Functional outcomes of the failed plate fixation in distal tibial fractures salvaged by hexapod external fixator

Running Title: Distal Tibial Non-union Salvage

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Statement:

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Abstract

Purpose:

The purpose of this study was to evaluate the clinical and functional outcomes of failed plate fixation in distal tibia fractures salvaged with hexapod circular fixators.

Material and Methods:

The database of a specialized limb reconstruction centre was searched for all patients with failed plate fixation undergoing limb reconstruction with a circular external fixator between 2008 and 2017. Patients between the ages of 18-65 years, with a symptomatic distal tibia mal-union or non-union following plate and screw fixation were included. The SF-12 and Foot Function Index (FFI) scoring systems were used to measure clinical and functional outcomes.

Results:

Ten patients with a mean age of 38±13years met the inclusion criteria. Seven patients had an infected non-union, two hypertrophic non-unions, and one a mal-union. The mean follow-up was 41.7±28.3 months. The mean duration of external fixation was 232.9±146.6 days. The SF-12 demonstrated a mean score of 49.4±7.7 for the physical component, and a mean score of 55.3±8.1 for the mental component. Five patients (50%) scored above 45 points for the SF12 physical component and nine patients (90%) scored above 45 points for the mental component, indicating good outcome can be achieved. The mean FFI score was 24.9±19.9, and six patients had a score below 14 points (good outcome). Radiological union was observed in all 10 patients at a mean of 29±14 months.

Conclusions:

The results of this study suggest that hexapod circular external fixation is an attractive surgical alternative for the treatment of failed plate fixation of distal tibial fractures, and can reliably achieve bony union and result in very satisfactory clinical outcomes.

Key Words:

Distal tibial fractures; non-union; plate fixation; circular external fixation; hexapod

Level of Evidence:

Level IV case series

Introduction

Distal tibia fractures are often high-energy complex injuries, prone to complications, and can later present chronic problems that may be difficult to resolve [1]. Surgical treatment is generally indicated, and techniques considered include plate osteosynthesis, external fixation, intramedullary nailing, and minimally invasive techniques [2,3]. Potential complications following operative treatment include wound breakdown, deep infection, malunion, and non-union [4], reportedly involving up to fifty percent [5]. In a large retrospective analysis of tibia fracture the reported non-union rate was 12% [6], and Vallier et al. identified a malunion rate of 8.3% with medial plating of distal tibial fractures [7]. One of the challenges in treating these injuries is that the distal fragment is often short with flaring of the metaphyseal bone, and plates or nails may not provide adequate stbility to achieve rapid union [8].

Periarticular distal tibial non-union can be even more difficult to treat [9]. Small distal bone fragments, disuse osteopenia, soft tissue atrophy, infection, and adjacent joint contractures create genuine challenges. Various treatment options exist including primary arthrodesis or joint preservation [9]. Fixation techniques include blade-plates, conventional plates, external fixation, or circular external fixation with or without bone transport, shortening, distraction osteogenesis, or a combination of these techniques.

The use of external fixators in distal tibia fractures is well established [10-12]. Hybrid and Illizarov fixation allows early weight bearing and ankle motion, and good outcomes have been described [8,13]. For the treatment of distal tibial non-unions or infections following fracture fixation limb salvage is possible, but commonly involves ankle fusion, microvascular free tissue transfers, and bone grafting [14,15]. The diagnosis of deep infection is generally associated with considerable morbidity, and often requires multiple procedures and a protracted course of treatment [16,17]. Although successful limb salvage can be achieved in approximately 80% of cases, amputation is not uncommon [16-18]. Given these uncertain outcomes it was therefore the purpose of this study to evaluate functional outcomes following failed plate fixation in distal tibia fractures salvaged with hexapod circular fixators. We hypothesised that salvage with circular hexapod fixation would result in joint preservation, bony union, and limb salvage with acceptable functional outcomes.

