



## Risk Factors for Delayed Union in Diaphyseal Fractures of the Tibia Treated with Stable Elastic Intramedullary Nailing in Children and Adolescents

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### Abstract

**Introduction:** Elastic stable intramedullary nailing (ESIN) is an alternative treatment for tibial shaft fractures in skeletally immature patients. Although consolidation rates are high, factors associated with delayed union have not been well established.

**Objective:** To identify risk factors for delayed union in tibial shaft fractures in skeletally immature patients treated with ESIN.

**Methods:** Consecutive retrospective cohort of patients with tibial shaft fractures treated with ESIN between 2006 and 2019 in the same pediatric trauma service. Demographic data, injury mechanism, fracture characteristics, surgical details and timing of initial weight bearing were analyzed. The outcome evaluated was the presence of delayed union at 6 months evaluated on leg anteroposterior and lateral radiographs. For the statistical analysis, a univariate and multivariate regression was performed.

**Results:** Totally, 32 patients with tibial shaft fractures were included. We found 10 patients with delayed union. Multivariate logistic regression showed that transverse and multifragmentary fractures were predictors of delayed union.

**Conclusions:** Transverse, multifragmentary and delayed onset of load (4.8 weeks) in tibial shaft fractures are directly associated with delayed union in patients treated with ESIN.

**Keywords:** Tibial Shaft Fracture; Elastic Stable Intramedullary Nailing; Delayed Union

### Introduction

There is an increase in the incidence of fractures in the pediatric population before 17 years of age. The main causes are traffic accidents, falls, direct impact and sports injuries. Leg fractures are the second to require surgical treatment (13%) after the distal forearm (24%). The most common fracture site requiring surgical management was the distal forearm (24%), followed by the tibial/fibular shaft (13%). Treatment for most leg fractures in pediatric population is through cast immobilization and/or closed reduction. For those fractures that require surgical treatment, different fixation alternatives have been described, such as plates, solid nails, external fixators and stable elastic intramedullary nailing.

In recent times, an increase in the use of ESIN in the treatment of tibial fractures has been described (Essilfie 2019). There have

been reports of good clinical results and low complication rates with this strategy. Advantages include pin insertion through small incisions, preservation of the fracture site, low risk of infection, and preservation of the growth plate. And among the disadvantages, specific training in the technique is required and stabilization is more difficult to obtain in overweight children and those with unstable fractures.

Complications of treatment with ESIN are infrequent, these include delayed union, nonunion, and malunion.

Some discrepancy between studies was observed in the definition of delayed union and non-union. Delayed union was variably defined as fracture healing time greater than 12 weeks, 10 weeks,

or 24 weeks. Nonunion or nonunion was defined as the absence of callus formation at 24 weeks or 36 weeks of follow-up.

In a meta-analysis, Fanelli observed a union rate of 97.5%, with a mean time to union of  $11.9 \pm 7.3$  weeks, delayed union was found in 32 cases (3.8%), and only one patient (0.1%) required reintervention. Taking into account the specific complications, malunion was observed in 71 cases (8.5%) as the most frequent, of which only 16 required surgical intervention (1.9%), two of them were early malunion and were treated with manipulation under anesthesia. Gordon determines that a conservative approach in unstable or open fractures could increase the rate of complications due to union defects, for which this type of injury must count on an adequate therapeutic approach according to specific patient factors (age, weight).

Very few studies have described factors that make it possible to predict delayed consolidation and non-union after ESIN in pediatric population. The objective of our study is to identify risk factors for delayed union in tibial diaphysis fractures in patients with immature skeletons treated with ESIN.

## Materials and Methods

After the approval of the Ethics Committee (IRB) of our institution, a consecutive retrospective cohort study of patients with diaphyseal fractures of the tibia treated with stable elastic intramedullary nailing was carried out between July 2006 and December 2019.

The inclusion criteria were: 1) diaphyseal fracture of the tibia, 2) open distal and proximal physes, 3) treatment with ESIN, 4) clinical follow-up until radiographic consolidation. The exclusion criteria were; 1) fracture with joint or physeal involvement, 2) pathological bone fracture and 3) loss of radiographic follow-up. Demographic data of the patients were gathered (age and gender), mechanism of injury (high and low energy), characteristics of the fracture trait (short oblique, long oblique or transverse), presence of focus comminution, location of the fracture (proximal, middle or distal third), presence of concomitant fibular fracture, closed vs. open fracture, operative details (focus opening, TENS diameter, canal filling and use of end caps) and time of load starting after surgery.

