ORIGINAL ARTICLE

Outcomes Following Treatment of Complex Tibial Fractures with Circular External Fixation: A Comparison between the Taylor Spatial Frame and TrueLok-Hex

Jaco Naude[1], Muhammad Manjra[2], Franz F Birkholtz[3], Annette-Christy Barnard[4], Vaida Glatt[5], Kevin Tetsworth[6], Erik Hohmann[7]

Abstract

Aim: The purpose of this study was to compare the functional and radiological outcomes of complex tibia fractures treated with two different hexapod fixators.

Material and methods: This is a retrospective comparative study of patients treated for complex tibial fractures between 2010 and 2015. Inclusion criteria was patients between 18 years and 60 years of age, who sustained a complex comminuted open or closed tibial fracture with or without bone loss, who had a minimum of 12 months' follow-up, and who have been treated definitively using either Taylor Spatial Frame (TSF) or TrueLok-Hexapod System (TL-HEX). The outcome measures were Association for the Study and Application of the Method of Ilizarov (ASAMI) score, foot function index (FFI), EQ5-D, four-step square test (FSST), and timed up and go (TUG) test. Descriptive statistics were used to assess patient demographic information. Categorical variables (ASAMI and EQ5D-5L) were analysed using the χ^2 test. Continuous variables (FFI, functional tests, and radiographic outcomes) were analysed with two-tailed Student's *t* tests.

Results: In all, 24 patients were treated with the TL-HEX and 21 with the TSF. The mean time for external fixation was 219 $\pm$ 107 days (TL-HEX) and 222 $\pm$ 98 days (TSF). Union occurred in 92% (TL-HEX) and 100% (TSF). The mean follow-up was 777 $\pm$ 278 days (TL-HEX) and 1211 $\pm$ 388 days (TSF). Using the ASAMI scores, there were 17 excellent and 6 good results for the TL-HEX and 10 excellent and 11 good results for the TSF ($p = 0.33$). The FFI was 30 $\pm$ 28.7 (TL-HEX) and 26.1+23.9 (TSF) ($p = 0.55$). The EQ5D was 0.67 $\pm$ 0.3 (TL-HEX) and 0.73 $\pm$ 0.2 (TSF) ($p = 0.43$). The mean TUG and FSST were 9.2 $\pm$ 3.2 and 10 $\pm$ 2.9 seconds (TL-HEX) and 8.4 $\pm$ 2.3 and 9.6 $\pm$ 3.1 seconds (TSF) ($p = 0.34$ and 0.69).

Conclusion: The results of this study suggest that both hexapod external fixation devices have comparable clinical, functional, and radiographic outcomes. Either fixator can be used for the treatment of complex tibial fractures, anticipating good and excellent clinical outcomes in approximately 80% patients.

Level of evidence: Therapeutic level III

Keywords: Circular external fixation, Complex tibial fractures, Taylor spatial frame, TrueLok-Hex.

Strategies in Trauma and Limb Reconstruction (2019): 10.5005/jp-journals-10080-1443

Introduction

Complex tibial fractures are often difficult to manage,[1] and the relatively superficial location makes the tibia more susceptible to open fractures and associated bone loss with resulting nonunion and deep infection.[2] Current treatment options include intramedullary nailing, plate fixation, and external fixation. However, all these techniques are associated with various complication rates.[2,3] Webb et al. reported a 31% rate of nonunion for intramedullary nailing of open tibial fractures, with a 15% incidence of deep infection and a 40% prevalence of both nonunion and infection when the monolateral external fixation was used.[3] Dickson et al. reported that plate fixation resulted in 17% nonunion and 11% infection, and intramedullary nailing resulted in a 7% prevalence of nonunion and 11% risk of infection; while monolateral external fixation had a reported 11% incidence for both nonunion and infection.[2] In contrast, circular external fixation of grade III open tibia fractures had only a 2% rate of nonunion and a 1% rate of deep infection, although there was a superficial pin site infection rate of 31%.[2]

Circular external fixation is now commonly used in many centres, and the insertion of wires and half-pins allows stable fixation of almost any fracture configuration.[4] Because the periosteal and endosteal blood supply remains intact, and the construct provides high shear stiffness, it allows patients to bear weight immediately.[5,6]

