Cell and Organ Transplantology
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КЛІТИННА ТА ОРГАННА ТРАНСПЛАНТОЛОГІЯ | КЛІТИННА ТА ОРГАННА ТРАНСПЛАНТОЛОГІЯ

ORIGINAL RESEARCH
Cell and Organ Transplantology. 2026; 14(1):e2026141187
https://doi.org/10.22494/cot.v14-1.187

Comparative analysis of clinical outcomes following regenerative injection therapy with autologous platelet concentrates in patients with partial rotator cuff tears

Strafun S., Holiuk Ye., Magomedov S., Sokolov I., Maslova T., Ivanova O.
[1]*National Institute of Traumatology and Orthopedics, National Academy of Medical Sciences of Ukraine, Kyiv, Ukraine*
**Corresponding author's e mail: holyuk@yahoo.com*

Abstract

In recent decades, there has been a growing interest in the use of stem cells and other biotechnological products aimed at enhancing tendon and tendon-bone junction repair and regeneration.

***Aim**. To compare the clinical efficacy of platelet-rich plasma (PRP) and platelet lysate in patients with partial rotator cuff tears of the shoulder.*

***Materials and methods**. This study analyzed clinical outcomes of regenerative injection therapy in 73 patients with shoulder pathology associated with partial rotator cuff tears. Depending on the type of biotechnological product used, patients were divided into two groups: Group 1 (n = 29) received intra-articular injection of leukocyte-poor platelet-rich plasma (LP-PRP), and Group 2 (n = 44) – platelet lysate. Diagnosis and confirmation of rotator cuff pathology were based on magnetic resonance imaging (MRI). Ultrasound guidance was used for the injection of the biotechnological products. Clinical outcomes and quality of life were assessed using the UCLA Shoulder Score, Oxford Shoulder Score (OSS), and the Visual Analogue Scale (VAS). Evaluations were performed before treatment and at 3, 6, and 12 months after treatment.*

***Results**. The analysis demonstrated a significant improvement in function and pain reduction as early as 3 months after treatment with autologous platelet concentrates (platelet lysate and LP-PRP) in patients with partial rotator cuff tears ($p < 0.05$) according to the UCLA, OSS, and VAS scales. At 12 months, clinical outcomes were significantly better in the group treated with regenerative injection therapy using platelet lysate compared with the LP-PRP group, as reflected by UCLA, OSS, and VAS scores ($p < 0.05$).*

***Conclusions**. Platelet lysate demonstrated advantages over leukocyte-poor platelet-rich plasma in terms of long-term pain relief and functional recovery of the shoulder joint over a 12-month follow-up period after treatment.*

***Keywords**: regenerative injection therapy; shoulder joint; rotator cuff tear; autologous platelet concentrates; platelet-rich plasma; platelet lysate*

Introduction

Pain in the shoulder and elbow resulting from degenerative diseases and post-injury conditions is a common clinical problem associated with substantial socioeconomic burden and prolonged work disability, including among military personnel. For example, from 2000

to 2015, direct healthcare expenditures related to shoulder injuries in the United States alone were estimated at approximately 7 billion USD. These conditions are multifactorial and may arise from disorders such as bursitis, tendinitis, rotator cuff tears, adhesive capsulitis, avascular necrosis, osteoarthritis, or subacromial impingement syndrome. All of these pathologies significantly impair occupational performance and quality of life in both civilian populations and military personnel.

In particular, rotator cuff pathology is one of the most prevalent musculoskeletal disorders worldwide and represents the leading cause of shoulder pain complaints [1]. The prevalence of shoulder disorders in primary care settings in the United Kingdom is approximately 2.4 % [2], and rotator cuff pathology accounts for 30–70 % of all cases of shoulder pain [3]. Intrinsic risk factors contributing to rotator cuff injury include age, obesity, smoking, diabetes mellitus, genetic predisposition, and anatomical variations of the subacromial space [4]. Among these, age is considered the dominant factor associated with both the incidence and progression of rotator cuff degeneration. While intrinsic factors reduce the structural integrity of the tendon, extrinsic factors such as occupational load and sports-related activity may lead to excessive mechanical stress, contributing to rotator cuff injury [5].