Methods

Patient Identification and Data Collection

This study was conducted with a retrospective cross-sectional design. Prior approval to conduct this investigation was obtained from the local Institutional Review Board and Human Research Ethics Committee. Patients who were treated for failed plate fixation of distal tibial fractures between 2008 and 2017 were identified from the database of a specialized limb reconstruction and trauma center. Patients were included if aged between 18-65 years, and had a failure of plate fixation of the distal one third of the tibia with an existing non-union or malunion, whether infected or not. Malunion was defined as a coronal deformity of greater than 5° varus or 10° valgus, or a sagittal deformity of greater than 15° [19]. Non-union was defined as the lack of any clinical or radiological evidence of union at six months [20]. The Cierny-Mader classification system for chronic osteomyelitis was utilized to stage cases with infection [21]. Patients were excluded if the initial fracture was more than 5 cm proximal to the ankle joint, was a segmental or intra-articular fracture, or had a history of previous ipsilateral tibial fractures, polytrauma, or closed head injuries. The medical records and radiographs were screened by an independent research associate. To preserve patient confidentiality, each case was allocated a unique study identification number.

Surgical treatment protocol

All patients had their implants removed and treatment followed a standardized protocol, described previously [22]. Briefly, this treatment protocol includes eight defined steps:

(1) debridement, PMMA spacer with the Masquelet technique [23], and provisional stabilization with external fixation, (2) soft tissue coverage and wound closure, (3) definite

fracture fixation with a hexapod capable circular frame, (4) later removal of the PMMA spacer and corticotomy, (5) latency period and gradual distraction, (6) docking site modification, (7) functional rehabilitation, (8) frame removal, long-term surveillance. These steps served as a guide and were applied according to the clinical requirements, individualized to the specific characteristics of each patient. This protocol adheres to the established principles of staged management for complex limb salvage and reconstruction, particularly when treating infected non-unions and chronic osteomyelitis [24, 25].

Outcome measures

Functional outcomes were evaluated with the SF-12v2 [26,27] and Foot Function Index [28]. The SF-12v2 is a validated score consisting of twelve questions in eight health domains; physical function, bodily pain, general health perception, vitality, physical role functioning, emotional role functioning, mental health, and social role functioning. It uses an algorithm to generate the physical and mental health composite scores. An individual mean score of less than 45 for physical and mental scores indicates impairment of function [26]. The FFI was used to assess foot and ankle function, and has been used previously [7, 29]. The FFI consists of twenty-three items covering pain, disability, and activity restriction; the values for each aspect range from zero to one. The total foot function score is then calculated as the mean of the three subscale scores, expressed in percentages by multiplying the final score by 100. A higher FFI score indicates greater impairment and is indicative of a poorer outcome. To reduce interviewer bias, participants were asked to complete both questionnaires without assistance from the research associate.

Radiographic union was assessed using the criteria from Whelan et al. and defined as the presence of bridging callus of at least three cortices at the fracture site with a RUST score of ≥ 9 [30]. This scoring system has been shown to be reliable and valid with an ICC above 0.8 for both intra- and inter-observer correlations [30]. The duration each patient spent in a frame and any complications that developed were extracted from the medical records.

Statistical analysis

Descriptive statistics (means and standard deviation) were used for the demographic variables, as well as FFI and SF-12 scores. All analyses were conducted using STATA SE (Version 12.0; StataCorp, College Station, Texas, USA) for Windows.

Results

Twelve patients met the inclusion criteria, nine males and three females, although two patients could not be contacted and were excluded. Pertinent demographic details and outcome scores are summarized in Table 1. The mean age of participants was 38±13 years, with a mean follow-up was 41.7±28.3 months. The mechanism of injury was a fall in seven, motorbike accident in two, and motorvehicle accident in one patient. In seven cases the aetiology of fixation failure was infection (Cierny-Mader IVA), and in two cases inadequate surgical fixation with fracture instability. One patient presented with a malunion and talar subluxation. His original injury was recorded as a Gustillo-Anderson IIIA open distal tibial fracture following a motor vehicle accident, and initial treatment occurred at another center with a medial distal tibial plate. (Figures 1 -3).

Table 1: Demographic data, FFI, SF-12 scores and radiological outcomes.

	Sex	Age	Mechanism of injury	Diagnosis	SF-12 PCS	SF-12 MCS	FFI	Radiological union
1	F	24	Fall	Septic nonunion	52.1	41.3	11	Y
2	F	29	Fall	Hypertrophic nonunion	39.1	55.6	40	Y
3	M	35	MBA	Septic nonunion	39.7	57.2	10	Y
4	M	29	MBA	Septic nonunion	45.1	57.3	45	Y
5	M	56	Fall	Septic nonunion	36.6	67.3	13	Y
6	M	51	Fall	Septic nonunion	45.1	61.5	10	Y
7	M	57	Fall	Septic nonunion	57.2	54.7	11	Y
8	M	45	Fall	Hypertrophic nonunion	52.1	60.3	11	Y
9	F	18	MVA	Malunion	34.3	47.1	62	Y
10	M	42	Fall	Septic nonunion	36.6	67.3	30	Y
Mean/SD		38±13			49.4 ± 7.7	55.3± 8	24.9±18	

