

# Titanium Elastic Nailing with Temporary External Fixator versus Bridge Plating in Comminuted Pediatric Femoral Shaft Fractures: A Comparative Study

## Abstract

**Background:** High-velocity trauma, associated injuries, risk of iatrogenic devascularization of fragments and need for maintaining alignment upto union make comminuted fracture in pediatric femur a formidable fracture to treat. This comparative study was conducted to evaluate the outcomes of two modes of management in such cases: titanium elastic nailing supplemented with external fixator and submuscular bridge plating (BP). **Materials and Methods:** Thirty eight children (aged 6–12 years) with comminuted fracture shaft femur who were randomized into two groups underwent systematic evaluation. One group was operated with titanium nailing with temporary external stabilization by fixators (titanium nailing with external [TNE] group) for 4 weeks. The other underwent submuscular BP with locked plates (BP group). Clinical and radiological outcomes, operative time, blood loss, radiation exposure, difficulties in removal and complications were evaluated. **Results:** Both groups achieved union ( $10.7 \pm 1.9$  weeks BP,  $11 \pm 1.6$  weeks TNE), satisfactory knee flexion ( $138.2 \pm 6.4^\circ$  BP,  $136 \pm 7.3^\circ$  TNE), and painless weight bearing ( $7.3 \pm 0.9$  weeks vs.  $7.3 \pm 1.4$  weeks) in acceptable alignment. Functional outcomes were excellent in majority of both BP (15 of 19) and nail external fixator groups (15 of 18). Operating time and radiation exposure ( $69.5 \pm 14.5$  s vs.  $50.9 \pm 12.9$  s) were more in TNE than in BP ( $P < 0.01$ ). However, implant removal was more difficult in BP ( $56.4 \pm 12.4$  min in BP vs.  $30.1 \pm 8.8$  min TNE). Pin-tract infections ( $n = 3$ ) and hardware prominence ( $n = 2$ ) in TNE group and deep infections ( $n = 2$ ) in BP group were notable complications. **Conclusion:** Two groups were similar in radiological and functional outcomes. Inserting elastic nails and external fixator was a more exacting surgery, while removal was more difficult in BP group. Both techniques had acceptable success and complication rates.

**Keywords:** External fixator, intraoperative radiation, pediatric femoral fractures, pediatric rehabilitation, polytrauma, submuscular bridge plating, titanium elastic nail

**MeSH terms:** Pediatrics, multiple trauma, femoral fractures, intramedullary nailing

## Introduction

Pediatric femoral fractures are common injuries accounting for approximately 1.6% of all skeletal injuries in children.<sup>1</sup> Most of these fractures were caused by low-energy injuries in the past. However, with the increase in road traffic injuries, high-velocity fractures are becoming increasingly common. Low-velocity injuries can be treated by various techniques. Closed reduction with hip spica application, delayed hip spica following traction, elastic intramedullary nailing, open or bridge plating (BP) and external fixators are the major methods of treatment of these fractures.<sup>2</sup> High-velocity injuries, however, are difficult cases to address. In unstable

femur shaft fractures, conservative treatment methods often lead to malunion and shortening.<sup>3</sup> Due to comminution, elastic intramedullary nails often fail to prevent shortening, angulation, and malrotation.<sup>4,5</sup> Open reduction with plating also has the risk of devitalizing the fragments due to excessive tissue dissection.<sup>6</sup> Elastic nails, when supplemented with an external fixator for initial 4 weeks, can maintain the length as well as alignment till union. Minimally invasive BP has also proved to be an effective mode of fixation as the fracture site is bypassed and there is only minimal insult to the soft tissues and bones due to surgical dissection.<sup>7-10</sup> These two techniques hold promise for effective management of unstable comminuted shaft femur fractures in children. This comparative study was conducted with the primary objectives

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of investigating and comparing radiological and clinical results of each technique and to explore any possible difficulties or complications from clinical and technical standpoint.

