of internal rotation, and 50° of forward flexion. Computed tomography imaging did not reveal any glenoid bone loss. He was operated on after his COVID-19 status was confirmed to be negative under full personal protective equipment precautions as was the protocol for all surgeries. He underwent open reduction through a deltopectoral approach. During surgery, the following difficulties were encountered: (1) reduction of the GT was not possible without debulking the lateral part of the proximal metaphysis of the proximal humerus as ossification and fibrosis restricted the anterior reduction of the GT and (2) the lesser tuberosity (LT) was not visible even with a medial retraction of the conjoint tendon because of severe medial displacement of the proximal humerus. Hence, a coracoid osteotomy was performed that enabled the conjoint tendon to be retracted further medially and allowed the exposure of the LT and the attached subscapularis. The entire subscapularis had to be detached (later repaired) to allow the reduction of the humeral head to the glenoid. We also released the posterior capsule from the glenoid in order to reduce the head on the glenoid. However, the head kept slipping out anteriorly with even the slightest of rotation of the arm and was found to be unstable because of the severe contractures. Ultimately, the chronicity of the neglected dislocation resulted in severe contractures around the head; hence, two K-wires were used to fix the acromion to the humeral head (Fig. 1B) in order to keep the humeral head stable in the glenoid cavity. The GT was dissected from the surrounding fibrosis and fixed to the humerus with the help of suture anchors. The neglected status of the injury led to an increased surgery duration (3.5 hours) because extensive capsular release, entire subscapularis release, proximal metaphysis debulking to reduce the GT, and K-wire fixation to stabilize the head were required. There were also two instances of uncontrolled bleeding that necessitated packing the wound for 15 minutes until the bleeding subsided. The coracoid tip that had been osteotomized was reattached to its base with the help of cerclage sutures through the tip and the remaining coracoid bone. Postoperatively, there was no neu-

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rovascular deficit or any other complication, and both the K-wires were removed at 4 weeks. This case was more complicated than the other case (case no. 2) of neglected shoulder dislocation because the displaced GT fracture resulted in a loss of lateral restraining forces on the humeral head, causing it to displace far too medially. The patient's pain (VAS score) and external rotation improved from 8 points and −10° preoperatively to 3 points and 55° at 6 months of follow-up. Further, the forward flexion increased from 50° preoperatively to 80° at 6 months of follow-up, and internal rotation improved from L4 to the T12 vertebral level. The 6-month follow-up X-ray showed persistent subluxation of the humeral head (Fig. 1C and D), and the patient reported mild pain (VAS score 2/10).

Case 2

Neglected (3 months) anterior shoulder dislocation

A 17-year-old boy fell from his bed on May 1, 2020, and sustained an anterior shoulder dislocation of the left shoulder (Fig. 2). He went undiagnosed for 2 months because the local doctors did not perform an X-ray and he could not travel to a more equipped center because of the lockdown. He presented to us with pain

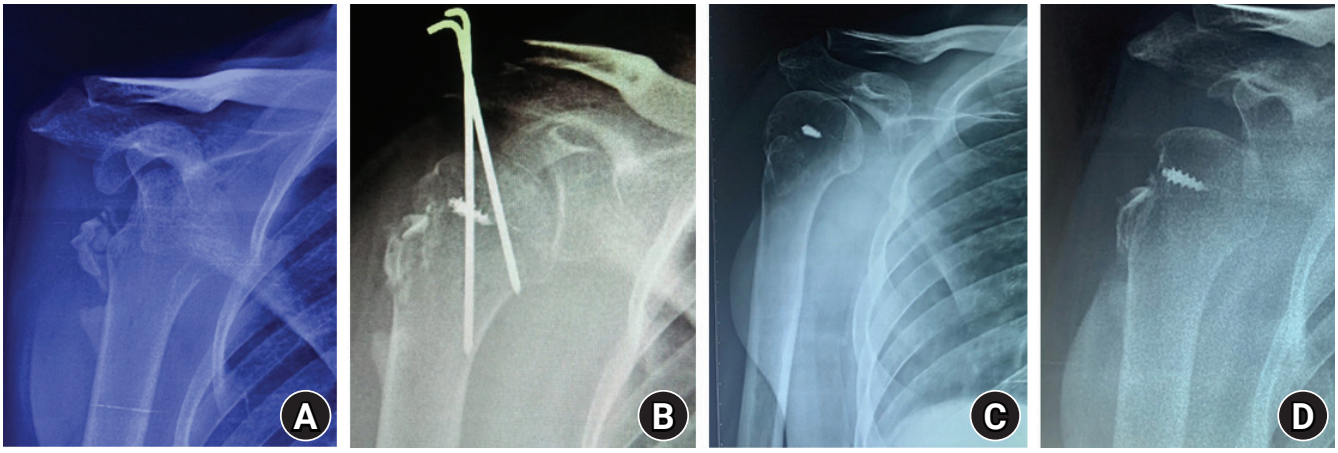

Fig. 1. Case 1. (A) An X-ray showing an anteroposterior view of the right shoulder of a 30-year-old man with a 3-month-old neglected anterior shoulder dislocation along with a greater tuberosity (GT) fracture. (B) A postoperative X-ray showing K-wire fixation from the GT to the humeral head to stabilize the joint. (C) A 6-month follow-up X-ray with arm in external rotation. (D) A 6-month follow-up X-ray with arm in neutral rotation showing subluxation of the humeral head.

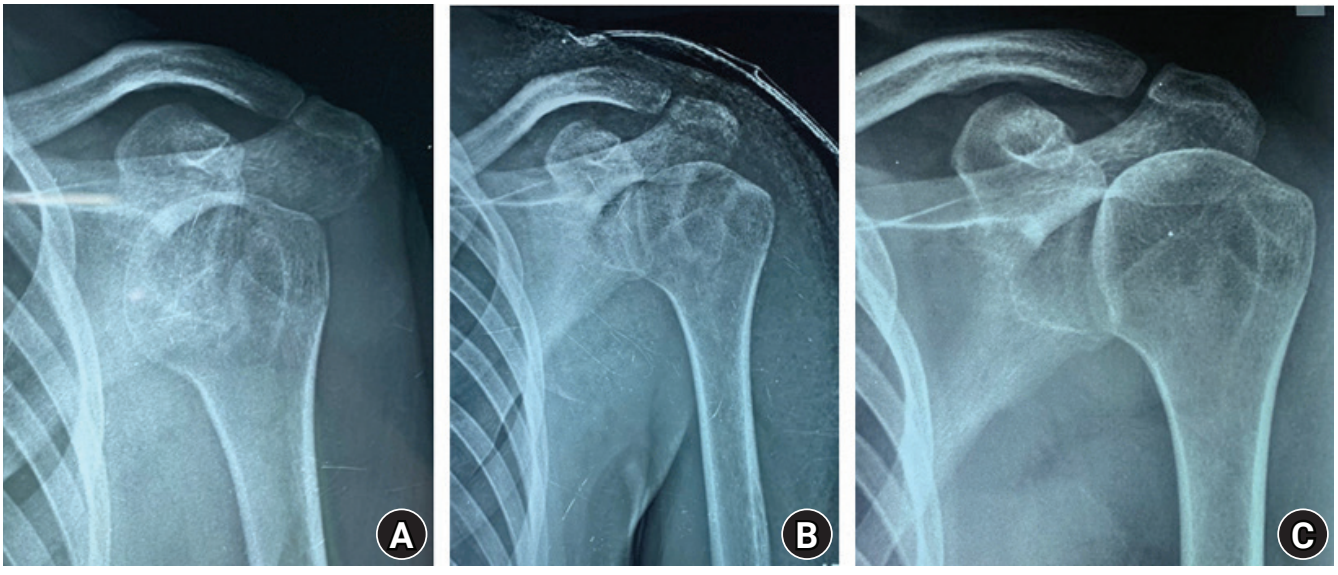

Fig. 2. Case 2. (A) An X-ray showing an anteroposterior view of the left shoulder of a 17-year-old boy with a 3-month-old neglected anterior shoulder dislocation. (B) A postoperative X-ray showing reduced humeral head in the glenoid cavity. (C) A 6-month follow-up X-ray showing a stable glenohumeral joint.

