

# Pediatric Long-Bone Diaphyseal Fracture Fixation using Titanium Elastic Nails Results in a Low Rate of Easily Manageable Complications, and is Cost-Effective - At Least in a Developing Country

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## ABSTRACT

**Introduction:** Fractures of long-bones in pediatric patients are a common occurrence throughout the world. The purpose of this prospective study was to report clinical outcomes in pediatric patients who were surgically treated for diaphyseal fractures of long-bones using titanium elastic nails.

**Material and methods:** Forty-nine patients having a mean age of 7.5 years (four to 12) were included. Forty patients had femoral, six had tibial and three had humeral fractures. Fracture patterns were short-oblique in 15, transverse in 12, spiral in 10, long-oblique in eight and comminuted in four patients. The follow-up period ranged from 10 to 36 months.

**Results:** Time to initiate weight-bearing on the fractured limb ranged from six to eight weeks for all but two femoral fracture patients who took 12 to 16 weeks. Time to radiographic union was 12 to 14 weeks in all but the same two cases of delayed unions, which took up to 24 weeks. According to the TEN scoring criteria, outcomes were excellent in 40 and satisfactory in nine patients. Nine complications were observed: limb length discrepancy in three patients, delayed union in two, and skin irritation and superficial wound infection at the nail entry site in two each. All complications except for limb length discrepancy resolved uneventfully at the last follow-up visit for these patients, resulting in a final complication rate of 6.1%. Overall cost of treatment ranged from \$743 to \$829.

**Conclusion:** Fixation using titanium elastic nails is safe and effective, resulting in good to excellent clinical outcomes. It is an economical procedure, especially for patients in a developing country where paying out-of-pocket is preferred.

**Keywords:** Diaphysis; Fracture; Pediatric; Long-Bones; Closed Reduction; Titanium Elastic Nails; Cost-Effective

## INTRODUCTION

Fractures of long-bones are attributed to common etiologies such as domestic fall, sports injury, road traffic accident and child abuse, and are more common in the upper extremities compared to lower extremities with higher prevalence in boys compared to girls.<sup>1-5</sup> Patients must immediately seek guidance of an orthopaedic specialist who can determine the appropriate course of treatment, however, in most cases in developing countries, parents or care takers of the patient resort to in-home remedies such as massage, bone-setting or splintage, which can lead to delayed hospital presentation by as much as 10 days.<sup>5</sup> This often adds to the challenge in determining the type of treatment for such patients, who often end up requiring surgery to correct what could have been avoided if the fracture was presented to an orthopaedic care setting within 24 hours of its occurrence. This is especially

true for length stable fractures of the long-bone diaphysis.

Conservative treatment options for diaphyseal shaft fractures in pediatric patients include traction therapy or closed reduction followed by spica casting, which are economical and recommended to be reserved for use in cases of stable fractures caused by low-energy trauma.<sup>6,7</sup> Although used historically with good clinical results, such techniques require lengthier periods of hospital stay and immobilization, and patients take a long time to walk independently and to return to school.<sup>8-10</sup> Besides, complications such as mal-alignment, limb length discrepancy (LLD) and refracture result in unacceptable outcomes and may require surgical intervention for correction.<sup>8-10</sup> These factors can certainly have a detrimental effect in the overall development of the school going child.<sup>8</sup>

Increasingly, surgical treatment options are being preferred by orthopaedic surgeons for their pediatric patients presenting

with any fracture type or pattern. Moreover, technological advancements in implant and instrument designs have led to easier techniques, reduced operative times and superior clinical outcomes. Broadly, surgical options for fracture fixation can be classified into three categories: i) closed reduction with external fixation (CREF), ii) closed reduction with internal fixation (CRIF), and iii) open reduction with internal fixation (ORIF). Both CREF and CRIF are minimally invasive and use pins, k-wires, external fixators, elastic IM nails or rigid IM rods for fixation. In contrast, ORIF is invasive and reserved for either complex diaphyseal mid-shaft fractures, or proximal or distal physeal fractures, requiring the use of bone plate and screws for fixation.<sup>6,7</sup>

The aim of our study was to report clinical outcomes and complications in pediatric patients treated with a CRIF procedure using titanium elastic nails (TENs). Additionally, cost data for the entire treatment is also presented and discussed. Our hypothesis was that CRIF with TENs would result in a safe and cost-effective technique with a low number of complications.

