

Comparison between two different platelet-rich plasma preparations and control applied during anterior cruciate ligament reconstruction. Is there any evidence to support their use?

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KEYWORDS

Platelet-rich plasma
Anterior cruciate ligament reconstruction
Graft maturation

ABSTRACT

Introduction: To compare the clinical, analytical and graft maturation effects of two different platelet-rich plasma (PRP) preparations applied during anterior cruciate ligament (ACL) reconstruction.

Materials and methods: A total of 150 patients with ACL disruption were included in the study. Arthroscopic ACL reconstruction with patellar tendon allograft was conducted on all knees using the same protocol. One hundred patients were prospectively randomised to either a group to receive double-spinning platelet-enriched gel (PRP) with leukocytes (n=50) or to a non-gel group (n=50). Finally, we included 50 patients treated with a platelet-rich preparation from a single-spinning procedure (PRGF Endoret® Technology) without leukocytes.

Inflammatory parameters, including C-reactive protein (CRP) and knee perimeters (PER), were measured 24 hours and 10 days after surgery. Postoperative pain score (visual analogue score [VAS]) was recorded the day after surgery. Follow-up visits occurred postoperatively at 3, 6, and 12 months. The International Knee Documentation Committee scale (IKDC) was included to compare functional state, and MRI was conducted 6 months after surgery.

Results: The PRGF group showed a statistically significant improvement in swelling and inflammatory parameters compared with the other two groups at 24 hours after surgery ($p<0.05$).

The results did not show any significant differences between groups for MRI and clinical scores.

Conclusions: PRGF used in ACL allograft reconstruction was associated with reduced swelling; however, the intensity and uniformity of the graft on MRI were similar in the three groups, and there was no clinical or pain improvement compared with the control group.

Level of Evidence: II

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Introduction

The rest period required following surgical treatment of rupture of the anterior cruciate ligament (ACL) is often very long. Different methods have been evaluated in an attempt to shorten the time required for the graft to acquire biomechanical properties similar to those of the original ACL [1].

ACL reconstruction with grafts is usually successful and predictable [2]. Various aspects of reconstruction, such as graft options, tunnel placement, tensioning and fixation techniques, are being revised repeatedly to improve the results. Nevertheless, the healing process of ligament and tendon is extremely complex

and not fully understood [3–7]. Platelet-rich plasma (PRP) has been recognised as a powerful adhesive and haemostatic agent and a potent source of autologous growth factors [8–12]. Consequently, there has been strong clinical interest in the use of PRP as an aid in tissue regeneration.

The use of PRP treatment has become more widespread in sports medicine [3,5,13–16], mainly because of the advantage of using the patient's own growth factors, and ease of preparation [3,5]. Some studies in ACL reconstruction have reported favourable clinical outcomes using different PRP treatments [16–18], whereas others found no advantages [19–21].

There is insufficient scientific evidence from current research to prove the safety and effectiveness of PRP treatment [1]. Most of the published research comprises case reports or case-series studies that have no control group or that have insufficient sample sizes to enable calculation of statistical significance: more research is needed using randomised double-blind methods [5,22,23].

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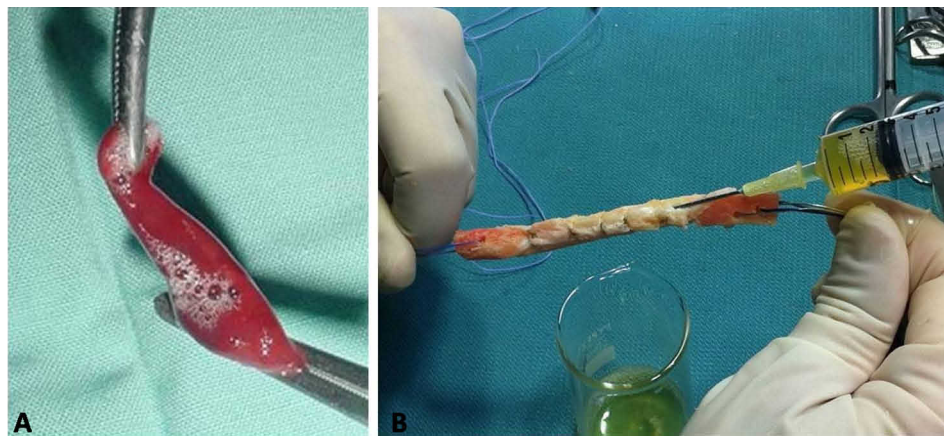


Fig. 1. (A) Clot of PRP after activation was placed on the tibial tunnel at the end of surgery. (B) PRGF injection inside the allograft after addition of calcium chloride 10%.