## Materials and Methods

Thirty eight consecutive children with comminuted fracture of the shaft of femur were included for the prospective study. The study was conducted between March 2011 and February 2015 in two institutes which deal with a high volume of pediatric trauma cases annually. 28 patients were from Institute 1 and the rest were from the institute 2. The study received prior approval from the Institutional Review Boards of both institutes separately. The inclusion criteria were: age between 6 and 12 years with a closed or Grade I open fracture of <2 weeks' duration. Higher grades of open fractures were excluded since they would confound the outcomes. The fracture had to be essentially within the zone between 5 cm distal to lesser trochanter and 5 cm proximal to growth plate of distal femur, as fractures outside this zone were not amenable to treatment by the two investigated techniques. In the series of comminuted shaft femur published by Samora *et al.*, union time in weeks showed a standard deviation of 2.27.<sup>11</sup> Taking this value of standard deviation as baseline,  $\alpha = 0.05$ ,  $\beta = 0.1$ , and effect size of 2.5, the sample size required to give a statistical power of 90% was found to be 35 (18 in Group A and 17 in Group B). Hence, the authors started the investigation with 19 individuals in each group.

The patients were randomized into titanium nailing with external fixator (TNE) group and the BP group according to the randomization protocol using random number generating software (Research Randomizer, Version 4.0, Urbaniak G. C. and Plous S., 2015, Pennsylvania). Since this was a multicenter study, an offsite computer performed the allocation concealment and transmitted allocation directives to both the centers from a common source. The patients in either group were prepared for surgery after assessment of the general status.

### Operative procedure

The patients in the closed nailing group were placed on the fracture table. They underwent titanium elastic nailing using a retrograde ( $n = 13$ ) or antegrade approach ( $n = 6$ ). Intraoperative traction was used to achieve closed reduction under an image intensifier. If closed methods failed, a mini incision at the fracture site was made to introduce bone hooks to enable reduction. After the nailing had been accomplished, the fracture was further stabilized using external fixators. Two Schanz pins or smooth pins (3.5 or 4.5 mm) proximal and two pins distal connected with a bar spanned the fracture site.

In the plating group, patients were placed supine on a radiolucent table. Indirect maneuvers were performed using manual traction and folded towels were used under the

limb to achieve reduction. Fracture site was opened through small incision only if there was gross malreduction despite closed maneuvers. We followed the two incision techniques as described by Samora *et al.*<sup>11</sup> A 4.5-mm (or 3.5 mm in small bones) locking compression plate was contoured on table in accordance with the lateral cortex of the opposite femur to accommodate the proximal and distal metaphyseal flares of the femur. It was passed across the fracture side through a submuscular (epiperiosteal) plane using minimally invasive approach through small incisions and was fixed with locking screws through small stab incisions. The plate so selected had to be long enough to span the site of comminution and should have secure purchase on at least six cortices by three screws on either side of fracture.

Gentle hip and knee mobilization and quadriceps exercises started from the first postoperative day and progressive assisted range of motion and strengthening exercises were continued for successive 2 months. However, the extent of therapy differed as it was tailored to patient's general condition and other injuries. Postoperative radiographs were taken on day 1, day 28, at 6 weeks, and then at each successive month until union. For patients with nailing with external fixator, the fixator was removed routinely at 4 weeks under sedation or general anesthesia.

To prevent observer bias, clinical parameters were assessed by one of the authors (DD) who was not a part of the surgical team. Parameters in the study were presence or absence of pain, knee range of movement, symmetry of gait, and any symptoms due to hardware. Clinical union was defined as absence of tenderness over the fracture site and pain-free weightbearing. Radiological union was defined as presence of bridging callus and/or restoration of continuity in at least three of the four cortices in two orthogonal radiographs. Radiological assessment of the alignment was done as per Flynn's criteria.<sup>4</sup>

Surgical parameters which were assessed both during the index surgery and during implant removal were as follows: blood loss, duration of surgery, and intraoperative radiation exposure. Intraoperative blood loss was quantified by weighing the soaked sponge and measuring the collection in the suction machine. Duration of surgery was defined as the time from skin incision to application of the last stitch or skin staple in the wound. Radiation exposure was defined as the duration of fluoroscopy in seconds used during the surgery. Implant removal was performed after union and ensuring sufficient remodeling. Removal was done earlier in the symptomatic implants and electively in rest of the cases according to patients' convenient opportunity.

