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ALLOGENEIC PLATELET-RICH PLASMA VERSUS CORTICOSTEROID INJECTION FOR THE TREATMENT OF ROTATOR CUFF DISEASE. A RANDOMIZED CONTROLLED TRIAL

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# **Appendix**

Allogeneic Platelet-Rich Plasma versus Corticosteroid Injection for the Treatment of Rotator Cuff Disease: A Randomized Controlled Trial

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#### Method 1: Inclusion & Exclusion Criteria

#### **Inclusion Criteria**

Participants should meet all the inclusion criteria. Patients must consent in writing to participate in the study by signing and dating an informed consent document approved by IRB indicating that the patient has been informed of all pertinent aspects of the study prior to completing any of the screening procedures

- 1) Male or female 18 years of age and older
- 2) Patients who have unilateral shoulder pain.
- 3) Patients who have had pain at least for 3 months
- 4) To be included in the study- participants are required to have a & b.(mentioned below)
  - a. Pain with one of the two tests
    - Neer's sign: passive overpressure at full shoulder flexion with the scapula fixed
    - Hawkins test: passive internal rotation at 90 degree of shoulder flexion in the scapular plane and in progressive degree of horizontal adduction
  - b. Pain with one of the two tests
    - Painful arc: active shoulder abduction
    - oJobe's test: The examiner passively elevates the patient's shoulder to 90 degrees of abduction with internal rotation. The examiner then applies a downward pressure against the arm

#### **Exclusion Criteria**

Participants who met a single condition were excluded from the study

- 1) Patients who received any drug by subacromial injection for treatment within 3 months prior to this enrollment
- 2) Patients who have a history of shoulder trauma including dislocation- subluxation- and fracture- breast cancer- or surgery around shoulder- neck and upper back
- 3) Patients who have a isolated acromioclavicular joint pathology
- 4) Patients who have a full-thickness rotator cuff tear (evidenced by MR or ultrasonography)
- 5) Patients with symptomatic cervical spine disorders
- 6) Patients who have a History of allergic adverse reactions to corticosteroid
- 7) Patients are unable to give informed consent to participate in the study
- 8) Patients are unable to come into the clinic for regular follow-up
- 9) Patients with adhesive capsulitis- acromioclavicular arthropathy- polyarthritis- infectious arthritis- rheumatoid arthritis or diagnosed fibromyalgia
- 10) Patients with concurrent bilateral shoulder pain
- 11) Patients with neurological deficit
- 12) Patients who have severely abnormal radiological findings including malignancy, severe osteoarthritis of the glenohumeral joint, severe skeletal abnormalities decreasing the subacromial space and etc.
- 13) Presence of shoulder pain with limitation of both active and passive movements of the glenohumeral joint of 25% in at least 2 directions (abduction, flexion, external rotation, internal rotation), as compared with the contralateral shoulder or with normal values
- 14) Patients with Diabetes mellitus
- 15) Patients taking anticoagulants
- 16) Pregnant women or lactating mothers
- 17) Patients who are difficulty participating in data collection due to communication problem and serious mental illness
- 18) Patients with serious condition which can affect this study such as severe cardiovascular diseases- renal diseases- liver diseases- endocrine diseases- and cancers

# **Method 2: Allogeneic Platelet-Rich Plasma Preparation**

PRP was obtained one day before surgery using a plateletpheresis system with a leukoreduction set (COBE Spectra LRS Turbo, Caridian BCT, Lakewood, Colorado) as previously described. An aliquot was used for determining complete blood counts using a fully automated analyzer (XE- 2100, Sysmex Corporation, Kobe, Japan), and the concentration of fibrinogen using an automated coagulation analyzer (CA-7000, Sysmex Corporation). For injection, platelet counts in PRP were adjusted with saline to 1,000 x 10³ platelets per microliter. To activate platelets, 10% calcium gluconate was added to PRP at 1:10 (vol/vol), and three PRPs were mixed. The concentrations of 7 growth factors, including epidermal growth factor, transforming growth factor β1, vascular endothelial growth factor, connective tissue growth factor, basic fibroblast growth factor, platelet-derived growth

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factor AB, and insulin-like growth factor in PRP were determined by enzyme-linked immunosorbent assay according to the manufacturer's protocol. The activation status of platelets was determined by flow cytometry with CD61 and CD62P. Three prepared PRPs were then mixed and frozen until use.

## Method 3: Ultrasonography Guided Platelet-Rich Plasma Injection

Under ultrasonography guidance, all injections were performed with the patient in sitting position with the arm internally rotated in front of the abdomen. The transducer and the patient's skin were sterilized with 2% chlorhexidine and 10% povidone-iodine solution. After sterile gel was applied to the transducer, the subacromial bursa between the acromion and rotator cuff tendon was visualized. A 25-gauge needle was introduced under the transducer and visualized in real-time as a thin hyperechoic line. Injection of 4 mL of allogeneic PRP was made into the subacromial space, avoiding direct injection into the rotator cuff tendon. In the control group, 1 mL of triamcinolone acetonide (purchased from Dong Kwang Pharm, 40 mg/mL) in 3 mL of 2% lidocaine (Daehan Pharmaceutical) was injected.

### **Method 4: Postinjection Home Exercise Program**

After injection, a home exercise program for shoulder and scapular stretching was encouraged twice a day for 20 minutes each session. Strengthening exercises were encouraged when stretching exercise and active elevation did not cause pain in the shoulder. All pain medications except the rescue analgesics, a combination tablet of 18.5 mg of tramadol and 162.5 mg of acetaminophen, were discontinued.