## MATERIAL AND METHODS

This prospective observational study was conducted from October 2016 to May 2019 at an urban hospital and research centre in the east Indian state of West Bengal. During this period, 56 patients with diaphyseal fractures were evaluated and treated. Of these, seven patients presenting with concomitant injuries, co-morbidities, metabolic bone disease, non-ambulatory children, Type III fractures per Gustilo-Anderson classification, epiphyseal or metaphyseal fractures, and neuromuscular disease were excluded, thus reducing the total number of patients included to 49. There were 37 boys and 12 girls having a mean age of 7.5 years at the time of surgery (range: four to 12 years). The parents of these patients were informed about this study, who obtained their child's assent to participate. All procedures followed were in accordance with the ethical standards per the Helsinki Declaration of 1975, as revised in 2008. Forty patients had femoral, six had tibial and three had humeral shaft fractures, with 27 affecting the right and 22 affecting the left limb. Upon initial presentation at the emergency department, all patients were managed with a temporary plaster of paris back-slab for immobilization of the fractured limb. A detailed clinical and radiographic pre-operative evaluation was conducted to determine the cause and type of fracture in each patient. The causes of fracture were domestic fall in 27, road traffic accident in 10, sports injury in seven and fall from bicycle in five patients. Per the AO/OTA classification of fractures as summarized by Meinberg et al<sup>11</sup>, 15 femoral fractures were type 32A1, 15 type 32A3, eight type 32A2 and two type 32B2, four tibial fractures were type 42A3, one type 42A1 and one type 42A2, and two humeral fractures were type 12A3 and one type 12A2. Overall, fracture patterns were transverse in 21, spiral in 16, oblique in 10 and wedge with a butterfly component in two patients. Fracture location was proximal one-third diaphysis in five of the 40 femur fractures, and middle one-third in all other femur, tibia and humerus fractures. Patient demographic and pre-operative evaluation data is summarized in Table I. Pre-operative radiographs of

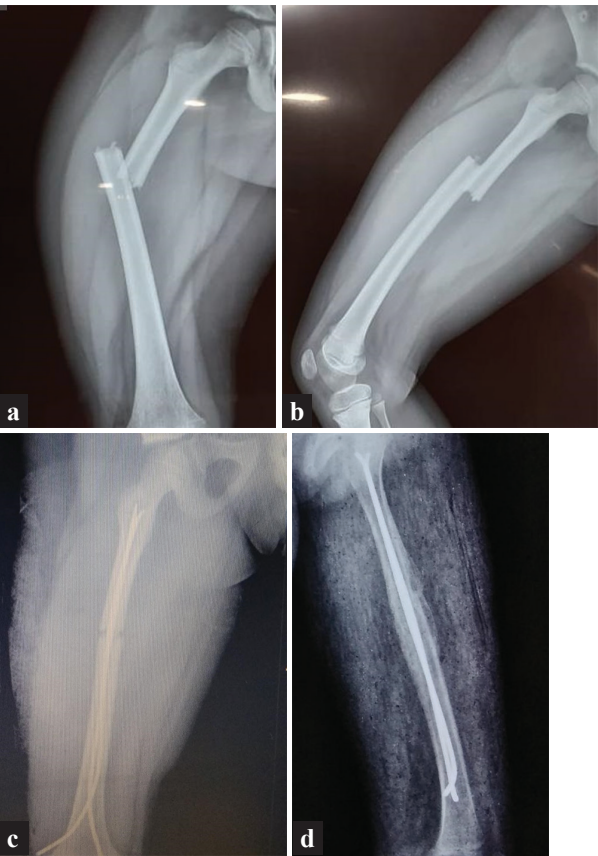
the fractures are visualized in Figures 1a, 1b, 2a, 2b, 3a and 3c for the femur, tibia and humerus, respectively.