In tendon pathology models, mechanical loading plays a critical role in the development of degenerative changes [6], and repetitive biomechanical stress significantly increases the risk of tendon injury [7]. Rotator cuff lesions often begin as tendinopathy and may progressively evolve into partial or full-thickness tendon tears, resulting in pain and functional impairment [8]. In most cases, tendinopathy does not initially cause severe disability; therefore, conservative management, including physiotherapy and analgesic treatment, is recommended as first-line therapy [9]. However, patients with tendinopathy have an increased risk of tendon rupture, which further rises with age [10]. Acute shoulder trauma may also result in partial or complete tendon tears requiring surgical intervention.

A systematic review including 15 studies (371 patients) reported a 43 % failure rate within 12 months after rotator cuff repair, with rates reaching up to 90 % in elderly populations [11, 12]. Postoperative recovery following arthroscopic rotator cuff repair typically requires several months, and athletes often need more than 6 months to return to training [13]. Additionally, scar tissue formation at the injury site may lead to adhesions and joint stiffness, impairing biomechanical properties and increasing the risk of re-tear [14].

In response to these challenges, there has been growing interest over the past decade in regenerative injection therapies using platelet concentrates to enhance tendon and tendon-bone junction repair and regeneration [15-19].

Therefore, the present study is relevant from both theoretical and practical perspectives, and its findings may contribute significantly to the development of regenerative orthopedics.

Aim of the study – to compare the clinical efficacy of platelet-rich plasma and platelet lysate in patients with partial rotator cuff tears of the shoulder.

Materials and methods

This study was conducted at the Scientific and Practical Center for Regenerative Orthopedics and Innovative Biomedical Technologies of the National Institute of Traumatology and Orthopedics of the National Academy of Medical Sciences of Ukraine during the period from 2021 to 2024. Prior to inclusion in the study, all patients provided written informed consent to participate. The study was performed in accordance with the principles of bioethics (Protocol No. 1 of the Bioethics Committee dated 11 January 2021).

Patient characteristics. Patients with partial rotator cuff tears of the shoulder were included in the study. The mean age of the patients was 49.0 ± 8.1 years; 33 patients were male and 40 were

female. All patients had declined surgical treatment. Diagnosis of rotator cuff injury was confirmed by magnetic resonance imaging (MRI).

Depending on the type of regenerative injection therapy, patients were divided into two groups: Group 1 included 29 patients treated with leukocyte-poor platelet-rich plasma (LP-PRP), and Group 2 included 44 patients treated with autologous platelet lysate. The preparation methods of the biological products have been described in detail in our previous publications [20]. Each patient received six injections of 3 mL of the biotechnological product at 7-day intervals; thus, the treatment course consisted of six injections in total. All injections were performed exclusively under ultrasound guidance.

Outcome measures. The subjective functional status of the shoulder was assessed using the UCLA (University of California, Los Angeles) Shoulder Score, which evaluates pain, functional activity, muscle strength, range of motion, and overall patient satisfaction. The total score ranges from 0 to 35, where lower scores indicate severe dysfunction and functional limitation, whereas higher scores indicate minimal symptoms and satisfactory functional recovery. The questionnaire consists of both a patient-reported component and a physician-assessed component [21].

The 60-point Oxford Shoulder Score (OSS) was also used [22]. This questionnaire includes 12 items addressing pain, limitations in activities of daily living such as dressing and lifting objects, as well as the impact of shoulder condition on sleep and social activities. The total score ranges from 12 to 60, where 60 indicates maximal dysfunction and 12 corresponds to the absence of symptoms and optimal shoulder function.

Pain intensity was assessed using the Visual Analogue Scale (VAS), allowing patients to self-rate pain severity from 0 (no pain) to 10 (worst possible pain) [23].

Patients completed all questionnaires at baseline and during follow-up at 3, 6, and 12 months after treatment.

Statistical analysis. Statistical analysis was performed using Microsoft Excel software (*Microsoft*, USA). Quantitative data were expressed as mean (M) ± standard deviation (σ). Intergroup comparisons and longitudinal changes were analyzed using the nonparametric Mann–Whitney U test.

