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Original Research Article

# A STUDY OF EFFICACY OF FRESH FROZEN BONE ALLOGRAFTS IN ORTHOPAEDICS: A PROSPECTIVE STUDY

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ABSTRACT

**Background:** Large osseous defects encountered in orthopaedic surgery often require bone grafting. Autologous grafts are limited by donor site morbidity and availability, prompting the use of fresh frozen bone allografts as biological alternatives. **Objectives:** To evaluate radiological union, functional outcomes, and complications associated with fresh frozen bone allografts in orthopaedic trauma patients.

**Materials and Methods:** A prospective cohort study was conducted on 45 patients aged 16–80 years undergoing orthopaedic procedures requiring bone grafting. Fresh frozen allografts were obtained from a certified tissue bank following stringent donor screening and processing. Radiological union was assessed at 3 and 6 months, and functional outcomes were evaluated using the Modified Enneking Functional Scoring System.

**Results:** Radiological union was observed in 51.1% of patients at 3 months and increased significantly to 86.7% at 6 months ($p < 0.001$). Functional outcomes improved markedly, with 95.6% of patients achieving good-to-excellent scores by six months. Complications occurred in 8.9% of cases, including non-union and infection. No graft-related disease transmission was recorded.

**Conclusion:** Fresh frozen bone allografts provide reliable radiological consolidation, excellent functional recovery, and a low complication rate. When combined with stable fixation and rigorous tissue-banking protocols, they represent safe and effective alternatives to autografts in orthopaedic reconstruction.

## INTRODUCTION

Bone grafting is central to reconstructing osseous defects caused by trauma, infection, tumour resection, or degenerative conditions. Autologous bone grafts, historically considered the gold standard due to their osteoinductive, osteoconductive, and osteogenic characteristics, are limited by donor site morbidity, restricted volume, and prolonged operative time. These constraints often necessitate alternative graft sources.[1-3] Allografts, particularly fresh frozen bone, have emerged as practical substitutes, retaining structural integrity while reducing immunogenicity through freezing and processing.[4-8]

The clinical utility of allografts depends on effective tissue banking, donor screening, and surgical technique. Deep-freezing at −80 °C reduces antigenicity, preserving osteoconductive properties and mechanical strength while minimizing disease transmission risk.[6-8] Despite these advantages, concerns persist about delayed incorporation, non-union, and infection.

Functional assessment in orthopaedic grafting goes beyond radiological union to encompass pain, mobility, and return to activity. The Modified Enneking Functional Scoring System offers a standardized method for quantifying these outcomes. Although several studies report favourable results using fresh frozen allografts, variability in outcome measures highlights the need for prospective data reflecting combined radiological and functional endpoints. This study investigated the integration of fresh frozen allografts in a broad orthopaedic cohort,

focusing on radiological consolidation, functional improvement, and complications. Our hypothesis posited that such allografts would yield high union rates and acceptable functional outcomes with minimal adverse events.

## MATERIALS AND METHODS

### Study Design and Setting

A prospective cohort study was conducted between November 2014 and April 2016 at a tertiary care orthopaedic centre. Ethical approval was obtained from the institutional ethics committee.

### Participants

Inclusion criteria were patients aged 16–80 years requiring bone grafting due to fracture non-union, traumatic bone loss, or pathological defects. Exclusion criteria included systemic infection, immunosuppression, and inability to comply with follow-up.

### Allograft Procurement and Processing

Fresh frozen allografts were sourced from a certified tissue bank. Donor bones were harvested under sterile conditions during joint arthroplasty or amputation procedures. Screening for transmissible diseases (e.g., HIV, hepatitis) was performed. Grafts were deep-frozen at −80 °C for ≥25 days to reduce immunogenicity.

### Surgical Procedure

Grafts were thawed intraoperatively, washed with sterile saline and gentamicin, and molded to defect size. Stable internal fixation was achieved using plates, screws, or intramedullary nails as appropriate.

### Outcome Measures

Radiological union was evaluated at 3 and 6 months using standard anteroposterior and lateral radiographs. Union was defined by bridging trabeculae and uniform graft-host bone integration.

