Study Protocol Title: Impact of Platelet-Rich Fibrin on Donor Site Regeneration and Functional Recovery after ACL Reconstruction with BPTB Autograft

Version: 01, 18 September 2020

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Full Title: Impact of Platelet-Rich Fibrin on Donor Site Regeneration and Functional Recovery after ACL Reconstruction with BPTB Autograft

Protocol ID: 17/VI-3 (Ethics Committee Approval)

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Institution: University Clinical Center of Serbia / Faculty of Medicine, University of Belgrade

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1. Background and Rationale

Anterior cruciate ligament (ACL) injuries are among the most common knee injuries in young athletes. Reconstruction using a bone–patellar tendon–bone (BPTB) autograft remains a widely accepted technique. However, donor site morbidity, including sensory deficits and anterior knee pain, are frequent complications. Platelet-rich fibrin (PRF), an autologous biological product, has been suggested to improve wound healing and potentially reduce donor site complications. This study was designed to investigate whether PRF can reduce sensory deficits and improve functional outcomes after ACL reconstruction with BPTB autograft.

2. Objectives

Primary Objective: To evaluate the effect of PRF application on sensory disturbances at the donor site 12 months after ACL reconstruction.

Secondary Objectives: To assess MRI healing of the donor site, functional outcome scores (IKDC, Lysholm), patient satisfaction, and adverse events.

3. Study Design

This is a single-center, prospective, cohort pilot study. Fifty-three patients undergoing ACL reconstruction with BPTB autograft were included. Patients were divided into two groups: Group 1 (PRF group, n=24) with PRF applied at the donor site, and Group 2 (Control group, n=29) with standard closure without PRF. Patients were followed for 12 months postoperatively.

4. Eligibility Criteria

Inclusion Criteria:

- Age 18–40 years
- Isolated ACL rupture confirmed by MRI and clinical examination
- Planned ACL reconstruction with BPTB autograft
- Written informed consent provided

Exclusion Criteria:

- Previous surgery on the affected knee
- Associated ligament injuries requiring additional reconstruction
- Outerbridge grade III–IV cartilage damage outside donor site
- Systemic diseases interfering with healing (e.g., diabetes, autoimmune disease)

- Active infection
- Refusal or inability to consent

5. Interventions

Group 1 (PRF group): Intraoperatively prepared autologous PRF was applied to the donor site after graft harvesting.
Group 2 (Control group): Standard closure without PRF application.

6. Outcome Measures

Primary Outcome: Absence of sensory deficit at the donor site 12 months after surgery.

Secondary Outcomes:
- MRI assessment of donor site healing
- Functional outcome scores (IKDC, Lysholm)
- Patient-reported satisfaction
- Adverse events related to surgery or PRF application

7. Study Procedures and Follow-up

Patients were evaluated at baseline, and postoperatively at 4, 8, and 12 months. Clinical assessments included sensory testing, range of motion, and functional scores. MRI was performed to evaluate donor site healing. Patient satisfaction was assessed at 12 months.

8. Ethics and Regulatory Considerations

The study was approved by the Ethics Committee of the Faculty of Medicine, University of Belgrade (Approval No. 17/VI-3). Written informed consent was obtained from all participants prior to enrollment. The study adhered to the Declaration of Helsinki principles.

9. Statistical Analysis

Descriptive statistics were used to summarize baseline characteristics. Chi-square test and t-tests were used to compare categorical and continuous variables between groups. A post-hoc power calculation for the primary endpoint was performed based on the 12-month results. All analyses were conducted using standard statistical software.