

# Efficacy of Allograft in Fracture Healing

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## ABSTRACT

In the last few decades there have been an increased number of accidents leading to trauma including crush injuries and open fractures with bone loss. In Orthopaedic surgery, bone harvested from donor sites is the gold standard for grafting procedure. Although autograft is the standard that all bone graft substitutes must meet or exceed, autograft has significant limitations. Allograft provides an excellent scaffold for the production of the host bone. Allograft bone is available in an unlimited quantity and better quality. Therefore, this study was conducted to evaluate efficacy of Allograft in fracture healing.

30 patients who had bone loss due to fractures, which resulted due to trauma, osteomyelitis, non-union and other causes, were included in this study. They were treated with allograft as a bone graft substitute in the institution between the period of January 2023 to February 2024.

This study concludes that pure cancellous allograft has properties similar to autograft and has complete graft incorporation. The bone allograft has no donor site morbidity as compared to autograft. The main challenge in using allograft is control of infection which was solved by using meticulous surgical and medical techniques to counter the infection. There was no significant difference in graft incorporation in infected and non-infected patients. Thus, we could conclude that

allograft behaves in the same way in infected and non-infected cases.

**Keywords:** Fracture, Trauma, Allograft, Grafting, Bone Loss

## INTRODUCTION

India has one of the highest road accident rates in the world. In India, an accident occurs every minute and a death every 8 minutes<sup>1</sup>. The development and the increase in the average speed of a motor vehicle on the road have resulted in an increased number of high speed accidents leading to trauma including crush injuries and open fractures with bone loss. Fractures with massive bone loss apart from trauma are also caused by several other diseases including osteomyelitis, non-union, tumor resection and others. The orthopaedician thus faces numerous challenges in treating these complex injuries.

With the exception of blood, bone is the most frequently transplanted tissue in humans. Virtually every operative day, orthopaedic surgeons, neurosurgeons, craniofacial surgeons and periodontists need to fill defects in the bone or augment deficient bone. Bone harvested from donor sites is the gold standard for grafting procedure<sup>2</sup>. Although autograft is the standard that all bone graft substitutes must meet or exceed, autograft has significant limitations. Limitations include donor site morbidity, scar pain, neuroma, inadequate amount or inappropriate quality (osteoporotic), increase

in the operative time and morbidity<sup>3,4,5</sup>. Thus, there is an obvious need for a bone graft substitute to serve as an off-the-shelf alternative to autograft.

Several types of bone grafts and bone graft substitutes exist and encompass a variety of materials, material sources and origins.<sup>6</sup> The different substitutes should comply by the functions of the gold standard bone graft which include.<sup>7</sup>

1. Osteoconduction: provides a scaffold to support or direct bone formation.
2. Osteoinduction: causes differentiation of pluripotent stem cells to osteogenic cells.
3. Osteogenic Potential: provides undifferentiated stem cells or osteogenic cells.
4. Provision of immediate structural support.

Allograft bone ticks the boxes in the following departments

- The ease of procurement due to the increasing number of joint replacement surgeries and the development in the technology for processing and storing the allograft bone.
- Allograft bone is osteoconductive and osteoinductive to a small extent. It provides an excellent scaffold for the production of the host bone. Allograft bone is available in an unlimited quantity and better quality.<sup>8</sup>
- Allograft bone has no graft site morbidity for the recipient.

Allograft bone, thus, is a promising alternative to the gold standard autograft bone.

Thus, the following study was conducted with the following objective

1. To analyze and observe prospectively the efficacy of allogeneous bone graft in fracture healing where the bone loss is caused due to
  - Traumatic fractures
  - Bone defects caused due to osteomyelitis
  - Bone defects caused by tumor resection
  - Non union
2. To outline the surgical technique

3. To outline the system of procurement and distribution of allograft from the donor to the recipient
4. To assess the duration of graft incorporation
5. To assess the duration of union if present
6. To discuss the complications of the procedure
7. To discuss the role of infection in allograft

## **MATERIALS & METHODS**

30 patients who had bone loss due to fractures, which resulted due to trauma, osteomyelitis, non-union and other causes, were included in this study. They were treated in a Department of Orthopaedics, Silchar Medical College between the period of January 2023 to February 2024.

