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Original article

Autologous Conditioned Plasma for tendon healing following arthroscopic rotator cuff repair. Prospective comparative assessment with magnetic resonance arthrography at 6 months' follow-up

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ABSTRACT

Introduction: Despite improvements in technique and materials for rotator cuff repair, mean re-tear rates remain close to 30%. The aim of the present study was to assess injection of Autologous Conditioned Plasma (ACP™, Arthrex) for tendon healing after arthroscopic repair. The study hypothesis was that ACP™ improves the tendon-healing rate.
Material and method: A non-randomized comparative prospective study included all patients aged over 18 years operated on in 2010 for arthroscopic repair of full-thickness rotator cuff tear with ≤ 2 fatty degeneration on the Goutallier classification, whatever the severity of retraction, on virgin non-osteoarthritic shoulder without contraindications for magnetic resonance (MR) arthrography. The surgical protocol was standardized. The first half of the patient sample received end-of-procedure ACP™ injection to the repaired tendon, tuberosity freshening surface and subacromial space, and the second (control) half received no supplementary treatment. The main endpoint was tendon healing on MR arthrography at 6 months according to Sugaya. Secondary endpoints comprised shoulder pain at rest on a numerical scale (0 = no pain to 10 = worst imaginable pain) and Constant functional score.
Results: Two of the 58 patients refused MR arthrography and 7 were lost to follow-up. Forty-nine patients (26 ACP™, 23 controls) were analyzed: 20 male, 29 female; mean age, 61 ± 7.3 years. There were no significant intergroup differences in healing rate at 6 months (ACP™ 73.1% vs. 78.3% controls; $p = 0.75$), shoulder pain (2 ± 1.8 vs. 2.6 ± 1.7, respectively; $p = 0.24$), or Constant score ($77 \pm 13.5/100$ vs. 72.4 ± 12.3, respectively; $p = 0.18$).
Conclusion: Associating ACP™ did not improve healing after arthroscopic rotator cuff repair. Sample size, however, had been calculated for a large expected difference, leading to lack of power.
Level of evidence: III; case-control study.

1. Introduction

Rotator cuff pathology is frequent and potentially disabling [1]. Only some tears are really symptomatic [2]; surgical repair is recommended in case of pain and/or functional impairment [3]. Several techniques, open or arthroscopic, are available, and no superiority had been established [4].

Causes of healing failure are controversial. According to the literature review by Mall et al., factors comprise a generally unfavorable diathesis associated with advanced age, large tear, and fatty infiltration [5]; but no particular surgical technique showed superiority in regard to rotator cuff tendon structure healing.

Platelet-rich plasma (PRP) seems to improve healing and is widely used in orthopedic and sports surgery. Several experimental studies reported improved healing in various animal models [6–9]. A recent meta-analysis of 18 randomized comparative studies found that PRP improved healing, pain and postoperative function following rotator cuff repair [10], although results varied according to the type of PRP. Mazocca et al. demonstrated that Autologous

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Conditioned Plasma (ACP™) contained significantly fewer platelets and growth factors than other PRPs [11].

The aim of the present study was to assess the impact of injection of ACP™ (Arthrex) on tendon healing after arthroscopic rotator cuff repair. The study hypothesis was that ACP™ improves tendon-healing rates.

2. Materials and methods

A non-randomized comparative prospective study was conducted in 2010 over 2 successive 6-month periods. Patients' consent was obtained.

2.1. Selection criteria

Inclusion criteria comprised: age > 18 years, full-thickness tear of 1, 2 or 3 rotator cuff tendons, fatty degeneration ≤ 2 on the Goutallier classification [12], regardless of retraction severity according to Patte [13], and repair under arthroscopy. Exclusion criteria comprised: history of inflammatory rheumatoid pathology and/or of surgery to the operated shoulder, radiologic or arthroscopic signs of osteoarthritis in the operated shoulder, contraindications to MR arthrography (pace-maker, mechanical cardiac valve, claustrophobia, ocular metallic foreign body, history of allergic reaction to contrast medium), and rotator cuff tear found intraoperatively to be inoperable.

Two groups were constituted according to 2 successive 6-month periods. The first half of the population received end-of-procedure ACP™ injection to the repaired tendon, tuberosity freshening surface and subacromial space; the second (control) group had no supplementary treatment.