and limited movement of the shoulder. No closed reduction was attempted because of the chronicity of the problem, and an open reduction approach was planned; he finally underwent open reduction at our facility 3 months after the injury. We used the deltopectoral approach, did not perform a coracoid osteotomy, removed the superior half of the subscapularis, and reduced the head in the glenoid. Intraoperatively, the joint was stable, no K-wire fixation was needed, no capsulolabral repair was attempted, and the subscapularis tendon was repaired. Postoperatively, we did not notice any neurovascular deficit or immediate complications. The surgery duration was 60 minutes, and the duration of the hospital stay was 2 days. The patient's pain (VAS score) and external rotation in adduction improved from 6 points and 0° preoperatively to 0 points and 60° at 6 months, while the forward flexion increased from 50° preoperatively to 140° and the internal rotation improved from the sacroiliac joint to the T12 vertebral level at 6 months. Additionally, at 6 months of follow-up, the constant score improved to 74 points from a preoperative score of 13 points, and X-ray imaging showed a humeral head concentrically reduced in front of the glenoid.

Case 3

Neglected (2 months) GT fracture

A 31-year-old man fell down while riding his two-wheeler on May 10, 2020, and sustained a distal-end radius fracture of the right wrist and GT fracture of the left shoulder (Fig. 3). His wrist fracture was managed by plaster immobilization in a local hospital. The expertise to surgically manage the GT fracture was absent at the local hospital, and no other center's help could be sought due to the limited availability of resources in the area of his residence, the limited functioning of specialized trauma services in the local area, and the travel restrictions in place during the initial lockdown period. After the lockdown was partially lifted, he was referred to us for his GT fracture management (i.e., a delay of 7 weeks from the injury). We fixed his GT in a double-row fashion with two suture anchors medially and a cannulated fully threaded 4-mm screw laterally as a lateral post, using a deltoid-splitting approach. We did not observe any immediate postoperative complications or neurovascular deficit. The fracture could have been managed arthroscopically in the acute period, however as he presented 2 months late, we decided to manage the fracture and the surrounding adhesions using an open deltoid-splitting approach because, in our experience, mobilizing a posteriorly displaced GT fragment in a chronic case is completed more easily via an open approach. The fracture united at 3 months of follow-up and the patient's pain improved from a preoperative VAS score of 5 points to 0 points at 6 months of follow-up; additionally, his elevation, external rotation, internal rotation, and constant score improved from 0°, 0°, L1, and 13 points preoperatively to 110°, 50°, T12, and 62 points at 6 months of follow-up.

Case 4

Six-week-old fracture–dislocation of the proximal humerus

A 55-year-old woman sustained a fracture–dislocation of the left proximal humerus (Fig. 4) after falling from her hospital bed during an episode of epileptic convulsions at a COVID-19 care center on May 3, 2020. The woman was symptomatic with cough and fever, had a past history of epilepsy, and had been admitted to the COVID facility 3 days prior to the incident. However, her

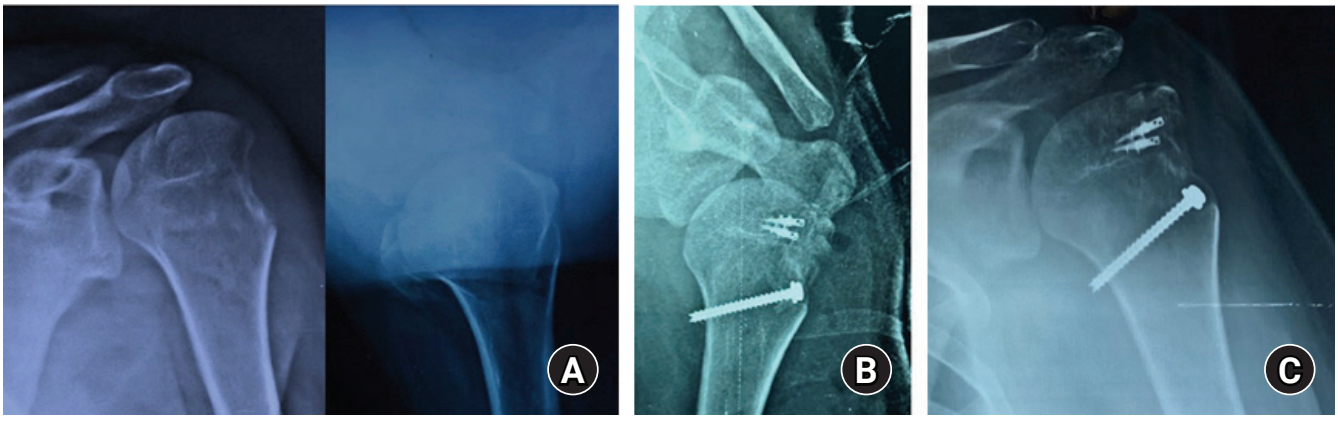

Fig. 3. Case 3. (A) An X-ray showing an anteroposterior view and axial view of the left shoulder in a 31-year-old man with a 2-month-old neglected greater tuberosity (GT) fracture. (B) A postoperative X-ray showing double-row fixation of the GT with the help of two suture anchors as medial row and a 4-mm cannulated screw as a lateral row post. (C) A 6-month follow-up X-ray showing the healed GT fracture.

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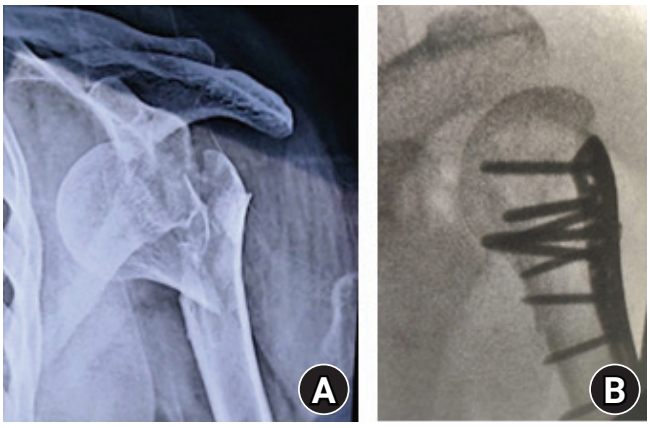

Fig. 4. Case 4. (A) An X-ray showing an anteroposterior view of the left shoulder in a 55-year-old woman with a 6-week-old fracture–dislocation of the left proximal humerus. (B) A postoperative X-ray showing precontoured locking plate fixation of the proximal humerus fracture–dislocation.

fracture could not be operated upon at the index hospital because of her concurrent infected status. She was discharged from the COVID-19 facility after 2 weeks; however, confirmation of her fitness for surgery was further delayed due to her uncontrolled epilepsy and COVID-19 status, and she finally underwent operative intervention after a delay of 45 days after swab-testing negative for COVID-19 twice and after her seizures were controlled. She could not afford a humeral head replacement and was not covered by any health insurance policy that would pay for her implant and procedure costs; hence, we fixed her fracture with a precontoured locking plate through a deltopectoral approach. Although there was an increased risk of avascular necrosis, this risk was explained to the patient. The surgery duration was 75 minutes, and the duration of hospital stay was 4 days. This patient was lost to follow-up after 6 weeks.