The patients were received at the general hospital outpatient department or the trauma centre according to the type of injury. The patients were screened for associated injuries and initial treatment which included hemodynamic stabilisation and primary stabilisation of the fracture was done. They were then assessed clinically and radiologically for definitive treatment.

Each fracture was classified according to the AO fracture classification system and the Gustilo Anderson classification<sup>9</sup> for open and closed fractures respectively. Data which included the age, sex, type of fracture, magnitude of bone loss, details of primary and definitive treatment, complications and the final outcome of fracture union were determined according to graft incorporation time and the Lane and Sandhu scoring system.<sup>10</sup>

### **Selection criteria:**

A: Inclusion criteria:

- Fractures in the upper and lower limbs  
Closed and open fractures
- Bone loss caused due to osteomyelitis
- Patients with fracture non union

B: Exclusion criteria:

- Grade 3c open fracture

- Associated with vascular injury and compartment syndrome
- Co-existing degenerative / metabolic bone disease
- Expectation of non-compliance because of mental illness or alcoholism

**Protocol:**

Patients were admitted and those who satisfied the criteria were included in the study. Pre op assessment was done. Pre op X-ray was taken. Operative procedures were performed according to the fracture type. Immediate post operative X-rays were taken for assessment of the stability of fixation. Post operative physiotherapy was given. Follow up was taken every month with X-rays to determine the status of graft incorporation and union. Lane and Sandhu radiological score were used to outline union.

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**1. PRE-OP PREPARATION AND ASSESSMENT**

- Patient's name, I.R. No., date of admission and operation, demographic data and history were collected.
- Information regarding mode of injury, site of injury, region of injury, open/close injury, neurovascular status, associated injury and associated illness was taken.
- Primary management in the form of I.V. fluids, antibiotics, immobilization, elevation, traction, debridement, external fixation, blood transfusion was given according to the requirement and protocol.
- Radiograph of particular region was taken.
- Fracture was classified according to AO classification and Gustilo Anderson Classification.<sup>9</sup>

**2. PRIMARY SURGICAL TECHNIQUE**

- According to the fracture present, limb involved and the skin and soft tissue status, the primary management of the patient was decided.

- For open grade fractures in the upper and lower limbs with significant bone loss a primary external fixation was done to allow the soft tissue to heal and to stabilize the vital parameters of the patient.

- **Technique:** With the patient positioned on a radiolucent table, the involved limb was painted and draped as per norms. Antibiotic prophylaxis was administered and standard intra-operative fluoroscopy was used throughout the procedure.

External fixator frame was decided according to the fracture type and site.

**3. SURGICAL TECHNIQUE IN THE PRESENCE OF INFECTION**

- The presence of active infection is a contraindication for allograft surgery so it was our goal to provide a sterile infection free environment for the graft to enhance bone healing.
- **Technique:** Under sterile aseptic precautions on a radiolucent table the infected area was opened up using appropriate approach for the involved limb. Thorough debridement of the affected area was done and all necrotic tissue was cleaned and sent for culture sensitivity. Bone cement was mixed with 2gm vancomycin and 40mg gentamicin. This bone cement was then moulded over threaded Ilizarov rod and inserted in the medullary cavity of the infected bone.
- The patient was then given antibiotics according to the culture sensitivity reports and the load of infection monitored using weekly serial erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP).
- The patient was then taken up for definitive surgery only after two serial ESR and CRP reports were found to be in the normal range



FIGURE 1 : Bone Defect with Cement in situ

#### 4. DEFINITIVE SURGICAL TECHNIQUE:

Patients managed by definitive surgery were:

- Patients previously managed with primary external fixation
- Patients with bone loss with closed injury
- Patients with non-union
- Patients previously treated for osteomyelitis using bone cement
- Technique:
  - a. Incision: The incision was placed over the affected limb using appropriate approaches according to the limb affected after the patient was painted and draped according to the norms.
  - b. Dissection: The bone defect and the bone were exposed using standard dissection techniques using scalpel and electrocautery was used for hemostasis.
  - c. Once the bone defect was approached, appropriate wash was given with normal saline and the defect was cleaned off all soft tissue, hematoma and bone.
  - d. Implant: the fracture was fixed using the appropriate implant.
  - e. Allograft procured from the bone bank was thawed and placed in the bone defect over a bed made of absorbable gelatin sponge.