MBA, motorbike accident; MVA, motor vehicle accident; Y, yes; SD, standard deviation; SF-12 ,short form 12;

PCS, physical component score; MCS. Mental component score; M, male; F, female

Fig. 1: Radiographs of 18-year-old female involved in motor vehicle accident with malunion distal tibia and talus subluxation following medial plating
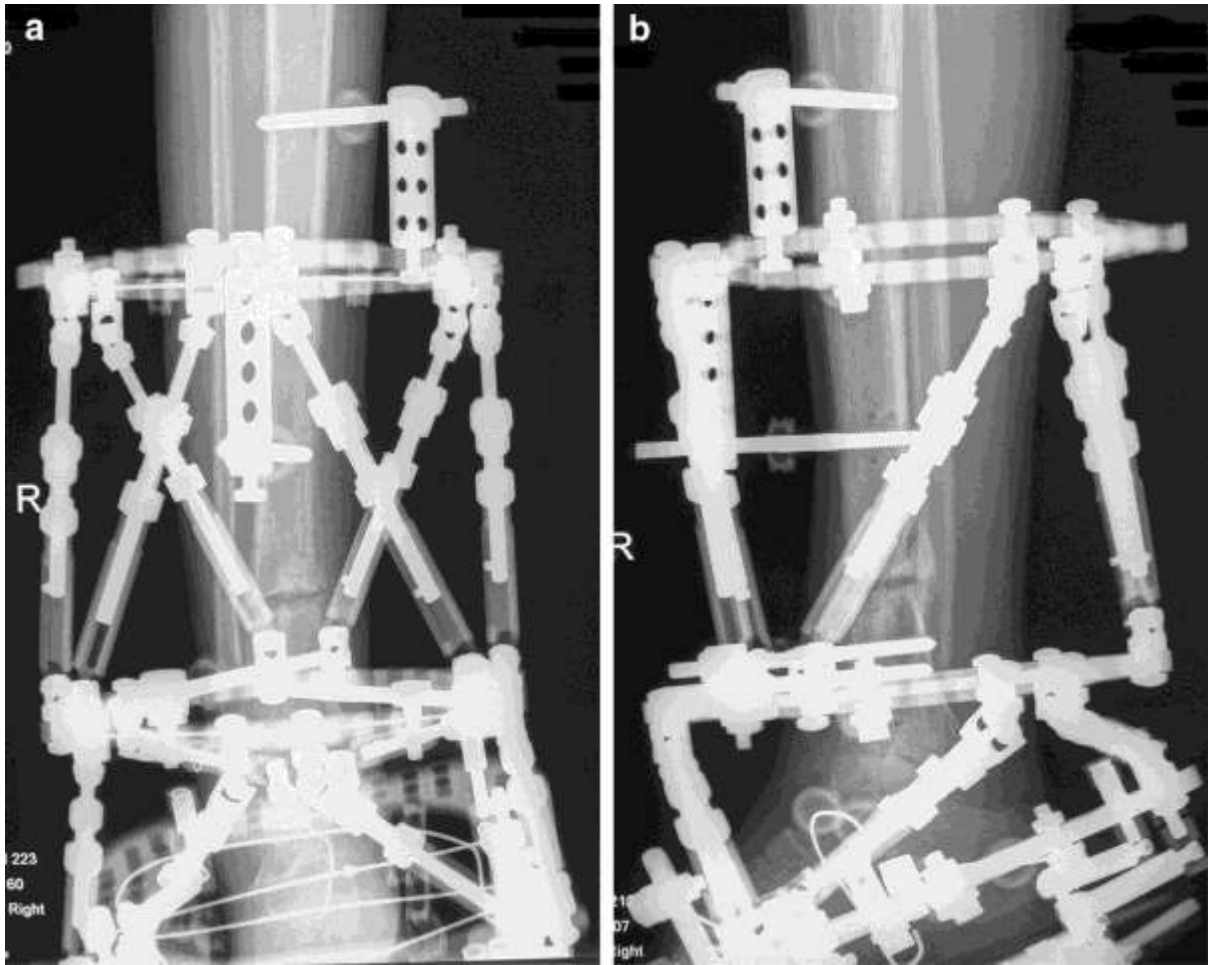
Fig. 2: Radiographs following removal of implants and corrective osteotomy with hexapod external fixator application, Taylor Spatial Frame
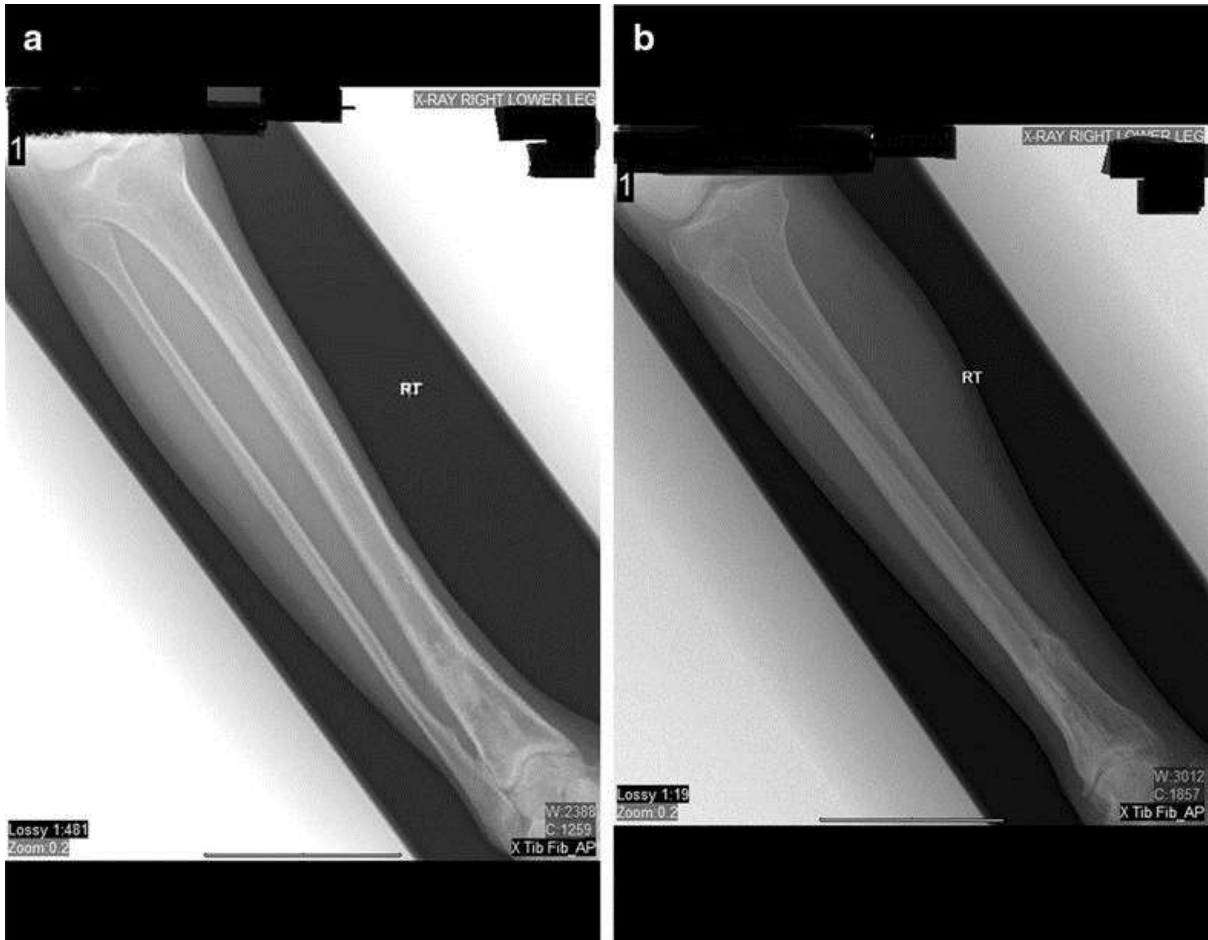
Fig. 3: Radiographs following removal of external fixator and correction of deformity

The course of treatment was often difficult and protracted, and the mean duration of external fixation was 232.9±146.6 days. Although the sample size was small and the distribution into groups unequal, there was a very large discrepancy in the time course of treatment between cases that were infected compared to aseptic cases. For the patients with septic non-unions (n=7), the mean duration of external fixation was 274.1±154.8 days. For the aseptic cases (n=3), the mean duration of external fixation was 136.7±71.1 days.

