# **Original Research Article**

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# A study of clinical outcome and patient quality of life in timing of free flap cover in type IIIB open fractures

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#### **ABSTRACT**

**Background:** Open fractures of leg classified under type IIIB, those requiring free flap cover could be done as emergency procedure. The ideal timing has still remained controversial. Although it appears imperative to operate early and reduce length of hospital stay, costs, disability adjusted life years and put the patient back on his feet, our study was necessitated in the context of differing views regarding ideal timing of free flap.

**Methods:** The prospective observational study was conducted for duration of 4 years between October 2015 to September 2019. Patients were taken up for free flap cover after optimization for the major surgery. Details of flap complications and the procedures for salvage were noted. At the end of one year following the injury, patient quality of life (PQOL) was tabulated for all patients.

**Results:** Most common mode of injury was road traffic accidents. Early flaps were done in 28 and primary flaps in 22 patients. One patient had partial flap necrosis while 7 others had sub flap collections and partial flap necrosis. Duration of hospitalization was significantly lower in early flap cover group. PQOL measured with EQ-5D (EuroQol 5D) was significantly higher in the early flap covers.

**Conclusions:** From our study we concluded that timing of free flap cover positively influenced clinical outcome of reduced hospitalization, although there was no relation of timing of free flap to flap or bone complications. The functional outcome measured by PQOL was significantly higher in patients who had microvascular reconstruction early.

**Keywords:** Free flap timing, Type IIIB fracture of the leg, Gustilo Anderson classification, Patient quality of life, Lower limb fracture

# INTRODUCTION

The incidence of open fractures of the long bones has ever been increasing, particularly in developing nations owing to road traffic accidents. The young and working segment of population is the most involved. An epidemiology data analysis by Dandona et al on road traffic accidents in India indicated morbidities from road

traffic accidents was found to be clustered in pedestrians, motorized two-wheelers and cyclists at 6.4, 6.3, and 5.1/100 persons/year, respectively. Also the annual disability rate was 35.1/100,000.

Around 60% of the total number of disability adjusted life years (DALYs) lost globally following road traffic accidents occurs among young adults' aged between 15-

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44 years. According to the WHO, The Injury Chart Book, India and China had the greatest road traffic injury burden, with most of them men.<sup>2</sup> The number of DALYs lost by men in these countries exceeded those lost in any other world region.

The onus of treating them falls on the shoulders of Indian hospitals where already the patient doctor ratio is skewed and most big medical centers are burdened. These patients need multi specialist team approach starting from resuscitation to rehabilitation to get them back on their feet

Of our interest are open fractures of the leg classified under type IIIB.<sup>3</sup> The procedures in such patients may differ beginning with the type of skeletal fixation to choose of free flap cover. But they follow similar principles of immediate surgical debridement and skeletal stabilization done immediately and soft tissue covers preferably soon after optimization. External fixation is the established method of skeletal fixation.<sup>4</sup>

The concept of early soft tissue reconstruction proposed by Godina promised superior clinical outcomes such as lower flap failure and infections, shorter bone-healing time and length of hospital stay.<sup>5</sup> The ideal timing still has remained controversial with reports finding no association with the outcomes.<sup>6,7</sup>

Our country being a developing one driven by a large young workforce, it is imperative to reduce length of hospital stay and disability adjusted life years. Need for reconstructions in major injuries further burdens the health infrastructure. These patients need multidisciplinary approach. Defects with extensive soft tissue loss or composite losses that is not amenable to local tissue transfer need reconstruction with free flaps. Although requiring microsurgical expertise and longer operating time, free flaps are an established reliable option. <sup>8,9</sup>

The need for this study arose in the context of differing views regarding timing of free flap cover in type IIIB open fractures of the leg, which we intended to evaluate based on the clinical and functional outcomes.

The timing factor has been compounded by concomitant injuries, lack of microvascular capability at all centres, delayed referral, infection to name a few. Significant advances in resuscitation, perioperative and intraoperative management, critical care and by large the availability of microvascular surgery has facilitated major reconstructions to be done sooner.