Results and discussion

Table 1 presents the dynamics of clinical outcomes during the follow-up period according to the UCLA Shoulder Score, depending on the type of biotechnological product.

Table. 1. Dynamics of clinical outcomes during the follow-up period according to the UCLA Shoulder Score, depending on the type of biotechnological product used in Group 1 (leukocyte-poor PRP) and Group 2 (platelet lysate), M ± σ.

UCLASS	**Follow-up period**							
	Before treatment		**3 months**		**6 months**		**12 months**	
Group	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**
Total score, points	15.8 ± 4.6	16.1 ± 5.4	21.2 ± 3.6	23.7 ± 4.1*	26.1 ± 2.3*	26.5 ± 3.3*	23.6 ± 2.2*	31.9 ± 2.6*#
Pain score	2.5 ± 0.4	2.3 ± 0.5	4.6 ± 0.5*	4.9 ± 0.6*	6.1 ± 0.9*	6.3 ± 0.6*	6.9 ± 0.8*	9.1 ± 0.7*#
Joint function score	3.1 ± 0.3	3.3 ± 0.4	5.2 ± 0.4*	5.3 ± 0.4*	6.7 ± 0.3*	7.0 ± 0.5*	6.9 ± 0.4*	9.2 ± 0.5*#
Joint stiffness score	2.4 ± 0.6	2.2 ± 0.7	3.2 ± 0.5*	3.4 ± 0.6*	3.4 ± 0.4*	3.7 ± 0.4*	3.6 ± 0.6*	4.4 ± 0.5*#

Activity and mobility score	1.7 ± 0.7	1.5 ± 0.5	2.5 ± 0.4*	2.6 ± 0.6*	3.1 ± 0.5*	3.3 ± 0.3*	3,6 ± 0.3*	4.5 ± 0.2*#
Patient satisfaction	0	0	1.5 ± 0.4*	1.6 ± 0.6*	2.9 ± 0.5*	3.3 ± 0.3*	3.5 ± 0.3*	4.6 ± 0.3*#

*Notes: * $p < 0.05$ compared with baseline values; # $p < 0.05$ compared with Group 1.*

Thus, the analysis of Table 1 shows that prior to treatment the overall UCLA score was markedly reduced and did not differ significantly between the groups ($p > 0.05$).

Under both treatment approaches, an improvement in overall shoulder joint function was observed throughout the follow-up period; however, the dynamics differed between the study groups. At 3 months, a greater improvement in shoulder function was observed in Group 2 compared with Group 1. At 6 months, no statistically significant difference in overall shoulder function was detected between the groups. At 12 months, a significant difference in the overall UCLA score was observed between Groups 1 and 2 in favor of patients in Group 2.

The dynamics of treatment outcomes in patients with shoulder joint injuries were further evaluated using the Oxford Shoulder Score, depending on the type of biotechnological product. Table 2 presents the results assessing subjective shoulder function with an emphasis on activities of daily living and patient-reported well-being. Before treatment, the scores in both groups did not differ significantly, indicating a high level of patient dissatisfaction with shoulder function.

Table 2. Dynamics of treatment outcomes in patients depending on the type of biotechnological product according to the OSS, at baseline, and at 3, 6, and 12 months after treatment (Group 1 – leukocyte-poor platelet-rich plasma; Group 2 – platelet lysate), M ± σ.

Follow-up period	**Group 1**	**Group 2**
Before treatment	31.8 ± 5.1	34.2 ± 4.8
3 months	18.2 ± 4.4*	16.2 ± 3.8*
6 months	20.1 ± 4.1*	17.1 ± 3.6*
12 months	29.5 ± 3.4*	15.8 ± 3.9*#

*Notes: * $p < 0.05$ compared with baseline values; # $p < 0.05$ compared with Group 1.*

At 3 months after treatment, a marked reduction in OSS scores was observed in both study groups, with no significant difference between them, indicating the effectiveness of both treatment modalities. At 6 months, a slight deterioration in shoulder joint function was noted in both groups. At 12 months, a significant difference between the two groups was observed. The results indicate that platelet lysate therapy provides superior long-term improvement in daily activity and patient-reported well-being compared with leukocyte-poor PRP.