#### **Method 5: Outcome Measures**

A Visual Analog Scale (VAS) was used to evaluate pain at rest, during motion and at night: participants were asked to use a 10-cm scale ranging from "no pain" to "unbearable pain". The results of the mean and worst pain scores were also recorded. Range of motion was measured with a goniometer in active forward flexion, abduction, external rotation with the arm at the side, and internal rotation. Internal rotation was measured using vertebral levels, and these were translated into numbers from 1 for the buttocks to 17 for T2. The strength of the supraspinatus, infraspinatus, and subscapularis muscle was measured using a handheld electronic scale (CHS, CAS, Yangju, Korea). The additional functional scores included the Shoulder Pain and Disability Index (SPADI), the American Shoulder and Elbow Surgeons (ASES) score, the University of California, Los Angeles (UCLA) score, the Simple Shoulder Test (SST) and the Disabilities of the Arm, Shoulder and Hand (DASH) score. To evaluate the overall satisfaction and function, five questions were asked with answers being "yes" or "no" to the following: (1) their willingness to undergo injection again, (2) whether they were prepared to recommend an injection to others and (3) whether they were able to work as they did before getting sick. Using the 10-cm scale we also evaluated (4) overall function and satisfaction, marked from "I cannot use it" to "I feel normal" for function (the single assessment numeric evaluation (SANE)), and (5) overall satisfaction from "never satisfied" to "very satisfied". Participants were advised to take the rescue medication (18.75/ 162.5mg tramadol HCl/acetaminophen) only if needed.

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**Table E1. Summary of Adverse Events** 

	Allogeneic PRP (n=30)	Steroid (n=30)
Patients with AE		
All	2 (6.7%)	0
Treatment-related	0	0
Patients with SAE		
All	0	1 (3.3%)
Treatment-related	0	0

Abbreviation: PRP, platelet-rich plasma; SAE, serious adverse event.

Groups	System	Adverse events	Grade	Management	Outcome	Treatment -relation
Allogeneic PRP	Musculoskeletal	Pain in extremity*	2	Rescue drug	Recovered	No
	Musculoskeletal	Pain in extremity*	2	Rescue drug Recovered		No
Steroid	Musculoskeletal	Open reduction internal fixation due to right.5 <sup>th</sup> metatarsal bone fracture <sup>†</sup>	3	Removal of hardware	Recovered	No

<sup>\*</sup>The two adverse events were radiating pain to the ipsilateral upper extremity at 1 and 3 months after injection. They were managed with rescue drugs. No patients were discontinued from the study because of adverse events.

<sup>&</sup>lt;sup>†</sup>The one serious adverse event in the steroid group was hospital admission for metal hardware removal due to a right 5th metatarsal bone fracture in 2008.

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Table S2. Changes of Clinical Outcomes with A Generalized Linear Mixed Model
Table S2. A. Changes of the Constant Score and Visual Analog Scales for Pain after PRP and Steroid injection

Variable	Allogeneic PRP(n=30) Mean (95%CI)	P Value*	Steroid (n=30) Mean (95%CI)	P Value*	Between - group mean difference (baseline adjusted)	<i>P</i> Value⁺
The Constant so	core					
Preinjection	65.5 (61.1 to 69.9)		64.7 (61.0 to 68.5)			
1W	66.6 (62.7 to 70.6)	.922	70.7 (66.8 to 74.6)	.001	-5.8 (-10.3 to -1.3)	.012
1M	67.9 (63.8 to 72.1)	.145	72.7 (69.2 to 76.2)	<.001	-5.7 (-11.3 to -0.1)	.045
3M	69.3 (62.9 to 75.8)	.218	68.4 (63.0 to 73.8)	.112	-1.8 (-8.0 to 4.5)	.577
6M	74.4 (68.4 to 80.4)	.002	68.8 (63.1 to 73.9)	.135	4.4 (-2.2 to 11.0)	.187
Pain at rest						
Preinjection	2.3 (1.6 to 3.0)		2.2 (1.5 to 2.9)			
1W	2.0 (1.2 to 2.8)	.856	1.7 (0.9 to 2.4)	.131	0.4 (-0.6 to 1.3)	.278
1M	1.5 (1.0 to 2.1)	.053	1.5 (0.9 to 2.1)	.050	0.2 (-1.0 to 1.3)	.816
3M	0.8 (0.3 to 1.2)	.001	2.1 (1.3 to 2.9)	.494	-1.0 (-2.2 to 0.2)	.056
6M	1.0 (0.4 to 1.5)	.003	1.6 (0.8 to 2.5)	.110	-0.5 (-1.7 to 0.7)	.322
Pain on motion						
Preinjection	4.1 (3.3 to 4.9)		4.1 (3.4 to 4.8)			
1W	4.0 (3.0 to 5.0)	.823	2.6 (1.9 to 3.3)	<.001	1.4 (0.5 to 2.4)	.003
1M	3.0 (2.2 to 3.8)	.008	1.9 (1.3 to 2.6)	<.001	1.1 (-0.1 to 2.2)	.063

