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Original Article

# Clinical effects of sodium hyaluronate combined with platelet-rich plasma injection on rotator cuff injury in arthroscopic repair

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ABSTRACT

*Objective:* Rotator cuff injury is one prevalent shoulder condition that often leads to pain and dysfunction. The study explored the clinical effects of sodium hyaluronate combined with platelet-rich plasma (PRP) injection on rotator cuff injury in arthroscopic repair.

*Methods:* A total of 92 cases with rotator cuff injury were randomly divided into the control group (n = 46, treated with shoulder arthroscopy repair combined with subacromial space injection of sodium hyaluronate) and the experimental group (n = 46, treated with subacromial space injection of autologous PRP on the basis of the treatment in the control group). Visual analogue scale (VAS), Constant-Murley scale (CMS), University of California, Los Angeles (UCLA), American Shoulder and Elbow Society (ASES), and quality of life (QOL) scores, as well as complications were compared in the two groups before surgery and at 3 and 6 months after surgery. Shoulder range of motion (ROM) was measured before and after surgery.

*Results:* VAS scores of patients in the two groups at 3 and 6 months after surgery were lower than those before surgery, and the VAS scores of patients in the experimental group at 3 and 6 months after surgery were much lower than those in the control group (all $P < 0.05$). The scores of CMS, UCLA, ASES, and QOL, and shoulder ROM in both groups at 3 and 6 months after surgery were higher than those before surgery, and these shoulder joint function scores, QOL and shoulder ROM in the experimental group at 3 and 6 months after surgery were higher than those in the control group (all $P < 0.05$). No statistically significant difference presented in the incidence of complications between the two groups ($P > 0.05$).

*Conclusion:* Arthroscopic rotator cuff repair and sodium hyaluronate combined with PRP injection can effectively reduce pain symptoms, improve shoulder joint function and shoulder ROM, and improve QOL in patients with rotator cuff injury.

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## 1. Introduction

Rotator cuff injury is a prevalent shoulder disorder that often leads to pain and dysfunction [1]. Rotator cuff injuries often occur in master athletes, and more often in overhead athletes. There are a variety of risk factors, non-modifiable factors including aging and degeneration, and modifiable factors containing volume of activity and loss of motion, as well as muscle weakness [2]. Rotator cuff tears are regarded as the most common disorder in the middle-aged and even older adults of all shoulder disorders, making it the primary cause of shoulder surgery in this population. In addition, rotator cuff tears as well as rotator cuff disorders are significant sources of disability in the middle-aged that are influenced by nontraumatic shoulder dysfunctions [3,4]. Most rotator cuff tears happen at the bone-tendon interface and cause disability and pain [5]. As one of the most likely causes of shoulder pain in adults, rotator cuff tears potentially leads to protracted disability. Additionally, managing rotator cuff tears is associated with considerable costs [6].

Shoulder arthroscopic is conventionally applied in repairing rotator cuff tears [7]. A previous study has reported that the gold standard strategy for rotator cuff repair is arthroscopic rotator cuff repair (ARCR) [8]. Injections are good choices to conventional treatment-resistant patients with rotator cuff lesions before

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surgery. Moreover, in the long term, platelet-rich plasma (PRP) injection works for pain relief, function, and quality of life (QOL) in patients with rotator cuff lesions [9]. It has been reported that sodium hyaluronate is an anti-adhesive agent in a series of surgical procedures [10]. Hyaluronic acid could increase not only tendon derived cell viability but also collagen type I expression *in vitro* [11]. It is believed that hyaluronic acid has the ability to occupy the intradermal space, thus supporting the regenerative process by its combination in the damaged extracellular matrix [12]. A previous study has demonstrated that hyaluronic acid is implemented in subacromial injection to conservatively treat rotator cuff tears [13]. As an autologous and multi-purpose platelet concentrate of the blood, PRP activates the cartilage healing process and repairs the injury that is resulted from articular disease [14]. Currently, PRP is the most exploited method in the clinical practice to offer a regenerative stimulus to tendon healing [15]. As previously reported, PRP may relieve pain related to rotator cuff injuries and lateral epicondylitis [16]. Hyaluronic acid and PRP are both widely implemented intra-articular therapy modalities that particularly generate clinical interest in the present literature [17]. Intra-articular hyaluronan or PRP is widely utilized in knee osteoarthritis (OA) treatment [18]. Evidence has displayed that the integrated application of hyaluronic acid and PRP is able to improve degenerated cartilage and slow knee osteoarthritis progression [19]. Consequently, this research was aimed at investigating the clinical effects of sodium hyaluronate combined with PRP injection in treating rotator cuff injury in arthroscopic repair, thus offering a distinct research direction and furnishing effective therapeutic strategies for rotator cuff injury.