2.2. ACP™ preparation technique

ACP™ production was developed by Arthrex® (Naples, FL, USA). Preparation began at the beginning of surgery: 1 cc Anticoagulant Citrate Dextrose A (ACD-A) was loaded in a double syringe to avoid sample coagulation, then 9 cc blood was taken from the non-operated arm. The double syringe was then closed and placed in a centrifuge for 5 minutes' centrifugation at 1500 rpm. Plasma supernatant was identified and aspirated into the second syringe. Total preparation time was 10 to 15 min, with amounts ranging from 3 to 5 cc.

2.3. Surgical technique

All surgery was ambulatory, with arthroscopic repair performed by a single senior surgeon. Patients were under general anesthesia with interscalene block, in lateral decubitus with 3 kg traction along the axis of the limb in 30° abduction and 15° antepulsion. Joint exploration used a 30° arthroscope. Shoulder pressure was held between 50 and 60 mmHg by arthropump. Tenotomy or tenodesis of the long head of the biceps systematically used an anterior approach through the rotator interval. Any subscapularis lesion was repaired after freshening the lesser tuberosity. Tear debridement used an anterolateral approach, as did greater tuberosity freshening down to the subchondral bone. Subacromial bursectomy systematically used the anterolateral approach. Repair used 5.5 or 6.5 mm Bio Corkscrew® screwed anchors (Arthrex®, Naples, FL, USA). A second row was systematically applied in suture-bridge by 4.5 mm PushLock anchors (Arthrex®, Naples, FL, USA). Anterior acromioplasty was systematic for all Bigliani type 2 or 3 acromia [14].

In the ACP™ group, the arthroscope was left in subacromial position above the repair at end of procedure and physiological saline was removed from the shoulder. ACP™ was then injected by a 21-gauge intramuscular needle (Néolus, Térumo, Guyancourt, France) into the repaired cuff, tuberosity freshening surface and subacromial space.

2.4. Postoperative care and follow-up

Systematic postoperative oral non-steroidal anti-inflammatory analgesia (ketoprofen LP 100 mg, morning and evening) was prescribed for a maximum 3 days, associated to a gastric anti-secretion drug (omeprazole 20 mg, evening). The shoulder was immobilized in a non-strict Velpeau jacket (Médisport®, Ruaudin, France). No rehabilitation was undertaken during the first month; a physiotherapist then performed joint mobilization and passive pendular exercises, followed by gentle passive and aided active recovery of range of motion. Exercises against resistance were not performed for the first 3 months; active exercises were then initiated to recover range of motion by concentric and excentric contraction without restriction in abduction, with maximal loading adapted to pain.

Clinical assessment by an independent observer was performed at 1, 3 and 6 months, with MR arthrography at 6 months.

2.5. MR arthrography protocol

Anatomic assessment on arthrography and MR arthrography (1.5 Tesla, Gyroscan Intera T15, Philips Medical Systems, Best, Netherlands) was performed at 6 months.

First, arthrography was performed, using a mixture of 6 ml ioxaglic acid 320, 4 ml gadoteric acid and 1 ml adrenaline, injected into the joint deltopectorally. The MR arthrography protocol comprised coronal T1 and T2 fat-sat, axial T1 and T2 fat-sat, axial T1 and sagittal T2 sequences.

Radiologic assessment was performed by an independent radiologist specialized in osteoarticular imaging and an orthopedic surgeon, blind to treatment status. In case of disagreement, a third interpretation was made by the two observers plus the senior orthopedic surgeon who had performed the operation.

2.6. Endpoints

The main endpoint was tendon healing, defined as absence of major rotator cuff discontinuity on MR arthrography (Sugaya type V [15]) at 6 months.

Secondary endpoints comprised: pain at rest on a numerical scale (from 0 = no pain to 10 = worst imaginable pain), Constant functional score (/100) [16] and insertion quality (Sugaya [15] index: types I-IV) on MR arthrography at 6 months.

2.7. Statistical analysis

A minimum 46 (23 + 23) subjects was calculated to be required to detect a 45% clinically relevant intergroup difference in tendon healing, with 90% power and alpha risk of 0.05. Non-parametric tests were used: Mann–Whitney and Wilcoxon for quantitative variables and Fisher exact test for qualitative variables. Factors for healing were analyzed on univariate analysis; no multivariate analysis was attempted, in view of sample size. The significance threshold was set at $p < 0.05$.

3. Results

3.1. Description of patients

Fifty-eight of the 70 eligible patients were included, and 49 analyzed: 26 ACP™, 23 controls (Fig. 1).