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3M	2.8 (1.8 to 3.8)	.011	2.9 (2.0 to 3.8)	.007	0.1 (-1.1 to 1.4)	.847
6M	2.1 (1.2 to 3.0)	<.001	2.7 (1.8 to 3.6)	.012	-0.7 (-1.9 to 0.6)	.314
Pain at night						
Preinjection	4.6 (3.6 to 5.7)		4.5 (3.6 to 5.3)			
1W	3.9 (2.8 to 5.0)	.016	3.3 (2.3 to 4.3)	.001	0.3 (-0.8 to 1.4)	.583
1M	3.7 (2.8 to 4.6)	.012	2.7 (1.9 to 3.4)	<.001	0.7 (-0.6 to 2.0)	.266
3M	3.2 (2.0 to 4.3)	.038	3.1 (2.1 to 4.1)	.016	0.2 (-1.3 to 1.6)	.828
6M	2.5 (1.4 to 3.6)	.002	3.1 (2.2 to 4.1)	.006	-0.8 (-2.3 to 0.7)	.283
Mean pain						
Preinjection	3.7 (3.0 to 4.3)		3.6 (3.0 to 4.2)			
1W	3.3 (2.5 to 4.1)	.231	2.5 (1.8 to 3.2)	.001	0.7 (0.0 to 1.5)	.064
1M	2.7 (2.1 to 3.4)	.004	2.0 (1.4 to 2.6)	<.001	0.6 (-0.3 to 1.6)	.179
3M	2.2 (1.4 to 3.0)	.003	2.7 (1.8 to 3.5)	.014	-0.2 (-1.3 to 0.8)	.647
6M	1.8 (1.0 to 2.6)	<.001	2.5 (1.7 to 3.3)	.004	-0.7 (-1.7 to 0.4)	.222
Worst pain						
Preinjection	7.9 (7.2 to 8.5)		7.0 (6.4 to 7.7)			
1W	6.8 (5.8 to 7.8)	.016	5.8 (4.9 to 6.7)	.005	0.2 (-1.1 to 1.5)	.799
1M	6.3 (5.2 to 7.3)	.001	4.6 (3.6 to 5.6)	<.001	0.8 (0.7 to 2.3)	.307
3M	5.9 (4.7 to 7.0)	.001	4.8 (3.6 to 6.0)	.001	0.5 (-1.2 to 2.1)	.575

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6M 4.4 (3.1 to 5.7)

<.001

5.0 (3.8 to 6.2)

.001

-1.5 (-3.2 to 0.1)

.071

Abbreviation: PRP, platelet-rich plasma.

<sup>\*</sup>Comparison between the baseline and each time point

<sup>†</sup>Comparison of mean difference in change from baseline between the PRP and steroid groups

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Table S2. B. Changes of ROM after Platelet-Rich Plasma and Steroid Injection

Variable	Allogeneic PRP(n=30) Mean (95%CI)	P Value*	Steroid (n=30) Mean (95%CI)	P Value*	Between - group mean difference (baseline adjusted)	<i>P</i> Value <sup>†</sup>
orward flexion						
reinjection	162.3 (157.3 to 167.3)		165.2 (161.3 to 169.1)			
W	161.7 (156.9 to 166.6)	.999	167.8 (164.7 to 171.0)	.115	-2.8 (-8.6 to 3.1)	.354
M	162.9 (157.3 to 168.4)	.637	167.2 (163.1 to 171.4)	.206	-1.4 (-8.6 to 5.9)	.708
M	161.2 (153.4 to 169.0)	.943	161.7 (155.7 to 167.8)	.522	1.6 (-6.5 to 9.6)	.703
M	159.6 (152.2 to 166.9)	.636	158.8 (151.9 to 165.6)	.168	3.6 (-4.8 to 12.0)	.397
bduction						
reinjection	166.3 (160.8 to 171.9)		169.0 (165.2 to 172.8)			
W	166.0 (160.3 to 171.8)	.931	172.3 (169.2 to 175.5)	.017	-3.5 (-11.2 to 4.1)	.363
M	167.0 (160.5 to 173.4)	.900	172.8 (169.2 to 176.3)	.009	-3.6 (-13.0 to 5.8)	.452
M	165.4 (155.0 to 175.8)	.966	166.2 (161.0 to 171.3)	.634	0.5 (-9.9 to 10.8)	.925
M	166.1 (157.5 to 174.7)	.863	161.3 (152.2 to 170.3)	.184	7.2 (-3.6 to 17.9)	.190
xternal rotation	with arm at the side					
reinjection	44.3 (39.1 to 49.5)		46.7 (42.7 to 50.5)			
W	45.2 (39.9 to 50.5)	.862	48.7 (44.3 to 53.1)	.272	-1.7 (-7.1 to 3.6	.529
M	43.6 (39.1 to 48.1)	.518	49.1 (43.9 to 54.4)	.232	-3.9 (-10.3 to 2.6)	.236

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3M	47.8 (41.3 to 54.3)	.159	46.3 (40.5 to 52.2)	.999	2.1 (-4.9 to 9.2)	.548
6M	51.1 (44.0 to 58.2)	.046	43.8 (37.9 to 49.6)	.392	8.0 (0.7 to 15.2)	.031
Internal rotation						
Preinjection	10.3 (9.6 to 11.1)		10.4 (9.6 to 11.2)			
1W	10.3 (9.5 to 11.2)	.798	10.5 (9.5 to 11.4)	.842	0.0 (-0.9 to 0.9)	.990
1M	10.5 (9.8 to 11.2)	.702	11.0 (10.1 to 11.8)	.267	-0.4 (-1.5 to 0.7)	.481
3M	10.7 (9.7 to 11.8)	.519	10.7 (9.6 to 11.8)	.513	0.0 (-1.3 to 1.2)	.962
6M	10.8 (9.9 to 11.7)	.279	10.7 (9.6 to 11.8)	.626	0.1 (-1.1 to 1.4)	.842

Abbreviation: PRP, platelet-rich plasma.

<sup>\*</sup>Comparison between the baseline and each time point †Comparison of mean difference in change from baseline between the PRP and steroid groups

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Table S2. C. Changes in Strength of the Rotator Cuff Muscles after PRP and Steroid Injection