We hypothesised that PRP may improve the outcome of ACL reconstruction by enabling better graft remodelling, immediate postoperative rehabilitation or an earlier return to sports activities. To test this hypothesis, we compared clinical, analytic and MRI results of two different PRP systems (PRGF® and PRP with white blood cells) with those of a control group.

Methods

Based on a previous randomised, double-blind trial [20] we decided to conduct a new comparison with two different PRP systems.

Patient inclusion criteria were as follows: diagnosis of ACL disruption established by an orthopaedic surgeon, including laxity assessment by the Lachman test, pivot-shift test, and MRI studies; no prior knee surgery; and normal contralateral knee. Patients with previous knee pathology or symptoms before ACL rupture were excluded. All patients were informed about the purpose of the study and provided informed consent. No patient refused to participate.

One hundred patients undergoing arthroscopic ACL reconstruction were randomised using a computer programme into two groups: 1) the control group comprised 50 patients with patellar tendon allograft reconstruction and 2) the PRP group comprised 50 patients with patellar tendon allograft reconstruction and platelet-enriched gel with leukocytes. The results from these two groups were published. A third group was added for the current study: this group comprised 50 more consecutive patients with patellar tendon allograft reconstruction and platelet-enriched gel (PRGF-Endoret®) [20].

Platelet-rich plasma

According to the literature, platelet-rich concentrate should have a 2- to 5-fold increase in platelet concentration over baseline [24]. The patients in the current study had a baseline blood platelet count of $201 \times 10^6/\text{ml}$.

One hour before surgery, 40 ml of blood was collected into sterile sodium citrate tubes 3.8% (wt/vol) in the PRP and PRGF groups (for every 9 ml of blood, we obtain 2 ml of platelet-enriched gel).

The first method for obtaining PRP was a double-spin procedure using a standard centrifuge technique (Beckman J-6B, Beckman Coulter Spain, Madrid, Spain; 8 minutes at 3,000 rpm [2,217 g] and 6 minutes at 1,000 rpm [380 g]) with a mean platelet concentration of $837 \times 10^6/\text{ml}$ (469% increase) with platelet recovery of 63.8% from patient blood and a mean leukocyte concentration of $8,100/\mu\text{l}$. We obtain one pipette with

PRP (including leukocytes and some blood cells) and another with platelet-poor plasma. To initiate clotting, calcium chloride 10% (0.05 ml of calcium chloride per ml PRP) was added to the liquid PRP aliquots just before administration.

The second method for obtaining PRP involved following Anitua's technique (PRGF-Endoret® Technology) using centrifugation at 580 g for 8 minutes at 1,800 rpm at room temperature (BTI System II; BTI Biotechnology Institute, Vitoria, Spain). The top volume of plasma, with a platelet count similar to peripheral blood ($242 \times 10^6/\text{ml}$), was separated and deposited in a collection tube and calcium chloride (10% wt/vol) added in the operating room to cause formation of a biocompatible fibrin that was applied at the tibial tunnel.

The plasma fraction, located just above the sedimented red blood cells but not including the buffy coat, was collected in another tube. This plasma contains a moderate enrichment in platelets ($504 \times 10^6/\text{ml}$; 2- to 3-fold the platelet count of peripheral blood) with no leukocytes. Pipetting was carried out with extreme care to avoid inflammation under a laminar flow.

Thereafter, in the operating room 10% calcium chloride was added to activate platelets to release growth factors (0.05 ml of calcium chloride per ml PRP). Within approximately 15 minutes, the coagulum had solidified and the gel obtained.

Surgical technique

All ACL reconstructions were performed by the same surgical team, using the same anaesthetic technique (general anaesthesia with a laryngeal mask) and with tourniquet ischaemia of 300 mm Hg. Arthroscopy was conducted to repair associated lesions, then the ACL was reconstructed using a patellar tendon allograft transtibial technique with femoral tunnel at the 10 or 11 o'clock position for a right knee and the 1 or 2 o'clock position for the left knee, and immediately anterior to the over-the-top position, leaving a 1 to 2-mm posterior cortical wall with a RigidFix technique (DePuy Mitek, Raynham, MA) [25] with two biodegradable cross pins to fixate the femoral bone and a tibial biodegradable (Byocril) interference screw.

All meniscal repairs were performed with all-inside methods (Fast-Fix Meniscal Repair System Smith & Nephew Endoscopy, Andover, MA).

In the PRP group the ligament was covered with the platelet-rich gel and sutured over itself with gel in its interior. After activating the poor platelet concentration we obtained a gel that was introduced after implantation of the graft inside the tibial tunnel, after shutting off the water. No technical variation was needed at any time.

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