The SF-12 mean score was 49.4± 7.7 for the physical component, and 55.3 ± 8.1 for mental component. Overall five patients had good outcomes with a physical component score (PCS) above 45 (Table1). Eight patients had good mental health outcomes, indicated by a MSC

score above 50 (Table 1). The Foot Function Index had a mean value of 24.9 ± 18.9 points. In six patients the FFI score was less than 14, indicating good outcomes. One of the patients had a score above 62, indicating an unsatisfactory outcome; this was the individual with a tibial malunion following a high-energy motor vehicle accident. When compared to the contralateral extremity, seven patients displayed normal ankle movements, one patient had restricted plantar- and dorsiflexion and two patients had a stiff ankle joint in the neutral position allowing mobilization. However one of the patients with a stiff ankle joint relied on a CAM boot for mobilization. Eight patients returned to work, one went into early retirement and one patient was unable to work because of depression despite minimal pain.

Radiographic union was achieved in all 10 patients; the time from the salvage procedure to union was a mean of 29±14 weeks. Seven patients did not demonstrate any radiographic evidence of osteoarthritis and three patients showed Takakura stage I degenerative changes. The mean duration in a frame was 233±147 days. The overall complication rate was 40%. The distal wire broke in one patient and had to be replaced 4 weeks after the index procedure; similarly, one half pin broke 4 weeks after the index procedure. One wire was removed on the proximal ring in another case because of soft-tissue irritation, and one patient was treated for recurring deep infection which settled with aggressive debridement, irrigation, and reapplication of the external fixator.

Discussion

The most important finding of this study was that distal tibia fractures that had previously failed to unite with plate fixation could be successfully treated with hexapod external

fixation. Bone union was achieved in all cases, and the functional outcome was rated good in over 60% of patients.

Distal tibial non unions are difficult to treat, and the small distal fragment presents a major challenge for the surgeon [9]. Several authors have reported on the outcomes of treating distal tibial non-unions [9,14,15,31,32]. Earlier studies have used ankle arthrodesis as a salvage procedure [14, 15], while more recent studies have attempted to preserve the integrity of the ankle joint [9, 31, 32]. Marsh et al. treated seven patients with distraction osteogenesis and ankle arthrodesis, and achieved union in six cases at an average of 7.9 months; one patient required a below knee amputation [15]. Of their six patients treated successfully, three had good, two fair, and one poor outcome, with lower SF 36 scores than the standard age-matched population [15]. Zalavras et al. reported on their experience treating infected distal tibial metaphyseal fractures. They used a similar staged protocol to that employed in the current study, with debridement, antibiotic cement spacers, external fixation, soft-tissue coverage, and ankle fusion [14]. Union was achieved in all of their cases, and all patients were able to walk without assistive devices and were pain free at a mean follow-up of 5.5 years [14]. These results are similar to our findings, although seven of the ten patients in our cohort were infected non-unions. Union was achieved in all seven cases, and the outcome scores indicated a high functional recovery in six of the seven patients with excellent mental health scores in four patients. Our results demonstrate that limb salvage without ankle fusion is an attractive option, achieving, very similar, if not better, outcomes.

Richmond et al. [31] suggested treating non-unions of the distal tibia with reamed intramedullary nailing. Seven of their 32 patients had a history of infection, but none had any

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signs of active infection at the time of surgery. They reported a union rate of 91% at a mean of 3.5 months, but 43% of the previously infected cases developed deep infection requiring further surgical interventions [31]. The functional outcomes were not reported. Obviously this technique is only suitable if there is sufficient distal bone stock available.

More recently, Laklouk et al. reported on their experience with 13 cases of failed internal fixation, of which three had an infected non-union [32]. Following treatment with Ilizarov external fixation, union was achieved in all cases. They used the ASAMI score, and eleven patients had good and fair outcomes at a mean of 24 months follow-up [32]. Eralp et al. also treated 13 cases of infected non-union of the juxta-articular region of distal tibia [9]. The Ilizarov fixator was used in 12 cases, and the Taylor Spatial Frame was used in one [9]. Union was achieved in all cases, and 12 patients had good or excellent results when the functional outcomes and bone healing were assessed using Paley's criteria. However, five patients (38%) required an ankle arthrodesis. Eralp et al have utilized the Ilizarov fixator which allows compression, distraction, lengthening, bone transport, and deformity correction, all by manipulating the frame configuration, similar to a hexapod system [9]. In contrast to Eralp, none of your patients required ankle arthrodesis with a very similar length of follow-up.

