ORIGINAL RESEARCH

The Applicability of Dynamic External Fixator in a Prospective Evaluation of Open Tibial Fracture Treatment

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Received on: 10 August 2023; *Accepted on:* 27 March 2024; *Published on:* 06 May 2024

Abstract

Aim: This prospective study assessed the clinical and radiological outcomes of open tibia fractures treated with a dynamic external fixator.

Materials and methods: Twenty-five patients underwent surgical debridement and stabilisation with a dynamic external fixator between November 2016 and April 2022. Regular follow-up evaluated bone healing progression.

Results: Favourable outcomes were demonstrated in 20 patients. However, there were three cases of non-union, two of which subsequently deformed, and two cases of pin site-related infection. There were no fracture site infections.

Conclusion: This study demonstrates the use of dynamic external fixation in the treatment of open tibia fractures. The low incidence of complications suggests its effectiveness and potential.

Keywords: Bone healing, Complications, Dynamic external fixator, Open tibia fractures, Surgical debridement.

Strategies in Trauma and Limb Reconstruction (2024): 10.5005/jp-journals-10080-1606

Introduction

Open tibial shaft fracture require urgent treatment involving antibiotic therapy, debridement of devitalised tissue, lavage, and skeletal stabilisation. The options for fracture stabilisation include casting, external fixation, or internal fixation.[1]

External fixation is a technique that allows for stabilisation with less additional soft tissue trauma.[1] Its use can be temporary, with subsequent conversion to internal synthesis, or as a definitive treatment. There is extensive literature on the subject of stabilisation in open fractures; the use of locked intramedullary nails (IMNs) was advocated by Bhandari even in type IIIA open fractures (Gustilo and Anderson classification).[2–5] The literature emphasises difficulties with the stability of the Schanz pin, which tends to loosen when there is delayed healing and prevents minor adjustments in reduction.[6–10] However, Rodrigues et al. found similar results between IMNs and standardised external fixators in 2014.[11]

The possibility of using a dynamic linear external fixator with hydroxyapatite-coated Schanz pins may reduce the difficulties encountered with the biplanar external assembly. This technique could offer easier reduction, allow dynamisation, reduce pin loosening, and maintain reduction until union is achieved.[2]

Therefore, the objective of this study is to prospectively evaluate a series of patients with open tibial fractures treated with a dynamic linear external fixator, aiming to find another safe option for the treatment of open tibial fractures.

Materials and Methods

A prospective study was conducted and recruited 27 patients with open tibial fractures who underwent surgery between November 2016 and April 2022 at the accredited hospitals of the orthopaedic and traumatology service. Informed consent was obtained from all patients prior to surgery. The inclusion criteria were patients over 18 years of age with open tibial shaft fractures classified as Gustilo and Anderson type 1, type 2, and type 3A and AOTA 42.[3]

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How to cite this article: Bezerra BS, Araujo TA, Cardonia GG, *et al*. The Applicability of Dynamic External Fixator in a Prospective Evaluation of Open Tibial Fracture Treatment. Strategies Trauma Limb Reconstr 2024;19(1):36–39.

Source of support: Nil

Conflict of interest: None

Participants who did not meet the eligibility criteria were those with fractures classified as Gustilo and Anderson type 3B and type 3C and AOTA 41 and 43.

The surgical technique begins with wound debridement followed by bone stabilisation using a dynamic external fixator (X-Caliber, Orthofix SRL, Verona, Italy). Fixation starts with the smaller segment in the anteromedial region of the tibia. Incisions of 15–20 mm are made for each pin, ensuring that the skin around each pin is not under tension. A guide is inserted perpendicular to the longitudinal axis of the bone, and the bone is drilled using a 3.2 mm drill bit for cancellous bone or a 4.8 mm drill bit for cortical bone. Three hydroxyapatite-coated pins are inserted into one fragment and then the fixator is positioned in such a way that it allows the pins into the other fragment to pass through, utilising the same technique. The body of the fixator is positioned parallel to the bone axis. The fixator body is adjusted to the appropriate length, ensuring that it is neither completely closed nor fully open in order to provide sufficient 'freedom' in manipulation to achieve the final fracture reduction. The locking nut of the central body should be positioned outward from the bone so that it can be tightened without obstructing the view of the fracture site. The fixator is positioned at least 2 cm away from the skin to allow for potential postoperative swelling and necessary dressings. Fine adjustment of the final reduction is performed due to the presence of a universal joint in the central body of the fixator.