Variable	Allogeneic PRP(n=30) Mean (95%CI)	P Value*	Steroid (n=30) Mean (95%CI)	P Value*	Between - group mean difference (baseline adjusted)	<i>P</i> Value <sup>†</sup>
Supraspiatus						
Preinjection	8.5 (6.2 to 10.7)		8.8 (6.8 to 10.7)			
1W	9.8 (7.8 to 11.8)	.031	9.8 (7.9 to 11.8)	.072	-0.1 (-1.5 to 1.4)	.914
1M	9.7 (7.8 to 11.6)	.035	10.8 (9.1 to 12.5)	.007	-0.9 (-2.7 to 0.8)	.297
3M	10.7 (8.3 to 13.2)	.006	9.6 (7.7 to 11.5)	.242	0.8 (-1.1 to 2.7)	.416
6M	10.9 (8.5 to 13.2)	.022	9.4 (7.7 to 11.2)	.501	1.6 (-0.4 to 3.6)	.114
Infraspinatus						
Preinjection	7.6 (6.2 to 9.0)		8.0 (6.5 to 9.5)			
1W	8.8 (7.3 to 10.4)	.009	8.9 (7.4 to 10.5)	.061	0.1 (-1.2 to 1.3)	.924
1M	9.0 (7.3 to 10.7)	<.001	9.9 (8.6 to 11.2)	.001	-0.4 (-1.9 to 1.2)	.624
3M	9.7 (7.7 to 11.7)	.007	8.9 (7.1 to 10.6)	.487	0.8 (-0.9 to 2.5)	.349
6M	9.9 (7.9 to 11.9)	.041	8.6 (7.1 to 10.1)	.379	1.3 (-0.5 to 3.0)	.155
Subsacpularis						
Preinjection	11.9 (9.6 to 14.1)		11.9 (10.0 to 13.9)			
1W	13.0 (10.7 to 15.3)	.186	12.6 (10.6 to 14.5)	.272	0.1 (-1.6 to 1.8)	.890
1M	12.8 (10.6 to 14.9)	.081	14.2 (12.1 to 16.3)	.008	-0.8 (-2.9 to 1.3)	.444

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3M	14.3 (11.6 to 17.0)	.014	13.4 (10.7 to 16.2)	.172	0.5 (-1.8 to 2.7)	.688
6M	13.4 (10.8 to 15.9)	.167	12.7 (10.6 to 14.8)	.475	0.7 (-1.6 to 3.0)	.540

Abbreviation: PRP, platelet-rich plasma.

<sup>\*</sup>Comparison between the baseline and each time point 
†Comparison of mean difference in change from baseline between the PRP and steroid groups

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Table S2. D. Changes of the SPADI, ASES, UCLA, SST, DASH Scores after Platelet-Rich Plasma and Steroid Injection

Variable	Allogeneic PRP(n=30) Mean (95%CI)	P Value*	Steroid (n=30) Mean (95%CI)	P Value*	Between - group mean difference (baseline adjusted)	<i>P</i> Value <sup>†</sup>
SPADI						
Preinjection	34.3 (28.5 to 40.2)		33.8 (29.7 to 37.8)			
W	35.6 (28.5 to 42.7)	.675	24.3 (18.9 to 29.7)	.001	10.5 (3.5 to 17.4)	.003
М	28.4 (21.9 to 34.9)	.017	19.4 (14.4 to 24.4)	<.001	7.9 (-0.5 to 16.3)	.066
<b>SM</b>	26.0 (18.2 to 33.8)	.007	25.3 (17.3 to 33.4)	.015	1.3 (-7.8 to 10.5)	.776
M	17.7 (10.5 to 24.8)	<.001	24.5 (16.5 to 32.6)	.022	-8.2 (-17.7 to 1.2)	.088
ASES						
Preinjection	64.7 (58.6 to 70.7)		64.9 (60.8 to 69.0)			
W	65.6 (58.5 to 72.7)	.594	73.4 (67.7 to 79.0)	.002	-7.3 (-13.8 to -0.8)	.028
М	71.3 (65.3 to 77.2)	.010	79.9 (74.2 to 85.7)	<.001	-7.9 (-15.8 to 0.1)	.053
BM	75.8 (68.3 to 83.3)	.002	74.1 (66.2 to 82.1)	.006	0.1 (-8.7 to 8.8)	.988
M	81.9 (74.7 to 89.1)	<.001	75.2 (67.6 to 82.8)	.004	6.9 (-2.2 to 16.0)	.136
JCLA						
Preinjection	19.5 (18.2 to 20.8)		20.8 (19.5 to 22.2)			
W	21.5 (19.7 to 23.3)	.008	25.3 (23.7 to 27.0)	<.001	-2.5 (-5.0 to 0.0)	.047
М	24.2 (22.0 to 26.4)	<.001	27.6 (25.5 to 29.7)	<.001	-2.0 (-4.9 to 1.0)	.198

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3M	24.4 (21.8 to 26.9)	.001	26.1 (23.5 to 28.7)	<.001	-1.1 (-4.4 to 2.1)	.487
6M	26.3 (23.6 to 29.0)	<.001	26.3 (24.1 to 28.5)	<.001	1.1 (-2.2 to 4.4)	.504
SST						
Preinjection	7.5 (6.5 to 8.5)		7.2 (6.5 to 8.0)			
1W	7.8 (6.4 to 9.3)	.497	7.9 (7.0 to 8.9)	.094	-0.3 (-1.6 to 1.0)	.621
1M	8.0 (7.0 to 9.0)	.168	9.5 (8.2 to 10.8)	<.001	-1.7 (-3.2 to -0.1)	.040
3M	8.1 (7.0 to 9.2)	.238	8.7 (7.5 to 9.9)	.014	-1.0 (-2.7 to 0.8)	.273
6M	9.7 (8.5 to 10.9)	.003	8.4 (7.1 to 9.7)	.059	1.1 (-0.7 to 2.8)	.242
DASH						
Preinjection	26.0 (21.3 to 30.7)		23.8 (20.0 to 27.5)			
1W	27.3 (22.1 to 32.5)	.681	20.9 (15.9 to 25.9)	.185	3.7 (-2.2 to 9.5)	.218
1M	23.2 (18.6 to 27.8)	.126	14.9 (10.8 to 19.0)	<.001	5.1 (-2.0 to 12.2)	.156
3M	20.2 (14.1 to 26.4)	.036	21.1 (14.2 to 28.0)	.232	-2.6 (-10.4 to 5.1)	.504
6M	14.3 (8.9 to 19.7)	<.001	20.3 (13.6 to 27.1)	.281	-9.0 (-17.0 to -1.0)	.028

Abbreviation: PRP, platelet-rich plasma; SPADI, Shoulder Pain And Disability Index; ASES, American Shoulder and Elbow Surgeons; UCLA, University of California at Los Angeles; SST, Simple Shoulder Test; DASH, Disabilities of the Arm, Shoulder, and Hand Questionnaire.