For analysis of parameters and outcomes, Chi-square test, Mann-Whitney U-test, Kolmogorov and Smirnov Test and Fisher's exact test were applied as appropriate using the Statistical Analysis Software version 9.4 (SAS Institute Inc, Cary, North Carolina, USA). The statistical significance was set at 95% confidence interval ( $P = 0.05$ ).

## Results

A total of 387 cases of fracture shaft femur were encountered during the study period in the age group of 6–12 years. Of these, 54 cases were comminuted fracture shaft of femur [Figure 1]. Out of these, 38 cases were enrolled for intervention. One patient died on the 4<sup>th</sup> postoperative day due to peritonitis associated with abdominal injury.

The preoperative parameters in two groups such as TNE fixator and BP were similar [Table 1]. The mean age of the patients was 8.7 ( $\pm 1.7$ ) years. There were 25 boys and 13 girls. They presented to the hospital after a period of 12.9 ( $\pm 9.5$ ) hours after having suffered injury. They were operated at an average of 30.7 ( $\pm 13.8$ ) h after the injury. Along with femur fracture, 21 of 38 children also suffered abdominal injury ( $n = 4$ ), head injury ( $n = 5$ ), chest injuries ( $n = 4$ ), faciomaxillary injuries ( $n = 3$ ), and limb injuries ( $n = 8$ ) alone or in combination. In six cases, other system surgeries were performed in the same sitting. BP took shorter time (72 [ $\pm 10.7$ ] min) compared to nailing and external fixator group (80.5 [ $\pm 11.9$ ] min) and the difference was statistically significant ( $P = 0.03$ ). In addition, radiation exposure was significantly more ( $P < 0.001$ ) in TNE group (69.5 [ $\pm 14.5$ ] s) as compared to the BP group (50.9 [ $\pm 12.9$ ] s). Severe brain injuries were excluded: By definition, these are patients with more than 6 hours of unconsciousness and/or Glasgow Coma scale 8 or less. Less severe head injuries were included in the study.