The outcome evaluated was the presence of delayed union, which was defined as lack of union after 24 weeks from surgery. Union was defined as radiological evidence, on anteroposterior and

lateral radiographs, of bridging bone calluses in at least three out of four cortices. The surgical procedure was performed by certified pediatric orthopedists, using the standard technique described by Lascombes. To determine the diameter of the nails, the canal was measured on the radiograph with the aim of obtaining 80% canal filling. The nails were molded in a C shape, leaving the apex of the curvature at the level of the fracture site. The stability and fixation of the construct was verified with intraoperative fluoroscopy. Patients were evaluated in serial clinical controls at least until confirmation of bone consolidation on radiography. Those patients in whom no consolidation was observed in 3 of the 4 cortices at 24 weeks were considered in the delayed consolidation group. The variables were compared between the groups with normal consolidation and those with delayed consolidation.

## Statistic analysis

A univariate analysis was performed to explore the influence of individual factors on outcomes, and Homer-Lemeshow multivariate logistic regression models were subsequently used to understand the interaction between the prognostic factors themselves. Statistical analysis was performed using the statistical software STATA16.

## Results

The sample consisted of 32 patients with tibial diaphysis fracture. 72% were men and 28% women. The study includes pediatric patients between 5 and 17 years old with a mean age of  $12.1 \pm 2.9$  years at the time of surgery. 31.1% of the fractures involved high-energy accidents. The most frequent location of the fracture occurred in the middle third ( $n = 23$ , 71.9%). Simple fractures were 65.6% ( $n = 21$ ) of the cases. A concomitant fracture of the fibula was observed in 78.1% of cases ( $n = 25$ ) and in 7 patients the fractures were open. The most used nail diameters were 3.5 and 4 mm in 34.4% ( $n = 11$ ) of the cases each. The most used nail diameters were 3.5 and 4 mm in 34.4% ( $n = 11$ ) of the cases each. Medullary canal filling greater than 80% was achieved in 46.9% ( $n = 15$ ) cases, while only 1 case did not reach 60% canal filling. Radiographic follow-up in all cases was made until fracture consolidation. The analysis groups are categorized as 22 patients with normal consolidation and 10 patients with delayed consolidation. These groups were comparable in gender and age. Of the 10 patients who experienced delayed union, 40% ( $n = 4$ ) had a transverse fracture and 70% ( $n = 7$ ) had a comminuted fracture, with an average of  $4.8 \pm 1.9$  weeks from the start of partial load.

The univariate analysis showed that the type of transverse trait, the opening of the focus, open fracture, comminuted fracture and the weeks of loading had an influence on the time of consolidation

with a  $p < 0.05$  as observed in table 1. The linear regression analysis determined that the longest waiting time to indicate initiation of loading was related to consolidation delay and was statistically significant ( $\chi^2$ :  $p$  value  $< 0.005$ ).

Factors	Normal consolidation (n = 22)	Consolidation delay(n = 10)	Odds ratio	p Value 0.05	IC	95%
Gender(masculine/feminine)	17/5	6/4	2.3	0.319	0.45 - 11.3	
Trasverse type	6	4	13.3	0.046	1.05 - 169.5	
Age of surgery (years)	11.5 ± 0.6	13.2 ± 0.9	1.28	0.141	0.92 - 1.77	
Energy mecahism Low/High	17/5	5/5	3.4	0.132	0.69 - 16.7	
Focus (No/Yes) opening	19/3	4/6	0.1	0.012	0.018	- 0.61
Closed Fracture /Exposed	20/2	4/6	15	0.006	2.18 - 103.03	
Simple Fracture /conminute	18/4	3/7	10.5	0.008	1.86 - 59.4	
Filling of medular canal <80%/>80%	12/10	5/5	1.2	0.811	0.27 - 5.36	
Partial load weeks	3.36 ± 1.5	4.8 ± 1.9	1.72	0.048	1.0 - 2.93	

**Table 1:** Univariable analysis of risk factors.

Other factors such as age, gender, energy mechanism and canal filling did not reach statistical significance to determine association with delayed consolidation.

Analysis with the Homer-Lemeshow criterion showed that for  $p < 0.1$ , the transverse type, the comminuted fracture and the time of onset of load has an important association as a risk factor for delayed consolidation table 2.

