Angel® System for Nonsurgical Approach of cPRP in Upper Extremity

Scientific Information on Unapproved Uses of Cleared Products

The Angel system is not FDA-cleared or approved for use in knee osteoarthritis. Current indications for the Angel system include the use of PRP intraoperatively at the point of care for the safe and rapid preparation of autologous platelet concentrate (platelet-rich plasma) from a small sample of peripheral blood or a small sample of a mixture of peripheral blood and bone marrow. The platelet-rich plasma is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics. Contraindications include blood supply limitations and previous infections, which may retard healing, and/or any active infection or blood supply limitations. Adverse events can include infections, both deep and superficial, allergies and other reactions to device materials, hematoma, damage to blood vessels, and nerve damage resulting in pain or numbness from autologous sampling and/or delayed wound healing. Healthcare providers (HCPs) should exercise clinical judgment and consider FDA-approved treatments before recommending PRP injections for knee osteoarthritis.

As outlined in the FDA's guidance related to Scientific Information on Unapproved Uses (SIUU) of Approved/Cleared Medical Products in January 2025, this SIUU communication serves to provide communications intended for Healthcare Providers (HCP) related to unapproved uses of Arthrex products. This handout is intended for healthcare professionals only. This handout and its contents are to be used for educational purposes only and are not intended for promotional purposes.

Please reach out to the Clinical Advisory Team (CAT@arthrex.com) with any questions about this content.

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CLINICAL STUDIES WITH A POSITIVE OUTCOME

One-shot platelet-rich plasma (PRP) injection is non-inferior to extracorporeal shockwave therapy in the management of supraspinatus tendinosis.

Moretti L, Bizzoca D, Cassano GD, Coviello M, Franchini A, Moretti B

The authors declared that they have no conflicts of interest.

Patients: 142 **Follow-up: 6 months** **Study type: Retrospective cohort study**

Purpose

The aim of the study was to assess the efficacy and safety of a single ultrasound-guided PRP injection for the treatment of supraspinatus tendinosis, compared with widely used shockwave therapy.

Methods

This retrospective cohort study included 72 amateur athletes with supraspinatus tendinosis (ST) who were treated with an intratendinous injection of Angel® cPRP at a 7% HCT setting. All the patients underwent clinical evaluation at baseline (T0), and at 1-month (T1), 3-month (T2), and 6-month (T3) follow-up using the following clinical scales: the Visual Analogue Scale for pain (VAS), the Constant score, and the Disabilities of the Arm, Shoulder and Hand Score (DASH). Ultrasound examinations were also performed in the cPRP group at T0 and T3. The findings in the recruited patients were compared with the clinical results of a retrospective control group of 70 patients treated with extracorporeal shockwave therapy (EWT).

Results

- A significant improvement in VAS, DASH, and Constant scores was observed from T0 to T1. Improvements in clinical outcome scores were maintained through T3. No significant difference was observed in the VAS score between both groups.
- An improvement in the tendon structure was observed on ultrasound examination in the cPRP group.
- No local or systemic adverse events were observed.

Limitations

Limitations of the study include a small sample size and no comparison between single and multiple injections. Additionally, there is no MRI comparison before and after the injection, and the improvement evidenced by the US examination cannot be objectively demonstrated. Furthermore, the follow-up period was short; therefore, long-term effectiveness was not assessed.

> **Conclusion:** In conclusion, considering the benefits of PRP, the one-shot infiltration in the tendon site of the supraspinatus muscle and peritendinous at the subacromial space represents a valid conservative treatment to reduce pain, improve quality of life and functional scores, even at a midterm follow-up of 6 months. Therefore, further investigation and studies are needed in the future about this topic.

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Platelet-rich plasma injection for thumb carpometacarpal joint osteoarthritis.

Hasley IB, Bies MM, Hollman JH, Carta KG, Sellon JL, Brault JS

The authors declared that they have no conflicts of interest.

Patients: 19 | **Follow-up: 32.4 months** | **Study type: Retrospective case series**

Purpose

The aim of the study was to assess the effects of PRP injection among patients with thumb carpometacarpal (CMC) joint osteoarthritis (OA).

Methods

This retrospective case series from a single institution included 19 patients who received a single ultrasound-guided Angel® cPRP injection for the treatment of thumb CMC OA. An average of 116 mL of whole blood was processed in the Angel system at a 1% HCT setting. The patients were identified through a retrospective electronic medical record chart review. Outcome measures included symptom improvement (subjective and Visual Analog Scale), duration of benefit, subsequent procedures, satisfaction, and side effects/adverse events and were based on chart review and follow-up surveys.