These patients were followed up for one year after surgery with outpatient clinical checks every three months and with periodic radiographic assessments. Partial weight-bearing was allowed 1 month after the surgery and exercises for knee and ankle strength and range of motion were initiated immediately postoperatively. The outcomes measured were fracture union, as determined through periodic radiographs looking for the presence of bridging callus in at least three out of the four cortices to confirm union. Potential complications, such as infection, were also evaluated at the pin sites and the fracture site and were diagnosed based on clinical signs. Non-union, defined as a failure to achieve union by the end of the study, was also recorded. Finally, we measured for unacceptable fracture malalignment, defined as deviations exceeding the following limits: Less than one centimetre of shortening; up to ten degrees of anterior and posterior angulation; five degrees of valgus; and no varus deviation. The measurements were taken immediately postoperatively, at 6 months, and at 12 months postoperatively.

At the end of the one-year postoperative follow-up, patients undertook the SF-36 quality of life questionnaire to assess the physical, social, and psychological impact of treatment with the dynamic external fixator. The scores are categorised into various parameters, each representing a specific aspect of well-being and the results are presented in Table 1. The numbers described in the maximum and minimum columns do not have a specific unit of measurement and are referred to as the raw scale. The values are derived from the transformation of scores given in the questionnaire, ranging from 0 to 100, where 0 represents the worst state and 100 represents the best state.

The observed variables among patients included age, sex, smoking status, and fracture grade of exposure according to Gustilo and Anderson.[3] There were two patients lost to follow-up, who were subsequently excluded from the study and all statistical analyses due to insufficient data for evaluation.

Spearman's rank correlation coefficient (ρ) was used to correlate study variables. The Kruskal–Wallis test was used to observe any association between the degree of exposure and the presence of complications, as well as between the age of participants and the presence of complications. The Mann–Whitney *U* test was used to detect the effects of smoking on the incidence of complications among patients. The same test was used to determine whether the incidence of non-union during recovery would increase the incidence of malalignment after 1 year.

Results

The research included a total of 27 participants. However, only 25 patients were analysed as 2 patients were lost to follow-up due to returning to their home states, making it impossible to assess them adequately. The mean age of the patients was 36.84 years. Among the sample, 8 patients were smokers, while 17 were non-smokers. Of the observed patients, 21 were male while 4 were female.

A total of 4 patients had grade I open fractures, 13 patients with grade II open fractures, and 8 patients with grade IIIA open fractures. It is noteworthy that the majority of patients had grade 2 exposure.[12]

Table 1: Quality of life by the SF-36 test

	Minimum	*Maximum*	*Average*	*Median*	*Standard deviation*
Functional capacity	5	90	51. 4	50	25. 15
Limitation by physical aspects	0	100	32. 0	25	34. 25
Pain	0	100	58. 4	52	30. 21
General health status	25	100	65. 9	62	19. 02
Vitality	20	100	65. 6	70	20. 48
Social aspects	13	100	69. 0	75	29. 56
Emotional aspects	0	100	64. 0	100	47. 06
Mental health	16	96	66. 6	68	20. 26

Table 2 shows the correlations between the study variables classified using Spearman's rho (ρ). A strong association is observed between reduction loss and pseudoarthrosis with deviation after 6 months; between reduction loss with deviation after 6 months; between complications with deviation after 1 year; between reduction loss with deviation after 1 year; and between deviation after 6 months with deviation after 1 year. Spearman's rho showed a negative correlation between smoking and sex; between complications with a grade of exposure; and between reduction loss with quality of life.