A good debridement, definitive bony fixation, absence of infection and patient optimization were indispensable and hence free flap cover could be safely delayed. Still there need to be more studies on outcome analysis to find a consensus on timing of free flap cover.

In our study, we categorized the timing of free flap cover as emergent (<24 hours), early (<5 days), primary (6 to 21 days), or delayed (>21 days) free flap cover.

#### Aims and objectives

The aim of the study was to evaluate the influence of timing of free flap cover in the management of type IIIB open fractures of the leg with regards to flap and bone complications, length of hospital stay and functional outcome.

#### **METHODS**

#### Study place

This study was conducted at RajaRajeswari Medical College and Hospital, Bengaluru, India.

# Study population

All the patients admitted to the hospital during the study period who underwent a free flap cover for type IIIB open fractures of the leg.

#### Study duration

The study was conducted for duration of 4 years between October 2015 to September 2019. All the patients were followed up for 1 year.

# Study design

The prospective observational study was conducted.

#### Inclusion criteria

All the patients of type IIIB open fractures of the leg admitted to our hospital during the study period and underwent a free flap cover.

#### Exclusion criteria

Patients referred to our hospital with complications, those under the age of 18 years, those with severe injury to the contralateral lower limb and patients with severe injury proximally or distally in the same limb affecting outcomes were all excluded.

# Method of data collection

Case series method was used to include all patients managed at our hospital in the study duration. The proforma was designed based on the objective of this study and case series method was employed to recruit patients. A general informed consent was taken for participation in the study.

After resuscitation, relevant X-rays were taken. They underwent debridement and skeletal fixation by external fixators. Post debridement, the type IIIB open fracture patients who satisfied the inclusion and exclusion criteria requiring free flaps were requested to be part of the study, and a written consent was obtained.

In the pre-operative assessment demographic parameters of the patient, defect size and extent and fracture characteristics were recorded. Immediately post debridement external fixator was applied. Patient was taken up for free flap cover after optimization for the major surgery.

The operative details regarding choice of free flap and recipient vessels, anastomosis and ischemia time was noted. After revascularization, when the arterial clamp was released, 2500 IU heparin was given to all patients except where contraindicated.

Post operatively all patients were kept in the postoperative ward. The flaps were frequently examined clinically for colour, temperature, brisk bleeding and hand-held Doppler examination. Cases were taken up for flap salvage immediately, if required. Details of flap complications and the procedures for salvage were noted.

Patients visit were scheduled frequently as necessary during the first month of follow up where any problems with the flap were duly noted. The subsequent monthly visits were tailored to the patients' progress, complications or need for further interventions. Secondary bone procedures were done by the orthopaedic department based on the type of fracture, bone defect and in case of complications such as non-union, osteomyelitis and stiffness. These details were noted in the study. At the end of one year following the injury, patient quality of life (PQOL) was tabulated for all patients.

Expected outcomes of the study was whether the timing of free flap cover influenced the clinical outcomes of flap and bone complications, duration of hospital stay and the functional outcomes assessment by PQOL (quality of life scale).

#### Sample size

The expected sample size was calculated based on the previous studies. Marko Godina study which included free flaps done to both upper and lower extremities was 532 in 7 years, i.e., 76 patients per year. Francel et al had 72 patients of open tibial fractures operated with free flaps in 18 months, i.e., 48 patients in a year. Hertel et al had 24 type IIIB open fractures of the lower extremity in 6 years and 9 months. Study by Karanas et al included 14 patients in over 5 years. After reviewing the above studies, and our case load, the number of patients expected in this study after the inclusion and exclusion criteria should be 40 to 50.

#### Statistical methods

Descriptive and inferential statistical analysis will be carried out in the study. Mean±SD will be calculated for continuous measures. Significance will be assessed at 5% level of significance. Student t-test (two tailed, independent) will be used to find the significance of study parameters on continuous scale between two groups (inter group analysis) on the metric parameters. Chi-square/Fisher Exact test was used to find the significance of study parameters on categorical scale between two or more groups and non-parametric setting for qualitative data analysis.

# Statistical software

Microsoft word and Excel was used to generate tables and graphs. The SPSS 22.0 software will be used for analysis of the data.