[1,2]Department of Orthopaedic Surgery, University of Pretoria, Pretoria, Gauteng, South Africa

[3]Department of Trauma and Orthopaedics, University of Pretoria, Pretoria, Gauteng, South Africa; Walk-a-Mile Centre for Advanced Orthopaedics, Centurion, South Africa

[4]Department of Orthopaedic Surgery, Walk-a-Mile Centre for Advanced Orthopaedics, Pretoria, Gauteng, South Africa

[5]Department of Orthopaedic Surgery, University of Texas Health Science Center, San Antonio, Texas, USA

[6]Department of Orthopaedic Surgery, Royal Brisbane Hospital, Brisbane, Queensland, Australia

[7]Medical School, University of Pretoria, Pretoria, Gauteng, South Africa

Corresponding Author: Erik Hohmann, Medical School, University of Pretoria, Pretoria, Gauteng, South Africa, Phone: +27 971507130282, e-mail: ehohmann@hotmail.com

How to cite this article: Naude J, Manjra M, Birkholtz FF, *et al.* Outcomes Following Treatment of Complex Tibial Fractures with Circular External Fixation: A Comparison between the Taylor Spatial Frame and TrueLok-Hex. Strategies Trauma Limb Reconstr 2019;14(3):142–147.

Source of support: Nil

Conflict of interest: None

The resulting axial micromotion offers a favourable environment for bone healing.[5,6] Hexapod circular fixators such as the TSF (Smith & Nephew, Inc., Memphis, TN, USA) and the TL-HEX (Orthofix, Verona, Italy) are versatile systems, spanning the fracture with six crossing telescopic struts connecting two or more rings across the fracture site.[4,7,8] Adjusting these struts with their six degrees of freedom allows fracture reduction as well as correction of multiplanar deformities such as angulation, rotation, and translation and leg lengthening to a nearly unlimited degree.[4,9] These corrections can be either performed acutely or gradually, with the assistance of software programs available from the manufacture of each device.[8]

Many authors[1–4,10–14] confirmed the efficacy of the management of complex tibial fractures with circular external fixation. When comparing hexapod fixators to the Ilizarov frame, hexapod circular fixation resulted in greater precision and more reliable correction of paediatric deformities.[15]

Deformity correction with either a unilateral Orthofix fixator or an Ilizarov fixator was accurate for short to medium distances.[9] In contrast, the TSF allows multiplanar corrections and lengthening without complex modifications.[9] Healing indices did not differ between the three devices, but there was a shorter distraction–consolidation time, lower complication rate, and higher rate of accuracy using the TSF.[9] Greater ease of application of the TSF was accomplished by replacing a computer-based deformity correction planning with an web-based program resulting in increased surgeon and patient satisfaction.[7,9,15] The TrueLok Hex circular fixator is similar to the TSF in concept and function.[8,16] However, there are some fundamental differences between the two fixators. With the TSF the software assumes orthogonal mounting of the reference ring in both the sagittal and the coronal planes and the surgeon has to address these assumptions during frame mounting.[17] In contrast, the TL-HEX allows the surgeon to accommodate reference rings that are not orthogonally mounted.[8] The major structural difference lies in the configuration of the struts.[18] The TL-HEX attachments are on the outside of the rings via stable ball joints which open up more holes within the rings, potentially increasing their arc of motion and hence the extent of correction allowed.[18] However, the TL-HEX struts attach to the ring through a small pin inserted perpendicular to axial loads, at risk of failure when weight-bearing. This is in contrast to the TSF which attaches via holes within the main body of the ring itself,[18] an inherently stronger point of attachment.

Although both devices have been used in lower extremity trauma,[4,12,19,20] direct comparative studies have not yet been published. The purpose of this study was, therefore, to compare the functional and radiological outcomes of complex tibia fractures treated with either the TSF or the TL-HEX. We hypothesised that this study would demonstrate similar functional and radiographic results for both devices.

