ORIGINAL ARTICLE

Tibial diaphyseal fractures in children: indications and limitations of the treatment with monolateral and hybrid external fixator

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ABSTRACT

Aim To report our indications and limitations about the use of external fixation in children.

Methods It was retrospectively reviewed all tibial fractures treated with monolateral and hybrid external fixator, at our three Centres. It was included 32 fractures which did not show an acceptable reduction after an attempt under anaesthesia. The exclusion criteria were: open fractures, children with previous fractures of the lower limbs, with skeletal congenital diseases, fractures involving the physis and with neurovascular involvement. All fractures were classified according to the AO (*Arbeitsgemeinschaft für Osteosynthesefragen*) classification. An outcome was evaluated according to the time needed to obtain radiographic bone healing, the range of motion (ROM) of the ankle, the asymmetry of the lower limbs, the malunion, and complications.

Results The average time of consolidation was 10.66 weeks (6-17 weeks). There were no cases of deep infection, but only seven cases of superficial pin infections. No patients reported loss of ROM of the knee or ankle. We had zero cases of residual angle greater than 5°, and in all cases the difference in length between the limbs was <1 cm.

Conclusion The external fixation is a viable technique in the treatment of tibial fractures in children. Therefore, the external fixation, both monolateral and hybrid, should be considered a viable treatment for this type of fracture.

Key words: bone fixation, paediatric, tibia fractures, trauma

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INTRODUCTION

Tibial fractures account for about 15% of all fractures in children taking the third place in frequency (1). In 70% of cases, the fracture affects only the tibia, while in the remaining 30% there is also an involvement of the fibula. In 10% of cases they are open (1,2). About 60% of the fractures are located at the distal tibial shaft (1,2). An oblique line fracture shows 35%, 32% are comminuted, 20% transversal line and 13% are spiral (2).

The most frequent causes are road accidents, and above all, sport injuries, like mountain bike, rollerblade, ski, snowboard, etc.) (3). In spiral fractures the traumatic mechanism is almost always represented by a torsional force, with the foot blocked to the ground, having as the initial site of injury the distal portion at the level of the anteromedial cortical and then developing in posterolateral direction (4). Transverse or multifragmented fractures are instead caused mostly by direct trauma (5). The complications such as vascular or nerve injuries or compartment syndrome are rare (4,5). Secondary complications include malunion and premature physeal closure in fractures extending to physis (4,5).

The most commonly used treatment for the tibial child fracture is a reduction under anaesthesia and cast-immobilization (6). In those cases where adequate reduction cannot be obtained, surgical treatment is indicated (6). Other indications for surgical treatment are: open fractures, compartment syndrome, fractures in children with spasticity, floating knee and highly unstable fractures, for which it is not possible to obtain or maintain an adequate stability (7,8). Although conservative treatment has been practiced for many years with satisfactory results, several aspects have led to an increase in the number of surgical procedures including changes of living, sport habits, economics, and patient's request to treatment (7,8).

The most widely used means of synthesis are: titanium intramedullary nails, metal or absorbable pins, plates and screws; external fixators are instead used almost exclusively in open fractures (9-11).

The aim of our study is to evaluate clinical and radiographic results of external fixation, both hybrid and monolateral in the non-open tibial shaft fractures.

PRIENTS AND METHODS

Patients and study design

From January 20014 to December 2019 we enrolled all tibial shaft fractures treated at five Trauma Level I Centres (four in Italy, and one in Spain) with external monolateral fixator (Hoffmann II, Stryker, Kalamazoo, Michigan, United States) and hybrid fixator (Tenxor, Stryker, Kalamazoo, Michigan, United States). Data were collected retrospectively, including patient demographics and fracture classification according to the AO (*Arbeitsgemeinschaft für Osteosynthesefragen*) paediatric comprehensive classification of long-bone fractures (2): diaphyseal fractures 42-D: fractures of both bones, simple - complete transverse (< 30°), 42-D/4.1; fractures of both bones, simple - complete oblique or spiral (≥30°), 42-D/5.1; fractures of both bones, simple - complete oblique or spiral (≥ 30°), 42t-D/5.1; fractures of both bones, multifragmentary - complete transverse (< 30°), 42-D/4.2; fractures of both bones, multifragmentary - complete oblique or spiral (≥30°), 42-D/5.2; fractures of both bones, multifragmentary - complete transverse (< 30°), 42t-D/4.2; fractures of both bones, multifragmentary - complete oblique or spiral (≥ 30°), 42t-D/5.2; isolated fractures of the fibula, simple - complete transverse (< 30°), 42f-D/4.1; isolated fractures of the fibula, simple - complete oblique or spiral (≥ 30°), 42f-D/5.1; isolated fractures of the fibula, multifragmentary - complete transverse (< 30°), 42f-D/4.2; isolated fractures of the fibula, multifragmentary - complete oblique or spiral (≥ 30°), 42f-D/5.2.