#### RESULTS

This study is a prospective observational study carried out at a tertiary care trauma centre. This study was done from October 2015 and September 2019 and all the patients were followed up for 1 year. Total 50 patients were included in the study according to inclusion and exclusion criteria.

#### Age wise distribution of all patients in the study

Most of the patients in the study were in their 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> decades of their life.

Table 1: Age distribution.

A co in	Time to free	Total	
Age in years	Early flap (%)	Primary flap (%)	Total (%)
18-20	1 (3.6)	2 (9.1)	3 (6)
21-30	3 (10.7)	8 (36.4)	11 (22)
31-40	8 (28.6)	3 (13.6)	11 (22)
41-50	9 (32.1)	4 (18.2)	13 (26)
51-60	4 (14.3)	5 (22.7)	9 (18)
61-70	2 (7.1)	0	2 (4.0)
71-80	1 (3.6)	0	1 (2.0)
Total	28 (100)	22 (100)	50 (100)

#### Sex wise distribution of patients in the study

There were 46 (92%) males and 4 (8%) females in the study.

# Side of the affected leg

Patients with affected right leg were more in number (44 patients- 88%) compared to those with affected left leg (6 patients- 12%).

Table 2: Fracture site.

Sites in the leg	No of patients
Proximal 1/3 <sup>rd</sup> leg	3
Proximal-mid 1/3 <sup>rd</sup> junction	1
Mid 1/3 <sup>rd</sup> leg	7
Mid-distal 1/3 <sup>rd</sup> junction	12
Distal 1/3 <sup>rd</sup> leg	21
Medial malleolar	3
Lateral malleolar	1
Bimalleolar	4
Assosicated ankle dislocation	3
Total	55

# Distribution of open fractures and site of defect in the leg

Most of the cases had mid-distal (21.8%) and distal (38.2%) part of the leg affected.

# Distribution of free flaps

Anterolateral thigh (ALT) flap (27 patients) was the most commonly used free flap to cover the defect followed by gracilis muscle flap (20 patients) and latissmus dorsi flap (3 patients).

Table 3: Mode of injury distribution.

Mode of injury	No. of patients (%)	
RTA	44 (88)	
Fall of heavy object	2 (4)	
Fall from train	1 (2)	
Furnace blast	1 (2)	
Gunshot injury	1 (2)	
Machine crush injury	1 (2)	
Total	50 (100)	

#### Mode of injury

Road traffic accident (RTA) was the most common mode of injury constituting 88% (44) of the study group.

# Distribution of timing of free flap cover

28 patients had early (1-5 days) flap cover while 22 patients had primary flap cover.

**Table 4: Type of flap complications.** 

Flap complication	Early flap	Primary flap	Total
Necrosis of margin	0	1	1
Sub flap collection with partial flap loss	3	4	7
Total flap loss	0	0	0
Total	3	5	8

#### Distribution of flap complications in all patients

In those who underwent flap cover early had flap complications in 3 patients (10.7%) and all of it was subflap collection leading to partial loss of flap. 5 patients (22.7%) in primary flap group had complications of which 1 patient had margin necrosis while 4 patients had sub flap collection with partial flap loss (Table 4).

# Flap complications in all the patients

There was no relation between timing of free flap cover and development of flap complications in the study.

**Table 5: Flap complications.** 

Flon	Time to free	Total	
Flap complications	Early flap (%)	Primary flap (%)	(%)
No	25 (89.3)	17 (77.3)	42 (84)
Yes	3 (10.7)	5 (22.7)	8 (16)
Total	28 (100)	22 (100)	50 (100)

P=0.277, not significant (Chi-square test).

# Distribution of bone complications in all patients

Bone complications were noted in 8 patients of the early flap group (EFG) and 9 patients of the primary flap group (PFG). Nonunion was present in 6 patients of EFG and 4 patients of PFG; non infected union was noticed in 1 patient of EFG & 3 patients of PFG; avascular necrosis was seen in 1 patient of PFG; ankle stiffness and equines was noted only in 1 patient of PFG while knee joint infection was present in 1 patient of PFG.