<sup>\*</sup>Comparison between the baseline and each time point

<sup>&</sup>lt;sup>†</sup>Comparison of mean difference in change from baseline between the PRP and steroid groups

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Table S2. E. Changes of Overall Satisfaction and Function after Platelet-Rich Plasma and Steroid Injection

Variable	Allogeneic PRP (%) Mean (95%CI)	P Value*	Steroid (%) Mean (95%CI)	P Value*	Between - group mean difference (baseline adjusted)	<i>P</i> Value <sup>†</sup>
Willingness to	undergo injection again					
W	80.0 (61.4 to 92.3)	NA	83.3 (65.3 to 94.4)	NA	NA	NA
М	78.6 (59.0 to 91.7)	NA	86.2 (68.3 to 96.1)	NA	NA	NA
М	84.0 (63.9 to 95.5)	NA	76.9 (56.4 to 91.0)	NA	NA	NA
М	82.6 (61.2 to 95.0)	NA	67.9 (47.6 to 84.1)	NA	NA	NA
o recommend	injection to another					
N	76.7 (57.7 to 90.1)	NA	86.7 (69.3 to 96.2)	NA	NA	NA
М	78.6 (59.0 to 91.7)	NA	86.2 (68.3 to 96.1)	NA	NA	NA
М	84.0 (63.9 to 95.5)	NA	76.9 (56.4 to 91.0)	NA	NA	NA
Л	78.3 (56.3 to 92.5)	NA	71.4 (51.3 to 86.8)	NA	NA	NA
an't work due	to pain					
einjection	86.7 (69.3 to 96.2)		80.0 (61.4 to 92.3)			
V	86.2 (68.3 to 96.1)	.999	76.7 (57.7 to 90.1)	.706	3.1 (-18.8 to 24.9)	.783
Л	92.9 (76.5 to 99.1)	.564	86.2 (68.3 to 96.1)	.480	-1.3 (-23.5 to 21.0)	.912
Л	96.0 (79.6 to 99.9)	.564	92.3 (74.9 to 99.1)	.083	-4.2 (-22.8 to 14.3)	.656

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6M	82.6 (61.2 to 95.0)	.180	85.7 (67.3 to 96.0)	.414	-10.7 (-36.2 to 14.8)	.411
Overall function						
Preinjection	47.7 (4.1.0 to 54.3)		53.3 (45.5 to 61.1)			
1W	49.3 (41.2 to 57.4)	.459	63.0 (57.4 to 68.6)	.016	-0.7 (-1.9 to 0.4)	.219
1M	52.9 (45.3 to 60.4)	.184	65.7 (59.2 to 72.2)	.006	-0.7 (-2.0 to 0.7)	.339
3M	58.4 (48.8 to 68.0)	.042	60.4 (50.6 to 70.2)	.251	0.3 (-1.1 to 1.8)	.639
6M	70.0 (60.8 to 79.2)	<.001	59.3 (48.9 to 69.6)	.315	1.7 (0.3 to 3.1)	.020
Overall satisfaction	on					
1W	41.4 (28.8 to 54.0)	NA	60.0 (50.0 to 70.0)	NA	NA	NA
1M	55.9 (45.0 to 66.8)	NA	69.1 (60.9 to 77.4)	NA	NA	NA
3M	53.6 (40.9 to 66.3)	NA	64.6 (53.5 to 75.8)	NA	NA	NA
6M	67.0 (55.3 to 78.7)	NA	65.0 (54.6 to 75.4)	NA	NA	NA

Abbreviation: PRP, platelet-rich plasma; NA, not available

<sup>\*</sup>Comparison between the baseline and each time point †Comparison of mean difference in change from baseline between the PRP and steroid groups

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Table S3. A. Changes of the Constant Score and Visual Analog Scales for Pain after PRP and Steroid injection

Variable	Allogeneic PRP(n=30) Mean (95%CI)	P Value*	Steroid (n=30) Mean (95%CI)	P Value*	Between - group mean difference (baseline adjusted)	<i>P</i> Value⁵
The Constant s	core					
Preinjection	66.7 (61.9 to 71.6)		63.5 (59.8 to 67.2)			
1W	67.1 (62.9 to 71.4)	.802	69.9 (65.6 to 74.1)	.002	-6.0 (-10.8 to -1.2)	.015
1M	69.6 (65.3 to 73.8)	.063	71.7 (68.1 to 75.3)	<.001	-5.4 (-11.5 to 0.7)	.085
3M	70.6 (64.1 to 77.1)	.102	68.4 (63.0 to 73.8)	.112	-1.1 (-7.8 to 5.7)	.755
6M	74.0 (67.7 to 80.3)	.003	67.5 (61.9 to 73.0)	.186	3.3 (-3.9 to 10.4)	.369
Pain at rest						
Preinjection	2.1 (1.4 to 2.8)		2.4 (1.6 to 3.2)			
1W	2.0 (1.0 to 3.0)	.848	1.9 (1.1 to 2.8)	.274	0.4 (-0.6 to 1.3)	.435
1M	1.5 (0.9 to 2.1)	.040	1.6 (0.9 to 2.3)	.072	0.2 (-1.0 to 1.3)	.777
3M	0.8 (0.3 to 1.3)	.001	2.1 (1.3 to 2.9)	.494	-1.0 (-2.2 to 0.2)	.097
6M	1.0 (0.4 to 1.5)	.003	1.8 (0.9 to 2.7)	.151	-0.5 (-1.7 to 0.7)	.399
Pain on motion						
Preinjection	4.2 (3.2 to 5.2)		4.2 (3.5 to 5.0)			
1W	4.1 (2.8 to 5.3)	.752	2.8 (2.1 to 3.5)	.002	1.3 (0.2 to 2.3)	.020
1M	3.0 (2.0 to 4.0)	.007	2.1 (1.4 to 2.8)	<.001	1.0 (-0.3 to 2.3)	.142
3M	2.8 (1.7 to 3.8)	.001	2.9 (2.0 to 3.8)	.007	-0.1 (-1.5 to 1.3)	.895