The surgical technique for CRIF of long-bones using TENs has been well established and published in detail over the past couple of decades. The technique particularly described by Flynn et al<sup>12,13</sup> has been widely used by many authors<sup>14-16</sup> with good success, and was used for all patients in our study by the lead author, who performed all the surgeries. For femoral and humeral fractures, the TENs were inserted in a retrograde fashion, whereas an antegrade insertion method was performed for tibial fractures. Two TENs were used in all cases with diameters ranging from 2.5 to 3.5 mm for the femur, 2.5 to 3.0 mm for the tibia and 2.5 mm for the humerus. Although an attempt was made to reduce the fracture in a closed manner in all cases, a mini-incision at the fracture site was necessary in four patients to ensure accuracy of alignment of the fractured bone segments prior to fixation with TENs. There were no intra-operative complications. The mean injury to surgery interval was three days (range: one to five days). For cases of humeral surgeries, early mobilization of the shoulder, elbow and wrist was allowed from the second day as tolerated by the patients. The arm was supported with the use of a sling until pain and swelling subsided (up to two weeks post-operatively). For cases of femoral and tibial surgeries, none of the patients were placed in a cast and in-bed mobilization was allowed from the second day while knee flexion and extension exercises were encouraged from the fourth day as tolerated by the patients. Ambulation with crutches was allowed following radiographic evidence of soft-callus formation at the fracture site. Complete weight-bearing was allowed only after radiographic confirmation of fracture union. Table II summarizes all surgery related data. The follow-up period for each patient was at least until the time of radiographic confirmation of fracture union, i.e. observation of the callus fracture sign. Post-operatively, the following clinical outcomes were collected for each patient: time to soft-callus formation, time to complete radiographic union, time to full weight-bearing, results of TEN outcome scoring per Flynn et al<sup>12</sup>, time to TENs removal and post-operative complications. The out-of-pocket cost of treatment to the patient was also evaluated.

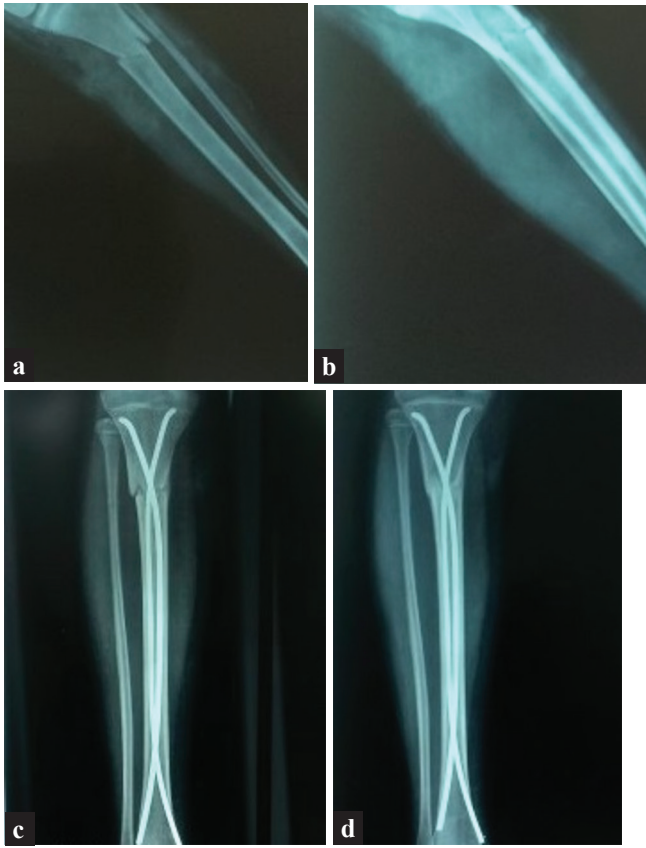
## RESULTS

The results of our study are summarized in Table III. The mean follow-up period was 18.8 months (range: 10 to 36). Soft-callus formation was observed in all but two patients between six to eight weeks. Weight-bearing of the fractured limb was therefore initiated for these 47 patients at the same time. Mean time to complete radiographic union was observed for the same 47 patients between 12 to 14 weeks. According to the TEN outcome scoring per Flynn et al<sup>12</sup>, 40 patients had excellent, nine had satisfactory (six cases of femur, two of tibia and one of humerus) and none had poor outcomes. Figures 1c, 1d, 2c, 2d, 3c and 3d show radiographic and clinical images of the post-operative healing period at different time-points for femoral, tibial and humeral fracture cases, respectively.

Nine patients experienced complications in our study i.e. an 18% complication rate. Three patients had LLD including



**Figure-1:** Radiographic images showing a case of pediatric femoral shaft fracture. Images 1a and 1b are pre-operative, 1c is at 6-weeks post-operatively and 1d shows complete radiographic union at 14-weeks post-operatively and prior to TENs removal.