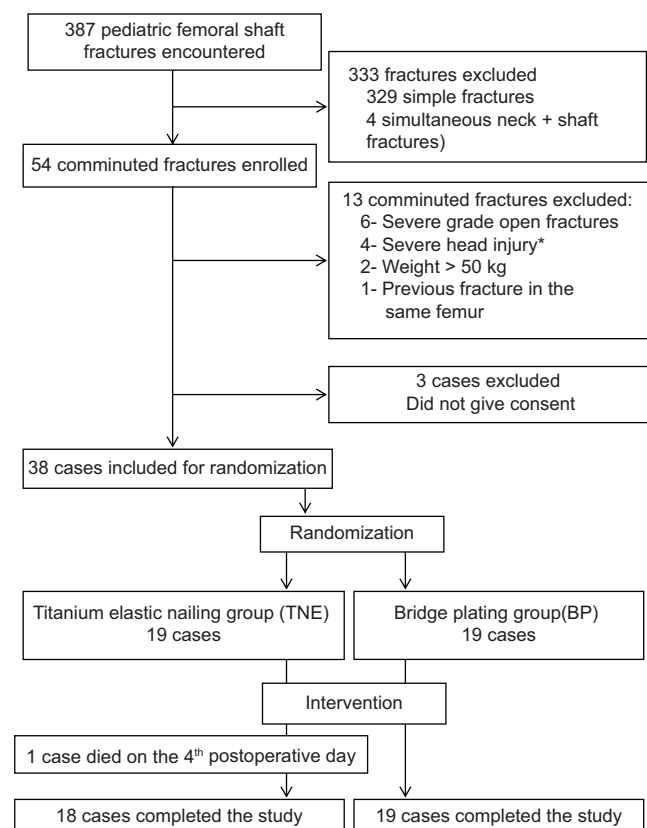


Figure 1: Study profile

The mean time to bear full weight in TNE group was 7.3 ( $\pm 1.4$ ), while that in BP group was 7.3 ( $\pm 0.9$ ) weeks ( $P = 0.48$ ) [Table 2]. The radiological union in the TNE group was seen after a mean of 11 ( $\pm 1.6$ ) weeks [Figure 2], while for BP group it was 10.7 ( $\pm 1.9$ ) weeks ( $P = 0.73$ ) [Figure 3]. All the patients achieved pain-free symmetrical gait at their latest followup.

The knee flexion in the BP group showed significantly better range ( $119.5^\circ \pm 11.2^\circ$ ) at 1 week compared to the

Table 1: Comparison of preoperative parameters in two groups

Parameters	Mean $\pm$ SD		P
	Plating	Nailing	
Age (years)	8.6 $\pm$ 1.9	8.7 $\pm$ 1.6	0.427
Sex (male:female)	14:5	11:8	0.495
Height (cm)	126 $\pm$ 8.6	128 $\pm$ 5.8	0.263
Weight (kg)	27.8 $\pm$ 5.3	27.2 $\pm$ 5.9	0.373
Time at presentation (h)	10.7 $\pm$ 6.1	15.3 $\pm$ 11.7	0.075
Other system injuries	11	10	0.96
Fracture pattern (AO/OTA)			
B1	7	7	0.83
B2	3	2	
B3	4	3	
C1	4	4	
C3	1	3	
Time at surgery (h)	27.5 $\pm$ 9.2	32 $\pm$ 17.1	0.163

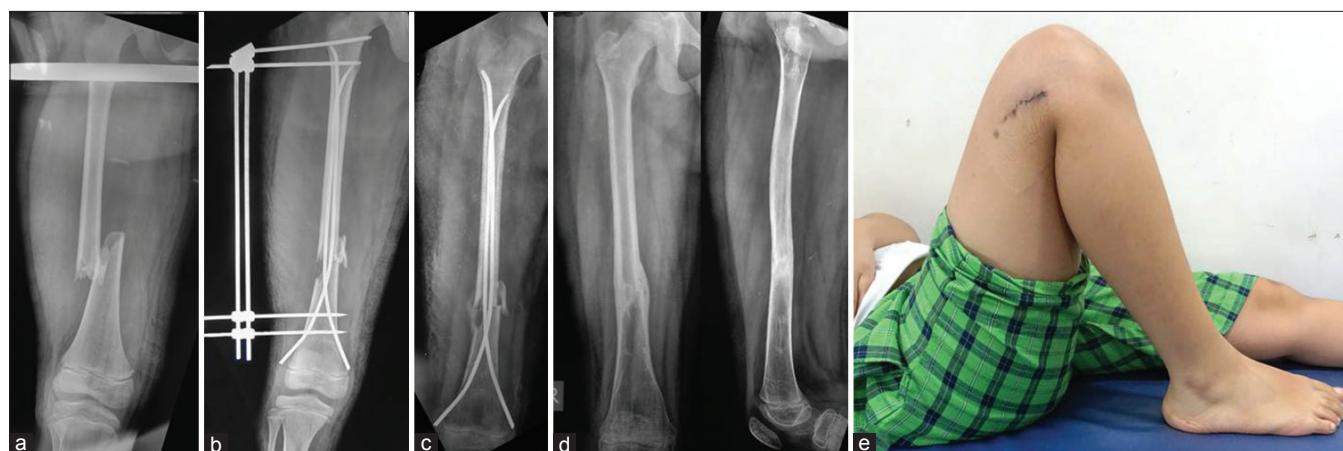
AO/OTA=AO Foundation and Orthopaedic Trauma Association fracture classification system, SD=Standard deviation

