

## Evaluating The Efficacy Of Combining Platelet-Rich Fibrin With Biphasic Calcium Phosphate For Improving Fracture Healing

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### ABSTRACT:

### INTRODUCTION:

*The global health burden of fractures is substantial, and projections show that the impact on morbidity and mortality is rising. Combining platelet-rich fibrin (PRF) with biphasic calcium phosphate (BCP) presents a viable way to enhance the healing process. The purpose of this study is to assess how well PRF + BCP works to promote fracture healing, especially in the early stages of callus formation.*

### MATERIALS AND METHODS:

*A prospective randomized open-control trial was conducted at Saveetha Medical College over two years, from 2021 to 2023. The study included 26 patients aged 20-70 with upper limb diaphyseal fractures treated with plate osteosynthesis. Patients meeting inclusion criteria were allocated into two groups, with 13 patients in each. Radiological assessments were performed monthly to monitor fracture healing progress.*

### RESULTS:

*The combination of PRF + BCP demonstrated significantly higher levels of callus formation at the 4th and 6th weeks compared to the control group. By the 8th week, 92.3% of cases treated with PRF + BCP exhibited callus formation, while only 46.2% of controls showed similar results by the 12th week.*

### CONCLUSION:

*Adding PRF to BCP significantly promotes early callus formation and accelerates the fracture-healing process. The simplicity of PRF preparation and its autologous nature make it a safe and effective adjunct to orthopedic treatments. The findings underscore the potential of PRF in improving fracture healing outcomes, offering a promising avenue for future orthopedic interventions.*

### KEYWORDS:

*Platelet Rich Fibrin- PRF, Biphasic Calcium Phosphate - BCP, Vascular endothelial growth factor - VEGF, Platelet-derived growth factor - PDGF,  $\beta$ tricalcium Phosphate -  $\beta$ TCP*

### INTRODUCTION

In the future, fractures are expected to rise to the top of the global disease burden, accounting for 11% of deaths and disabilities. Six million deaths and sixty million injuries are predicted from fractures [1-3]. Orthopaedic trauma care and fracture management have advanced significantly over the past 50 years [4]. Our capacity to treat

musculoskeletal injuries has significantly improved thanks to developments in fixation devices, soft tissue management, and our understanding of the biology and biomechanics of the musculoskeletal system [4]. Numerous therapies and treatment approaches hold promise for revolutionizing orthopedic care by reducing invasiveness and shortening recovery times [4,5]. Given that fractures constitute a significant number of trauma cases in developing countries, there is a dire need for novel therapies to improve patient outcomes [5]. Along with the development of new therapies, efforts to improve fracture care ought to emphasize cost-effectiveness.

Platelet-rich fibrin (PRF), an autologous fibrin matrix, was introduced by Choukroun et al. PRF is a second-generation platelet concentrate that contains leukocytes and does not require anticoagulation; it was initially used in oral and maxillofacial surgeries [6]. PRF preparation is carried out through a simple venous blood centrifugation technique [6]. Numerous studies have demonstrated that PRF has a high concentration of growth factors that promote bone mending [6]. Made of hydroxyapatite (HA) and  $\beta$ -tricalcium phosphate ( $\beta$ -TCP), biphasic calcium phosphate (BCP) is a synthetic bone substitute that is frequently used as an osteoconductive biomaterial. [7]. Combining BCP and PRF provides a therapeutic alternative that improves existing grafting materials, increasing the versatility of bone substitutes [7].

While animal studies on PRF augmentation in bone healing have produced promising results, human studies in orthopedics using PRF + BCP augmentation are limited. Therefore, the goal of this research is to ascertain how effective PRF combined with BCP is during the fracture healing process [8].

## **MATERIALS AND METHOD**

This study aimed to compare the early callus formation of PRF+BCP-treated fractures to that of a control group and assess the effectiveness of this treatment combination in promoting fracture healing. The research was carried out at Saveetha Medical College using an open, randomised, prospective design. The two-year study period runs from 2022 to 2024.

### **INCLUSION CRITERIA**

- Patients aged 20-70 years
- Patient's consent
- Upper limb diaphyseal fractures treated via plate osteosynthesis (closed fractures).

### **EXCLUSION CRITERIA**

- Severely comminuted fractures
- Fractures requiring bone grafting
- Infected fractures
- Patients who smoke or consume alcohol
- Diabetic patients
- Open or pathological fractures.

### **SAMPLE SIZE DETERMINATION**

24 patients divided into two groups, with 12 patients in each group.

### **DATA COLLECTION METHOD**

Patients with upper limb diaphyseal fractures were taken in as inpatients to Saveetha Medical College. Detailed clinical histories and pertinent data were acquired, including patient demographics, fracture type, and comorbidities.