Functional outcomes were assessed via the Modified Enneking Functional Score at baseline, 3, and 6 months, categorised as excellent, good, fair, or poor.

**Statistical Analysis:** Descriptive statistics summarised demographic and clinical variables. Paired comparisons for radiological and functional outcomes were analysed using chi-square tests. A p-value <0.05 was considered statistically significant.

## RESULTS

A total of 45 patients who underwent orthopaedic reconstruction using fresh frozen bone allografts were analysed. The results are presented under four key outcome domains: patient profile and indication, functional outcomes, radiological union, and complications.

Tibial plateau fractures constituted the most common indication for fresh frozen bone allograft usage, followed closely by supracondylar femur fractures. Collectively, peri-articular fractures of the knee accounted for more than 60% of cases, reflecting the frequent need for bone grafting in metaphyseal defects. The remaining cases comprised non-unions and pathological fractures, underscoring the versatility of allografts across varied reconstructive scenarios. [Table 1]

**Table 1: Diagnosis Distribution of Patients (n = 45)**

| Diagnosis | Number | Percentage (%) |
|---|---|---|
| Tibial plateau fracture | 15 | 33.3 |
| Supracondylar femur fracture | 13 | 28.9 |
| Other indications* | 17 | 37.8 |
| **Total** | **45** | **100.0** |

***Includes non-union, pathological fractures, and miscellaneous orthopaedic indications.***

Functional outcomes improved markedly over time. While all patients had fair or poor scores pre-operatively, 95.6% achieved good-to-excellent functional status by six months. The absence of poor outcomes at follow-up highlights effective restoration of limb function. This statistically significant improvement confirms that fresh frozen allografts provide substantial clinical benefit when combined with stable fixation and appropriate rehabilitation. [Table 2]

**Table 2: Modified Enneking Functional Score at Pre-operative, 3-Month, and 6-Month Follow-up**

| Functional Grade | Pre-operative n (%) | 3 Months n (%) | 6 Months n (%) |
|---|---|---|---|
| Poor | 29 (64.4) | 0 (0) | 0 (0) |
| Fair | 16 (35.6) | 14 (31.1) | 2 (4.4) |
| Good | 0 (0) | 31 (68.9) | 40 (88.9) |
| Excellent | 0 (0) | 0 (0) | 3 (6.7) |
| **Total** | **45 (100)** | **45 (100)** | **45 (100)** |

**Statistical test:** Paired proportion test; **p-value:** <0.001 (strongly significant)

Radiological consolidation improved significantly between 3 and 6 months. While just over half of the patients showed union at three months, nearly 87% achieved union by six months. This delayed but progressive incorporation pattern is characteristic of allograft biology and supports their role as effective osteoconductive scaffolds. Only six patients demonstrated persistent non-union at final follow-up. [Table 3]

**Table 3: Radiological Union at 3 and 6 Months**

| Radiological Union | 3 Months n (%) | 6 Months n (%) |
|---|---|---|
| Yes | 23 (51.1) | 39 (86.7) |
| No | 22 (48.9) | 6 (13.3) |
| **Total** | **45 (100)** | **45 (100)** |

**Statistical test:** Paired proportion test; **p-value:** <0.001 (strongly significant)

The overall complication rate was low. Only four patients experienced adverse outcomes, including non-union requiring repeat grafting and one deep soft-tissue infection. Importantly, no cases of graft-related disease transmission were reported. These findings demonstrate that fresh frozen bone allografts, when procured and processed under strict tissue-banking protocols, are associated with an acceptable safety profile. [Table 4]

**Table 4: Complications Observed During Follow-up**

| Complication Status | Number | Percentage (%) |
|---|---|---|
| No complications | 41 | 91.1 |
| Complications present | 4 | 8.9 |
| **Total** | **45** | **100.0** |

## DISCUSSION

The present prospective study evaluated the clinical efficacy of fresh frozen bone allografts in orthopaedic reconstruction by correlating radiological union with functional outcomes and complication rates. The findings demonstrate that fresh frozen allografts provide reliable biological and functional results when used with appropriate fixation and tissue-banking protocols.