Table 3 presents the dynamics of treatment outcomes in patients with shoulder joint injuries depending on the type of biotechnological product, assessed using the Visual Analogue Scale.

Table 3. Dynamics of treatment outcomes in patients depending on the type of biotechnological product according to the VAS (Group 1 – leukocyte-poor platelet-rich plasma; Group 2 – platelet lysate), M ± σ.

Follow-up period	**Group 1**	**Group 2**
Before treatment	7.8 ± 0.7	8.0 ± 0.6
3 months	5.1 ± 1.1	4.8 ± 0.9*
6 months	4.5 ± 1.0*	4.3 ± 1.1*
12 months	4.2 ± 1.2*	2.2 ± 1.0*#

*Notes: * $p < 0.05$ compared with baseline values; # $p < 0.05$ compared with Group 1.*

Before treatment, pain intensity was high in both groups. At 3 months after treatment, a reduction in pain severity was observed in both groups. At 6 months, a further decrease in pain intensity was noted in both groups, with better results observed in Group 2 compared with Group 1. At 12 months, pain levels in both groups remained lower compared with baseline values; however, the VAS score in Group 2 at 12 months was significantly better than in Group 1.

The widespread implementation of regenerative technologies in trauma and orthopedics has necessitated a personalized approach to their application. One of the key components of this approach is the selection of an appropriate biotechnological product or their combination, depending on the underlying pathology and the individual clinical characteristics of the patient.

Regarding the use of autologous blood-derived biotechnological products as alternatives to platelet-rich plasma (PRP), numerous studies have been conducted in recent years comparing and evaluating the efficacy of different types of platelet concentrates in various pathologies, not limited to trauma and orthopedics [24-29]. The aim of these studies was to determine whether alternative products offer advantages over conventional PRP or to assess their clinical effectiveness. In particular, platelet lysate appears to be a promising option for regenerative injection therapy in musculoskeletal disorders [30]. Its efficacy has been reported in patients with knee osteoarthritis [28] and in patients with rotator cuff injuries of the shoulder [29].

In the study of Markazi et al., forty patients received weekly subacromial injections of platelet lysate (a total of 3 injections), while the control group received two injections of ketorolac administered once every two weeks. Subjective outcome measures included VAS and SPADI scores, as well as shoulder range of motion, assessed at baseline, 1 and 6 months after injection. The results demonstrated a clear superiority of the platelet lysate group across all parameters during the 6-month follow-up period [29].

Thus, the use of platelet concentrates other than standard PRP is both relevant and promising, particularly in patients with shoulder joint pathology. The difference in the effectiveness of different types of autologous platelet concentrates may be due, in particular, to different concentrations of platelets and their growth factors, as well as different kinetics, that is the nature and speed of the release of growth factors during platelet destruction, as evidenced by some of studies [31-33]. It is this aspect that may influence the better effectiveness of platelet lysate compared to standard PRP.

Conclusions

1. The analysis of autologous injectable platelet concentrates (platelet lysate and leukocyte-poor platelet-rich plasma) in patients with partial rotator cuff tears demonstrated a significant improvement in shoulder function and pain reduction as early as 3 months after treatment, according to the UCLA, OSS, and VAS scales.
2. At 12 months after treatment, significantly better outcomes according to the UCLA, OSS, and VAS scales were observed in the group of patients treated with regenerative injection therapy using platelet lysate.

AUTHOR CONTRIBUTIONS. *Conceptualization: S.S.; Methodology: S.S., H.Ye.; Investigation: H.Ye., M.T. – clinical investigations, M.S., I.O. – laboratory investigations ; Formal analysis: H.Ye.; Writing – original draft: H.Ye., S.I.; Writing – review & editing: S.S., H.Ye. All authors approved the final manuscript.*

ARTIFICIAL INTELLIGENCE (AI) USAGE DECLARATION. *The authors declare that no artificial intelligence (AI) tools or generative AI technologies were used in the writing, preparation, analysis, figure creation, or editing of this manuscript. All scientific content was developed exclusively by the authors.*

CONFLICT OF INTEREST STATEMENT. *The authors declare that they have no conflicts of interest related to the research, authorship, and/or publication of this article.*

Received: March 7, 2026
Accepted: May 28, 2026
Published online: May 30, 2026

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