## 2. Methods and materials

### 2.1. Ethics statement

This study was ratified by the Ethics Committee of our hospital. The patients and their families provided their informed consent for this study and signed the informed consent form.

### 2.2. Study subjects

A total of 92 patients with rotator cuff injury treated in our hospital from January 2018 to January 2020 were selected as study subjects, and the general data of the patients were displayed in Table 1.

Inclusion criteria: 1) Patients' age was ≥18 years old; 2) Patients were diagnosed with rotator cuff injury by physical examination, musculoskeletal ultrasound and MRI, and it was unilateral rotator cuff injury; 3) Patients were conservatively treated for more than 3 months with poor effects; 4) Patients had indications for surgery, including rotator cuff tear width >5 mm and thickness more than half of the rotator cuff.

Exclusion criteria: 1) Patients with severe rotator cuff injury (rotator cuff tear width >5 cm); 2) Patients with glenoid labrum injury and subscapularis tendon tear requiring repair; 3) Patients with calcific tendonitis; 4) Patients with malignancy that caused damage to shoulder and adjacent tissues; 5) Patients who withdrew from the study midway [20,21].

### 2.3. PRP preparation

During the surgery, PRP was prepared using a PRP preparation kit (Shangdong Wego New Life Medical Devices Co., Ltd., Shandong, China). Before the completion of arthroscopic debridement, 50 mL of autologous peripheral venous blood was drawn from patients in the observation group using a syringe in a sterile operating environment, and injected into a sterile centrifuge tube with PRP preparation kit (containing sodium citrate). PRP was prepared utilizing secondary centrifugation, and centrifuged at 2000 r/min for 10 min. Then the well-centrifuged supernatants, intermediate layer leukocytes, platelets and 1/3 upper layer erythrocytes were aspirated with a pipette, injected into sterile centrifuge tubes, and then centrifuged at 2200 r/min for 10 min. It could be seen that there was white membrane-like material (i.e. platelet layer) depositing on the bottom layer of erythrocytes. At the moment, a sterile tip was replaced, and the supernatants were discarded. The middle white membrane layer was transferred to another sterile centrifuge tube, and it was called PRP, which was then shaken and stored in a 4 °C refrigerator [22].

### 2.4. Grouping and treatment

Patients were randomly separated into 2 groups: the control group (treated with ARCR and sodium hyaluronate injection) and the experimental group (treated with ARCR and sodium hyaluronate combined with PRP injection), with 46 patients in each group.

ARCR was performed in patients of the two groups by the same surgeon. In detail, the patients were placed in the beach chair position. After general anesthesia with tracheal intubation, a posterior access was established, and the arthroscope was inserted. Then the relevant structures within the glenohumeral joint and the surrounding conditions were fully explored to clarify the patients' articular cartilage and rotator cuff damage. If there was an intra-articular synovial proliferation, an anterolateral approach needed to be created, and then the required surgical instruments were accurately placed to remove it. The arthroscope was adjusted to the subacromial space. Then the bursa was located, and completely

**Table 1**
Comparison of patients' general data.

| General data | The control group (n = 46) | The experimental group (n = 46) | *P* value |
|---|---|---|---|
| Gender | | | 0.144 |
| Male (n/%) | 26/56.52% | 18/39.13% | |
| Female (n/%) | 20/43.48% | 28/60.87% | |
| Age (years) | 54.15 ± 5.74 | 56.21 ± 5.48 | 0.082 |
| Affected side | | | 0.834 |
| Left side (n/%) | 22/47.83% | 20/43.48% | |
| Right side (n/%) | 24/52.17% | 26/56.52% | |
| BMI (kg/m$^2$) | 23.04 ± 2.79 | 22.58 ± 2.88 | 0.439 |
| Average course of disease (months) | 7.59 ± 2.02 | 8.15 ± 2.80 | 0.252 |
| Cofield classification | | | 0.575 |
| Small (n/%) | 11 (23.91%) | 7 (15.22%) | |
| Moderate (n/%) | 27 (58.70%) | 30 (65.22%) | |
| Large (n/%) | 8 (17.39%) | 9 (19.56%) | |