- f. The allograft was mixed with 2 gm vancomycin and 40mg gentamicin.
- g. It was then covered with gelatin sponge and appropriate soft tissue coverage done.
- h. Plastic surgery in the form of a split thickness skin graft or a flap was performed if sufficient soft tissue coverage was not possible.



FIGURE 2: Bone Defect with Allograft in situ

#### 5. FOLLOW UP

- Patients were followed up at regular intervals.
- First follow up was done every week till the removal of sutures which was usually two weeks post operatively.
- Post suture removal, patient was followed up every month till radiological and clinical union.
- The patients were then followed up every year.
- Evidence of union was collected radiologically and clinically.
- Allograft incorporation was assessed by X-rays. In the post op X-ray, there was a radiolucent zone between bony cavity and graft and the allograft was well defined. In the follow up X-rays, loss of this radiolucent zone, haziness around the allograft, indistinctness of margins of allograft, fading of the allograft was taken as signs of bone formation and incorporation of graft.<sup>11</sup>

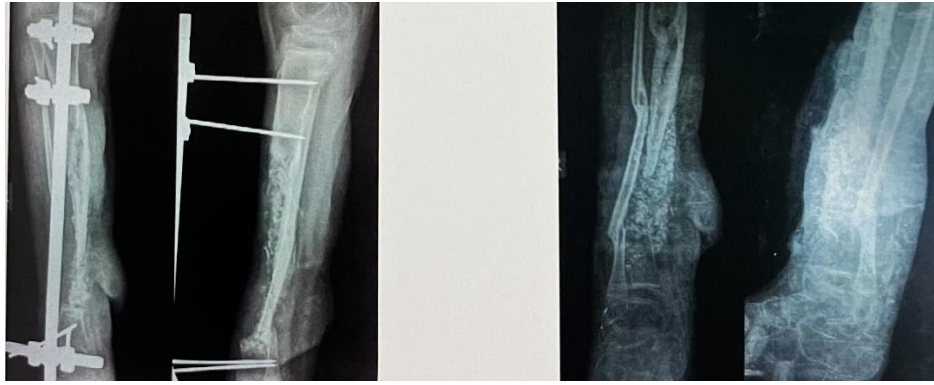
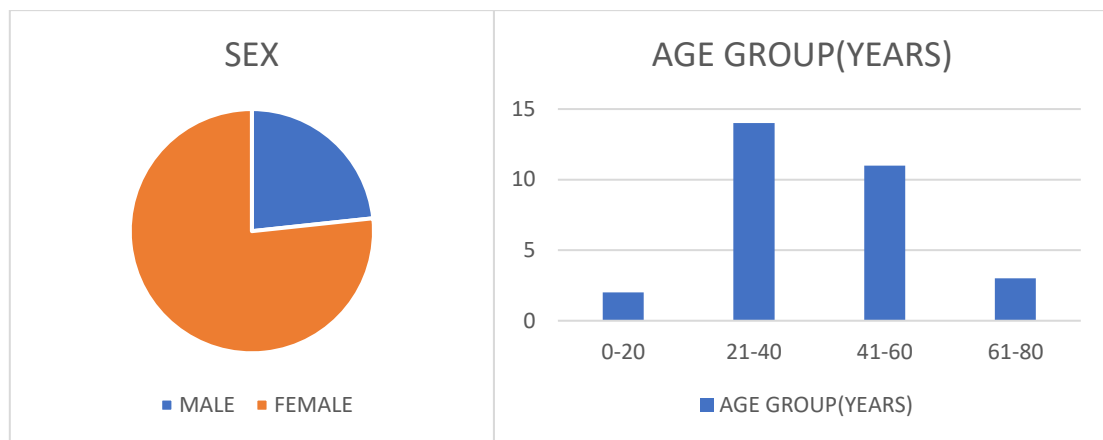


FIGURE 3: Follow up at one month (A) and three months (B)