Materials and Methods

Patient Identification and Data Collection

This study was conducted as a retrospective case series. All patients who had complex tibial fractures treated with hexapod circular fixators between November 2010 and July 2015 were identified from the database of a specialised trauma and limb reconstruction centre. The study received prior approval from the institutional review board and Human Research Ethics Committee, and all patients gave written informed consent to participate. Patients were included if they were aged between 18 years and 60 years, sustained a complex comminuted open or closed tibial fracture with or without bone loss, had a minimum of 12 months' follow-up, and were treated definitively using either TSF or TL-HEX. Patients with open fractures with soft tissue defects requiring soft tissue cover and patients who presented with bone loss requiring bone transport were also included. Exclusion criteria included contralateral lower extremity trauma, polytrauma; chest or abdominal trauma; neurological disorders and vertebral fractures; spinal cord injury; closed head injuries; ipsilateral fractures of the femur, ankle or foot; and patients requiring acute lower limb amputation.

Patient Management

All hexapod ring fixators were applied by two orthopaedic trauma surgeons trained and specialised in limb reconstruction. A standard protocol was used to all cases which have been described previously.[12] Briefly it consists of eight sequential steps and follows the principles of staged management for complex tibial trauma:

- Debridement, polymethyl methacrylate (PMMA) spacer if required and provisional stabilisation with external fixation,
- Soft tissue coverage and wound closure,
- Definitive fracture fixation with a hexapod circular frame,
- Removal of the PMMA spacer and corticotomy, if required,
- Latency period and gradual distraction when required,
- Docking site modification,
- Functional rehabilitation, and
- Frame removal and long-term surveillance.

In patients who sustained closed injuries without bone loss, the first two steps were generally omitted. The surgical technique consisted of the "rings first" method, placing the rings orthogonal to the proximal and distal bone segments, and acute adjustment of fracture alignment was achieved using the six adjustable struts. Web-based software was used to modify the position of the rings for those fractures that did not have an accurate initial reduction. Postoperatively patients conducted their own pin site care, and early mobilisation with weight-bearing was encouraged as tolerated. The allocation of either a TSF or TL-HEX was determined by implant availability and by surgeon preference. Frame removal was considered if the regenerate demonstrated cortication over its entire length and measured at least 2 mm on all four cortices.[21] Radiographic union was defined as an evidence of bridging callus of at least three cortices or obliteration of the fracture lines.[22] Once the union was achieved, the frames were destabilised, left *in situ*, and patients were asked to mobilise weight-bearing as tolerated. The frames were removed within 7–10 days if patients were pain free, and there was no evidence of radiographic deformity on full-length radiographs.[12] Following removal of the frame, the leg was protected in a functional brace for an additional 6 weeks.[12]

Outcome Measures

Patient demographics were recorded, including age, gender, body mass index, and comorbidities. Time to union (defined as time in frame), complications, mechanism of injury, and fracture type were also recorded. Periodic clinical assessment included wound healing, signs of sepsis or infection, and knee and ankle range of motion. Outcome measures included the ASAMI score, the FFI, and the EQ5-D. The ASAMI score assesses both bone and functional results.[23] Functional results are based on five categories: pain; need for walking aids or braces; foot, ankle, or knee deformity or contracture; ankle and/or subtalar loss of range of motion; and the ability to return to normal activities of daily living (ADLs) and/or work. Bone results are based on five categories, including union, infection, deformity, leg length discrepancy of fewer than 2.5 cm, and the cross-sectional area of union of the regenerate bone and docking site. The FFI is a self-administered questionnaire that evaluates the foot and ankle in three domains via 17 questions including pain, disability, and activity restriction.[24] The EuroQol Group developed a standardised measure, the EQ5D, to provide a simple measure of general health and perceived quality of life.[25] The EQ5D-5L index score has five categories (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and five levels (no, slight, moderate, severe problems, and inability). The patient can also score their perceived general health on a score chart from 0 ("worst imaginable health") to 100 ("best imaginable health"), comprising the EuroQol Visual Analogue Scale (EQ-VAS) score.

Functional tests included the and TUG test. The FSST is the duration of a patient stepping and changing direction over a low object in a square, measuring dynamic standing balance and mobility.[26,27] The TUG test measures the time to stand up from a chair, walk a short distance, turn around, and return to the chair. The TUG test is an objective test to assess the function and balance and requires minimal equipment, training, and expenses.[28]

Radiographic union was defined as the evidence of bridging callus of at least three cortices or obliteration of the fracture lines.[22] During the latest follow-up, long-leg weight-bearing radiographs were assessed for alignment using the Bone Ninja iPad mobile application (Apple Inc., Cupertino, CA, USA). Bone Ninja is an iPad application that has been verified and compared to Picture Archive and Communication System (PACS) systems and found to be reliable in measuring limb length differences and angles for preoperative planning and deformity education.[29] Deviations of 5° in any plane were considered significant.