Results

- Subjects reported moderate or excellent symptom improvement in 68.8% of injected joints.
- Mean patient reported duration of benefit was 15.6 months (±19.5), with a mean follow-up duration of 32.4 (±18.1) months.
- No major complications or adverse events were attributed to the procedure.

Limitations

The major limitations of the study were the small sample size, retrospective and uncontrolled design, and low follow-up response on established PROMs such as qDASH and VAS pain scores. The numbers in the study were likely insufficient to determine whether there was a relation between PRP cellular composition (e.g. platelet concentration factor or dose) and patient outcomes. The retrospective nature of this study meant it was limited to a chart review. The poor response rate to electronically established questionnaires (VAS pain and qDASH) prompted the authors to obtain follow-up data via post-hoc phone survey responses, introducing the potential for recall bias.

> **Conclusion:** PRP injection appears to be a safe and potentially effective treatment option for pain related to thumb CMC OA. There is a paucity of studies on this emerging treatment for a common and debilitating condition. This study suggests that a single, ultrasound-guided injection of erythrocyte/neutrophil-poor PRP can provide worthwhile pain relief for a heterogenous group of patients with thumb CMC OA. Further study is needed to optimize treatment protocols and better understand which patients are most likely to benefit.

Arch Rehabil Res Clin Transl. 2023;5(1):100257. doi:10.1016/j.arrct.2023.100257

CLINICAL STUDIES WITH A NEGATIVE OUTCOME

Ulnar nerve dysfunction at the elbow after platelet-rich plasma treatment for partial ulnar collateral ligament injuries.

Thompson RG, Bradley K, Lourie GM

The authors declared that they have no conflicts of interest.

Patients: 3 **Follow-up: N/A** **Study type: Case report**

Purpose

The aim of the study was to present and discuss the complication of ulnar nerve fibrosis and resulting cubital tunnel syndrome after PRP injection for the treatment of a partial UCL injury.

Methods

This is a retrospective review of 3 high-level baseball players who received a single Angel cPRP injection for treatment of their partial UCL injury. The PRP was leukocyte-poor with an average 5 mL of PRP at a platelet concentration of 1145 K/µL. All 3 were noted to have an asymptomatic subluxing ulnar nerve at the time of presentation. Their postinjection course is presented, and the complication of cubital tunnel syndrome is highlighted.

Results

- After completing the rehab program, all 3 patients reported symptoms consistent with ulnar nerve dysfunction, including numbness in the ring and small fingers, with a positive Tinel's sign and elbow flexion test.
- Patients presented with signs of cubital tunnel syndrome. Examination showed that their ulnar nerve was no longer subluxing but was adherent and tender in the cubital tunnel.
- The surgical procedure to release the cubital tunnel revealed a pronounced fibrosis surrounding the ulnar nerve and neurodesis of the ulnar nerve to the floor of the cubital tunnel.

Limitations

None disclosed.

> **Conclusion:** As the field of orthobiologics continues to grow and the use of PRP continues to broaden, it is important to remain aware of the possible adverse risks it may pose. The possibility of PRP induced ulnar nerve dysfunction of the elbow in partial UCL injuries should be recognized, especially in the throwing athlete with a pretreatment asymptomatic subluxing ulnar nerve.

JSES Rev Rep Tech. 2020;1(1):41-44. doi:10.1016/j.xrrt.2020.11.006

OUTCOME DEFINITIONS

Outcome	Definition
Positive	A positive outcome is defined as a significant improvement of the treatment group of interest compared to the comparison group (control, placebo, or other treatment) or the pretreatment condition in one or more primary or secondary outcome measures. A positive outcome can also be assigned to a study describing an equivalent outcome in combination with other benefits described by the authors.
Neutral	A neutral outcome is defined as no significant difference between the treatment group of interest and the comparison group (control, placebo, or other treatment) in any primary or secondary outcome measures, and no additional medical benefit is reported by the authors.
Negative	A negative outcome is defined as a significantly worse result in the treatment group of interest compared to another treatment group or no improvement compared to the pretreatment condition, control, or placebo group in one or more primary or secondary outcome measures. The outcome is also assessed as negative when the authors make a negative conclusion or report additional medical risks or adverse events associated with the treatment.

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