### **STUDY PROCEDURE**

The efficacy of platelet-rich fibrin (PRF) and biphasic calcium phosphate (BCP) in fracture healing was evaluated.

Patients were divided into Study and Control groups. X-rays were taken postoperatively at monthly intervals to assess fracture healing.

### PREPARATION OF PRF

PRF was prepared according to Choukroun et al.'s protocol. Venous blood was collected, centrifuged, and the PRF clot was mixed with BCP.

### INTRAOPERATIVE PROCEDURE

In the Study Group, PRF+BCP paste was applied over the fracture site following open reduction and internal fixation. Control Group patients underwent standard open reduction and internal fixation without PRF+BCP.

### POST-OPERATIVE FOLLOW-UP

Fracture healing was monitored using monthly X-rays. The time taken for callus appearance indicated the initiation of fracture healing. Non-union was defined as healing that did not occur within six months. X-rays included Anteroposterior (AP) and Lateral views, assessed using the radiological Union Score (RUS) system. Time to callus appearance was compared between groups.

### RESULTS

Of the 26 individuals who took part in the study, 16 (61.5%) were men and 10 (38.5%) were women[Table-1]. The standard deviation and mean age of the population were  $38.69 \pm 13.97$  years. An analysis of fracture types in different age groups showed that the 20–34 year old age group had a greater prevalence, which increased with age. A higher incidence of humerus fractures was seen in both the study group (53.8%) and the control group (37.2%), according to a comparison of fracture types between the two groups[Table-2][Figure-1]. The study looked at the individuals' early callus formation in terms of weeks; most of the study group developed callus early, in less than 8 weeks, but the control group's callus didn't show up until 8 weeks later[Table-3]. More specifically, compared to the control group, a sizable fraction of the research group showed early callus appearance in less than 6 weeks. Based on early callus appearance, a statistically significant difference ( $p < 0.05$ ) was observed between the study and control groups. 76.9% of patients receiving PRF+BCP by the sixth week showed early callus formation, while only 38.5% of controls showed callus formation by the twelfth week.

### DISCUSSION

A fracture is a break in bone continuity caused by damage to the musculoskeletal system, which includes bones, joints, tendons, and muscles. Fractures are classified into various types based on their patterns, causes, and displacement. The healing process is broken down into stages, with callus formation playing a crucial part. Platelet-derived products, such as Ghanaati, S., Booms, P., et al. PRF, act as biological mediators, facilitating the healing process. PRF, a second-generation platelet concentrate, contains a high concentration of platelets and leukocyte cytokines within an autologous fibrin matrix, earning it the title of healing biomaterial (9). Biphasic calcium phosphate (BCP), a synthetic graft material, is osteoconductive, osteoinductive, and biocompatible (10). The purpose of this study was to see how well PRF and BCP worked together to heal upper limb diaphyseal fractures. The study included a Sándor, G. K. Et al group and a control group, with ethical approval and informed consent obtained (11). In contrast to studies that primarily employ animal models, the study lasted two years. Unlike previous research, this study focused on humans and used informed consent (12). Comparisons with other studies, such as Ozdemir et al's evaluation of bone augmentation in an animal model, revealed the study's unique approach (13). Radiological evaluations were performed monthly until fracture healing, and the PRF + BCP group demonstrated statistically significant greater efficacy than the control group in the fourth and sixth weeks (14). In contrast to Zhang et al.'s findings, which showed no difference between bovine bone graft alone and PRF combined with bovine bone graft, our study found significantly higher efficacy with fractures filled with PRF + BCP at the 4th and 6th weeks. Our findings, which are those of Abdelmagid et al and Bolukbasi et al, showed that adding PRF to BCP increased bone formation, affirming the efficacy of PRF in amalgamation with BCP, particularly in the early stages of fracture healing (15). The follow-up study lasted two years, with radiological evaluations conducted monthly until the fracture healed.

**CONCLUSION**

We can conclude, within the limitations of this experimental study, that PRF may aid in the formation of new bone in addition to BCP. PRF's efficacy is influenced by the qualities of the co-administered grafting material in addition to its own features. PRF is said to dissolve more slowly than other platelet concentrates, but this difference does not last longer than months when clinical samples are the only ones that can be obtained. As a result, more experimental research is needed to determine how PRF and co-administered biomaterials affect bone healing.