Statistical Analysis

Descriptive statistics were used to assess patient demographic information. Categorical variables (ASAMI and EQ5D-5L) were analysed using the $\chi 2$ test. Continuous variables (FFI, functional tests, and radiographic outcomes) were analysed using two-tailed Student's *t* tests. An *a priori* sample size analysis was conducted using G*Power 3.1.9.2 based on the FFI using the following variables: calculated effect size 0.86, $p = 0.05$, power = 0.8, critical $t = 2.01$, β error 0.2, two-tailed, functional minimal clinically important difference (MCID) 7,[24] assuming a mean FFI of 25.[30] The sample size calculation based on these parameters indicated that a minimum of 21 patients per group was required to provide 80% statistical power. All analyses were conducted using STATA SE (Version 12.0; StataCorp, College Station, TX, USA) for Windows.

Results

Demographics

Chart review revealed that a total of 65 patients were treated with hexapod circular fixation for tibial fractures and were eligible for inclusion. Of these, 20 were excluded. Fifteen patients were unable to return for follow-up because they lived in rural and remote areas. Two were lost to follow-up, two did not give consent, and one patient died of unrelated cause. A total of 45 patients were therefore included in the study, with 24 patients treated using the TL-HEX and 21 with the TSF. The patient demographics and comorbidities are summarised in Table 1.

In the TL-HEX group, the mean external fixation time was 219 ± 107 (range 93–459) days. Two patients required lengthening via distraction of 20 and 66 mm. Union was achieved in 92% (22/24) of patients. The mean follow-up was 777 ± 278 days. The mean external fixation time in the TSF group was 222 + 98 (range 84–486) days. Seven patients required lengthening via distraction of 73, 40, 55, 105, 97, 29, and 74 mm. All patients united, but one patient required bone grafting for delayed union. The mean follow-up was 1211 ± 388 days.

Table 1: TL-Hex vs TSF comparison

	Item	*TL-Hex*	*TSF*
Demographics	Patients	24	21
	Age	15–57	21–62
	Male	19	20
	BMI	28.5 (±5)	28.3 (±4)
	Comorbidities	10	8
	Smoking	8	10
	Alcohol	9	9
Mechanism of injury	Motor cycle accident	11	11
	Injury on duty	3	1
	Motor vehicle accident	3	2
	Pedestrian vehicle accident	1	2
	Fall from height	1	1
	Gunshot wounds/assault	1	1
	Other	4	3
Fracture classification	Closed fractures	6	7
	Open grades 1 and 2	8	2
	Open grade III	10	12
Fracture location	Proximal	5	6
	Mid-shaft	6	11
	Distal	13	4
Bone loss	<40 mm	1	2
	>40 mm	1	5

In the TL-HEX group, there were 11 (46%) cases with superficial pin site infections, 2 (8%) deep infections, 2 (8%) Achilles tendon contractures requiring lengthening, and 2 (8%) other complications including one compartment syndrome and one episode of strut loosening. In the TSF group, there were 7 (33%) cases with superficial pin site infections, 1 (5%) deep infection, 1 (5%) patient with an Achilles tendon contracture requiring lengthening, and 1 (5%) patient with medial and dorsal foot paraesthesia that did not resolve.

Outcome Measures: Scores

The results of the ASAMI bone and functional scores are shown in Table 2. Statistical analysis revealed no significant differences between the groups ($\chi^2 = 3.448$, $df = 3$, $p = 0.33$). The results of the FFI and EQ5D are summarised in Table 3. No significant differences were observed between the groups for FFI ($p = 0.55$), EQ5D index value ($p = 0.43$), and EQ5D VAS ($p = 0.58$) (Table 2).

Outcome Measures: Functional Tests

The mean TUG test in the TL-HEX group was 9.2 ± 3.2 seconds and 8.4 ± 2.3 seconds in the TSF group, but these differences were not significant ($p = 0.34$). The mean time for the FSST in the TL-HEX group was 10 ± 2.9 seconds, and 9.6 ± 3.1 seconds in the TSF group; but these differences were not significant ($p = 0.69$) (Table 3).