## RESULT

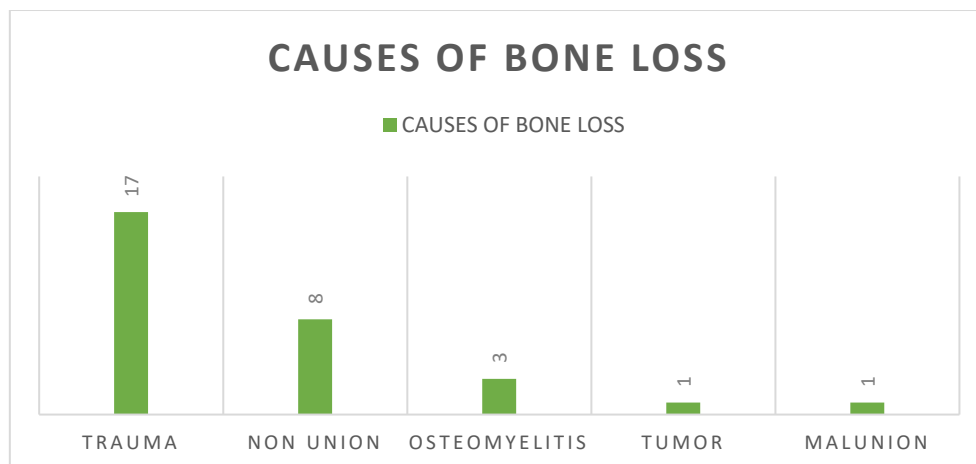
### AGE AND SEX



Total 30 patients were included in the study amongst whom 23.3% (7 patients) were female and 76.66% (23 patients) were male

and the majority of patients were in the young and adult age group. The average age was  $25.5 \pm 13.435$ .

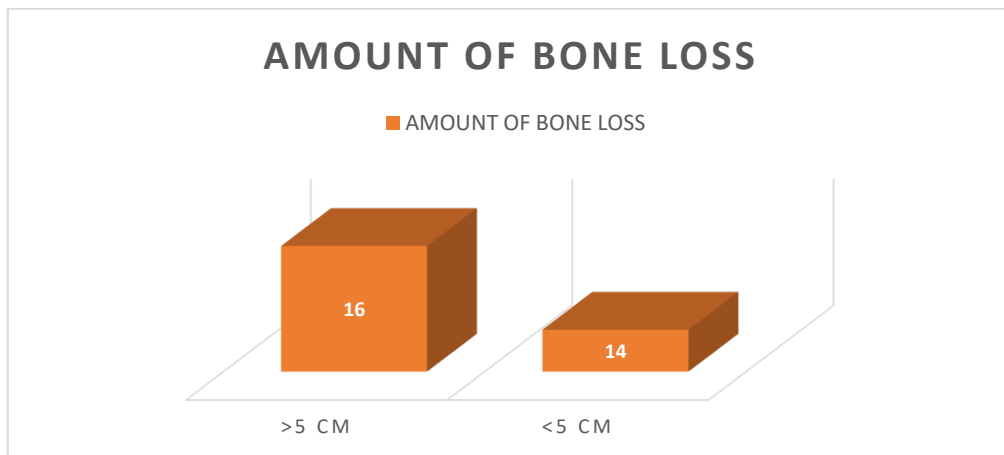
### CAUSES OF BONE LOSS



In this study, 56.6% (17 patients) had fractures due to trauma, 26.6% (8 patients) had fracture non union, 1% (3 patients) had osteomyelitis induced bone loss.



### AMOUNT OF BONE LOSS



Among the patients with fractures 53.3% (16 patients) had bone loss more than 5 cm and 46.6% (14 patients) bone loss within 5cm.

### TIME INTERVAL BETWEEN DIAGNOSIS AND DEFINITIVE SURGERY

### FRACTURE TYPE

Fracture Type AO	Number
31	1
32	1
33	7
34	1
41	6
42	9
43	1
Scaphoid	1
Tumor in proximal Tibia	1

DAYS	NUMBER
0-15	18
16-30	0
31-45	0
46-60	0
61-120	4
121-240	6
241-360	1

In this study, maximum patients had fractures involving the tibial diaphysis followed by fractures of the distal femur according to the AO classification.

The patients were either definitively treated within 15 days of trauma or were treated after 60 days of injury during which the fracture was treated with temporary stabilisation for healing of the soft tissue insult. The average time interval between diagnosis and definitive surgery was  $65.8 \pm 93.5$  days.

### OPEN VERSUS CLOSED

FRACTURE	PATIENTS	TIME OF UNION (weeks)
Open	8	$34.75 \pm 4.4$
Closed	21	$32.1 \pm 4.7$

The study group consisted of closed injuries and open grade 1, 2, 3a and 3b. Open group 3c was excluded from the study. Open

fractures had a mean time of union slightly more than closed type of fracture.