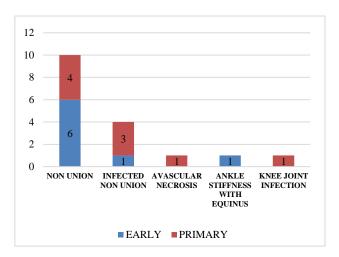


Figure 1: Type of bone complications.

# Comparison of bone complications in early and primary flap groups

There was no relation of time to free flap cover on the bone complications.

Table 6: Bone complication comparison between groups.

Bone	Time to fre	Total	
complications	Early flap (%)	Primary flap (%)	(%)
No	20 (71.4)	13 (59.1)	33 (66)
Yes	8 (28.6)	9 (40.9)	17 (34)
Total	28 (100)	22 (100)	50 (100)

P=0.361, not significant (Chi-square test).

#### Total hospital stay in all patients

The difference in total hospital stay between the early and primary flap cover groups was significant. Meaning, the hospital stay was significantly reduced in the patients who underwent early flap cover.

Table 7: Hospital stay duration.

Total	Time to fre	TF-4-1	
hospital stay (in hours)	Early flap (%)	Primary flap (%)	Total (%)
1-10	0 (0)	0 (0)	0 (0)
11-20	15 (53.6)	3 (13.6)	18 (36)
21-30	8 (28.6)	8 (36.4)	16 (32)
31-40	5 (17.9)	7 (31.8)	12 (24)
41-50	0 (0)	4 (18.2)	4 (8)
Total	28 (100)	22 (100)	50 (100)
Mean±SD	22.25±8.7 7	30.41±10.33	25.84± 10.24

P=0.004, significant (Student t test).

# Patient quality of scale of all patients

The time from injury to free flap cover compared with PQOL was significantly higher in the early group than the primary group (with 'p' value of 0.02).

Table 8: POOL assessment.

	Time to free flap	
	Early flap	Primary flap
Mean PQOL score	69	65
SD	5.5	6.5

P=0.02, significant (Student t test).

**Table 9: Secondary orthopaedic procedures.** 

Secondary	Time to free	-	
orthopedic procedures	Early flap (%)	Primary flap (%)	Total (%)
No	17 (60.7)	12 (54.5)	29 (58)
Yes	11 (39.3)	10 (45.5)	21 (42)
Total	28 (100)	22 (100)	50 (100)

P=0.661, not significant (Chi-square test).

#### Secondary orthopedic procedures

There was no relation of time to free flap cover and the secondary orthopedic procedures underwent in our patients.

#### **DISCUSSION**

All patients in the study underwent debridement and skeletal fixation by an external fixator soon after resuscitation. Further corrections of acidosis, blood loss were done and optimized for free flap surgery. The flaps used were free anterolateral thigh, free gracilis and free latissimus dorsi flaps. Development of complications such as infection, sub flap collections, necrosis of flap, partial or total loss of flap, bone complications such as non-union, infection were noted. The patients who underwent secondary procedures such reconstructions system (LRS) for bone transport, corticotomy, and bone graft were also noted. Also the total duration of hospitalization from multiple admissions were separately tabulated. In all the study patients, at 1 year follow up, quality of life scale was used for functional assessment.

There were 50 patients in this study which included 46 males (92%) and 4 females (8%). The 41 to 50 age group patients had 13 patients followed by 11 patients each in 21 to 30 and 31 to 40 age groups. Mean age was 40.42 years. Most common mode of injury was road traffic accidents in 44 patients comprising 88% patients of the study. Other modes of injuries were fall of heavy object in 2 patients (4%) and 1 patient each of fall from train, furnace blast, gunshot injury & machine crush injury. 44 patients (88%) in our study sustained injury to the right leg.

Most common site of open fracture was in the distal 1/3<sup>rd</sup> leg (21), followed by 12 in the mid-distal 1/3<sup>rd</sup> junction of leg. Patients who sustained another major injury in the same limb or the contralateral lower limb were excluded from the study.

All free flap were performed by plastic surgery consultants. Clinical assessment of the defect with respect to size, site of the defect, critical structures that need to be covered and the recipient pedicle were amongst the many considerations. ALT flap was most commonly used i.e., in 27 patients (54%), gracilis in 20 (40%) and latissimus dorsi in 3 patients (6%). Most common recipient artery was the posterior tibial artery in 39 patients (78%), anterior tibial artery was used in 9 patients (18%).