Table 2: ASAMI bone and functional results

ASAMI bone	*TL-Hex (%)*	*TSF (%)*	*ASAMI functional*	*TL-Hex (%)*	*TSF (%)*
Excellent	17 (71)	10 (48)	Excellent	16 (66)	15 (71)
Good	6 (25)	11 (52)	Good	4 (17)	4 (19)
Fair	0	0	Fair	1 (4)	0
Poor	1 (4)	0	Poor	3 (13)	2 (10)

Table 3: Functional tests

Functional score	*TL-Hex (±SD)*	*TSF (±SD)*	*p value*
Foot function index	30 (±28.7)	26.1 (±23.9)	0.55
EQ5D index value	0.67 (±0.3)	0.73 (±0.2)	0.43
EQ5D VAS*	76.5 (±25.6)	80 (±15.8)	0.58
Time up and go	9.2 (±3.20	8.4 (2.3)	0.34
Four-step square test	10 (±2.9)	9.6 (±3.1)	0.69

*Visual analog score

Table 4: Radiological results

	TL-Hex	*TSF*	*p value*
Patients with axis deviation >5°	7	11	
Coronal view deviation	3.4° (±2.2°)	4.7° (±4.1°)	0.22
Sagittal view deviation	3.2° (±3.3°)	3.6° (±2.6°)	0.70

Radiographic Outcome

In the TL-Hex group, seven patients had more than 5° of axial deviation, and in the TSF group 11 patients had deviation of more than 5° (Table 4). These differences were not significant ($\chi^2 = 1.073$, $df = 1$, $p = 0.30$).

Discussion

This is the first study comparing outcomes using either the TSF or the TL-HEX for the treatment of complex tibial fractures. Patient-reported subjective outcome measures, objective functional outcomes, and radiographic measures were all used to evaluate potential differences in clinically relevant outcomes for these two circular external fixators. The results of this study suggest that the findings were very similar according to every measure employed, and significant and clinically relevant differences were not observed.

The first widely available circular hexapod external fixator, the Taylor Spatial Frame, was introduced in 1996.[15] The principle of fixation is two complete or partial rings connected by six telescopic struts that allow gradual multiaxial correction with six degrees of freedom.[31] In contrast to the Ilizarov system, frame modification is not required to address multiplanar deformities.[31] Good functional outcomes and high union rates have been consistently reported using this frame.[1,4,11,13,14] Henderson demonstrated low residual deformities of less than 2°, return to normal function with EQ-5D scores no different from the general UK population, and good and excellent functional outcomes in over 80%.[5] Menakaya et al. compared fracture healing for Ilizarov and TSF in high-energy tibial fractures and demonstrated an identical median healing time of 163 days for both the groups.[13] When compared to intramedullary nailing and plate fixation, circular frames typically achieve union in less time.[2]

The TL-HEX was introduced in 2012, and similar to the TSF is a modification of the traditional ring fixator that also replaces longitudinal rods spanning the fracture site with a hexapod system of six obliquely oriented telescopic struts.[16] Like the TSF, these frames allow manipulation of a fracture and accurate correction of any deformity utilising web-based software that guides adjustment of the frame to improve fracture alignment.[16] Pesenti et al. investigated the TL-HEX for the correction of tibial deformity in children and demonstrated similar effectiveness to other hexapod fixators when correcting angular deformities, lengthening, and restoring the mechanical axis, with comparable complication rates.[16] Ferreira and Birkholtz reported that the TL-HEx allows referencing from a nonorthogonal ring, which is different from the TSF which assumes orthogonal mounting of the reference ring.[8] These fundamental differences must be considered when using either of these two systems.[8]