We observed fracture union in 22 out of 25 cases. Pseudoarthrosis occurred in three cases and pin site infection in two cases. There was no initial postoperative alignment deviation but, at 6 months, two cases showed malalignment, and at 1 year, the same two cases still had deviation, which were also the cases with pin site infection and loosening. There was no infection at the fracture site. Amongst the patients with pseudoarthrosis, the two cases with deviation underwent a switchover to circular external fixation, while the case without deviation was treated with compression plating. All cases eventually achieved consolidation.

We used the Mann–Whitney test to detect the effects of smoking on the incidence of complications among patients. Smoking was significantly related to the development of deviation and associated with patients who experienced septic loosening of the Schanz pins.

Using the Kruskal–Wallis test, no significant association was found between the degree of exposure and the presence of complications ($p = 0.332$), pseudoarthrosis ($p = 0.658$), infection ($p = 0.177$), deviation at 6 months ($p = 0.246$), and deviation at 1 year ($p = 0.177$) in the sample. Similarly, when assessing the potential impact of patient age on the incidence of complications, no discernible differences were observed across age groups for pseudoarthrosis ($p = 0.641$), infection ($p = 0.987$), loss of anatomical alignment ($p = 0.523$), deviation at six months ($p = 0.641$), and deviation at 1 year ($p = 0.523$).

The SF-36 questionnaire was administered to assess the quality of life. In terms of functional capacity, we observed an

Table 2: Variables correlation with Spearman's rho (ρ)

		Correlations										
		1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*
1	Age	1.000										
2	Sex	0.212	1.000									
3	Smoking	0.101	0.299	1.000								
4	Grade of exposure	0.246	0.100	0.131	1.000							
5	Quality of life	0.058	0.030	0.012	0.078	1.000						
6	Complication	0.031	0.294	0.022	0.259	0.068	1.000					
7	Pseudoarthrosis	0.111	0.161	0.274	0.075	0.137	0.560**	1.000				
8	Infection	0.185	0.089	0.140	0.062	0.198	0.241	0.553**	1.000			
9	Loss of anatomical alignment	0.063	0.327	0.086	0.092	0.333	0.842**	0.431*	0.102	1.000		
10	Deviation after six months	0.000	0.129	0.430*	0.045	0.020	0.497*	0.799**	0.060	0.590**	1.000	
11	Deviation after one year	0.063	0.327	0.086	0.092	0.333	0.842**	0.431*	0.102	1.000**	0.590**	1.000

*The correlation is significant at the 0.05 level (2 ends); **The correlation is significant at the 0.01 level (2 ends) [1]; ρ values range from –1 to 1, where –1 indicates a strong negative correlation, 1 indicates a strong positive correlation, and 0 indicates no correlation

average score of 51.4, indicating a moderate level, as shown in Table 1. This was similar for pain, general health status, vitality, emotional aspects and mental health. For the score of limitation by physical aspect, the average of 32.0 suggests a low level of limitation whereas for social aspects, the average score of 69.0 indicated the participants generally have good social interactions and engagement.

Discussion

Bhandari et al.[2] demonstrated better outcomes for the treatment of open tibial fractures using IMNs compared to external fixation. They reported a lower rate of reoperations and complications. However, a criticism of this meta-analysis is the lack of normalisation of external fixation, which can result in suboptimal stability, by being either too rigid or too flexible.

On the other hand, Rodrigues et al.[11] showed similar outcomes in a prospective study comparing the treatment of open tibial shaft fractures using IMNs s versus a standardised biplanar external fixator. The results of the external fixator group included a consolidation rate of 90.3%, no infection at the fracture site, 16.1% malunion, and no statistically significant difference in quality of life assessed by the SF-36 questionnaire compared to the intramedullary nail group. The limitations of the biplanar external fixation tested were the interference of the metal bar in radiographic imaging, an inability to correct small deviations postoperatively, and a lack of controlled dynamisation. Therefore, the promising results of this study encouraged us to continue researching and seek a fixator model capable of overcoming these limitations.