The definition of early flap cover in various previous studies varied grossly. Byrd et al in 1985 classified the cases they operated under acute (1-6 days), subacute (1-6 weeks) and chronic (>6 weeks). The study by Marko Godina in 1986 classified them as early (within 72 hours), delayed (between 72 hours-3 months) and late

reconstruction performed more than 3 months after injury.<sup>5</sup> The latest being Harrison et al who grouped them as emergent(<24 hours), early (<5 days), primary (6 to 21 days), or delayed (>21 days).<sup>6</sup>

There were no emergency flaps performed (within 24 hours of injury) in the study. Early flap cover (between 1 to 5 days) was done in 28 patients (56%) and primary flaps (between 6to 21 days) were 22 (44%). There were no flaps in the delayed group (>3 weeks) in the study. 7 patients had sub flap collection with partial flap loss and 1 flap had margin necrosis. These flaps were debrided and inset. All flaps survived. There was no significance of timing on the flap complications as the 'p' value was 0.277 by Chi-square test. Godina found flap failure rate of 0.75% in the early, 12% in delayed and 9.5% in the late reconstruction groups.5 Study by Karanas et al found no significance of timing of the free flap cover and they concluded reconstruction could be safely performed later and that a good debridement and stabilization of the injuries was paramount.9

All patients were given 40 IU/kg heparin intraoperatively after arterial anastomosis and continued heparin infusion post operatively for 5 days at 18 IU/kg/hour. Intraoperatively we also used heparin to flush the vascular lumen and irrigation during anastomosis. All patients were kept for flap monitoring in the post-operative ward for 5 days. Flaps were monitored based on color, warmth, turgor and bleeding in case of gracilis and LD free flaps and in addition performing a hand-held doppler hourly in ALT flaps.

Amongst the bone complications, 10 patients had non-union and 4 patients had infected non-union. One each had avascular necrosis, ankle stiffness and knee joint infection. There was no significance with respect to timing of the free flap on bone complications in our study as the 'p' value was 0.361. In the study by Godina, the duration of bone healing was longer in later reconstructions and also there was a linear increase in the number of operations with delay. Hertel et al found that the delayed reconstruction group needed longer time for bone healing and also had higher incidence of bone infections. It

The mean of the total length of hospital stay calculated by standard deviation was 25.84±10.24 days. On tabulating with time to free flap cover in our study, we found that the early flap cover patients had shorter mean hospitalization of 22.25±8.77 compared to that of primary flap cover patients which was 30.41±10.33. We used Student 't' test to confirm the same and 'p' value was found to be 0.004 (significant). Duration of hospital stay in the study by Godina was 27, 130 and 256 days for the early, delayed and late groups respectively. Hospital stay was similar in the immediate and delayed groups of the study done by Hertel et al. 11

We plotted PQOL scale against timing of free flap cover in our study and found early flap cover patients had statistically significant higher scores than those in the primary flap cover group.

The total duration of hospitalization will be shortened by early reconstructions and also found the functional scores were also higher in patients operated early.

#### **CONCLUSION**

The timing of free flap cover in type IIIB open fractures of the leg was being debated that early flap cover improved outcomes while others suggesting early flap cover alone could not have influenced outcomes and there were strong associations beginning from severity of injury to debridement, development of complications etc. We found that the timing of free flap cover done early reduced duration of hospitalization and also improved functional outcomes. 28 patients in the study came under early free flap group (1-5 days) and the rest 22 patients under primary free flap (>21 days). The minor flap problems could probably be related to various factors (not restricted to) good debridement, asepsis or surgical technique. We infer better functional outcomes were obtained by timing the of free tissue transfer early.

From our study we concluded that timing of free flap cover positively influenced clinical outcome of reduced hospitalization, although there was no relation of timing of free flap to flap or bone complications. The functional outcome measured by PQOL was significantly higher in patients who had microvascular reconstruction early.

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Institutional Ethics Committee

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