Table 2: Comparison of perioperative parameters, followup, and outcome measures

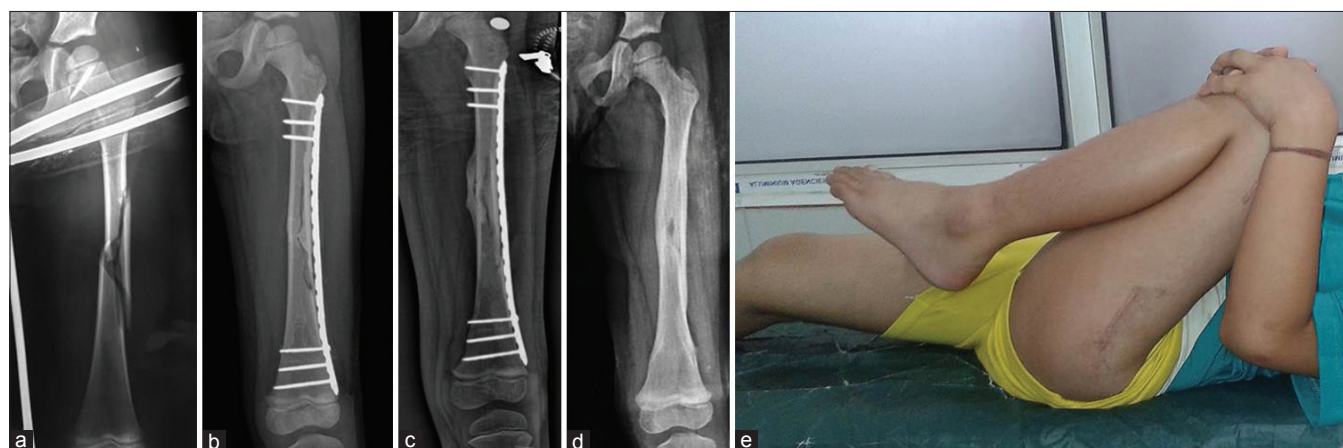
Particulars	Mean $\pm$ SD		P
	Plating	Nailing	
Duration of surgery (min)	72 $\pm$ 10.7	80.5 $\pm$ 11.9	0.03
Fluoroscopy time (s)	50.9 $\pm$ 12.9	69.5 $\pm$ 14.5	<0.001
Blood loss (ml)	71.8 $\pm$ 20.7	77.4 $\pm$ 24.8	0.234
Knee ROM ( $^\circ$ ) at day 7	119.5 $\pm$ 11.2	101.8 $\pm$ 8.6	0.039
At day 28	132.1 $\pm$ 6.3	126.2 $\pm$ 10.2	0.024
At 3 months	138.2 $\pm$ 6.4	136 $\pm$ 7.3	0.18
Varus valgus angulation (varus: +ve, valgus-ve)	5 $\pm$ 3.1	4.8 $\pm$ 3.2	0.457
Procurvatum ( $^\circ$ )	5.4 $\pm$ 3.6	6.7 $\pm$ 5.1	0.21
Implant removal time (months)	13.3 $\pm$ 1.8	12.1 $\pm$ 3.6	0.11
Removal surgery blood loss (ml)	64 $\pm$ 21.1	35 $\pm$ 12.7	<0.01
Removal surgery duration (min)	56.4 $\pm$ 12.4	30.1 $\pm$ 8.8	<0.01
Radiological union (weeks)	10.7 $\pm$ 1.9	11 $\pm$ 1.6	0.73
Time to bear full weight (weeks)	7.3 $\pm$ 0.9	7.3 $\pm$ 1.4	0.48
Functional results (Flynn's criteria)			
Excellent	15	14	0.673
Satisfactory	4	4	
Poor	0	0	
Followup period (months)	26.9 $\pm$ 6.3	25.4 $\pm$ 5.4	0.12