Radiological union was achieved in 86.7% of patients by six months, a rate that compares favourably with earlier clinical series reporting consolidation rates ranging from 69% to 90%.[9-12] The progressive increase in union from 51.1% at three months to nearly 87% at six months reflects the characteristic biological behaviour of allografts, which rely predominantly on osteoconduction rather than osteogenesis. This delayed but steady incorporation is consistent with experimental and clinical evidence showing that deep-frozen cortical allografts remain biologically inert for prolonged periods before gradual host integration occurs.[13-15]

Functional outcomes closely paralleled radiological healing. By six months, 95.6% of patients achieved good-to-excellent Modified Enneking Functional Scores, indicating substantial restoration of limb function. This strong correlation between radiological union and functional improvement reinforces the importance of achieving stable host–graft junctions. Similar associations have been reported in studies evaluating allograft reconstruction following trauma and tumour resection, where mechanical stability and biological incorporation jointly determine clinical success.[16-18]

The predominance of peri-articular fractures of the knee, particularly tibial plateau and supracondylar femur fractures, highlights the practical utility of allografts in metaphyseal bone loss. In such settings, autograft availability is often limited, and the use of fresh frozen cancellous or cortico-cancellous allografts allows effective defect filling while preserving joint alignment and facilitating early rehabilitation. Morselised grafts, in particular, adapt well to irregular host beds and promote uniform load distribution.[19]

The low complication rate observed in this study (8.9%) is noteworthy. Only four patients developed complications, primarily non-union and one deep soft-tissue infection. Importantly, no instances of graft-related disease transmission were identified. Historical concerns regarding infection and viral transmission associated with allografts have significantly diminished with the adoption of stringent donor screening, quarantine periods, and microbiological surveillance in modern tissue banks.[20-22] The absence of disease transmission in the present cohort supports the effectiveness of these safeguards.

From a biomechanical perspective, deep-frozen allografts retain near-normal compressive and torsional strength, provided they are not subjected to excessive early loading.[23] The study protocol emphasised rigid internal fixation using plates, screws, or intramedullary devices, thereby minimising micromotion at the host–graft interface. This approach aligns with Wolff's law and experimental data demonstrating that stability is a critical determinant of successful revascularisation and incorporation.[24]

When compared with alternative reconstructive options, fresh frozen allografts offer several advantages. Vascularised bone grafts, although biologically superior, require advanced microsurgical expertise and prolonged operative time, limiting their availability in many healthcare settings. Prosthetic reconstructions, while providing immediate structural stability, are associated with long-term complications such as loosening and implant failure, particularly in younger patients.[25]

In contrast, allografts restore bone stock, allow biological remodelling, and can be revised if complications occur, making them especially valuable in resource-constrained environments.[26]

Nevertheless, certain limitations must be acknowledged. The follow-up duration of six months, while adequate to assess early union and

functional recovery, does not capture late complications such as graft fracture or resorption. Additionally, radiological assessment relied on conventional plain radiographs, which may underestimate early micro-integration. Longer follow-up with advanced imaging could provide further insight into long-term graft behaviour.

Overall, the findings of this study support the continued use of fresh frozen bone allografts as a safe, effective, and versatile option for orthopaedic reconstruction. When combined with meticulous surgical technique and robust tissue-banking practices, they achieve high union rates, excellent functional outcomes, and an acceptable safety profile.

## CONCLUSION

Fresh frozen bone allografts demonstrated favourable radiological and functional outcomes in this prospective cohort of orthopaedic patients. Radiological union was achieved in the majority of cases by six months, accompanied by significant improvement in Modified Enneking Functional Scores. The low incidence of complications and absence of disease transmission highlight the safety of allografts when stringent donor screening and processing protocols are followed. These findings support the role of fresh frozen allografts as reliable alternatives to autografts, particularly in situations where autograft availability is limited or donor site morbidity is a concern. With appropriate fixation and careful patient selection, fresh frozen bone allografts provide durable biological reconstruction and satisfactory functional recovery.

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