The inclusion criteria were fractures of the tibial shaft which did not obtain an acceptable reduction after an attempt under anaesthesia. The exclusion criteria were: open fractures, children with previous fractures of the lower limbs, with systemic and metabolic disorders, children with skeletal congenital diseases, fractures involving the physis and fractures with neurovascular involvement.

Azienda Ospedaliera Universitaria Sanitaria Perugia/Italy Ethical Committee approved this research.

Methods

All patients underwent anterior posterior (AP) and lateral radiographs (L) of the tibia to assess the location and type (transverse, oblique, spiral or comminuted) of the fracture. The type of inter-

vention was explained to the patients' parents and a written consent was received. In all cases the intervention was performed within 48 hours after injury under general anaesthesia with the patient in the supine position on a radio transparent table. All patients received a prophylactic dose of cefazolin 30 minutes before the incision at a dose of 25mg / kg body weight (12).

In all cases it was possible to obtain closed reduction. All patients were discharged within two days after surgery, with instructions for the daily dressing of the pin with Sodium hypochlorite 1.1%.

At discharge, the patients were explained about the home rehabilitation program, aimed at the range of motion (ROM) recovery of the ankle and knee, the recovery of the quadriceps femoral muscle, ischio-crural and gluteal muscles. From the second day after the surgery a partial load was granted and gradually increased thereafter.

On average, the removal of the fixators was performed at 10 weeks (8-12 weeks).

Malunion was defined as a residual deformity exceeding 10° of angulation on the coronal plane and/or 10° of angulation on the sagittal plane and/or obvious clinical malrotation (14,15).

The return to recreational activities was gradual and secondary to muscle tone recovery. On average all patients resumed their activities between the 12^{th} and 16^{th} week.

Radiographs were made at 2, 5, 10, 16 weeks, 6 months and one year. The fracture was considered united when callus was visible on the radiographs in at least three cortices with no tenderness at the fracture site.

We took into consideration the angles on the frontal and sagittal planes both in the immediate postoperative and at longitudinal controls and at the final visit. At the last radiographic control at one year we performed x-rays in the erect standing position (orthostatism) to obtain measurements for a possible heterometry of the limbs. An inter-rater reliability analysis using the Kappa statistic was performed to determinate consistency among the ratings.

The clinical evaluation at follow-up included the ROM measurement of the ankle and knee, rotation and limb alignment, possible skin infections. Clinical outcomes were evaluated using modified criteria described by Flynn (13). The complications taken into consideration were the following: delayed union, nonunion: union after 9 months or after the second procedure; malalignment greater than 10° and/or heterometry of the limbs greater than 20 mm; skin infection, osteomyelitis.

To describe the possible infection we used the CkChan's scale (16). Checketts–Otterburns grading system, describes the possible infection in 5 grades: grade 1 - slight erythema, little discharge, treat with improved local pin care; grade 2 - erythema, discharge, pain, warmth, treat with improved local pin care and oral antibiotics; grade 3 - as per grade 2, but no improvement with oral antibiotics, pins/ex fix can be continued; grade 4 - severe soft tissue infection involving several pins ± pin loosening, ex fix must be discontinued; grade 5 - as per grade 4, but with bone involvement visible on radiographs, ex fix must be discontinued; grade 6 - major infection occurring after ex fix removal, treatment requires curettage of pin track.