removed. Next, the subacromial space was enlarged, and the acromion, rotator cuff and greater tuberosity of the humerus were carefully observed to clarify the impingement between them and the coracoacromial arch. If there was a subacromial lesion, acromioplasty needed to be carried out by an anterolateral and posterior approach. The patients' rotator cuff injury was carefully observed to clarify the differences in rotator cuff tear pattern and size, and the rotator cuff repositioning operation was performed according to the patients' different rotator cuff injury conditions. Double-row fixation was utilized to suture the rotator cuff of the patients. After shoulder ARCR completion and before arthroscope withdrawal, 2.5 mL of sodium hyaluronate (Meiji Seika Prarma Co., Ltd. Yokohama, Japan; specification: 2.5 mL: 25 mg) was injected into the subacromial space of patients in the control group under arthroscopic visualization; 2.5 mL of sodium hyaluronate and 5 mL of autologous PRP were injected into the subacromial space of patients in the experimental group. After surgery, routine irrigation, suturing and dressing, and routine anti-infection treatment (24 h) were conducted. The affected limb was fixed with the aid of a shoulder immobilisation device (30° of external rotation and 20° of abduction for 6 weeks) and rehabilitated under the guidance of a professional rehabilitation therapist. Moderate passive activity was performed 6 weeks after surgery and active exercise was started at 8 weeks after surgery. A 6-month post-operative outpatient follow-up was performed.

### 2.5. Visual analogue scale (VAS) score

VAS scores were utilized to assess the patients' shoulder pain before surgery, and at 3 months and 6 months after surgery. A 10-cm horizontal line was drawn on paper, 0 cm indicating no pain and 10 cm indicating severe pain. The patients chose the score according to their pain sensation, the higher the score, the more severe the shoulder pain. This was repeated 3 times and the average score was obtained [23].

### 2.6. Shoulder joint function scores

Constant-Murley scale (CMS) score, American Shoulder and Elbow Society (ASES) score, and University of California, Los Angeles (UCLA) score were implemented to evaluate the shoulder joint scores of patients in both groups before surgery, and at 3 and 6 months after surgery.

CMS score included 15 points for pain, 25 points for muscle strength, 40 points for shoulder joint function, and 20 points for daily living activity level, with a total score of 100 points, the higher the score, the better the shoulder joint function.

UCLA score included the degree of shoulder joint pain (10 points), shoulder joint function (10 points), upper extremity anterior flexion mobility and strength (10 points) and satisfaction (5 points), with a total score of 35 points. Higher scores demonstrated better recovery of shoulder joint function and better efficacy.

ASES score contained the patient's self-evaluation of pain, shoulder joint mobility, shoulder joint stability, and muscle strength, with a total score of 100 points, and the score was directly proportional to shoulder joint function [24].

### 2.7. Shoulder range of motion (ROM) test

A universal goniometer was applied to assess the ROM of the affected shoulder joint in four directions: anterior flexion, abduction, external rotation and internal rotation before surgery, and at 3 months and 6 months after surgery. The assessment was repeated 3 times and the average was taken [25].

### 2.8. QOL scale

QOL scale was applied to investigate the QOL of patients before surgery, and at 3 and 6 months after surgery. It contained 34 questions and 5 sub-scales: symptoms and physical discomfort questions (16 items); work-related questions (4 items); recreational activities, sports participation or competition questions (4 items); lifestyle questions (5 items); social and emotional questions (5 items). The total score of the QOL was 100 points where 0 score indicated the worst QOL and 100 score indicated the best QOL [26].