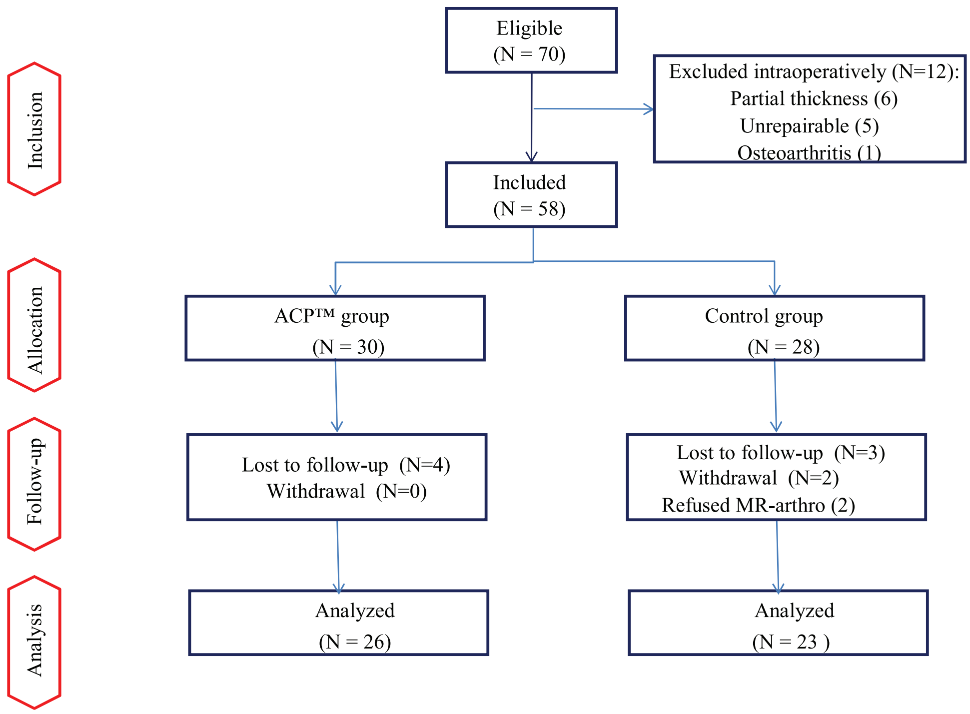

Fig. 1. Study flowchart.

Table 1
Preoperative data.

	ACP™ group ($n = 26$)	Control group ($n = 23$)	p
Mean age (years)	60.9 ± 7.7 (47–77)	61.1 ± 6.8 (48–72)	0.84
Gender	Male 10 (38.5%) Female 16 (61.5%)	Male 10 (48.5%) Female 13 (56.5%)	0.78
Dominant side	20 (76.9%)	18 (78.3%)	1
Risk-related history	3[a] (11.5%)	6[b] (26.1%)	0.27
Occupational status	Active 13 (50%) Retired 12 (46.2%) Unemployed 1 (3.8%)	Active 11 (47.8%) Retired 11 (47.8%) Unemployed 1 (4.4%)	1
Regular sports activity	15 (57.7%)	10 (48.5%)	0.40
Traumatic etiology	1 (3.9%)	2 (8.7%)	0.59
Preoperative Constant score	53.5 ± 11.7	54.1 ± 7.2	0.57
Preoperative pain (/10)	5.6 ± 1.8	6.1 ± 1.2	0.33
Frontal tendon retraction according to Patte [13]	Proximal (slight) 9 (34.6%) Intermediate 10 (38.5%) Up to shoulder 7 (26.9%)	Proximal (slight) 9 (39.1%) Intermediate 11 (47.8%) Up to shoulder 3 (13.1%)	0.49
Acromion morphology according to Bigliani [14]	Flat 7 (26.9%) Curved 14 (53.9%) Hooked 5 (19.2%)	Flat 6 (26.1%) Curved 14 (60.9%) Hooked 3 (13%)	0.92
Acromioplasty	19 (73.1%)	17 (73.9%)	0.94
Tendon lesions	Isolated supraspinatus 21(80.8%) 2 tendons 3 (11.5%) 3 tendons 2 (7.7%)	Isolated supraspinatus 17 (73.9%) 2 tendons 4 (17.4%) 3 tendons 2 (8.7%)	0.84
Fatty infiltration according to Goutallier et al. [12]	Grade 0: 0% Grade 1: 15 (57.7%) Grade 2: 11 (42.3%) Grade 3: 0% Grade 4: 0%	Grade 0: 3 (13.1%) Grade 1: 9 (39.1%) Grade 2: 11 (47.8%) Grade 3: 0% Grade 4: 0%	0.12

[a] 2 smokers (> 10 cigarettes/day) and 1 type-2 diabetic.
[b] 4 smokers (inc. 2 > 10 cigarettes/day), and 2 type-2 diabetics.