Comparison with the Pre–COVID-19 Period

To compare the numbers of neglected trauma cases managed in our unit during the pre–COVID-19 period with the ones managed recently, we retrieved our records of urgent shoulder trauma surgeries performed by our unit in the two 6-month periods preceding the COVID-19 lockdown, i.e., from October 1, 2019, to March 23, 2020, and from April 1 to September 30, 2019. In the former period, we performed 72 urgent shoulder trauma surgeries; of these 72 surgeries, there was one case of a neglected anterior dislocation managed with open reduction and one case of a neglected posterior dislocation managed with open reduction and the McLaughlin procedure. In the latter period, we had performed 65 urgent shoulder trauma surgeries, one of which was a case of neglected anterior dislocation managed by open reduction and one of which was a case of neglected fracture–dislocation of the proximal humerus managed by open reduction and plate fixation. Thus, the rate of neglected injuries corresponds to 3% of all treated injuries.

DISCUSSION

The aim of this report was to highlight the recent surge in complicated and neglected shoulder problems due to the social and economic impacts of the COVID-19 lockdown and to discuss the appropriate timing for surgery on a COVID-19–positive patient. Although recent reports indicated that a reduction in the overall incidence of shoulder-related trauma occurred during the COVID-19 lockdown period [3], four neglected presentations within a span of 2 months clearly represents a recent surge in chronic and neglected conditions due to the lockdown because neglected shoulder dislocations are not a commonly treated condition. A perusal of our past records showed that we operated on only two neglected anterior dislocations and one neglected fracture–dislocation within the one year preceding the COVID-19 pandemic. During the COVID-19 lockdown period in 2020, all elective surgeries were suspended at our hospital per the government directive; however, trauma and fracture surgeries were classified as urgent and were allowed to continue. The COVID-19 lockdown not only affected the scientific aspects of fracture care but also impacted its economic and social aspects, and these socioeconomic concerns eventually affected the care of patients. Although neglected shoulder dislocations are unusual, they have been regularly reported in published papers from developing countries [4] as well as developed ones [5]. However, neglected anterior dislocations in the younger age group may have been reported in slightly higher numbers from developing countries. Unless there are extenuating social or medical circumstances, it is unusual for a disabling condition like an anterior shoulder dislocation to be left untreated in younger patients. In our report, amongst the group of three patients whose care was neglected due to lockdown, the maximum age was 31 years and the patient with neglected shoulder dislocation was only 17 years old. Economic factors affecting the rescheduling of orthopedic surgeries have been recently reported from Europe [6], but the social aspects have received scant attention. Even though the socioeconomic impact of COVID-19 lockdown has been felt worldwide, the socioeconomic chiasm is bound to deepen in areas where it already existed. The three patients with neglected trauma were unable to seek proper care during the lockdown period because expert services were lacking and local hospitals were unable to mobilize the necessary resources. Additionally,

expert orthopedic services to surgically treat the fractures were not available in the patients' area of residence. In India, primary, secondary, and tertiary care centers are established in the order of increasing specialized service availability. Smaller cities and rural areas are served by primary health posts that are only equipped to manage common diseases. For any expert or specialized services, patients are usually referred to community (secondary) health centers or tertiary health centers. Tertiary health centers have the most specialized and advanced facilities but are located primarily in larger urban city areas, and they receive patients referred from primary and secondary centers. Primary health posts lack specialized services. The absence of expert and specialized services near our patients' homes may also have contributed to their conditions being left neglected. Additionally, the travel restrictions in place made it more difficult to seek proper care outside of their area. Two of these patients came from an area 150 kilometers away from the main city, where basic health services are available during normal times but may be limited during the lockdown. We showed that a neglected dislocation could be successfully managed in our 17-year-old patient with good outcomes during short-term follow-up. Meanwhile, the presence of GT fracture along with the dislocated head in the first case presented a challenging situation due to the absence of lateral restraining forces. Notably, this resulted in more severe medial migration of the humeral head; as a result, the surgery was prolonged, and the resulting forward flexion was suboptimal with persistent subluxation of the humeral head. However, the patient's external rotation improved significantly, which enabled him to carry out his daily activities. The prognosis of such severe injuries in a neglected scenario should be determined because they may not always achieve the desired outcome. Arthroplasty options for neglected shoulder dislocation may be available for the older age groups [5], but the options for the younger age group are limited and more nuanced. Open reduction of neglected anterior dislocations has been reported to yield variable results in the literature. Li and Jiang [4] reported high rates of instability after open reduction and coracoid transfer through a subscapularis cut-and-repair technique, but some authors have reported that average to good outcomes are achievable after open reduction with or without acromiohumeral K-wire fixation for stability [7]. Furthermore, conservative neglect has shown poor functional results and, hence, an attempt at open reduction may be made by shoulder surgeons because patients are in pain and have limited functional abilities [7]. A risk of neurovascular complications may also prevent some surgeons from attempting an open reduction in a neglected anterior dislocation, but several reports and our experience show that this fear is unfounded.

According to Siebenbürger et al. [8], delayed head-salvage procedures for fracture–dislocations of the proximal humerus may increase the risk of avascular necrosis of the humeral head. However, a recent report by Trikha et al. [9] stated that good results are achievable even in delayed reconstructions in patients who are younger than 60 years. If a patient with a fracture of the proximal humerus also has a concomitant COVID-19 infection, surgical intervention may have to be deferred in view of the increased risk and dangers of operating on a COVID-19–positive patient. Several authors have recommended that all surgically necessary operations may be performed after two real-time polymerase chain reaction tests are negative and the patient has become asymptomatic. However, some patients may continue to test positive via real-time polymerase chain reaction for up to 3 to 12 weeks after their initial symptoms [10] because viral RNA can be found in the throat in low amounts for up to 12 weeks, even though the symptoms have subsided and the patient has clinically recovered. However, several authors have stated that replication-competent viruses are rarely isolated beyond 10 days from an asymptomatic patient who had earlier tested positive. For a shoulder surgeon, a delay beyond few weeks may be undesirable in view of the entailed difficulties in achieving a proper reduction and consequent compromised results as was seen in our case 1 that had a GT fracture along with a chronic anterior dislocation.