Arvesen et al. assessed the efficacy of hexapod external fixation for the treatment of distal tibial nonunions with associated complex deformities [33]. They reported a 94% union rate, and reduced a mean 18 degree pre-operative deformity to less than 5 degrees after. Functional outcomes were not reported. Hexapod external fixation and its ability to perform 6-axis manipulation of the limb allows highly accurate correction of complex, multifocal

deformities. To achieve reliable and reproducible results with a high rate of union it is important to follow a formal standardized and structured approach. It may be argued that these difficult cases should be treated in a specialized centre to achieve better outcomes. This argument is certainly supported by the published trauma surgery literature [34,35]. Demetriades at al. demonstrated better outcome for level I trauma centers for specific injuries and Cudnik et al. showed that level I trauma centers had improved survival and better functional outcomes when compared to level II hospitals [34, 35].

Limb salvage using a hexapod external fixation system without ankle fusion remains a very attractive surgical option for distal tibial nonunions. Early soft-tissue management, restoration of limb length, deformity correction, and the ability to weight-bear promote functional recovery [22]. However, typical treatment times are long and complications are frequent [15], and patients should be informed about the expected time in frame and the associated high complication rate.

The mean duration of external fixation was 233 days, considerably longer than in previous publications. This clinical series has revealed a very large discrepancy in the time course of treatment between cases that were infected compared to aseptic cases. In this study, infected cases spent twice as long in an external fixator. For patients with septic non-unions the mean duration of external fixation was 274 days, and for the aseptic cases the mean duration of external fixation was only 137 days. However, the sample size was small and the distribution into groups unequal, and no meaningful statistical comparison can be performed.

Laklouk et al. [32] used the Ilizarov fixator to treat failed internal fixation in distal tibial fractures and reported a mean duration of external fixation of 146 days. However, they only treated 3 cases (23%) of deep infection, while in the current study 70% of the cases were infected. With any infected case, time to union is generally longer and union more difficult to achieve, and the results of this study support this contention. Eralp et al. treated 13 patients with infected nonunions and reported a mean time in external fixation of 198 days, further corroborating this argument [9]. In contrast, Zalavras treated six patients with infected distal tibial metaphyseal and plafond fractures and reported a mean duration of external fixation of only 174 days [14]. There are many potential confounding factors, and the duration of external fixation can depend on multiple other aspects such as the patient's immune status, presence of comorbidities, and the type and chronicity of the infection. It is also possible that an arthrodesis allows more aggressive debridement, radically removing bone and allowing bone transport of healthy well-perfused bone, potentially reducing the time in external fixation.

Limb salvage is often associated with a high rate of complications [18, 22]. The overall complication rate in this series was 40%, similar to the rate of complications reported previously [9,14,15,31,32]. One broken wire and one broken halfpin were successfully treated by removal and replacement. In one patient a recurrence of infection one month after the index procedure required frame removal, repeat debridement, and application of an suction/irrigation system. Following resolution of the infection, a new hexapod fixator was applied and the fracture united with a duration of external fixation of 150 days.

This study has several important limitations. The sample size was small, typical of all published studies reporting on limb salvage with complex trauma. The retrospective study design introduces the possibility of selection bias. The study was performed at a single centre specialised in limb reconstruction limiting its external validity, and the results reported here may be difficult to replicate in less experienced trauma units. However, treatment of distal tibial nonunions and osteomyelitis is a highly complex clinical condition, and requires experience and specialised knowledge to achieve satisfactory outcomes. It is acknowledged that over 70% of these cases had chronic osteomyelitis, and the inclusion of more non-infected cases may have resulted in higher functional outcomes and a reduced duration of external fixation.

Conclusion

The results of this study suggest that hexapod circular external fixation is an attractive surgical alternative for the treatment of failed plate fixation of distal tibial fractures, and can reliably achieve bony union and result in very satisfactory clinical outcomes.

Compliance with ethical standards

This project was approved by the University of Pretoria, South Africa, Institutional Review Board and Human Research Ethics Committee.

Conflict of interest

The authors declare no conflict of interest in relation to the presented body of research.

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