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6M	2.1 (1.2 to 3.0)	<.001	2.9 (2.0 to 3.8)	.020	-0.8 (-2.2 to 0.6)	.256
Pain at night						
Preinjection	4.8 (3.6 to 5.9)		4.7 (3.8 to 5.7)			
1W	4.0 (2.8 to 5.1)	.057	3.7 (2.7 to 4.7)	.005	0.2 (-1.0 to 1.4)	.733
1M	3.4 (2.4 to 4.4)	.011	2.9 (2.1 to 3.7)	<.001	0.5 (-1.0 to 2.0)	.503
3M	3.2 (1.9 to 4.4)	.038	3.1 (2.1 to 4.1)	.016	0.0 (-1.6 to 1.6)	.993
6M	2.5 (1.4 to 3.6)	.002	3.3 (2.4 to 4.3)	.012	-0.9 (-2.5 to 0.7)	.257
Mean pain						
Preinjection	3.7 (3.0 to 4.4)		3.8 (3.2 to 4.4)			
1W	3.3 (2.4 to 4.3)	.299	2.8 (2.1 to 3.5)	.007	0.6 (-0.3 to 1.5)	.166
1M	2.6 (1.9 to 3.3)	.003	2.2 (1.6 to 2.8)	<.001	0.5 (-0.5 to 1.6)	.317
3M	2.2 (1.4 to 3.1)	.002	2.7 (1.8 to 3.5)	.014	-0.4 (-1.5 to 0.8)	.531
6M	1.8 (1.0 to 2.6)	<.001	2.7 (1.8 to 3.5)	.008	-0.7 (-1.9 to 0.4)	.206
Worst pain						
Preinjection	8.0 (7.3 to 8.7)		7.2 (6.6 to 7.9)			
1W	7.1 (5.9 to 8.2)	.056	6.0 (5.1 to 6.9)	.009	0.3 (-1.2 to 1.8)	.672
1M	6.3 (5.1 to 7.5)	.002	4.8 (3.8 to 5.9)	<.001	0.7 (-1.0 to 2.4)	.425
3M	6.0 (4.8 to 7.1)	.002	4.8 (3.6 to 6.0)	.001	0.4 (1.4 to 2.1)	.672
6M	4.4 (3.1 to 5.7)	<.001	5.3 (4.1 to 6.6)	.004	-1.7 (-3.5 to 0.1)	.058

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Abbreviation: PRP, platelet-rich plasma.

\*Comparison between the baseline and each time point 
†Comparison of mean difference in change from baseline between the PRP and steroid groups

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Table S3. B. Changes of ROM after Platelet-Rich Plasma and Steroid Injection

Variable	Allogeneic PRP(n=30) Mean (95%CI)	P Value*	Steroid (n=30) Mean (95%CI)	P Value*	Between - group mean difference (baseline adjusted)	<i>P</i> Value <sup>†</sup>
Forward flexion						
Preinjection	161.1 (155.1 to 167.1)		164.0 (159.7 to 168.4)			
1W	162.6 (157.0 to 168.2)	.184	167.9 (164.3 to 171.5)	.028	-2.3 (-8.6 to 4.0)	.467
1M	164.3 (158.8 to 169.9)	.036	166.5 (162.0 to 171.0)	.206	0.8 (-7.1 to 8.6)	.849
3M	161.3 (152.9 to 169.7)	.944	161.7 (155.7 to 167.8)	.522	2.5 (-6.1 to 11.2)	.565
6M	159.6 (152.2 to 166.9)	.636	158.1 (150.7 to 165.4)	.182	4.4 (-4.6 to 13.5)	.335
Abduction						
Preinjection	165.2 (158.2 to 172.2)		167.7 (163.5 to 171.9)			
1W	166.7 (159.9 to 173.6)	.480	171.9 (168.4 to 175.5)	.005	-2.7 (-11.2 to 5.7)	.528
1M	168.5 (161.8 to 175.1)	.230	171.9 (168.1 to 175.8)	.016	-1.0 (-11.4 to 9.4)	.854
3M	165.4 (154.3 to 176.6)	.966	166.2 (161.0 to 171.3)	.634	1.8 (-9.5 to 13.1)	.760
6M	166.1 (157.5 to 174.7)	.863	160.6 (150.9 to 170.3)	.206	8.0 (-3.8 to 19.7)	.181
External rotation v	vith arm at the side					
Preinjection	45.9 (39.5 to 52.3)		46.3 (42.4 to 50.3)			
1W	48.0 (41.8 to 54.1)	.323	47.1 (42.5 to 51.8)	.651	1.3 (-4.6 to 7.2)	.670
1M	45.7 (40.4 to 51.0)	.929	47.9 (42.5 to 53.3)	.430	-1.8 (-8.9 to 5.3)	.624

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3M	49.5 (42.5 to 56.6)	.144	46.3 (40.5 to 52.2)	.999	3.6 (-3.9 to 11.2)	.343
6M	51.8 (44.5 to 59.1)	.036	42.9 (36.7 to 49.0)	.219	9.4 (1.6 to 17.1)	.018
Internal rotation						
Preinjection	10.4 (9.5 to 11.2)		10.4 (9.5 to 11.3)			
1W	10.6 (9.7 to 11.5)	.423	10.3 (9.3 to 11.4)	.830	0.3 (-0.7 to 1.3)	.571
1M	10.6 (9.9 to 11.4)	.285	10.8 (9.9 to 11.8)	.305	-0.2 (-1.5 to 1.0)	.702
3M	10.7 (9.6 to 11.9)	.520	10.7 (9.6 to 11.8)	.513	0.0 (-1.3 to 1.4)	.954
6M	10.8 (9.9 to 11.7)	.279	10.6 (9.4 to 11.8)	.714	0.2 (-1.2 to 1.6)	.776

Abbreviation: PRP, platelet-rich plasma.