**DECLARATIONS**

Funding : None

Conflict of Interest : None declared

Ethical Approval : Not required

| Parameters            | Frequency (n=26) | Percentage |
|-----------------------|------------------|------------|
| <b>Gender</b>         |                  |            |
| Male                  | 16               | 61.5       |
| Female                | 10               | 38.5       |
| <b>AGE (in years)</b> |                  |            |
| 20-34                 | 11               | 42.3       |
| 35-49                 | 9                | 34.6       |
| >50                   | 6                | 23.1       |

**Table 1** delineates the profile of the subjects

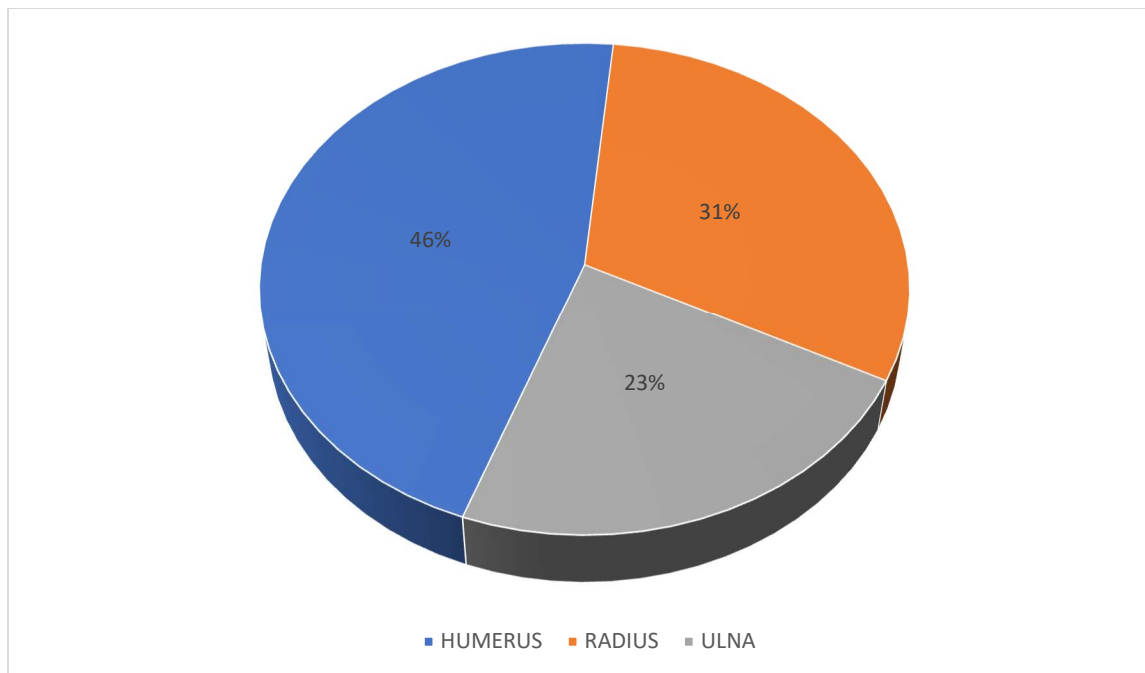
| <b>AGE GROUPS</b>   | <b>Types of fracture</b> |                   |                 |                  |
|---------------------|--------------------------|-------------------|-----------------|------------------|
|                     | <b>HUMERUS (%)</b>       | <b>RADIUS (%)</b> | <b>ULNA (%)</b> | <b>TOTAL (%)</b> |
| <b>20-34 years</b>  | 5(45.4)                  | 3(27.3)           | 3(27.3)         | 11(100)          |
| <b>35-49 years</b>  | 4(44.4)                  | 3(33.3)           | 2(22.2)         | 9(100)           |
| <b>&gt;50 years</b> | 3(50)                    | 2(33.3)           | 1(16.7)         | 6(100)           |

**Table 2** describes the type of fractures among different agegroups

| <b>DURATION</b>             | <b>STUDY GROUP (%)</b> | <b>CONTROL GROUP (%)</b> | <b>TOTAL (%)</b> |
|-----------------------------|------------------------|--------------------------|------------------|
| <b>4<sup>TH</sup> WEEK</b>  | 2(66.7)                | 1(33.3)                  | 3(100)           |
| <b>6<sup>TH</sup> WEEK</b>  | 8(100)                 | 0(0)                     | 8(100)           |
| <b>8<sup>TH</sup> WEEK</b>  | 2(25)                  | 6(75)                    | 8(100)           |
| <b>12<sup>TH</sup> WEEK</b> | 1(16.7)                | 5(83.3)                  | 6(100)           |
| <b>16<sup>TH</sup> WEEK</b> | 0(0)                   | 1(100)                   | 1(100)           |

|              |        |        |         |
|--------------|--------|--------|---------|
| <b>TOTAL</b> | 13(50) | 13(50) | 26(100) |
|--------------|--------|--------|---------|

**Table 3** explains the detection of early callus formation in relation to time in weeks among the study and control groups



**Figure 1** - depicts the location of fracture in the upper limb

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