Though recent reports indicate that shoulder trauma decreased in frequency during the COVID-19 lockdown, we are now seeing a surge in neglected shoulder trauma cases, such as neglected anterior dislocation and neglected GT fractures, even though the lockdown was only partially lifted. As the COVID-19 pandemic continues, we may face increased challenges in managing neglected upper limb trauma, either because of the lockdown hardships or concomitant COVID-19 diagnosis. Cases of anterior dislocation that are neglected for a few months can be managed with open techniques with good results; however, treating a concomitant GT fracture along with neglected anterior dislocation may present additional challenges during open reduction, such as extensive adhesions, instability, and prolonged surgical duration and may culminate in suboptimal results.

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When should reverse total shoulder arthroplasty be considered in glenohumeral joint arthritis?

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Anatomical total shoulder arthroplasty (TSA) has been used widely in treatment of glenohumeral osteoarthritis and provides excellent pain relief and functional results. Reverse total shoulder arthroplasty (RSA) was created to treat the complex problem of rotator cuff tear arthropathy. RSA also has been performed for glenohumeral osteoarthritis even in cases where the rotator cuff is preserved and has shown good results comparable with TSA. The indications for RSA are expanding to include tumors of the proximal humerus, revision of hemiarthroplasty to RSA, and revision of failed TSA to RSA. The purposes of this article were to describe comprehensively the conditions under which RSA should be considered in glenohumeral osteoarthritis, to explain its theoretical background, and to review the literature.

Keywords: Shoulder; Arthroplasty; Osteoarthritis; Rotator cuff; Stiffness

INTRODUCTION

Anatomical total shoulder arthroplasty (TSA) has been used widely in treatment of glenohumeral osteoarthritis (GHOA) and provides excellent pain relief and functional results [1-3]. As TSA is designed for restoring the biomechanics of a normal shoulder joint, adequate glenoid bone stock and intact rotator cuff tendons are essential for good results. Biomechanically, the TSA needs soft tissue balance and must permit translation in the glenohumeral joint. Reverse total shoulder arthroplasty (RSA) was created to treat the complex problem of rotator cuff tear arthropathy [4]. Biomechanically, the RSA provides a stable and fixed fulcrum of the arm for rotation, while increasing the moment arm and resting tension of the deltoid muscle, which enable arm elevation and abduction, even in massive rotator cuff tears [5,6]. For the last three decades, RSA for cuff tear arthropathy has been successful. RSA can be used not only for patients with cuff tear arthropathy, but also for those with other complex shoulder problems in whom the soft tissues or glenoid bone stock can be deficient. The indications for its use are expanding to include tumors of the proximal humerus, revision of hemiarthroplasty to RSA, and revision of failed TSA to RSA [4,6-8].

TSA requires restoration of the normal shoulder construct in soft tissue balance and bony architecture. If preoperative factors related with poor clinical outcomes in TSA are uncorrectable, satisfactory results cannot be obtained. In this situation, RSA could be an alternative option. Upon literature review, three factors have been mentioned commonly as related with poor clinical

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outcomes: rotator cuff dysfunction, glenoid bone deformity, and preoperative stiffness. These three factors independently can influence the outcome of TSA but sometimes coexist and can influence each other [9,10].

In terms of soft tissue balance, rotator cuff condition is the most important factor. Postoperative rotator cuff tear can cause instability, which can progress to glenoid loosening and failure. Preoperative rotator cuff tear, rotator cuff muscle atrophy (MA), and fatty infiltration (FI) are correlated with poor clinical results [1,9,11-13]. In terms of bony architecture, uncorrectable glenoid deformities (e.g., glenoid retroversion, posterior erosion, and humeral head subluxation) are negative factors related with poor clinical results after TSA. Joint stiffness is another negative factor commonly comorbid in TSA. The appropriate treatment of patients with GHOA and significant stiffness (limitation of motion) remains a controversial clinical dilemma [1,14]. Stiff shoulders can be associated with significant rotator cuff muscle dysfunction, even in the absence of a full-thickness rotator cuff tear. Advanced age and long-standing stiffness have been linked to increased FI and MA [10,13].

The goals of this study are (1) to describe the three conditions (rotator cuff dysfunction, glenoid bone deformity, and stiffness) in which RSA should be considered for treatment of GHOA, (2) to review the clinical and mechanical background of RSA and TSA, and (3) to review published clinical outcomes of RSA for treatment of GHOA.

ROTATOR CUFF TEAR

Clinical Outcome of RSA in GHOA with Intact Cuff

Recently, RSA has been performed for GHOA even in cases where the rotator cuff is preserved and has shown good results comparable with those of TSA. Wright et al. [14] compared TSA and RSA in patients 70 years and older with GHOA and an intact rotator cuff. There was no difference in patient-reported outcome measures, range of motion, American Shoulder and Elbow Surgeons (ASES) score, Western Ontario Osteoarthritis of the Shoulder index, or complication rate or revision surgery rate between the groups. All patients of the RSA group and 98% of the TSA group could achieve full or nearly full (>135°) forward elevation at a minimum of two years after the procedure [14]. Steen et al. [15] evaluated 24 consecutive GHOA patients who underwent RSA and matched them to 96 patients who underwent TSA. Postoperative ASES, Simple Shoulder Test score, and range of motion were similar between the groups. There was no significant difference in complication rate or revision surgery rate between groups. However, five TSA patients showed radiographic glenoid loosening, whereas no RSA patients did [15].

Incidence of rotator cuff tear in GHOA

The incidence of rotator cuff tear in the asymptomatic elderly population is high. Khoschnau et al. [16] evaluated prevalence of rotator cuff tears in a population with a mean age of 66 years who had never sought care for shoulder symptoms. Of the 106 individuals (212 shoulders), the prevalence of full-thickness cuff tear was 30% (21% of 212 shoulders). Another study investigated the clinical and ultrasonography results of shoulders from 420 asymptomatic volunteers aged between 50 and 79 years. Full-thickness tear of the rotator cuff was detected in 32 individuals (7.6%). The prevalence increased with age as follows: 50 to 59 years, 2.1%; 60 to 69 years, 5.7%; and 70 to 79 years, 15% [17]. Minagawa et al. [18] evaluated 664 residents in one village who had undergone ultrasonography. The prevalence of rotator cuff tear in the general population was 22.1%, which increased with age. Asymptomatic tear was twice as common as symptomatic tear. However, the incidence of rotator cuff tear in GHOA patients is controversial. Edwards et al. [13] described the results of TSA in 555 osteoarthritic shoulders, of which 42 (7.6%) had a rotator cuff tear. In Iannotti and Norris's study [1], most (n=115; 90%) of 128 shoulders had a structurally intact rotator cuff. Thirteen were found to have a full thickness tear, but only seven (5% of 128) had a tear >1 cm. However, since patients with large rotator cuff tear might be excluded from TSA study, the incidence of rotator cuff tear could be underestimated.

Significancy of rotator cuff in TSA

In GHOA, rotator cuff conditions are variable in tear size, cuff thickness, MA, and FI. Sometimes, even without cuff tear, MA and FI can be severe, or rotator cuff tendon can be thin. Several classifications have been used to describe the condition of rotator cuff in terms of MA, FI, and tear size [19-21]. GHOA commonly is accompanied by degenerative changes in the rotator cuff [22]. However, none of the classifications adequately describe the degenerative degree of the rotator cuff.