Surgical technique. In 21 cases we used a monolateral fixator and in the remaining 11 cases a hybrid fixator. The choice between the two types of fixators was imposed by the location of the fracture. Fractures located at the third medial of the tibial shaft were treated with monolateral fixation, while fractures localized at the distal third of the shaft (were treated) with hybrid fixation. In the case of the monolateral fixator after having realigned the fracture under fluoroscopy as much as possible, first we placed the distal screws (3) and then the proximal (3) and connected them with bars and clamps. Where necessary, in order to reduce the lever arm, we placed an intermediate pin, therefore reducing the fracture under fluoroscopic control.

Statistical analysis

To summarize the characteristics of this study group and subgroups we used descriptive statistics. This included both mean and standard deviation (SD) of all continuous variables. The t-test was used to compare continuous outcomes. To compare categorical variables the Fisher exact test was applied (these groups are smaller than 10 patients). The statistical significance was defined as $p<0.05$. To make a comparison between the predictive score of quality of life and outcomes we used the Pearson correlation coefficient (r). For simplicity of data, mean ages was rounded to the

closest year, including their standard deviations. Predictive score of outcomes and quality of life and their standard deviations were approximated at the first decimal, while at the second decimal it was approximated Pearson correlation coefficient (r). Cohen's kappa (k) was used to determine the reliability and validity of the correlation between functional osteosynthesis and bone healing.

RESULTS

A total of 32 patients were treated, 21 were males and 11 females.

According to the AO classification three patients were classified as A1, seven as A2, nine as B1 and five patients as C type (Table 1).

The mean age was 9.88 (±2.50; range 5-15y/o) years. The right side was affected in 15 cases and the left side in 17 cases (Table 1). A road accident was the cause of fracture in 17 cases, a fall from height in nine and a sport injury in six cases.

In 11 cases in which the hybrid fixator was used we first positioned three distal wires (1.5 or 2 mm) and then connected the semicircle to the proximal screws, in a number of 3 (Table 1). The average surgical time was of 38 min (±12.23; range 25-61). Under no circumstances open reduction of the fracture was necessary.

All 32 cases resulted in fracture healing and there were no cases of delayed union and nonunion. The average healing time was of 10.66 weeks (±3.09; range 6-17). The average coronal deformity was 3.47° (±1.74; range 0-7). The average sagittal deformity was 3.62° (±1.88; range 0-6). The average residual deformity heterometry was 3.47mm (±2.51; range 0-8) (Table 1).

We had no case when we had an angle >5°, and in all cases the difference in length between the limbs was <1 cm ($p>0.05$).

No child developed a deep infection, and only in seven cases grade 1 superficial infections of

Table 1. AO classification, results, complications, outcome, modified Flynn's criteria of 32 children with tibial diaphyseal fractures (42-D)

Patient's number	Age (years)	AO-OTA CLASS	Localization	Time of union (weeks)	Residual deformity Coronal plane (degrees)	Residual deformity Sagittal plane (degrees)	Residual deformity heterometry (mm)	Complications	Outcome
1	5	A1	Distal	6	0	0	0	None	Excellent
2	8	A1	Medial	6	0	0	0	None	Excellent
3	10	A1	Distal	7	0	0	0	Skin infection	Excellent
4	15	A2	Distal	7	2	3	3	None	Satisfactory
5	9	A2	Medial	6	3	5	2	Soft tissue irritation	Excellent
6	10	A2	Medial	6	1	3	0	Skin infection	Excellent
7	8	A2	Medial	7	2	6	4	None	Satisfactory
8	14	A2	Distal	8	5	5	3	None	Excellent
9	11	A2	Distal	9	4	0	2	Soft tissue irritation	Excellent
10	9	A2	Medial	11	5	5	2	None	Excellent
11	6	B1	Distal	15	4	4	5	None	Excellent
12	7	B1	Distal	11	4	4	2	Skin infection	Satisfactory
13	14	B1	Distal	16	3	5	7	None	Excellent
14	12	B1	Distal	9	5	5	1	None	Excellent
15	13	B1	Distal	13	3	3	7	None	Excellent
16	7	B1	Distal	14	4	5	7	Soft tissue irritation	Excellent
17	6	B1	Medial	15	2	0	0	None	Satisfactory
18	11	B1	Medial	11	5	4	4	Skin infection	Excellent
19	10	B1	Distal	11	5	5	4	None	Excellent
20	9	B2	Distal	11	2	2	8	None	Excellent
21	9	B2	Distal	14	5	4	4	Soft tissue irritation	Excellent
22	8	B2	Medial	13	4	5	4	Skin infection	Excellent
23	7	B2	Distal	11	4	5	1	None	Excellent
24	11	B2	Medial	10	1	5	4	Soft tissue irritation	Excellent
25	12	B2	Medial	9	4	5	1	None	Excellent
26	12	B2	Distal	9	5	5	1	None	Excellent
27	12	B2	Distal	17	5	4	8	Skin infection	Satisfactory
28	11	C	Medial	12	4	4	5	Skin infection	Excellent
29	8	C	Medial	11	5	4	6	None	Excellent
30	10	C	Distal	12	4	5	5	Soft tissue irritation	Excellent
31	12	C	Distal	11	7	1	6	None	Satisfactory
32	10	C	Distal	13	4	5	5	None	Excellent