Given the interaction between the first risk factors as important prognostic factors, a multivariate stepwise logistic regression anal-

Factors	Odds Ratio	Standard Error	z	p value 0.05	IC 95%
Transverse type	25.9	48.2	1.74	0.082	0.66 - 1007.6
Comminuted fracture	28.3	42.78	2.21	0.027	1.46 - 546.9
Weeks of partial load	2.17	0.89	1.89	0.058	0.97 - 4.84

**Table 2:** Multivariate Analysis of Risk Factors for consolidation delay.

**Discussion**

Stable elastic intramedullary nailing is an alternative with good results in the treatment of diaphyseal fractures of the tibia in patients with an immature skeleton. It has the advantage of being a minimally invasive technique, with preservation of physis, favoring early mobilization of the patient.

the focus, open fracture, comminuted fractures and the weeks of loading with the consolidation delay. Out of the 10 patients who experienced delayed union, 40% (n = 4) had a transverse fracture and 70% (n = 7) had a comminuted fracture, with an average of 4.8 ± 1.9 weeks from the start of partial load. Griffet recommends weight bearing on day 15 in transverse fractures, day 21 in short oblique fractures, day 30 in long oblique or spiral fractures and day 45 in comminuted fractures. In addition, the exposed fracture and the opening of the fracture focus presented a higher rate of consolida-

In our study, univariate analysis showed a statistically significant relationship between the type of transverse trait, the opening of

tion delay in the univariate analysis with 60% (n = 6) of the cases, but this was not replicated in the multivariate analysis, probably because the sample it was scarce. Treatment of open, unstable tibial fractures, such as those resulting from high-energy injury, represents a clinical challenge for which taking a conservative approach could result in higher rates of nonunion and malunion. Fanelli noted that higher rates of delayed union appear to be associated with higher-grade Gustilo-Anderson pediatric tibial fractures, as well as a higher incidence of post-surgical infections. Srivastava reported five delayed unions and two nonunions in a series of sixteen children with open tibial shaft fractures treated with ESIN.

Jenkins, given that we believe that the rate of bone consolidation would considerably improve, for in the group of patients with comminuted fracture without consolidation delay, the average number of days from the start of partial weight bearing was  $3.1 \pm 0.99$  weeks (16-28 days) with encouraging results.

The current study has several limitations. Channel fill does not represent a true three-dimensional percentage, as it was only measured as an approximation from radio occupancy in AP/lateral projections. In addition, we do not know the clinical or radiological specifications each surgeon employed as criterion to begin partial load on patients, or on other patient characteristics such as weight and age. Finally, the control radiographic projections prior to 6 months did not have specific times to be taken after surgery, which leaves us in the dark as to whether there were better consolidation times for those patients with earlier loading [1-23].

### Conclusions

Transverse fractures and comminuted fractures are directly associated with delayed union in patients with diaphyseal fractures of the tibia treated with stable elastic intramedullary nailing. In addition, postponing the start of partial weight bearing in these patients could also predispose to consolidation delay, these being the only independent factors with statistical significance in this study.

Identifying and characterizing the type of fracture in these patients with an adequate surgical plan, in addition to having a rehabilitation and follow-up program with early loading and providing means of additional stability, should be a main objective when dealing with this type of injury.

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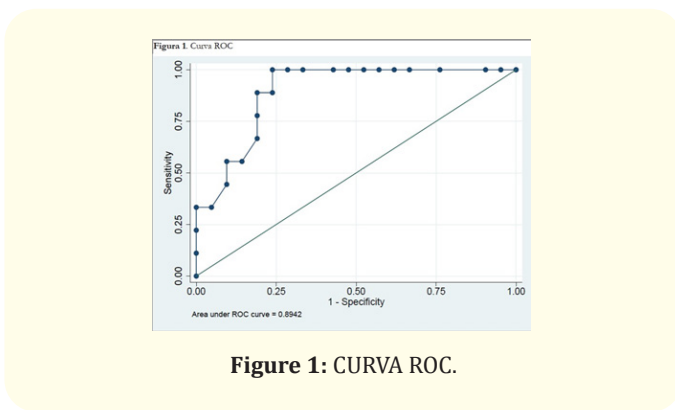


Figure 1: CURVA ROC.

The interesting new finding of our study is that the multivariate analysis showed that prognostic risk factors for delayed union as a complication of tibial diaphysis fractures in the pediatric population are the transverse type, comminuted fracture and late onset of weight bearing, with a validation of its ROC curve of 0.89, as a measure of discrimination figure 1. Having high specificity for their association. It is 25.9 and 28.3 times more likely to have delayed consolidation or post-surgical complications, in case of having transverse and comminuted fractures, as well as for every  $2.17 \pm 0.89$  weeks (approximately 15 days) that the start of weight bearing is delayed. Therefore, early loading is suggested, according to the type of fracture, the location and depending on whether we are facing a comminuted fracture, this should be within a period of no more than 45 days.

We believe that comminuted fractures that are not given early loading have the highest rate of delayed union, so it would be recommended to evaluate partial weight bearing assisted with a splint in patients with  $\geq 50\%$  cortical contact. in the transverse plane, which should not be painful, similar to that of the group of Kubiak and

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