<sup>\*</sup>Comparison between the baseline and each time point

<sup>†</sup>Comparison of mean difference in change from baseline between the PRP and steroid groups

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Table S3. C. Changes in Strength of the Rotator Cuff Muscles after PRP and Steroid Injection

Variable	Allogeneic PRP(n=30) Mean (95%CI)	P Value*	Steroid (n=30) Mean (95%CI)	P Value*	Between - group mean difference (baseline adjusted)	<i>P</i> Value <sup>†</sup>
Supraspiatus						
Preinjection	9.1 (6.5 to 11.6)		8.5 (6.5 to 10.5)			
1W	9.8 (7.7 to 11.9)	.153	9.9 (7.7 to 12.1)	.036	-0.6 (-2.3 to 1.0)	.438
1M	9.9 (7.9 to 11.9)	.139	10.8 (9.0 to 12.6)	.003	-1.5 (-3.4 to 0.5)	.153
3M	10.7 (8.3 to 13.1)	.009	9.6 (7.7 to 11.5)	.242	0.5 (-1.6 to 2.7)	.617
6M	10.8 (8.4 to 13.2)	.042	9.2 (7.4 to 10.9)	.447	1.1 (-1.1 to 3.4)	.322
Infraspinatus						
Preinjection	8.3 (6.7 to 9.9)		8.4 (6.4 to 10.3)		-0.1 (-1.8 to 1.5)	.861
1W	9.1 (7.2 to 11.0)	.125	9.3 (7.3 to 11.3)	.121	-0.3 (-2.3 to 1.6)	.732
1M	9.6 (7.9 to 11.2)	.002	10.0 (8.5 to 11.5)	.009	0.9 (-1.2 to 3.0)	.414
ЗМ	9.8 (7.7 to 11.9)	.028	9.0 (7.2 to 10.8)	.466	1.2 (-1.0 to 3.4)	.281
6M	9.8 (7.7 to 11.9)	.077	8.7 (6.8 to 10.5)	.692	-0.1 (-1.8 to 1.5)	.861
Subsacpularis						
Preinjection	12.4 (9.7 to 15.2)		12.3 (9.8 to 14.8)			
1W	12.7 (10.1 to 15.3)	.730	13.3 (10.9 to 15.6)	.189	-0.6 (-2.3 to 1.0)	.438
1M	13.0 (10.6 to 15.4)	.382	14.1 (11.9 to 16.4)	.024	-1.5 (-3. 4 to 0.5)	.153

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3M	14.2 (11.3 to 17.0)	.043	13.8 (11.1 to 16.5)	.139	0.5 (-1.6 to 2.7)	.617
6M	13.5 (10.7 to 16.2)	.250	12.8 (10.5 to 15.0)	.597	1.1 (-1.1 to 3.4)	.322

Abbreviation: PRP, platelet-rich plasma.

<sup>\*</sup>Comparison between the baseline and each time point 
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Table S3. D. Changes of the SPADI, ASES, UCLA, SST, DASH Scores after Platelet-Rich Plasma and Steroid Injection

Variable	Allogeneic PRP(n=30) Mean (95%CI)	P Value*	Steroid (n=30) Mean (95%CI)	P Value*	Between - group mean difference (baseline adjusted)	<i>P</i> Value <sup>†</sup>
SPADI						
Preinjection	35.7 (28.6 to 42.7)		34.7 (30.8 to 38.6)			
W	36.6 (27.8 to 45.3)	.746	25.8 (19.9 to 31.6)	.004	9.8 (1.9 to 17.8)	.016
M	28.6 (20.7 to 36.4)	.020	20.9 (15.6 to 26.1)	<.001	6.8 (-2.8 to 16.3)	.165
<b>SM</b>	25.8 (17.3 to 34.2)	.001	25.3 (17.3 to 33.4)	.015	-0.5(-10.7 to 9.7)	.924
M	17.7 (10.5 to 24.8)	<.001	26.3 (18.1 to 34.6)	.039	-9.6 (-20.2 to 0.9)	.072
ASES						
Preinjection	64.0 (56.7 to 71.2)		63.6 (59.7 to 67.4)			
W	64.7 (56.4 to 73.0)	.784	71.3 (65.3 to 77.4)	.002	-7.1 (-14.4 to 0.3)	.059
М	72.0 (65.0 to 79.0)	.009	78.7 (72.5 to 84.9)	<.001	-7.1 (-16.1 to 1.8)	.118
BM	75.8 (67.6 to 83.9)	.001	74.1 (66.2 to 82.1)	.006	1.2 (-8.4 to 10.9)	.802
M	81.9 (74.7 to 89.1)	<.001	73.5 (65.7 to 81.3)	.009	8.0 (-2.0 to 18.0)	.115
JCLA						
Preinjection	19.9 (18.4 to 21.4)		20.6 (19.1 to 22.1)			
W	21.4 (19.4 to 23.5)	.057	25.1 (23.3 to 27.0)	<.001	-3.0 (-5.8 to -0.2)	.037
М	24.3 (21.9 to 26.7)	<.001	27.0 (24.8 to 29.1)	<.001	-1.9 (-5.3 to 1.4)	.247