The time to union with the TL-Hex was 31.2 weeks compared to 31.7 weeks for the TSF, which is slightly longer than those reported in other studies. Henderson et al. noted mean times to union between 18 weeks and 31 weeks, depending on the OTA fracture type.[4] Dickson et al. demonstrated a mean time to union of 25.6 weeks for circular fixation in grade III open tibia fractures.[2] Similarly, Menakaya reported a median time to union of 23.3 weeks in high-energy tibial fractures.[13] These differences could be explained by the fact that patients who required bone lengthening were included in the current study. When excluding these patients the time to union in the TL-HEX group was 29.4 and in the TSF group was 24.4 weeks. Statistical analysis was not performed as the numbers were insufficient to reach adequate power, but the observed trend is clear. Another possible explanation for the differences observed may be that there were 75% open fractures in the TL-HEX, compared to 66% in the TSF group. Union rates were similar in both groups, and in the TL-HEX group the union rate was 92% compared to 100% in the TSF group. This could perhaps be explained by the higher rate of open fractures in the TL-HEX group. These union rates are again comparable to the current literature regarding treatment of similar injuries, ranging from 90 to 100%.[4,11,14,32]

Functional outcomes were assessed with the ASAMI score and the FFI. In the TL-HEX group, 83% achieved good and excellent outcomes compared to 90% in the TSF group. These differences were not significant, but a trend toward better outcomes was observed with the TSF. These results are similar to those reported in other published studies. Henderson et al. reported 87% good and excellent outcomes,[4] and Dickson et al.[2] demonstrated 76% good and excellent outcomes in patients treated with circular hexapod external fixation. Giotakis et al. treated 20 patients with segmental tibial fractures and reported good and excellent outcomes in all cases.[14] Nieuwoudt et al.[32] reported good short-term outcomes in a large series of patients with grade III open tibial fractures;

their series included 31 patients (33%) with HIV infection with CD4 counts ranging from 80 to 1005 cells/mm.[2] The mean FFI was 30 in the TL-HEX and 26 in the TSF group; these differences were not significantly different. The FFI is a valid and responsive clinical index that measures foot and ankle function, where high scores indicate pain and disability.[24] Castellani et al. have treated distal tibial fractures and reported the FFI score at a mean of 3.8 years following surgery ranged between 14 and 21. For comparison, the mean FFI score is between 15 and 23 following surgical treatment of calcaneal fractures.[33] Patients with rheumatoid arthritis have a mean FFI score of 28;[34] and in patients with moderate chronic foot and ankle pain, the mean score is 28.[35] The results of this study reveal patients with complex tibial fractures have substantial symptoms after completing treatment, with similar scores for patients receiving surgical treatment of calcaneal fractures, patients with chronic moderate foot and ankle pain, and patients with rheumatoid arthritis.

The TUG test is a simple tool to assess mobility and static and dynamic balance.[36] Reference values are age dependent and ranges between 8 and 11 seconds in healthy individuals over 60 years of age.[36] The FSST incorporates fast stepping while rapidly changing direction in a specific sequence and provides a good measure of dynamic standing balance and mobility.[37] In healthy adults, the FSST is also age dependent and ranges from 6 seconds in adults younger than 30 years to 10 seconds in healthy adults over 65 years.[38] In this study cohort, the TUG was 9.2 seconds for the TL-HEX group and 8.4 seconds in the TSF group; the FSST was 10 seconds for the TL-HEX group and 9.6 seconds in the TSF group. None of these differences was significant, suggesting mobility and balance were similar in both groups. However, the results also indicate that the ability to ambulate in these challenging and complicated cases is comparable to the level of a healthy adult aged 65 years and older.

The radiographic outcome was similar in both groups, with mean axial deviations between 3.4° and 4.7° in the coronal plane and 3.2° to 3.6° in the sagittal plane. Henderson et al. reported mean deviations of 1.8° in the coronal plane and 1.6° in the sagittal plane. Twenty-nine percent of patients in the TL-Hex group and 52% of patients in the TSF group had a demonstrated malunion with more than 5° deviation, but these results are higher than that reported in other series.[14,29] Nieuwoudt reported a rate of 5.3% malunions with less than 10° deviation,[32] and Giotakis reported that only 15% of patients had an axial deviation of more than 5°.[14] One possible explanation for these differences could be the time interval between frame removal and final radiographs in our series, which was substantially longer, and it is possible that the prolonged weight-bearing resulted in some recurrence of deformity.

Complication rates with limb salvage and circular external fixation are characteristically high.[2,4,12–14,39] The overall complication rate in this series was 48% and is similar to the rate of complications reported previously.[2,4,12–14,39] The most common complication was superficial pin site infection, noted in 46% of patients in the TL-Hex group and 33% in the TSF group.