Table 2
Tendon healing on Sugaya index [15] on MR arthrography at 6 months.

Sugaya type	ACP™ group(n = 26)	Control group(n = 23)	p
Sufficient thickness and homogeneous hyposignal	0 (0%)	1 (4.3%)	0.80
Sufficient thickness and heterogeneous hyposignal	12 (46.2%)	9 (39.1%)	
Thin tendon insertion	4 (15.4%)	6 (26.1%)	
Minor discontinuity	3 (11.5%)	2 (8.7%)	
Major discontinuity	7 (26.9%)	5 (21.7%)	

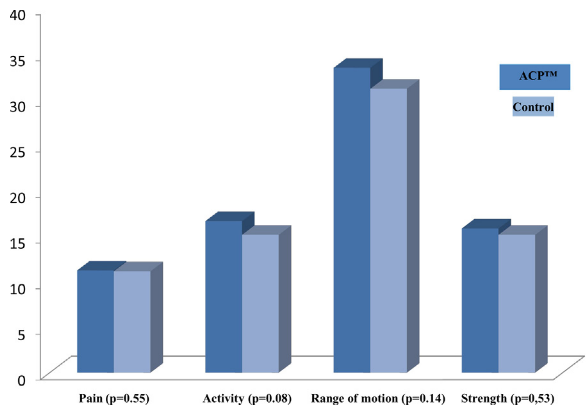

Fig. 2. Mean Constant score at 6 months by sub-items and group.

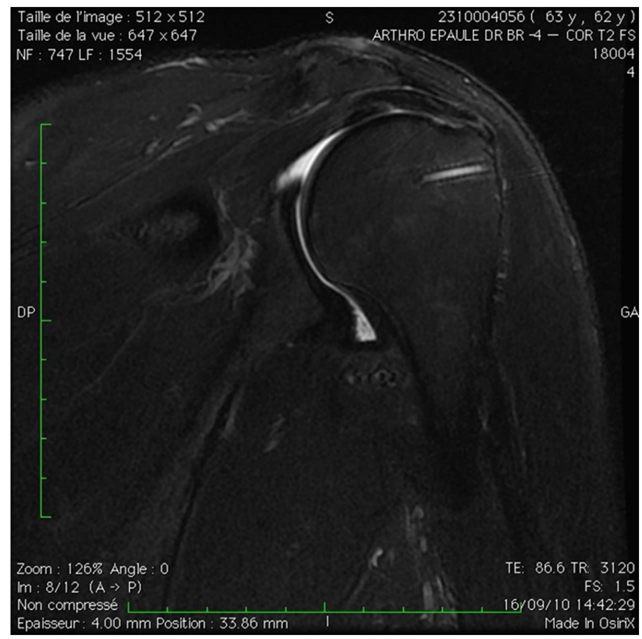

Fig. 3. Example of healing at 6 months in ACP™ group, Sugaya type 2.

Patients had had shoulder pain for a mean 14 months (range 4–36 months). All had had full medical treatment, with rehabilitation and at least 1 corticosteroid injection. Groups were comparable at inclusion (Table 1).

3.2. Main endpoint

There was no significant intergroup difference in tendon healing: Sugaya types I-IV, 19/26 (73.1%) in ACP™ group vs. 18/23 (78.3%) in controls; $p = 0.75$.

3.3. Secondary endpoints

There were no significant intergroup differences at 6 months in shoulder pain at rest ($2 \pm 1.8/10$ in ACP™ group vs. $2.6 \pm 1.7/10$ in controls; $p = 0.24$), total Constant score ($77 \pm 13.5/100$ vs. $72.4 \pm 12.3/100$, respectively; $p = 0.18$), Constant per sub-item (Fig. 2) or tendon healing quality on MR arthrography (Table 2, Fig. 3).

All patients showed improvement at 6 months for shoulder pain at rest ($5.8 \pm 1.6/10$ vs. $2.2 \pm 1.8/10$; $p < 0.00001$) and total Constant score ($53.8 \pm 9.7/100$ vs. $74.8 \pm 13/100$; $p < 0.00001$).

3.4. Factors for tendon healing

On univariate analysis, patients with healed tendons were significantly younger (58.4 ± 6.1 years vs. 69 ± 3.7 years; $p < 0.00001$), with better preoperative Constant score (56 ± 9.6 vs. 47.1 ± 6.9; $p = 0.004$), proximal (i.e., slight) preoperative retraction according to Patte [13] (46% vs. 8.3%; $p = 0.02$) and Goutallier [12] grade 0 or 1 preoperative fatty infiltration (70.3% vs. 8.3%; $p < 0.0001$). Gender, smoking status, diabetes and type of tear were not significantly related to healing ($p > 0.20$).