AO-OTA CLASS, *Arbeitsgemeinschaft für Osteosynthesefragen* (AO) / Orthopaedic Trauma Association (OTA) classification

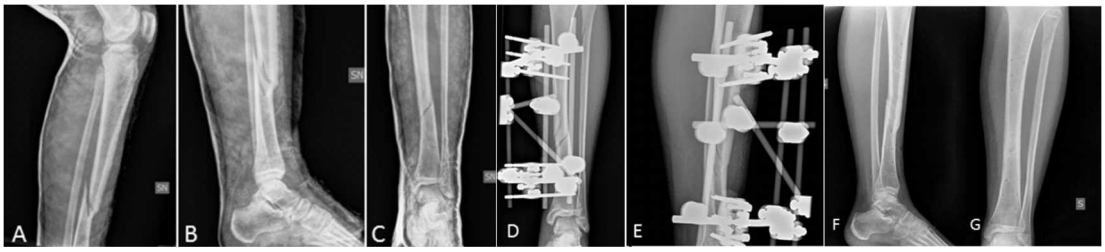

Figure 1. A 10-year-old patient. Fracture type 4.2 A3 (AO classification). A-C) Fist treatment: reduction under anaesthesia and cast immobilization; B, C) breakdown of the fracture and rotation defect; D, E) good reduction after application of external fixator; F, G) good healing without bone consolidation defects after 16 weeks (Meccariello L, 2017)

Figure 2. A 15-year-old patient, fracture type 4.3.C3 AO classification. A, B) breakdown of the fracture and rotation defect with cast immobilization; C,D) good reduction after application of external hybrid fixator; E, F) good healing of bone and skin without bone consolidation defects after 16 weeks; G, H) after 6 months the bone healing after the remontion of external fixator (Bisaccia M, 2015)

the pins according to CkChan's scale, all resolved with oral antibiotics. In all cases, infections were resolved with oral antibiotic therapy with amoxicillin+clavulanic acid 45 mg/6.4 mg/kg/day divided in two doses, for 7 days.

In twenty-six cases the outcome was excellent (Table.1)

External fixation was well tolerated by all children. No patients reported loss of ROM of the ankle or knee.

The average correlation of clinical-radiographic results and patients outcomes was high (Cohen κ: 0.80). A total of 26 excellent results and 6 satisfactory were noticed (Table 1, Figures 1, 2).

DISCUSSION

Tibial shaft fractures in the paediatric population are the ones that most often require hospitalization (17). Usually they do not present particular complications and can be treated with reduction and casting (18); however, this method requires a prolonged immobilization and a careful follow-up. Several studies, in fact, report good results with cast treatment, compared with the risk of secondary fracture displacement and the need of new surgery under anaesthesia to replace the cast and correct the displacement (19,20). Surgical treatment is recommended in cases of open fractures, in polytrauma patients, in the case of compartment syndrome, in fractures with neuro-vascular involvement and in highly unstable fractures and/or with impossible reduction to maintain conservatively (21-23).

Currently the intramedullary stabilization techniques are the most used in the majority of fractures of long bones in the paediatric population (24). Other techniques involve the use of pins, screws of percutaneous and plaques (24,25).