The size of the rotator cuff tear before surgery should be considered carefully. A repairable tear of the supraspinatus tendon is not a contraindication to TSA. If partial tear or small rotator cuff tears are well repaired during TSA surgery, they have little influence on the results of shoulder arthroplasty [1]. Raval et al. [23] evaluated 36 patients with a mean age 79.2 years who underwent TSA and had GHOA with partial-thickness rotator cuff tears observed on MRI for a mean follow-up of 5.8 years. The study showed that presence of a partial cuff tear on preoperative MRI does not significantly affect function after anatomical TSA in the

medium-term follow-up. However, a medium- to large-sized full thickness rotator cuff tear negatively influences the results of shoulder arthroplasty. Simone et al. [2] evaluated 33 patients who had rotator cuff repair with TSA for a mean follow-up of 4.7 years. Instability and glenoid loosening occurred in six patients with medium or large tear. Complications were noted in five patients, all with medium or large tear; four of these had symptomatic instability and one sustained a late peri-prosthetic fracture. Four patients required further surgery, three due to instability and one due to peri-prosthetic humeral fracture [2]. Coexistent tears of the rotator cuff prejudice the outcome of TSA by reducing active movement and strength and by predisposing to instability or subluxation of the replacement and loosening of the glenoid component (Fig. 1). Postoperative rotator cuff tears in TSA are not only related with decreased range of motion, but also instability or subluxation, which eventually lead to early glenoid loosening [1,12,13,24].

Subscapularis tear after TSA is a common complication but cannot be diagnosed reliably by physical examination or radiographs. Although there is an opinion that subscapularis integrity does not correlate with pain or subjective patient outcome, inadequate healing of the subscapularis tendon can lead to postoperative pain, weakness, and instability [25-27]. Postoperative subscapularis tear could induce upward migration of the humeral head, anterosuperior subluxation, an eccentric contact pattern, and higher stress to the glenoid component [28].

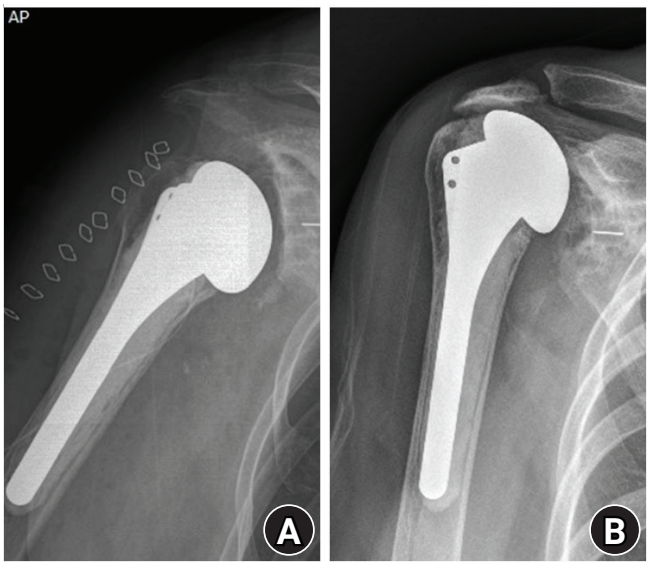

Fig. 1. (A) Immediate postoperative radiograph after total shoulder arthroplasty shows normal glenohumeral distance and contiguous scapulohumeral line. (B) In 3-year follow-up radiograph, superior migration (decreased acromiohumeral distance) and osteolysis around glenoid component are observed from the postoperative rotator cuff tear.

The clinical significance of subscapularis repair is controversial in RSA. A prospective randomized trial by Engel et al. [29] concluded that subscapularis tendon repair in RSA improves the Constant score and internal rotation at 12 months after surgery. In medialized design RSA, the subscapularis has an important role in preventing dislocation [30]. Although subscapularis repair is safe and effective for RSA, it cannot offer additional clinical or functional benefit in patients treated with lateralized RSA [31]. Therefore, in GHOA with inadequate subscapularis condition where postoperative retear is expected, RSA could be considered.

In addition to rotator cuff tear, MA and FA should be considered preoperatively in TSA. In GHOA patients, FI and MA of the rotator cuff are major factors associated with clinical outcomes after TSA. Conversely, they are not significant in RSA. Puzzitiello et al. [12] concluded that rotator cuff muscle quality as assessed by MA and FI does not impact clinical outcomes following RSA with a lateralized glenosphere in patients with GHOA and an intact rotator cuff. Therefore, if progressed MA and FI is combined with GHOA, RSA could be a reasonable decision even with an intact rotator cuff [2,10,12,13].

GLENOID DEFORMITY (GLENOID BONE LOSS, POSTERIOR GLENOID WEAR, AND INCREASED RETROVERSION)

Normal Anatomy of Glenoid

Prosthetic design and surgical considerations related to glenoid anatomy are based on numerous studies focusing on glenoid height, width, inclination, and version [32]. The "normal" range of glenoid version varies anywhere from 2° of anteversion to 8° of retroversion in most studies [33-35]. Studies using three-dimensional measurement techniques on computed tomography images have reported native glenoid version of approximately 7° [36,37]. However, arthritic shoulders generally have greater than 11° of retroversion, which should be corrected during TSA [33,38,39].

Classification and Clinical Significance of Glenoid Deformity

Walch et al. [40,41] devised a classification system for glenoid morphology that is based on the architecture and patterns of posterior wear in GHOA [32]. In type B2 glenoids, posterior humeral head subluxation and posterior glenoid wear can increase glenoid retroversion to values above 10°. Type C glenoids with evidence of dysplasia can show glenoid retroversion above 25°.

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Failure to replicate and restore characteristics of the normal glenoid articular surface can lead to early loosening. This can be particularly difficult in patients with biconcave glenoids and associated posterior humeral head instability. Failure to restore neutral glenoid version can increase the shear load across the glenoid. This subtype has problems in soft tissue balancing and is associated with a high rate of revision surgery because of glenoid loosening and instability [11,32,41,42].

Posterior wear and increased retroversion in glenohumeral arthritis often is associated with static posterior subluxation of the humeral head. Static posterior subluxation could be reversed by TSA using corrective glenoid reaming and soft tissue release [43]. However, if static posterior subluxation persists after TSA, postoperative subluxation can lead to eccentric loading of the glenoid component and accelerated loosening and wear [11,32,41,43].

Variable methods of correcting version and increasing stability of the glenoid component have been used intraoperatively. Asymmetric glenoid reaming, posterior glenoid bone grafting, and use of specialized glenoid implants are included. The choice among these options is based on the ability to assess accurately both glenoid version and the desired amount of correction intraoperatively. However, this often is limited by obscured bony landmarks and deficient bone stock. Even with preoperative three-dimensional imaging, implantation of a glenoid component to within 10° of a desired version is technically difficult even for an experienced shoulder surgeon in cases of severe retroversion [44].

Bone Grafting in TSA and RSA

Bone graft could be used in TSA in patients with osteoarthritis combined with increased retroversion or biconcavity. Bone grafting with internal fixation is a reconstructive technique with mixed clinical results. It has been used in limited cases of large segmental bone deficiencies or in cases of severe posterior wear causing severe component loosening. However, a very high rate of complications after bone graft such as bone resorption, nonunion, and early loosening were found. Because of the high complication rate of posterior bone graft with an anatomic prosthesis, Walch et al. [41] recommend RSA instead of TSA with neoglenoid retroversion [11,32,44]. However, the bone healing rate is very high and predictable in RSA [45].