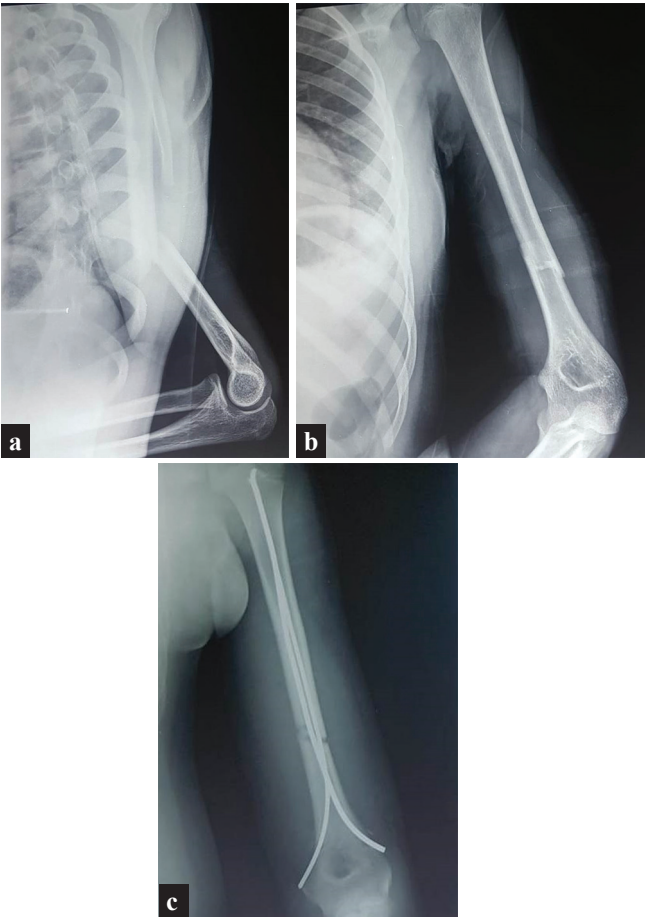


**Figure-2:** Radiographic images showing a case of tibial shaft fracture. Images 2a and 2b are pre-operative, 2c is at 4-weeks post-operatively and 2d at 8weeks post-operatively shows callus formation.

<b>Number of Patients</b>	49	<b>Bones Affected</b>	
<b>Age</b> (mean [range] in years)	7.5 [4 to 12]	Femur	40
<b>Gender</b>		Tibia	6
Boys	37	Humerus	3
Girls	12	<b>Cause of Fracture</b>	
<b>Limb Side</b>		Domestic Fall	27
Right	27	Road Traffic Accident	10
Left	22	Sports Injury	7
<b>Fracture Location</b>		Fall from Bicycle	5
Proximal One-Third	5 (all femur)	<b>Fracture Pattern</b>	
Middle One-Third	44	Transverse	21
Distal One-Third	0	Spiral	16
		Oblique	10
		Wedge	2
<b>Table-1: Patient Demographics and Pre-Operative Evaluation Data</b>			

<b>Injury to Surgery Interval</b> (mean [range] in days)	3 [1 to 5]	<b>Number of TENs</b>	2
<b>Length of Hospital Stay</b> (range in days)	3 to 5	<b>Size of TENs</b> (in mm)	
		Femur	2.5 to 3.5
		Tibia	2.5 to 3.0
		Humerus	2.5
<b>Table-2: Surgical Data</b>			





**Figure-3:** Radiographic and clinical images showing a case of humeral shaft fracture. Images 3a and 3b are pre-operative, 3c is immediately after the surgery and 3d shows the patient performing range of motion exercise at final follow-up after TENs removal.

one case of tibial shortening by 1.5 cm and two cases of femoral lengthening by 1 cm and 1.2 cm. Measurements to determine the presence or absence of LLD were made by comparing the operated and non-operated limbs using common anatomical landmarks. Delayed union was observed in two patients with femoral fractures. Soft-callus formation was observed at 12 and 16 weeks in these patients, and weight-bearing was initiated at that time. Time to complete radiographic union was observed in these patients at 22 and 24 weeks. Other minor complications observed were two cases each of skin irritation (one in femur and one in humerus) and superficial wound infection (one in femur and one in tibia) at the TENs entry site. At final follow-up, only the LLD complication in the three patients remained, while the other six complications had completely resolved with those patients reporting normal functioning of their operated limb. This resulted in a final complication rate of 6.1% (three out of 49) being observed in our study. Time to removal of the TENs was six to eight months for patients aged seven years and under, and greater than 12 months for patients over the age of seven years. These were removed owing to patient preference in most of the cases, with some requiring removal due to skin irritation and