The elastic intramedullary nails considering their mini-invasiveness are very useful in this type of fracture. This type of synthesis requires an entry site that does not involve the physis, allows early mobilization, rapid recovery of the ROM, lack of any stiff joint, short-term hospitalization, low costs and minimal surgical scar (26,27)

Elastic stable intramedullary nailing may be complicated by the loss of reduction following push out of the nails at the entry site in unstable tibial fractures and following technical failures (28).

This system in fact showed some limitations, especially in paediatric patients over 12 years of age and with high body weight, particularly in unstable fractures and in case of inadequate surgical technique (29,30). In these cases we may have shortening and angulation of the fragments in 5-12% of the cases (31).

In a study of 35 adolescents Deakin (32) reports 38% of malunion in tibial fractures treated with flexible intramedullary nails and a mean time for union of 17 weeks higher than as shown in our case histories.

Moreover, even the current indications are still greatly debated.

A recent review (25) claims that the current gold standard treatment of paediatric tibial fracture: ESIN (elastic stable intramedullary nailing) has been repeatedly modified using end caps, prebent nails, and optimized surgical techniques. In addition, new methods such as rigid locking nails and plates have been included in the treatment approaches for femur and tibia shaft fractures. All these methods of paediatric fractures care carry inherent advantages that require consideration for each clinical situation (33).

Instead, for what pertains the rigid intramedullary nailing, unlike the adult population, it may not be possible in paediatric tibial fractures due to limitations including the proximal tibial physis plate and the small canal diameter in these patients (34)

Other problems to keep into consideration are the postoperative knee pain, destruction of the intramedullary blood supply with more blood loss, iatrogenic propagation of the fracture, inadequate distal fixation and hardware failure, leading to malunion (35).

External fixation, all things consistent with the other techniques described in the literature, allows a good reduction of the fracture and excellent healing. It also has the advantage of being minimally invasive, does not require a second surgery for removal of synthetic means and allows quick mobilization of joints and in case of secondary displacement of the fracture it is possible to modify the external fixator to correct the displacement without the need for a second surgical intervention.

The disadvantage of external fixation implant could be the risk of a poor tolerance of this procedure, especially in young patients, and a requirement for a greater rate of compliance by the patient as compared to other synthetic means. In our patients, there were no reports of complaints during daily activities or medication of pins.

In the literature, the external fixation in paediatric tibial fractures is reported for open fractures (36).

Aslani et al. (34) compared the external fixation and elastic intramedullary nails without finding statistically significant differences between the two techniques of bone healing time, the end result, the percentage of malalignment or residual heterometry, osteomyelitis or secondary systemic infection and loss of range of motion.

The goal of our work was to analyse the results obtained with external fixation in the treatment of this type of fracture. External fixation allows a good reduction of the fracture and an excellent healing; it also has the advantage of being minimally invasive; it does not require a second surgical intervention for the removal of synthetic means, allows early mobilization of the joints, and in the event of fracture of the secondary decomposition it is possible to change the external fixator without the need for re-intervention (37). In addition, the minimally invasiveness at the soft tissue level, the absence of periosteal damage, less bloody supply destruction in the fracture site make this a very attractive method (38,39). Furthermore, this method shows a very low risk of infection. In fact in our case histories we only had 7 cases of superficial infections of the pin resolved with oral antibiotics, but no cases of deep infection. Skin infections are a problem commonly encountered by other authors (27). The disadvantage of the external fixation could be in the poor tolerability of the procedure, especially in young patients, and the need for better compliance by the patients towards other means of synthesis. In our survey the fixator was well tolerated by all patients.

In conclusion, more research is needed to determinate the optimum treatment strategy for this common paediatric injury. The existing literature is of poor quality; consisting mainly of retrospective reviews of patients' medical records, charts, and radiographs. Carefully designed, high-quality prospective cohort studies utilizing a nationalized multi-hospital approach are needed to improve understanding before protocols and guidelines can be developed and implemented.

From our results we can state that external fixation represents a valid alternative to intramedullary nails for this type of fracture. There are a lot of benefits, such as a quick mobilization of the joint, low invasiveness, only one surgery and the possibility to correct any secondary displacement. It is important to point out that the application of the external fixator should be done by a surgeon experienced in this method and that the patient and family must be cooperative until its removal.

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TRANSPARENCY DECLARATION

Conflict of interest: None to declare.

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