4. Discussion

The present prospective non-randomized comparative study showed that associating Autologous Conditioned Plasma (ACP™) provided no extra benefit in terms of tendon healing, function or pain at 6 months after arthroscopic rotator cuff repair. Sample size, however, had been calculated for an expected 45% difference, which was doubtless overambitious, leading to lack of power.

According to the meta-analysis by Hurley et al. [10], platelet-rich plasma improved tendon healing (30.5% vs. 17.2%) and functional results after surgical rotator cuff repair. None of the 3 randomized comparative studies of ACP™ in the literature reported efficacy. Hak et al. [17] found no difference in 6-week functional results in 25 patients with intraoperative injection of ACP™ versus saline serum, and the study was terminated prematurely. Wang et al. [18] reported on 60 patients, 30 in the ACP group and 30 controls, with MRI at 4 months; ACP was administered in 2 injections under ultrasound control, at 7 and 14 days; there were no significant differences in functional results at 6, 12 and 16 weeks or in tendon healing on MRI. Flury et al. [19] compared functional results and tendon healing on MRI at 2 years in 54 control patients and 49 patients with intraoperative ACP injection, and again found no significant differences. In the present study, patients with healed tendons were significantly younger, with better preoperative shoulder function, minimal tendon retraction and almost no fatty infiltration.

One explanation for discordance between in-vitro and in-vivo results for PRP in tendon healing may concern PRP composition and presentation. PRPs are produced from autologous blood samples. According to Kaux et al. [20], 0.6–1.2 ml PRP can be derived from 10 ml blood, with a mean platelet concentration of 741,000/μl, 3-fold higher than in the patient's blood. Bohu et al. [21] compared platelet concentrations between ACP and total blood in 14 patients, and found a low mean ratio of 1.6, with white and red cell counts below the limit of detection. High-concentration solutions, however, may induce paradoxical effects in the long term: Chan et al. [22] reported accelerated but fibrotic cicatrization in treated muscle tissue, incurring a risk of re-tear. The form of the PRP also plays a role in time of action: liquid forms are highly effective for 24 h, gel dissolves by 5 days in vitro, while the fibrin matrix of L-PRF prolongs activity beyond 7 days' culture [23]. Mesenchymal stem cells and gene therapy may offer a promising solution [24].

The choice of imaging technique was guided by our usual practice and the main endpoint: healing. MR arthrography is the most sensitive method for detecting rotator cuff tear and assessing tendon-healing quality. Matava et al. [25] reported 84% sensitivity, 96% specificity and 91% precision.

The present study showed several limitations:

- sample size was calculated for an overambitious difference, leading to lack of power;
- treatment groups were not randomized; however, the groups were comparable at inclusion, and all patients within each study period received the same treatment;
- a maximum 3 days' postoperative analgesia by oral non-steroidal anti-inflammatory drugs was systematic and may have reduced the impact of ACP™;
- follow-up was shorter than in most other studies of the topic. As the main endpoint was tendon healing, 6 months' follow-up was sufficient to address the study question. Kluger et al. [26], in a cohort study of 95 arthroscopic or open rotator cuff repairs with 7–11 years' follow-up, found that the great majority (74%) of re-tears occurred within 3 months, with 11% between 3 and 6 months; unlike in previous studies, all types of rotator cuff tear were included, reflecting usual practice in shoulder surgery;
- ACP composition was not analyzed; in a previous study, however, Bohu et al. [21] showed that platelet concentration was significantly higher in ACP than in total blood, with no white or red blood cells.

5. Conclusion

In the present study, Autologous Conditioned Plasma (ACP™) failed to improve tendon healing or function following arthroscopic rotator cuff repair at 6 months. However, the sample size, calculated for an expected difference of 45%, was probably overambitious, leading to lack of power.

Disclosure of interest

P. Hardy and T. Bauer are consultants for Arthrex and Zimmer. The others declare that they have no competing interest.

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None.

Author contributions

J.C. Aurégan: article writing.

S. Klouche: study methodology, statistical analysis and article writing.

B. Lévy: investigating surgeon.

T. Bauer: investigating surgeon.

B. Rousselin: radiologist, investigator and MR arthrography analysis.

M. Ferrand: data collection, patient follow-up and MR arthrography analysis. P. Hardy: principal investigating surgeon and MR arthrography analysis.

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