### 2.9. Complications

Postoperative cuff integrity was allocated into 5 categories following the system of Sugaya et al. [27] by means of oblique coronal and oblique sagittal T2-weighted MR images: type I, repaired cuff seemed to exhibit sufficient thickness in contrast to normal cuff with homogeneously low intensity on each image; type II, sufficient thickness in contrast to normal cuff related to partial high-intensity area; type III, insufficient thickness with no more than 50% of the thickness in comparison to normal cuff while without discontinuity, indicating a partial-thickness delaminated tear; type IV, on both oblique coronal and sagittal images, only one or two slices showed a slight discontinuity, indicating a small full-thickness tear; and type V, on both oblique coronal and sagittal images, more than two slices exhibited a major discontinuity, revealing a medium or large full-thickness tear. We defined retear as Sugaya classification type IV and V.

### 2.10. Statistics

SPSS 21.0 (IBM SPSS Statistics, Chicago, IL, USA) software was utilized for statistical analysis. Measurement data were presented as mean ± standard deviation. Paired *t*-test was implemented for intra-group comparisons and unpaired *t*-test was applied for inter-group comparisons. Enumeration data were presented as percentage or rate, and Fisher's exact test or $\chi^2$ test was implemented for comparisons between groups. $P < 0.05$ was an indicator for statistical significance.

## 3. Results

### 3.1. General data of patients

There was no statistical difference in gender, age, affected side, body mass index (BMI), average course of disease, and Cofield classification between the two groups (Table 1).

### 3.2. VAS scores between the two groups of patients before and after surgery

There was no significant difference between the preoperative VAS scores of patients in the control group and the experimental group ($P > 0.05$). At 3 and 6 months after surgery, the VAS scores of patients in both groups were lower than those before surgery ($P < 0.05$), and the AS scores of patients in the experimental group were lower than those in the control group ($P < 0.05$) (Table 2).

### 3.3. Shoulder joint function scores between the two groups of patients before and after surgery

The comparison of preoperative and postoperative shoulder joint function scores between the control group and the experimental group was displayed in Table 3. The differences between CMS, UCLA and ASES scores of the two groups before surgery were not

**Table 2**
Comparison of VAS scores between the two groups of patients before and after surgery.

| Group | Before surgery | 3 months after surgery | 6 months after surgery |
|---|---|---|---|
| The control group (n = 46) | 6.21 ± 0.95 | 3.42 ± 0.67* | 1.68 ± 0.73* |
| The experimental group (n = 46) | 6.33 ± 1.06 | 2.63 ± 0.61*# | 1.15 ± 0.58*# |

Note: *$P < 0.05$ vs the same group before surgery; #$P < 0.05$ vs the control group at the same time point.

**Table 3**
Comparison of shoulder joint function scores between the two groups of patients before and after surgery.

| Group | Time | CMS | UCLA score | ASES score |
|---|---|---|---|---|
| The control group (n = 46) | Before surgery | 52.56 ± 8.62 | 13.42 ± 1.33 | 41.76 ± 6.28 |
| | 3 months after surgery | 66.29 ± 3.45* | 20.36 ± 2.18* | 56.42 ± 5.85* |
| | 6 months after surgery | 79.96 ± 6.75* | 28.36 ± 3.07* | 77.45 ± 6.20* |
| The experimental group (n = 46) | Before surgery | 53.94 ± 6.42 | 13.30 ± 1.95 | 40.67 ± 7.38 |
| | 3 months after surgery | 72.36 ± 5.84*# | 25.41 ± 3.29*# | 67.73 ± 7.11*# |
| | 6 months after surgery | 87.04 ± 3.56*# | 32.02 ± 2.55*# | 83.24 ± 7.69*# |

Note: *$P < 0.05$ vs the same group before surgery; #$P < 0.05$ vs the control group at the same time point.

statistically significant (all $P > 0.05$). The CMS, UCLA and ASES scores of the two groups at 3 and 6 months after surgery were higher than those before surgery (all $P < 0.05$). Moreover, the experimental group had higher CMS, UCLA and ASES scores at 3 and 6 months after surgery than those in the control group (all $P < 0.05$).

### *3.4. ROM of the affected shoulder joint between the two groups of patients before and after surgery*

As displayed in Table 4, there was no statistical difference in the ROM of the affected shoulder joint between the two groups before surgery ($P > 0.05$). The activity of anterior flexion, abduction, external rotation and internal rotation of the affected shoulder joint in both groups at 3 and 6 months after surgery were greater than those before surgery (all $P < 0.05$). Furthermore, anterior flexion, abduction, external rotation and internal rotation activity of the affected shoulder joint of patients in the experimental group were greater than those in the control group at the same time (all $P < 0.05$).