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3M	23.9 (21.2 to 26.6)	.004	26.1 (23.5 to 28.7)	<.001	-1.5 (-5.0 to 2.0)	.400
6M	26.3 (23.6 to 29.0)	<.001	26.0 (23.6 to 28.3)	<.001	1.1 (-2.5 to 4.6)	.563
SST						
Preinjection	7.6 (6.6 to 8.6)		7.1 (6.4 to 7.8)			
1W	7.8 (6.0 to 9.6)	.790	7.7 (6.6 to 8.7)	.244	-0.4 (-1.8 to 1.1)	.624
1M	8.0 (6.9 to 9.2)	.233	9.3 (7.9 to 10.7)	.001	-1.8 (-3.5 to 0.0)	.049
3M	8.0 (6.8 to 9.3)	.430	8.7 (7.5 to 9.9)	.014	-1.1 (-3.0 to 0.7)	.228
6M	9.7 (8.5 to 10.9)	.003	8.2 (6.8 to 9.6)	.087	1.0 (-0.9 to 2.9)	.297
DASH						
Preinjection	27.3 (21.7 to 33.0)		24.6 (20.5 to 28.6)			
1W	28.5 (22.5 to 34.5)	.531	21.3 (15.8 to 26.8)	.168	4.5 (-2.1 to 11.1)	.183
1M	23.3 (17.9 to 28.6)	.118	15.8 (11.4 to 20.2)	<.001	4.7 (-3.3 to 12.6)	.246
3M	20.3 (13.7 to 26.9)	.022	21.1 (14.2 to 28.0)	.232	-3.5 (-12.0 to 5.0)	.413
6M	14.3 (8.9 to 19.7)	<.001	21.7 (14.7 to 28.7)	.400	-10.1 (-18.9 to -1.4)	.023

Abbreviation: PRP, platelet-rich plasma; SPADI, Shoulder Pain And Disability Index; ASES, American Shoulder and Elbow Surgeons; UCLA, University of California at Los Angeles; SST, Simple Shoulder Test; DASH, Disabilities of the Arm, Shoulder, and Hand Questionnaire.

<sup>\*</sup>Comparison between the baseline and each time point

<sup>&</sup>lt;sup>†</sup>Comparison of mean difference in change from baseline between the PRP and steroid groups

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Table S3. E. Changes of Overall Satisfaction and Function after Platelet-Rich Plasma and Steroid Injection

Variable	Allogeneic PRP (%) Mean (95%CI)	P Value*	Steroid (%) Mean (95%CI)	P Value*	Between - group mean difference (baseline adjusted)	<i>P</i> Value <sup>†</sup>
Willingness to ι	ındergo injection again					
1W	78.3 (56.3 to 92.5)	NA	84.6 (65.1 to 95.6)	NA	NA	NA
1M	78.3 (56.3 to 92.5)	NA	84.6 (65.1 to 95.6)	NA	NA	NA
ЗМ	82.6 (61.2 to 95.0)	NA	76.9 (56.4 to 91.0)	NA	NA	NA
6M	82.6 (61.2 to 95.0)	NA	65.4(44.3 to 82.8)	NA	NA	NA
Γo recommend	injection to another					
IW	73.9 (51.6 to 89.6)	NA	84.6 (65.1 to 95.6)	NA	NA	NA
М	78.3 (56.3 to 92.5)	NA	84.6 (65.1 to 95.6)	NA	NA	NA
M	82.6 (61.2 to 95.0)	NA	76.9 (56.4 to 91.0)	NA	NA	NA
iM	78.3 (56.3 to 92.5)	NA	69.2(48.2 to 85.7)	NA	NA	NA
Can't work due	to pain					
Preinjection	95.7 (78.1 to 99.9)		80.8 (60.6 to 93.4)			
W	91.3 (72.0 to 98.9)	.564	76.9 (56.4 to 91.0)	.706	-0.5 (-25.2 to 24.2)	.968
М	95.7 (78.1 to 99.9)	.999	84.6 (65.1 to 95.6)	.706	-3.9 (-27.1 to 19.4)	.746
M	95.7 (78.1 to 99.9)	.999	92.3 (74.9 to 99.1)	.083	-11.5(-28.7 to 5.7)	.189

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6M	82.6 (61.2 to 95.0)	.180	88.5 (69.8 to 97.6)	.317	-20.7 (-44.3 to 2.8)	.084
Overall function						
Preinjection	47.0 (39.0 to 54.9)		53.1 (44.5 to 61.7)			
1W	47.8 (38.1 to 57.6)	.842	61.2 (55.1 to 67.2)	.061	-0.7 (-2.1 to 0.6)	.289
1M	51.5 (42.6 to 60.4)	.384	64.4 (57.3 to 71.5)	.019	-0.7 (-2.2 to 0.8)	.379
3M	58.3 (47.9 to 68.7)	.067	60.4 (50.6 to 70.2)	.251	0.4 (-1.2 to 2.0)	.615
6M	70.0 (60.8 to 79.2)	<.001	57.3 (46.6 to 68.1)	.453	1.9 (0.3 to 3.5)	.020
Overall satisfaction	on					
1W	43.5 (29.8 to 57.1)	NA	59.2 (49.0 to 69.4)	NA	NA	NA
1M	57.6 (45.6 to 69.6)	NA	67.9 (58.8 to 76.9)	NA	NA	NA
3M	52.6 (38.9 to 66.4)	NA	64.6 (53.5 to 75.8)	NA	NA	NA
6M	67.0 (55.3 to 78.7)	NA	63.5 (52.5 to 74.4)	NA	NA	NA

Abbreviation: PRP, platelet-rich plasma; NA, not available

<sup>\*</sup>Comparison between the baseline and each time point †Comparison of mean difference in change from baseline between the PRP and steroid groups

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