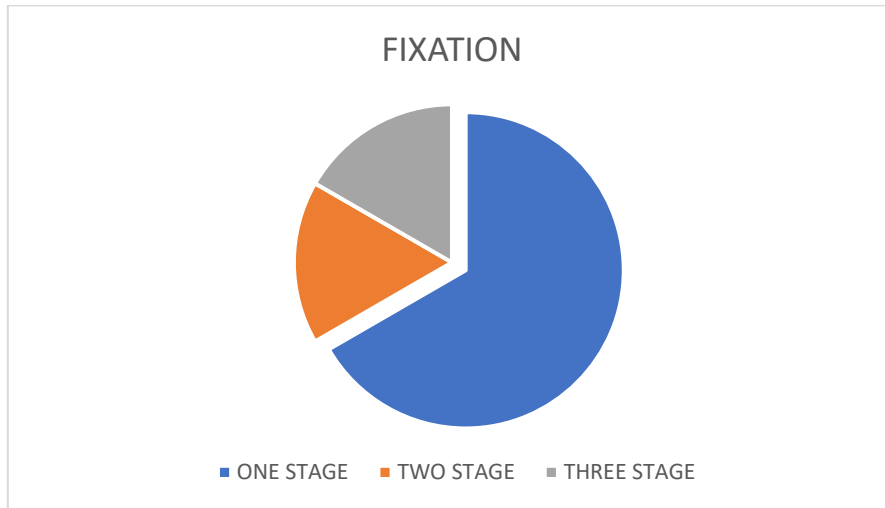
### SMOKERS AND NON-SMOKERS

SMOKING STATUS	Number of patients	Lane and Sandhu score	Time of graft incorporation
SMOKER	11	$8.36 \pm 1.95$	$12.0 \pm 2.96$
NON-SMOKER	18	$10 \pm 2.377$	$10.4 \pm 1.95$

The study included a total of 37.9% (11 patients) smokers and 62% (18 patients) non smokers, one person was excluded from this chart as the patient eventually ended up in an amputation. In smokers, the mean time of graft incorporation was  $12.0 \pm 2.96$  weeks and

in the non- smokers, the mean time of graft incorporation was  $10.4 \pm 1.95$  weeks. The total Lane and Sandhu score in smokers was  $8.36 \pm 1.95$  and in a non-smoker was  $10 \pm 2.377$  weeks

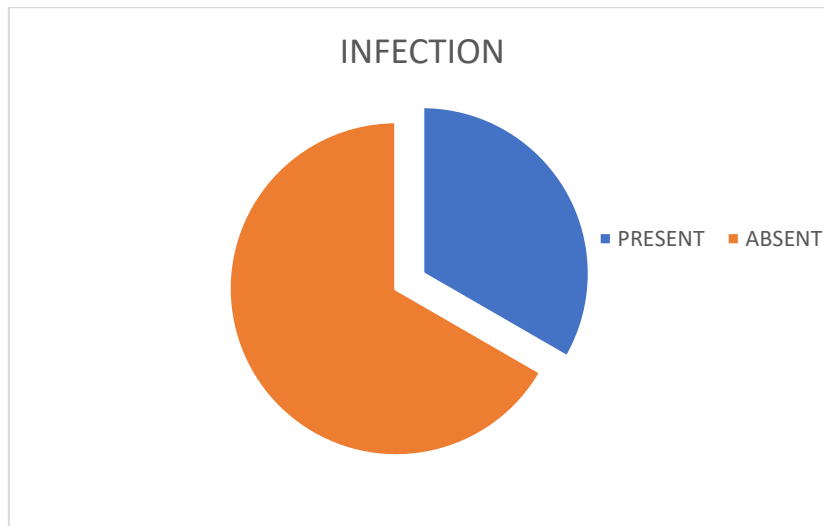
**PRIMARY FIXATION BEFORE DEFINITIVE FIXATION**



Amongst the 30 patients, 66% (20 patients) underwent definitive fixation in the first stage. Of the 33% (10 patients) who

underwent primary fixation, 5 underwent only one primary level fixation and 5 underwent two primary level fixations.

**INFECTION**



In this study, 30% (10 patients) of the patients had infection at the local area before the definitive surgery. It was diagnosed by culture sensitivity, ESR and CRP values.