### *3.5. QOL scores between the two groups of patients*

The preoperative QOL scores were both low in the two groups, with no statistical difference ($P > 0.05$). The QOL scores of patients in both groups were higher at 3 and 6 months after surgery compared with those before surgery ($P < 0.05$). Meantime, the postoperative QOL of patients in the experimental group was significantly better than that of patients in the control group ($P < 0.05$). The results were detailed in Table 5.

### *3.6. Complications between the two groups of patients*

The incidence of complications was compared between the two groups and the results were detailed in Table 6. There were 2 cases of incisional bleeding, 3 cases of fever, 2 cases of subcutaneous hematoma and 5 cases of re-tearing in patients of the control group, while in the experimental group, there were 1 case of incisional bleeding, 2 cases of fever, 2 cases of subcutaneous hematoma and 3 cases of re-tearing. There was no statistically significant difference in the incidence of complications between the experimental group (26.09%, 12/46) and the control group (17.39%, 8/46) ($P = 0.449$). According to Sugaya typing, the postoperative rotator cuff injury was classified into: type I: 28 cases, type II: 8 cases, type III: 5 cases, type IV: 3 cases, type V: 2 cases, and the re-tear rate of rotator cuff was 10.87% (control group); type I: 32 cases, type II: 7 cases, type III: 4 cases, type IV: 2 cases, type V: 1 case, and the re-tear rate of rotator cuff was 6.52% (experimental group). The re-tear rate of rotator cuff in the experimental group was lower than that in the control group, with insignificant difference between the two groups ($P > 0.05$).

## 4. Discussion

Rotator cuff injury is one prevalent clinical disorder of shoulder joints [28]. It is one of the most common reasons for shoulder pain and shoulder joint dysfunction [29]. Chronic rotator cuff tears are considered as debilitating injuries that greatly affect patients' QOL and impose heavy financial burden to the society [30]. This study focused on the clinical efficacy of sodium hyaluronate combined with PRP injection on rotator cuff injury in arthroscopic repair.

As previously reported, rotator cuff repair is involved in significant and hard to treat postoperative pain [31]. It is reported that patients with arthroscopic transosseous rotator cuff repair achieve significant improvements with the use of the needle based Omnicuff device [32]. In patients with recurrent posterior instability undergoing arthroscopic posterior stabilization, significant clinical positive results have been achieved in arthroscopic posterior labral repair and capsular plication with low recurrence and revision rate

**Table 4**
Comparison of the ROM of the affected shoulder joint between the two groups of patients before and after surgery.

| Group | Time | Anterior flexion | Abduction | External rotation | Internal rotation |
|---|---|---|---|---|---|
| The control group (n = 46) | Before surgery | 54.23 ± 9.35 | 43.50 ± 7.52 | 35.66 ± 6.52 | 36.30 ± 6.46 |
| | 3 months after surgery | 110.20 ± 10.69* | 106.73 ± 15.68* | 49.49 ± 5.02* | 42.96 ± 3.74* |
| | 6 months after surgery | 133.31 ± 16.75* | 136.70 ± 19.92* | 58.63 ± 6.57* | 54.70 ± 6.24* |
| The experimental group (n = 46) | Before surgery | 55.17 ± 10.02 | 41.97 ± 7.08 | 35.35 ± 4.79 | 36.25 ± 5.82 |
| | 3 months after surgery | 126.36 ± 15.84* | 115.38 ± 12.84* | 53.30 ± 6.84* | 49.75 ± 4.06* |
| | 6 months after surgery | 155.18 ± 16.17*# | 148.50 ± 17.08*# | 66.48 ± 9.67*# | 61.00 ± 6.63*# |

Note: *$P < 0.05$ vs the same group before surgery; #$P < 0.05$ vs the control group at the same time point.

**Table 5**
Comparison of quality of life scores between the two groups of patients.

| Group | Before surgery | 3 months after surgery | 6 months after surgery |
|---|---|---|---|
| The control group (n = 46) | 60.21 ± 10.32 | 73.85 ± 7.29* | 84.58 ± 7.37* |
| The experimental group (n = 46) | 59.73 ± 10.21 | 82.36 ± 7.38*# | 90.08 ± 5.89*# |

Note: *$P$ < 0.05 vs the same group before surgery; #$P$ < 0.05 vs the control group at the same time point.