Follow-Up Period (mean [range] in months)	18.8 [10 to 36]
Time to Initial Callus Formation (range in weeks)	
Normal Cases (n=47)	6 to 8
Delayed Union Cases (n=2)	12 to 16
Time to Start Weight-Bearing (range in weeks)	
Normal Cases (n=47)	6 to 8
Delayed Union Cases (n=2)	12 to 16
Time to Complete Radiographic Union (range in weeks)	
Normal Cases (n=47)	12 to 14
Delayed Union Cases (n=2)	22 to 24
TEN Scoring Criteria per Flynn et al	
Excellent	40
Satisfactory	9
Poor	0
Time to TENs Removal (range in months)	
≤ 7 years of age (n=24)	6 to 8
> 7 years of age (n=25)	≥12
Post-Operative Complications	
Limb Length Discrepancy	3
Delayed Union	2
Skin Irritation at TENs Entry Site	2
Infection at TENs Entry Site	2

**Table-3:** Post-Operative Patient Outcome Data

superficial wound infection as noted above. No complications were observed during the TENs removal procedure. All patients paid the entire cost of treatment out-of-pocket. The approximate total cost of treatment ranged from INR 52,000 to INR 58,000 (i.e. USD 743 to USD 829 assuming 1 USD = 70 INR). Pre-operative clinical and radiographic assessment charges ranged from INR 4,000 to INR 6,000 (i.e. USD 57 to USD 86), hospital, operation theatre and bed charges ranged from INR 13,000 to INR 15,000 (i.e. USD 186 to USD 214), implant cost was INR 5,000 for two nails (i.e. USD 71), surgeon and medical staff charges were INR 20,000 (i.e. USD 286), pharmacy charges ranged from INR 5,000 to INR 6,000 (i.e. USD 71 to USD 86) and post-operative follow-up assessment and rehabilitation charges ranged from INR 5,000 to INR, 6000 (i.e. USD 71 to USD 86).

DISCUSSION

The use of CRIF with TENs for pediatric diaphyseal fracture fixation has remained steady over the years, as is evident from the fact that peer-reviewed journal articles reporting on this topic have been continually published over the past decade.<sup>14-24</sup> It is technically easy and results in good to excellent clinical outcomes combined with easy to manage post-operative complications. In a meta-analysis of 1012 pediatric patients comparing TENs versus spica casting for fixation of femoral fractures, Imam et al<sup>10</sup> concluded that TENs results in shorter hospital stay, reduced period of immobilization, reduced

time to complete fracture union, lower rates of malunion/malalignment, quicker return to independent walking, reduced complications and increased parents' satisfaction. In the studies conducted by Barlas et al.<sup>25</sup> and Ramseier et al.<sup>26</sup>, they compared CREF with CRIF for pediatric femoral fracture fixation and observed that CREF results in a higher rate of complication, while CRIF with TENs results in improved outcomes like reduced time to full weight-bearing and earlier return to school. Ramseier et al.<sup>26</sup> also compared two other treatment methods, CRIF with rigid nails and ORIF with plates and screws, reporting that these methods and CRIF with TENs result in similar outcomes. Interestingly, in the study by Allen et al.<sup>23</sup> comparing CRIF with TENs and ORIF with plates and screws for pediatric diaphyseal femoral fracture fixation, the authors favored the use of CRIF because the latter resulted in higher blood loss, and increased operative time and cost, but in equivalent pain and clinical outcomes.

In their classic, well-cited study, Flynn et al.<sup>12</sup> reported excellent and satisfactory outcomes in 67% and 31% of patients, respectively, whereas in our study 82% patients had excellent outcomes and 18% had satisfactory outcomes. This improvement in results can be attributed to both technological advancements as well as increased learning through literature and hands-on training. Recently, Raut et al.<sup>17</sup> reported data on 30 patients (15 cases of radius-ulna fractures, seven of femur, seven of tibia and one of humerus) having a mean age of 9.67 years and a follow-up period of up to 12 months. Time to weight-bearing and radiographic union in their study was six to eight weeks and nine to 12 weeks, respectively. Outcomes per Flynn et al.<sup>12</sup> TEN scoring criteria were excellent in 25 (83%) and satisfactory in five (17%) patients, and a total of six complications were observed for a complication rate of 20%. Govindasamy et al.<sup>14</sup> reported data on 48 patients (all cases of femur fractures) having a mean age of nine years and a follow-up period of 12 to 40 months. Both time to weight-bearing and radiographic union in their study was nine to 12 weeks. Outcomes per Flynn et al.<sup>12</sup> TEN scoring criteria were excellent in 40 (83%) and satisfactory in eight (17%) patients, however, a total of 27 complications were observed for a high complication rate of 56%. Reddy et al.<sup>18</sup> reported data on 30 patients (all cases of femur fractures) having a mean age of 8.1 years and a follow-up period of up to 12 months. Time to weight-bearing was eight to 12 weeks, however, time to radiographic union in their study was much longer between six to 11 months. Outcomes per Flynn et al.<sup>12</sup> TEN scoring criteria were excellent in 24 (80%), satisfactory in five (17%) and poor in one (3%) patients, and a total of six complications were observed for a complication rate of 20%. The results of our study are very similar to the results of these recent studies, with two exceptions being the higher complication rate observed by Govindasamy et al.<sup>14</sup> and longer time to radiographic union noted by Reddy et al.<sup>18</sup>