Infection Free time (Weeks)	Number of Patients
0-4	4
4-8	3
8-12	2
12-26	1

Among the patients who were diagnosed to have infection, definitive surgery was done only after complete cessation of infection. Infection was treated by using antibiotics according to the culture sensitivity reports and surgery was done according to protocol. The patients had an infection free period of at least 4 weeks.

One patient had on-going infection while doing a definitive surgery leading to failure of surgery.

This incident taught us the importance of infection free interval before the definitive surgery and ways to achieve it.

The below chart summarises the study with respect to the most important complication in allograft bone being infection.

Infection free interval	No.	Graft incorporation time	Time of union	Complications			
				Serous discharge	Wound gaping	Infection	Presence of complication
Uninfected	20	11.05±2.35	30±4.05	1	0	0	0
12-16	1	14	42	1	0	0	0
8-12	2	9.5	31	1	1	0	0
4-8	3	12.3	40.66	2	2	0	1
0-4	4	10.25	31.33	0	3	1	0

In this study, 1 patient among 20 who belonged to the uninfected group had serous discharge at follow up which disappeared at subsequent follow ups when treated with anti-histaminics and appropriate antibiotics.

There was one patient who still had serous discharge on recent follow up.

The others who belonged to the previously infected group had either of the complications which were treated and at the recent follow up were complication free.

**COMPLICATIONS**

COMPLICATIONS	NUMBER OF PATIENTS	TREATMENT
Skin Gaping over incision site	3	Flap and STG surgeries
Serous discharge from incision site	7	Anti histamines and antibiotics
Infection	1	Amputation
Collapse of graft	1	Revision Surgery

In this study, 10% patients had complication of skin gaping over the incision site, 23% had serous discharge from the incision site and 3% had mal-union and infection respectively

**Graft Incorporation Time**

- In this study, the mean graft incorporation time was 10.93±2.389 weeks. The mean graft incorporation time for patients aged below 40 years was

10.5 ± 2.21 weeks and that of above 40 years was 11.31±2.46 weeks.

- The mean graft incorporation time for patients who had infection prior to definitive fixation was 11.1±2.18 weeks.
- The mean graft incorporation time for patients who did not have any infection prior to definitive fixation was 11.05±2.35 weeks.



**Union**

- In this study, the mean union time was 31.8±5.44 weeks.
- The mean time of union for patients who had infection prior to definitive fixation was 36±6.08 weeks.
- The mean union time for patients who did not have any infection prior to definitive fixation was 30±4.5 weeks.

**Lane and Sandhu Knee Score**

Bone formation	3.68±0.47
Union	3.24±0.98
Remodelling	2.48±1.37
Total	9.41±2.32

- Score in patients who had infection prior to surgery was 8.22.
- Score in patients who were infection free prior to surgery was 10.04.

**DISCUSSION**

In this study, bone loss was caused by a variety of causes; viz., high energy trauma, low energy trauma, osteomyelitis, non-union and others. The use of allograft as a bone graft substitute was found to be a reliable option with encouraging results.

30 patients with fractures ranging in all the limbs were treated with allograft as a bone graft substitute. Amongst these patients, 76.6% patients were male and 23.3% female, patients were of younger adult age group, the

main cause of the bone loss included trauma due to road traffic accidents suggesting young males having a predilection towards injury due to vehicular accidents.

In this study, there was no specific predilection towards a particular side of the limb but the bone most affected was the tibial diaphysis.

Amongst the patients included in the study, 53.3% of the patients had bone loss >5cm and the 46.6% had <5cm. Thus, our study covered the use of allograft in both massive bone loss surgeries and in day to day bone graft surgeries. 60% of the patients were treated with definitive methods within 15 days of diagnosis and 36% were treated 60 days after the initial diagnosis highlighting the study group had both simple closed trauma and complex open trauma.

The importance of primary bone and joint stabilisation was also highlighted. In this study, 33% of the patients underwent atleast one stage of primary fixation before the definitive surgery. Primary fixation in these patients was necessary for bone and soft tissue stabilisation.

John and colleagues in their study using allograft in 53 calcaneal osteotomies found that the mean time of graft incorporation was around 9.1 weeks in adolescents and 9.8 weeks in adults.<sup>12</sup> In our present study, the mean time of graft incorporation is 10.9 weeks. The difference can be attributed to the inclusion of long bones in the present study.