DIFFERENCES IN BONE GRAFT BETWEEN TSA AND RSA

RSA has some advantages compared to TSA. (1) Stable fixation: variable angle locking screw fixation creates a more stable construct and reduces baseplate micromotion. However, in TSA, cement-type fixation for glenoid components has been used commonly and can interfere with bone union. Bone grafting with internal fixation is a technically demanding procedure in TSA. The period of motion restriction can be prolonged, and the success rate is not high [32]. (2) Diminished force to graft: unequal radii of curvature between the humeral and glenoid components of TSA permit translation movement, which produces shearing force between the glenoid component and bone graft. However, a reverse prosthesis, designed with equal radii of curvature, can tolerate a joint-reaction force vector. Increased constraint secondary to the deeper and greater conformity of the concavity of the humeral articular surface prevents glenohumeral translation while providing sufficient stability [8,46]. (3) As the burden of restoring the joint line and soft tissue balance is lower in RSA than TSA, glenoid bone graft could be thick enough to achieve firm fixation. (4) It is easier to correct glenoid version in RSA than TSA as an asymmetric bone graft is possible [47-49].

STIFFNESS

Joint stiffness can cause difficulties in any surgery performed on the shoulder joint. In TSA, preoperative stiffness corresponds to a major risk of poor clinical results, and recovery of range of motion is difficult even after surgery. Stiffness is the most common cause of failure in TSA and postoperative stiffness has been considered a type of failure [9]. Joint stiffness can be confirmed by a decrease in passive range of motion [1].

The difficulties encountered during TSA procedure in a stiff shoulder joint are as follows. (1) Joint stiffness deteriorates the operation field exposure for the glenoid procedure, which is one of the reasons for difficult operation. (2) If the glenoid is not exposed sufficiently, problems can occur during glenoid preparation and glenoid component positioning. This condition could increase the risk of glenoid malposition, which leads to early loosening of the glenoid implant [50]. (3) Nerve injury is very rare in shoulder arthroplasty. However, in shoulders with stiffness, the risk of nerve injury could increase as excessive soft tissue traction or soft tissue release often is required [51-53]. (4) It often is difficult to repair the rotator cuff after implantation. The rotator cuff of a shoulder with longstanding stiffness could be irreparable after implantation or have short tendon excursion. In this condition, repair of the subscapularis can be incomplete or not possible, which could increase the extent of future subscapularis tear [3,9].

In RSA on a stiff shoulder, there are many difficulties. As the glenoid component of RSA is larger than that of TSA, a larger ex-

posure is required in RSA. In addition, the risk of fracture could increase during the reduction step of the procedure. Due to the convexity of the glenoid component, reduction requires sufficient traction. During this step, greater tuberosity fracture could occur. As the humerus is retracted posteriorly using a traction tool to expose the glenoid in the stiff shoulder joint, bone erosion or fracture by the traction tool can occur in the humeral head [54].

Despite the above difficulties, RSA is preferred for GHOA with stiffness because the results of TSA are inferior. Though there is no study comparing TSA and RSA in GHOA with stiffness, RSA could result in potentially good results even in stiff shoulders [54]. There are several technical advantages of RSA in GHOA with stiffness. (1) Freedom from rotator cuff preservation: in TSA, the rotator cuff tendon should be preserved and repaired at the last stage of surgery. In addition, MA and FI are important [10]. However, in RSA, the tendons of supraspinatus and infraspinatus can be removed, and MA and FI are not critical to clinical outcomes [12]. Moreover, superior rotator cuff removal could improve surgical field exposure and allows soft tissue release [12,31]. (2) Greater capacity of humeral bone cutting: in RSA compared to TSA, greater humeral head cutting is possible beyond the rotator cuff attachment. Increased humeral bone cutting improves the surgical field exposure and stiffness. (3) Freedom from subscapularis repair: as described in the previous paragraph, lateralized implantation of RSA does not require subscapularis repair. This is helpful to reduce soft tissue tension during operation and to prevent postoperative stiffness [31,55].

CONCLUSIONS

The indications for RSA gradually are expanding. For GHOA with intact rotator cuff, TSA is the gold standard treatment. However, RSA could be adopted. It is reasonable that RSA is selected preferentially for treatment of GHOA in which specific conditions are combined, such as rotator cuff degeneration (greater than 1 cm tear, advanced MA or FI, subscapularis insufficiency), glenoid bone deformity (glenoid bone loss or retroversion needing bone graft), and stiffness.

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CiSE provides electronic archiving and preservation of access to the journal content in the event the journal is no longer published, by archiving in the National Library of Korea. According to the deposit policy (self-archiving policy) of Sherpa/Romeo (http://www.sherpa.ac.uk/), authors cannot archive pre-print (i.e., pre-refereeing) but they can archive post-print (i.e., final draft post-refereeing). Authors can archive the publisher's version/PDF.

4. SUBMISSION AND PEER-REVIEW PROCESS

Submission

All manuscripts should be submitted online via the journal's website (https://submit.cisejournal.org/) by the corresponding author. Once you have logged into your account, the online system will lead you through the submission process in a stepwise orderly process. Submission instructions are available at the website. All articles submitted to the journal must comply with these instructions. Failure to do so will result in the return of the manuscript and possible delay in publication.

Peer Review Process

All papers, including those invited by the Editor, are subject to peer review. Manuscripts will be peer-reviewed by two accredited experts in the shoulder and elbow with one additional review by prominent member from our editorial board. CiSE's average turnaround time from submission to decision is 4 weeks. The editor is responsible for the final decision whether the manuscript is accepted or rejected.

- The journal uses a double-blind peer review process: the reviewers do not know the identity of the authors, and vice versa.
- Decision letter will be sent to corresponding author via registered e-mail. Reviewers can request authors to revise the content. The corresponding author must indicate the modifications made in their item-by-item response to the reviewers' comments. Failure to resubmit the revised manuscript within 4 weeks of the editorial decision is regarded as a withdrawal.
- The editorial committee has the right to revise the manuscript without the authors' consent, unless the revision substantially affects the original content.
- After review, the editorial board determines whether the manuscript is accepted for publication or not. Once rejected, the manuscript does not undergo another round of review.

Appeals of Decisions

Any appeal against an editorial decision must be made within 2 weeks of the date of the decision letter. Authors who wish to appeal a decision should contact the Editor-in-Chief, explaining in detail the reasons for the appeal. All appeals will be discussed with at least one other associate editor. If consensus cannot be reached thereby, an appeal will be discussed at a full editorial meeting. The process of handling complaints and appeals follows the guidelines of COPE available from (https://publicationethics.org/appeals). CiSE does not consider second appeals.

5. MANUSCRIPT PREPARATION

Authors are required to submit their manuscripts after reading the following instructions. Any manuscript that does not conform to the following requirements will be considered inappropriate and may be returned.