In many developing countries where most of the pediatric trauma patients are from the middle- or lower-income strata, affordability is an important factor in deciding the treatment of choice. In a recent study reported from Romania by Adam et al.<sup>20</sup>, the overall cost of treatment using TENs for pediatric

forearm fracture fixation was found to be between USD 471 to USD 1073, which is similar what we have observed in our study i.e. between USD 743 to USD 829. The cost of TENs was double in their study i.e. USD 142 compared to USD 71 for two nails.<sup>20</sup> They also reported that the mean cost of treatment using k-wires or cast alone was statistically lower than that using TENs. Cost of k-wire treatment ranged from USD 372 to USD 1096 and that of cast treatment ranged from USD 337 to USD 699.<sup>20</sup> They noted that with these two treatment modalities, patients were immobilized in a cast for several weeks, leading to prolonged impairment for those children, and thus added burden of cost to their families and the healthcare system.<sup>20</sup> In our opinion, the cost of TENs is similar and within the range noted for k-wire and cast treatments, and more importantly, the benefits of TENs far outweigh those of the other treatments. In a stark contrast, in the studies by Allen et al.<sup>23</sup> on pediatric femoral fractures and Heare et al.<sup>21</sup> on pediatric forearm fractures, which were conducted in a western developed country, the average cost of two TENs was reported at USD 605 and USD 1278, respectively, which is approximately 8.5 to 18 times the cost for the same implants used in our study, and is similar to or more than the cost of the entire treatment at the lower range in our study. Interestingly, even within the same country the cost of implants was more than double between the two institutions where these were used. In another recent study by Lewis et al.<sup>22</sup> conducted in the same developed country, the mean overall cost of treatment for pediatric fracture fixation was found to be USD 19,200 for spica casting and USD 59,700 for flexible intramedullary nailing. In contrast to many reports, they noted longer hospital stays and follow-up periods for the latter treatment modality, which in their observation led to significantly increased costs.<sup>22</sup> Nonetheless, it is extremely important to note the huge difference in treatment costs between the developing and developed countries for the same treatment methods using the same implants.

Our study is not without limitations. First, the number of patients amongst femur, tibia and humerus was uneven, and small for the latter two, therefore, statistical comparison of the outcomes between the different bones could not be performed. Second, the follow-up period was rather short, therefore it is difficult to ascertain the long-term success of this technique and implant, especially in those patients who had un-resolved complication of LLD. Nonetheless, it is important to note that those three patients who had LLD did not complain of any pain or functional shortcomings at their final follow-up. Their knee range of motion and gait was within normal limits. It is prudent, however, that long-term studies be conducted to follow-up patients both with and without short-term complications to evaluate whether not they develop related comorbidities of either the affected or the contralateral limb in the future.

## CONCLUSION

The present study provides data to add to the evidence base for supporting the use of CRIF with TENs for long-bone diaphyseal fracture fixation in the pediatric population. This technique and implant combination provides the necessary

post-operative reduction and stability required between the bone segments to allow for timely and successful healing of the fracture. In our study, 83% patients had excellent results while 17% patients had satisfactory results, and the complication rate at final follow-up was 6.1%. CRIF with TENs, at least in a developing country, is very economical and budget-friendly and should be chosen over non-operative techniques when clinically necessary. In such cases it is the surgeon's responsibility to explain to the patient or patient's family the benefits of choosing such a surgery over conservative methods. Based on our findings, we continue to recommend CRIF with TENs for long-bone diaphyseal fracture fixation in the pediatric age group.

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