ROM=Range of motion, SD=Standard deviation





**Figure 2:** (a) X-ray of thigh with hip and knee joint anteroposterior view showing comminuted fracture shaft femur (b) Titanium elastic nailing and external fixator (c) After external fixator removal at 4 weeks (d) X-ray of the thigh with hip and knee joint anteroposterior and lateral views at 12 months followup showing good alignment (e) Clinical photograph showing good range of motion



**Figure 3:** (a) X-ray of thigh with hip and knee joint anteroposterior view showing comminuted shaft femur fracture in a 9-year-old child (b) fixed with submuscular bridge plating, (c) progressive union at 4 months (d) Good alignment at 15 months postoperatively (e) Clinical photograph with normal knee range of motion

TNE ( $101.8 \pm 8.6$  degrees) ( $P = 0.039$ ). However, the knee range of movement improved in the successive weeks, especially after the fixator removal at 4 weeks. At the end of 3 months, there was no significant difference in the two groups in terms of knee flexion ( $138.2 \pm 6.4$  degrees in BP and  $136 \pm 7.3$  degrees in TNE,  $P = 0.18$ ).

As per criteria by Flynn *et al.*,<sup>4</sup> the results were excellent in 14 and satisfactory in 4 cases of the TNE group. The BP group could achieve excellent results in 15 and satisfactory in 3 cases. Two patients had marginal shortening (0.3 and 0.5 cm) and two limbs were longer (0.6 and 0.9 cm) in the BP group. The TNE group had four cases with shorter limb (mean 0.7 [range 0.5–1] cm) while in one case the limb was longer by 6 mm. However, the magnitude of discrepancy being small, none of the patients were symptomatic clinically.

### Complications

There were eight complications in the whole study. Most of the complications in the TNE group were associated with the pin-site infection ( $n = 3$ ). They were seen after a mean

of 16 days. Two cases responded to local debridement and pin-site care. One case with resistant infection required the external fixator to be removed at 20 days after the surgery. Two of the cases treated with elastic nail developed prominence of hardware. It was prominent from the immediate postoperative period and was not secondary to any collapse at the fracture site. One of the cases continued to move about with a prominent titanium nail as it was not painful and had the whole implant removed after 10 months. The second case, however, required trimming of the projecting distal end of the nail.

There were two cases of surgical-site infection in the BP group. One had an open metatarsal fracture of the same limb. The surgical wound site was debrided and the patient responded to parenteral antibiotics. The other case showed first signs of deep infection 7 weeks after the surgery. The implant was removed and functional femoral splint was used for 6 successive weeks. Infection was controlled and the fracture went into union at 13 weeks after the index surgery.

Implant removal was done in 16 of the TNE and 17 cases of the BP group till latest followup, As the implant removal was an elective procedure, priority was given to patient's convenience rather than a strict protocol for determining the timing of removal surgery. The surgical time required for removal of the titanium nail ( $30.1 \pm 8.8$  min) was significantly lesser than that required for removing a bridge plate ( $56.4 \pm 12$  min) ( $P < 0.01$ ). In addition, 13 cases (67%) of plate removal needed incisions bigger than the original scar of the index surgery. More blood loss associated with a plate removal ( $64 \pm 21.1$  ml) than with nail removal ( $35 \pm 12.7$  ml) was also significant ( $P < 0.01$ ). There was no case of refracture or any other complication secondary to the event of implant removal.

## Discussion

A comminuted fracture in the pediatric femur presents a distinct subset because of its unique management issues. These fractures by their virtue are unstable. Conservative methods such as hip spica pose a risk of collapse and malalignment at the site of comminution.<sup>10</sup> Moreover, the fractures are more often a part of polytrauma than an isolated injury. In the present study as well, 55% of cases presented with multiple injuries. Application of spica or other forms of external immobilization may interfere with the management of other system injuries such as abdominal trauma. These are also the cases which need early mobilization and comprehensive overall mobility.<sup>12,13</sup>

The strength of this study was its prospective randomized model comparing the outcomes of BP with elastic nailing supplemented with external fixator as far as the comminuted femur fractures are concerned. Most of the studies comparing intramedullary device with the surface fixation are retrospective in nature, reflecting surgeons' discretion and possibility of bias.<sup>14,15</sup>