General Requirements

- All manuscripts should be written in English.
- The manuscript must be written using Microsoft Word and saved as ".doc" or ".docx" file format. The font size must be 12 points. The body text must be left aligned, double spaced, and presented in one column. The left, right, and bottom margins must be 3 cm, but the top margin must be 3.5 cm.
- The page numbers must be indicated in Arabic numerals in the middle of the bottom margin, starting from the abstract page.
- Neither the authors' names nor their affiliations should appear on the manuscript pages.
- Only standard abbreviations should be used. Abbreviations should be avoided in the title of the manuscript. Abbreviations should be spelled out when first used in the text and the use of abbreviations should be kept to a minimum.
- The names and locations (city, state, and country only) of manufacturers of equipment and non-generic drugs should be given.
- Authors should express all measurements in conventional units using International System (SI) units.
- P-value from statistical testing is expressed as capital P.

Reporting Guidelines for Specific Study Designs

For specific study designs, such as randomized control studies, studies of diagnostic accuracy, meta-analyses, observational studies, and non-randomized studies, authors are encouraged to consult the reporting guidelines relevant to their specific research design. A good source of reporting guidelines is the EQUATOR Network (https://www.equator-network.org/) and NLM (https://www.nlm.nih.gov/services/research_report_guide.html).

Composition of Manuscripts

- The manuscript types are divided into Original Article, Review Article, Case Report, and other types. There is no limit to the length of each manuscript; however, if unnecessarily long, the author may be penalized during the review process.
- Original Articles should be written in the following order: title page, abstract, keywords, main body (introduction, methods, results, discussion), acknowledgments (if necessary), references, tables, figure legends, and figures. The number of references is limited to 30.
- Review Articles should focus on a specific topic. Format of a review article is not limited. Publication of these articles will be decided upon by the Editorial Board.
- Case Reports should be written in the following order: title page, abstract, keywords, main body (introduction, case report, discussion), acknowledgments (if necessary), references, tables, figure legends, and figures. The number of references is limited to 10.

The Aabstract should not exceed 200 words, and must be written as one unstructured paragraph. Authors are warned that these have a high rejection rate.

- Technical Notes should not exceed 1,500 words. The abstract should be an unstructured summary not exceeding 150 words. The body of these manuscripts should consist of introduction, technique, discussion, references, and figure legends and tables (if applicable). References should not exceed 10. A maximum of 3 figures and 1 table are allowed.
- Current Concepts deal with most current trends and controversies of a single topic in shoulder and elbow. Authors are recommended to update all the knowledge to most recent studies and researches.
- Systemic Review examines published material on a clearly described subject in a systematic way. There must be a description of how the evidence on this topic was tracked down, from what sources and with what inclusion and exclusion criteria.
- Meta-analysis: A systematic overview of studies that pools results of two or more studies to obtain an overall answer to a question or interest. Summarizes quantitatively the evidence regarding a treatment, procedure, or association.
- Letters to the Editor: The journal welcomes readers' comments on articles published recently in the journal or orthopedic topics of interest.
- Editorial is invited by the editors and should be commentaries on articles published recently in the journal. Editorial topics could include active areas of research, fresh insights, and debates in the field of orthopedic surgery. Editorials should not exceed 1,000 words, excluding references, tables, and figures.
- Concise Review is short version of systemic review requested to submit in the journal by the Editorial board. Usually, previous papers regarding such topic were published by the main author(s).
- Special Reports/Expert Opinions (Level V studies) of various topics in shoulder and elbow can be submitted. They are limited to 2,700 words excluding references, tables, and figures.

Title Page

- The title page must include a title, the authors' names and academic degrees (include ORCID*), affiliations, and corresponding authors' names and contact information. In addition, a running title must be written in English within up to 50 characters including spaces. The corresponding authors' contact information must include a name, addresses, e-mails, telephone numbers, and fax numbers.
- **ORCID:** We recommend that the open researcher and contributor ID (ORCID) of all authors be provided. To have an ORCID,

authors should register in the ORCID website: http://orcid.org/. Registration is free to every researcher in the world.

- If there are more than two authors, a comma must be placed between their names (with academic titles). Authors' academic titles must be indicated after their names.
- The contributions of all authors must be described using the CRediT (https://www.casrai.org/credit.html) Taxonomy of author roles. All persons who have made substantial contributions, but who have not met the criteria for authorship, are acknowledged here.
- All sources of funding applicable to the study should be stated here explicitly.

Abstract and Keywords

Each paper should start with an abstract not exceeding 250 words. The abstract should state the background, methods, results, and conclusions in each paragraph in a brief and coherent manner. Relevant numerical data should be included. Under the abstract, keywords should be inserted (maximum 5 words). Authors are recommended to use the MeSH database to find Medical Subject Heading Terms at http://www.nlm.nih.gov/mesh/meshhome.html. The abstract should be structured into the following sections.

- Background: The rationale, importance, or objective of the study should be described briefly and concisely in one to two sentences. The objective should be consistent with that stated in the Introduction.
- Methods: The procedures conducted to achieve the study objective should be described in detail, together with relevant details concerning how data were obtained and analyzed and how research bias was adjusted.
- Results: The most important study results and analysis should be presented in a logical manner with specific experimental data.
- Conclusions: The conclusions derived from the results should be described in one to two sentences, and must match the study objective.

Guidelines for the Main Body

- All articles using clinical samples or data and those involving animals must include information on the IRB/IACUC approval or waiver and informed consent. An example is shown below. "We conducted this study in compliance with the principles of the Declaration of Helsinki. The study's protocol was reviewed and approved by the Institutional Review Board of OO (IRB no. OO). Written informed consent was obtained / Informed consent was waived."
- Description of participants: Ensure the correct use of the terms "sex" (when reporting biological factors) and "gender" (identity, psychosocial, or cultural factors), and, unless inappropriate, report the sex and/or gender of study participants, the sex of animals or cells, and describe the methods used to determine sex and gender. If the study was done involving an exclusive population, for example, in only one sex, authors should justify why, except in obvious cases (e.g., ovarian cancer). Authors should define how they determined race or ethnicity and justify their relevance.
- Introduction: State the background or problem that led to the initiation of the study. Introduction is not a book review, rather it is best when the authors bring out controversies which create interest. Lead systematically to the hypothesis of the study, and finally, to a restatement of the study objective, which should match that in the Abstract. Do not include conclusions in the Introduction.
- Methods: Describe the study design (prospective or retrospective, inclusion and exclusion criteria, duration of the study) and the study population (demographics, length of follow-up). Explanations of the experimental methods should be concise, but yet enable replication by a qualified investigator.
- Results: This section should include detailed reports on the data obtained during the study. All data in the text must be presented in a consistent manner throughout the manuscript. All issues which the authors brought up in the method section need to be in result section. Also it is preferred that data to be in figures or table rather than long list of numbers. Instead, numbers should be in tables or figures with key comment on the findings.
- Discussion: The first paragraph of the discussion should deal with the key point in this study. Do not start by article review or general comment on the study topic. In the Discussion, data should be interpreted to demonstrate whether they affirm or refute the original hypothesis. Discuss elements related to the purpose of the study and present the rationales that support the conclusion drawn by referring to relevant literature. Discussion needs some comparison of similar papers published previously, and discuss why your study is different or similar from those papers. Care should be taken to avoid information obtained from books, historical facts, and irrelevant information. A discussion of study weaknesses and limitations should be included in the last paragraph of the discussion. Lastly you must briefly state your new (or verified) view of the problem you outlined in the Introduction.
- References must be numbered with superscripts according to their quotation order. When more than two quotations of the same authors are indicated in the main body, a comma must be placed between a discontinuous set of numbers, whereas a dash must be placed between the first and last numerals of a contin-

uous set of numbers: "Kim et al. [2,8,9] insisted…" and "However, Park et al. [11–14] showed opposing research results."
- Figures and tables used in the main body must be indicated as "Fig." and "Table." For example, "Magnetic resonance imaging of the brain revealed… (Figs. 1–3).