STUDY	SUBJECT	GRAFT INCORPORATION
Weing Feng et al 13	Allograft used in tibial plateau	90.91%
Komender et al 14	Allograft in 1125 cases	90%
Buckley et al 15	Allograft in acetabular revision surgery	88%
Present study	Efficacy of allograft in fracture healing	100%

In a study conducted by Wei Feng et al<sup>13</sup> they used fresh frozen and irradiated bone allograft for tibial plateau fractures and 0.91% allografts were incorporated in the host bone. Komender et al<sup>14</sup> analyzed the clinical results of transplantation of deep-frozen and radiation-sterilized allogenic bone grafts in 1,125 cases reporting that greater than 90% of patients reached full restoration or showed significant

improvement of their condition. Buckley et also also reported similar results, specifically a survivorship of 88% with revision as the end-point after a mean of 5 years in 123 patients who underwent acetabular revision surgery using allograft which were frozen, morselised and irradiated before grafting. In the present study where fresh frozen cancellous allograft bone was used, 100% graft incorporation was observed.

Schmitz et al<sup>16</sup>, Ristinemi et al<sup>17</sup> and Alemdaroglu et al<sup>18</sup> in their respective studies highlighted the delay in fracture union in smokers. In this study, smokers had a mean delay in union of around 2 weeks.

Drosos et al<sup>19</sup> in their study of factors affecting fracture healing after intramedullary nailing of tibial diaphysis for closed and open grade fractures showed that open fractures had a delay in union and in our present study, the mean delay was 2 weeks.

In our study, around 30% of the patients had infection prior to definitive surgery. These patients were treated according to the protocol and infection was eradicated before bone grafting surgery. Graft incorporation was assessed, the mean time of graft incorporation in infected patients and non-infected patients did not show significant difference. The important problem amongst the infected patients was of post operative serous discharge from the graft site, which was treated with appropriate antihistaminics and antibiotics according to the culture sensitivity reports.

According to the study by Atesch Aleschrang et al<sup>20</sup> where cancellous allograft was used to vitalize autograft in infected non-union of tibia, they had an infection persistence rate of 6.7% whereas the present study had an infection persistence rate of 10%. The study by Atesch Aleschrang et al also highlighted the union rate where the union rate was 73.3% and in the present study, the union rate was 90%.

Amongst the patients in this study who had discharge from the graft site, one patient still had the same complaint at her last follow up which was 28 weeks post operative. The challenges faced in the form of complications in our study included skin gaping over the fracture site in around 10% patients which was treated surgically using skin flaps or split skin thickness grafts. Serous discharge from the suture site was the other major challenge faced in around 23 % of patients which was countered by the use of antihistaminics and appropriate antibiotics according to the culture sensitivity reports. One patient in our study had a complication of fulminant

osteomyelitis in the grafted bone and had to undergo amputation of the limb. However, this patient had preexisting infection in its active stage at the graft site. This taught us the importance of surgical and medical techniques to eradicate infection before definitive bone graft surgery.

In published data by Silber JS et al<sup>21</sup> about donor site morbidity after anterior iliac crest bone harvest in cervical spine surgeries mentioned significant complications rate of 26%, on the contrary the present study has no graft site morbidity as allograft was used from a bone bank.

A study by Michael Flier et al<sup>22</sup> discussed the outcomes and complication rates of different bone grafting modalities in long bone fractures. In their study, the average time of union of the bone allograft was 55 weeks whereas our study had an average bone union time of around 31 weeks, this difference in the union time may be attributed to the use of demineralised bone matrix type of allograft in the former and the use of fresh frozen allograft in the latter.

## CONCLUSION

This study concludes that pure cancellous allograft has properties similar to autograft and has complete graft incorporation.

The bone allograft has no donor site morbidity as compared to autograft.

The main challenge in using allograft is control of infection which was solved by using meticulous surgical and medical techniques to counter the infection.

There was no significant difference in graft incorporation in infected and non-infected patients, thus, we could conclude that allograft behaves in the same way in infected and non-infected cases.

We also conclude that when fresh frozen allograft is used, which can be produced in a small to large orthopaedic hospital set up, the entire process of allografting is sterile as the closed chain is maintained.

## Declaration by Authors

**Ethical Approval:** Approved

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**Conflict of Interest:** The authors declare no conflict of interest.

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