**Table 6**
Comparison of complications between the two groups of patients (n/%).

| Complications | The control group (n = 46) | The experimental group (n = 46) |
|---|---|---|
| Incisional bleeding | 2 (4.35%) | 1 (2.17%) |
| Subcutaneous hematoma | 3 (6.52%) | 2 (4.35%) |
| Fever | 2 (4.35%) | 2 (4.35%) |
| Re-tearing | 5 (10.87%) | 3 (6.52%) |
| Incidence of complications | 12 (26.09%) | 8 (17.39%) |
| $P$ value | 0.449 | |

[33]. A previous research has reported that ARCR using a transosseous knotless technique has achieved a satisfactory outcome in patients with rotator cuff repair [34]. Patients that undergo ARCR show improved post-operative clinical outcomes in some functional outcomes [35]. Therefore, in our study, we also used ARCR to treat rotator cuff injury. Nakamura et al. have unveiled that patients undergoing ARCR that are administered with subacromial injection of hyaluronic acid show the improved functional outcome after operation in comparison to those are not administered this injection before operation [25].

Intra-articular injection treatment is a widely-utilized conservative therapy for rotator cuff injury in clinical practice [29]. Sodium hyaluronate is utilized as an alternative intra-articular approach for treating adhesive capsulitis of the shoulder joint [36]. Evidence has shown that postoperative injection of exogenous hyaluronan could allow the repaired rotator cuff tendon healing with minimal adhesion [37,38]. This is consistent with the therapeutic effect of sodium hyaluronate in our experiment on treating rotator cuff injury. A previous study has reported that PRP yields similar results to that of corticosteroids in most clinical conditions in patients with rotator cuff tendinopathies. In addition, ROM and pain may display greater improvement with the help of PRP [39]. It is also reported that PRP injections is associated with clinical improvements in pain and patient-reported outcome scores of patients diagnosed with partial-thickness rotator cuff tears [40]. It has been demonstrated that allogeneic PRP injections are safe in treating rotator cuff disease. Generally speaking, PRP, in a slow but steady manner, alleviates pain and improves shoulder function until 6 months [41]. All these articles confirmed the efficacy of PRP interjection in joint-related diseases.

Furthermore, increasing evidence has demonstrated the effects of PRP injection in healing partial-thickness rotator cuff tears ranging from small to medium. Moreover, the combined injection of sodium hyaluronate and PRP yields a much better clinical outcome than sodium hyaluronate or PRP alone [42]. Combined PRP with hyaluronate injection is usually safer than PRP injections alone, by evaluating the incidence of adverse events [43]. In our research, according to the comparisons of VAS scores, shoulder joint function scores, shoulder ROM, QOL scores, and complications before and after treatment, we found that there were better therapeutic effects in patients interjected with sodium hyaluronate combined with PRP injection. It has been shown that PRP combined with sodium hyaluronate is effective in improving shoulder function in patients with rotator cuff injury [42,44] and is superior to treatment with sodium hyaluronate or PRP alone. It has also been suggested that PRP may reduce the re-tear rate after repair of arthroscopic rotator cuff injuries [45,46]. However, there are no studies comparing the re-tear rate after rotator cuff injury treated with sodium hyaluronate combined with PRP injection during arthroscopic repair with that after sodium hyaluronate injection alone during arthroscopic repair for the time being. The results of this study showed no statistical significance in the re-tear rate after sodium hyaluronate combined with PRP injection treatment and after sodium hyaluronate injection treatment alone. However, the small sample size of this study may have an impact on the accuracy, and we will include more study subjects to further validate our findings in the future.

In summary, this research demonstrates that sodium hyaluronate combined with PRP injection treatment could efficiently improve shoulder joint function and the QOL in patients with rotator cuff injury. This research lays a foundation to assess the clinical effects of sodium hyaluronate combined with PRP injection on rotator cuff injury. Nevertheless, further evidence is needed to prove the efficacy of sodium hyaluronate combined with PRP injection treatment on rotator cuff injury in arthroscopic repair.

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## Conflicts of interest

The authors declare that they have no conflicts of interest.

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