Figures and Figure Legends

Figures should be cited in the text and are numbered using Arabic numbers in the order of their citation (e.g., Fig. 1). Figures are not embedded within the text. Each figure should be submitted as an individual file. Location of figure legends begins at the next page after last table. Every figure has its own legend. Abbreviation and additional information for any clarification should be described within each figure legend. Figure files are submitted in EPS, TIFF, or PDF formats. Requirement for minimum resolutions are dependent on figure types. For line drawings, 1,200 dpi are required. For grey color works (i.e., picture of gel or blots), 600 dpi are required. For color or half-tone artworks, 300 dpi are required. The files are named by the figure number.

- Staining techniques used should be described. Photomicrographs with no inset scale should have the magnification of the print in the legend.
- Papers containing unclear photographic prints may be rejected.
- Remove any writing that could identify a patient.
- Any illustrations previously published should be accompanied by the written consent of the copyright holder.

Tables

- Tables should be numbered sequentially with Arabic numerals in the order in which they are mentioned in the text.
- If an abbreviation is used in a table, it should be defined in a footnote below the table.
- Additional information for any clarification is designated for citation using alphabetical superscripts ($^{a)}$, $^{b)}$…) or asterisks (*). Explanation for superscript citation should be done as following examples: $^{a)}$Not tested. *P < 0.05, **P < 0.01, ***P < 0.001.
- Tables should be understandable and self-explanatory, without references to the text.

References

- The number of references is recommended to 30 for original article and 10 for case report and technical note.
- All references must be cited in the text. The number assigned to the reference citation is according to the first appearance in the manuscript. References in tables or figures are also numbered according to the appearance order. Reference number in the text, tables, and figures should in a bracket ([ ]).
- List names of all authors when six or fewer. When seven or more, list only the first three names and add et al.
- Authors should be listed by surname followed by initials.
- The journals should be abbreviated according to the style used in the list of journals indexed in the NLM Journal Catalog (http://www.ncbi.nlm.nih.gov/nlmcatalog/journals).
- The overlapped numerals between the first page and the last page must be omitted (e.g., 2025-6).
- References to unpublished material, such as personal communications and unpublished data, should be noted within the text and not cited in the References. Personal communications and unpublished data must include the individual's name, location, and date of communication.
- Other types of references not described below should follow ICMJE Recommendations (https://www.nlm.nih.gov/bsd/uniform_requirements.html).
- Examples of references are as follows:

Journal article

1. Kim IB, Kim EY, Lim KP, Heo KS, Does the use of injectable atelocollagen during arthroscopic rotator cuff repair improve clinical and structural outcomes? Clin Shoulder Elbow 2019;22:183-9.
2. Kovacevic D, Fox AJ, Bedi A, et al. Calcium-phosphate matrix with or without TGF-β3 improves tendon-bone healing after rotator cuff repair. Am J Sports Med 2011;39:811-9.
3. Nord KD, Masterson JP, Mauck BM. Superior labrum anterior posterior (SLAP) repair using the Neviaser portal. Arthroscopy 2004;20 Suppl 2:129-33.
4. Rohner E, Jacob B, Bohle S, et al. Sodium hypochlorite is more effective than chlorhexidine for eradication of bacterial biofilm of staphylococci and Pseudomonas aeruginosa. Knee Surg Sports Traumatol Arthrosc 2020 Feb 7 [Epub]. https://doi.org/10.1007/s00167-020-05887-9

Book & book chapter

5. Iannotti JP, Williams Jr GR. Disorders of the shoulder: diagnosis & management. 2nd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2007. p. 66-80
6. Provencher MP, LeClere LE, Van Thiel GS, et al. Posterior instability of the shoulder. In: Angelo RL, Esch JC, Ryu RK, eds. AANA advanced arthroscopy the shoulder. Philadelphia, PA: Saunders; 2010. p. 115-23.

Website

7. American Cancer Society. Cancer facts & figures 2020 [Internet]. Atlanta, GA: American Cancer Society; c2020 [cited 2020

Feb 5]. Available from: https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2020.html.

6. FINAL PREPARATION FOR PUBLICATION

Final Version

After the paper has been accepted for publication, the author(s) should submit the final version of the manuscript. The names and affiliations of the authors should be double-checked, and if the originally submitted image files were of poor resolution, higher resolution image files should be submitted at this time. Symbols (e.g., circles, triangles, squares), letters (e.g., words, abbreviations), and numbers should be large enough to be legible on reduction to the journal's column widths. All symbols must be defined in the figure caption. If references, tables, or figures are moved, added, or deleted during the revision process, renumber them to reflect such changes so that all tables, references, and figures are cited in numeric order.

Manuscript Corrections

Before publication, the manuscript editor will correct the manuscript such that it meets the standard publication format. The author(s) must respond within two days when the manuscript editor contacts the corresponding author for revisions. If the response is delayed, the manuscript's publication may be postponed to the next issue.

Gallery Proof

The author(s) will receive the final version of the manuscript as a PDF file. Upon receipt, the author(s) must notify the editorial office (or printing office) of any errors found in the file within two days. Any errors found after this time are the responsibility of the author(s) and will have to be corrected as an erratum.

Errata and Corrigenda

To correct errors in published articles, the corresponding author should contact the journal's Editorial Office with a detailed description of the proposed correction. Corrections that profoundly affect the interpretation or conclusions of the article will be reviewed by the editors. Corrections will be published as corrigenda (corrections of the author's errors) or errata (corrections of the publisher's errors) in a later issue of the journal.

7. ARTICLE PROCESSING CHARGES

There are no author fees required for manuscript processing and/or publishing materials in the journal since all cost is supported by the publisher, the Korean Shoulder and Elbow Society until there is a policy change. Therefore, it is the so-called platinum open access journal.

Author's checklist

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- ☐ Manuscript in MS-WORD (.doc) format.
- ☐ Double-spaced typing with 10-point font.
- ☐ Sequence of title page, abstract and keywords, introduction, methods, results, discussion, conclusions, acknowledgments, references, tables, and figure legends. All pages and manuscript text with line should be numbered sequentially, starting from the abstract.
- ☐ Title page with article title, authors' full name(s) and affiliation(s), address for correspondence (including telephone number, e-mail address, and fax number), running title (less than 10 words), and acknowledgments, if any.
- ☐ Abstract in structured format up to 250 words for original articles and in unstructured format up to 200 words for case reports. Keywords (up to 5) from the MeSH list of Index Medicus.
- ☐ All table and figure numbers are found in the text.
- ☐ Figures as separate files, in JPG, GIF, or PPT format.
- ☐ References listed in proper format. All references listed in the reference section are cited in the text and vice versa.
- ☐ Covering letter signed by the corresponding author.

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All authors appearing in manuscript should be signed in order.

Each of the undersigned is an author of the manuscript and all authors are named on this document.

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