Narayanan *et al.* pointed out that while titanium elastic nails are versatile in pediatric femoral fractures, those which more than 25% comminution of the fracture site require supplementary method of stabilization.<sup>5,16,17</sup> Sink *et al.* reported complications in as much as 57% in the cohort of 21 unstable femoral fractures, a majority of whom (71%) were treated with titanium nails alone.<sup>15</sup> The application of the external fixator for initial 4 weeks is to stabilize the length, rotation, and alignment at the same time avoiding the long term complications of prolonged use of fixators.<sup>18,19</sup> Submuscular plating has been included in the treatment modality for fracture shaft femur in patients older than 11 years in Clinical Practice Guidelines of AAOS.<sup>7</sup> However, excellent results have been reproduced by various authors in treating unstable or comminuted femoral fractures with submuscular BP in younger patients as well.<sup>20-22</sup> In the present study, both groups showed good outcomes in comminuted fractures of the pediatric femur. Fractures united at an average of 10.8 weeks (range 9–14 weeks). There was no case of malunion beyond the acceptable range and comminuted fragments united with

parent bones, showing that the vascularity of the fragments was not further compromised by any of the procedures. Both groups achieved excellent outcomes in a majority of cases (15 in BP and 14 in TNE) as per Flynn's criteria, while in the rest, outcome was satisfactory. Knee flexion range was satisfactory at 1 week and at 4 weeks with BP scoring better than the TNE group. The slight stiffness in the latter group may be attributed to the tethering of soft tissues by the pins. However, improvement in the knee flexion accelerated following the fixator removal and at the end of 3 months, the nailing group could achieve similar scores as that of its BP counterpart.

Pin-site infection is a frequent occurrence in external fixator application.<sup>23-26</sup> Majority of them respond to antibiotics and local debridement, as mentioned in other studies.<sup>23,24</sup> The patient who required premature fixator removal at 3 weeks due to pin-site infection and loosening responded well and safely went for union with good alignment. In the BP group, there were two cases of surgical-site infection. Infection in one of them possibly was hematogenous spread from the contamination of the open fracture of the metatarsals. Infections required debridement ( $n = 1$ ) and plate removal ( $n = 1$ ). However, the ultimate outcome was unaffected.

Regarding the technical issues, it took more time and radiation exposure to accomplish a closed nailing and external fixation than to perform a BP. The difficult task was to maneuver the elastic nail across the comminution into the distant fragment. The site of comminution often had an interposed fragment in the path of the nail. Conversely, in our study, removal of the nail was easier than to remove a bridge plate. In the latter group, it costs 29 ml more blood loss on an average, 26 min more time, and often a bigger scar ( $n = 13$ ) than the index surgery. All these difficulties may be attributable to the intimate contact at the plate–bone interface and progressive bone on-growth around the plate. Hence, many authors are of the view that removal of the locking plate from pediatric femora can at times become a more difficult task than insertion.<sup>22,27,28</sup> This factor needs to be kept in mind while considering submuscular plating in children.

The study suffers some limitations. The strict inclusion criteria which were necessary to accomplish an unbiased study also curtailed its sample size. Assessors of the outcome measures could not be blinded as the implants and surgical scars were readily visible both clinically and in the radiographs. Though the two randomized groups were similar in preoperative parameters, the possibility that concomitant other system injuries would confound the outcomes at least in the initial weeks cannot be ruled out. Finally, this is a study of the short term outcomes with a mean followup period of 26 months. Longer followup of the cases would provide further insight into the long term outcomes of the cases.

In summary, there was no significant difference in the outcomes between combined use of nail with external fixation and BP performed in a minimally invasive technique. Both methods showed good rate of fracture union with acceptable alignment, good postoperative range of movement, and restoration of normal gait. Nails with external fixators tend to require more surgical time and intraoperative radiation exposure, while their removal is easier compared to plates.

### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) and/or his legal guardian has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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