The chosen fixator option (X-Caliber, Orthofix SRL, Verona, Italy) had only been the subject of two previous retrospective studies.[5,13] Inan et al.[5] reported, in 32 patients treated with the external fixator, a consolidation rate of 87.5% (four malunion) and pin site infection rate of 15.6% (5 patients) in a group of patients with both closed and open tibial fractures. Beltsios et al.,[13] found that 87.27% of 212 patients with tibial fractures associated with soft tissue problems when treated with unilateral external fixators had achieved satisfactory results. The study demonstrated that primary and definitive treatment with unilateral external fixators is safe and associated with a low rate of deep infection. Both studies concluded that monolateral external fixation is a viable alternative as a definitive treatment.

In our prospective evaluation of the current patient group, we observed a consolidation rate of 88%, similar to what has been reported in the literature. A positive finding was the acceptable reduction achieved at the end of surgery in all patients. This can be attributed to the fact that the fixator is radiolucent, facilitating intraoperative radioscopic imaging, and allowing for small adjustments to be made in the operating room after the final radiograph.

Of the three patients (12%) who developed pseudoarthrosis, two were smokers and experienced early loosening of the Schanz pins. The statistical analysis revealed a significant relationship between pin site infection, pseudoarthrosis, and fracture deviation.

In 2008, Moroni et al.[12] conducted a histological and biomechanical analysis comparing conventional transosseous pins and hydroxyapatite-coated pins. They found that the interface between the pin and bone is more important for fixation stability than the specific characteristics of the pin, such as end shape, thread pitch, or self-drilling capability. When using hydroxyapatite-coated pins, proper integration between the pin and bone is crucial and smoking has been shown to be directly responsible for the loosening of this interface. In patients where pin-bone integration occurred, the system was stable enough to maintain fracture reduction until the end of treatment, even in the cases of pseudoarthrosis that had developed without angular deviation.

Another statistically significant relationship was found between the presence of pseudoarthrosis and fracture deviation at the 1 year follow-up. This was expected since inadequate bone consolidation allows movement at the fracture site, leading to deviation. The other results, such as age and degree of exposure, did not significantly affect the primary outcome.

The SF-36 questionnaire provided insights into the impact of the injury on the patients quality of life. When compared to the literature, we observed that the pattern of high impact on patients' quality of life remains consistent. While Rodrigues et al.[11] did not find significant differences between the IMNs and external fixator groups, this study appears to be an exception, as our findings correspond with the existing literature regarding a poorer quality of life outcome in patients using external fixators.[14]

Limitations of this study include a relatively small sample size and the lack of a control group. Although it was a prospective study, comparisons were made with the literature and with the two previous patient groups treated by the same team in the same hospitals.

Conclusion

This prospective study shows the effectiveness and potential of the dynamic external fixator as a treatment approach for open tibia fractures. The radiolucency and dynamic nature of this method of stabilisation and the associated low complication rate make it a good option for intraoperative reduction. The utilisation of a percutaneous technique also reduces the risk of infection and the incorporation of hydroxyapatite-coated pins enhances fracture stability over an extended period.

Clinical Significance

The clinical significance is to highlight a technique that offers potential advantages such as reduced complications, enhanced fracture stabilisation through hydroxyapatite-coated pins, and intraoperative adjustability for optimal reduction. By comparing this approach with existing methods and conducting a one-year prospective study, the research contributes to the understanding of effective orthopaedic interventions for open tibial fractures. Furthermore, the assessment of patients' quality of life using the SF-36 questionnaire adds a patient-centred dimension to the evaluation of treatment outcomes. While acknowledging limitations, such as sample size and absence of a control group, the findings may influence clinical practice and guide future research in orthopaedic trauma management.

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