This study has several inherent limitations. The retrospective data collection may have resulted in selection bias. The sample size was small but similar to other studies reporting on limb salvage and treatment of fractures with hexapod circular external fixation. An *a priori* sample size calculation was performed and based on the minimal clinically important differences. This introduces a slight possibility of a type II error, as the study was not powered to detect between-group differences smaller than the MCID. However, potential statistically significant differences based on smaller differences are most likely clinically not relevant and therefore meaningless. It is acknowledged that bone loss requiring distraction and bone lengthening may result in prolonged external fixation time, possibly introducing selection and reporting bias. However, the results of this study suggest that this is unlikely. External fixation times including standard deviation and range as a measure of dispersion are very similar in both groups. Similar functional outcomes do not suggest relevant between-group differences, making a type I error highly unlikely. This study has not been specifically stratified for fracture location, and it is possible that fracture location (proximal, distal, and mid-shaft) may have influenced outcomes. Ramos et al. investigated quality of life following the treatment of both proximal and distal tibial fractures using the EQ-5D and demonstrated equal values of 0.80 for both fracture locations.[40,41] It is therefore unlikely that fracture location had a major influence on treatment effects.

The study was performed at a single centre specialised in limb reconstruction and orthopaedic trauma, and all cases were treated by experienced fellowship-trained trauma surgeons. This may limit the external validity of the study, and the results reported here may be difficult to replicate in less experienced trauma units.

Conclusion

The results of this study suggest that both hexapod external fixation devices have very similar and comparable clinical, functional, and radiographic outcomes. Either fixator can be used for the treatment of complex tibial fractures, anticipating good and excellent clinical outcomes in approximately 80% of patients.

References

1. Court-Brown CM, Wheelwright EF, Christie J, et al. External fixation for type III open tibial fractures. J Bone Joint Surg Br 1990;72(5):801–804. DOI: 10.1302/0301-620X.72B5.2211760.
2. Dickson DR, Moulder E, Hadland Y, et al. Grade 3 open tibial shaft fractures treated with a circular frame, functional outcome and systematic review of literature. Injury 2015;46(4):751–758. DOI: 10.1016/j.injury.2015.01.025.
3. Webb LX, Bosse MJ, Castillo RC, et al. Analysis of surgeon-controlled variables in the treatment of limb-threatening type-III open tibial diaphyseal fractures. J Bone Joint Surg Am 2007;89A(5):923–928. DOI: 10.2106/JBJS.F.00776.
4. Henderson D, Barron E, Hadland Y, et al. Functional outcomes after tibial shaft fractures treated using the Taylor spatial frame. J Orthop Trauma 2015;29(2):54–59. DOI: 10.1097/BOT.0000000000000192.
5. Ilizarov GA. The tension-stress effect on the genesis and growth of tissues. Part I. The influence of stability of fixation and soft-tissue preservation. Clin Orthop Relat Res 1989;238(238):249–281. DOI: 10.1097/00003086-198901000-00038.
6. Gasser B, Boman B, Wyder D, et al. Stiffness characteristics of the circular Ilizarov device as opposed to conventional external fixators. J Biomech Eng 1990;112(1):15–21. DOI: 10.1115/1.2891120.
7. Hasler C, Krieg A. Current concepts on leg lengthening. J Child Orthop 2012;6(2):89–401. DOI: 10.1007/s11832-012-0391-5.
8. Ferreira N, Birkholtz F. Radiographic analysis of hexapod external fixators: fundamental differences between the Taylor spatial frame and truelok-hex. J Med Engin Technol 2015;39(3):173–176. DOI: 10.3109/03091902.2015.1025993.
9. Dammerer D, Kirschbichler K, Donnan L, et al. Clinical value of the Taylor spatial frame: a comparison with the Ilizarov and orthofix fixators. J Child Orthop 2011;5(5):343–349. DOI: 10.1007/s11832-011-0361-3.

10. Wani N, Baba A, Kangoo K, et al. Role of early Ilizarov ring fixator in the definitive management of type II, IIIA and IIIB open tibial shaft fractures. Int Orthop 2011;35(6):15–23. DOI: 10.1007/s00264-010-1023-7.
11. Quinnan SM. Definitive management of distal tibia and simple plafond fractures with circular external fixation. J Orthop Trauma 2016;30:S26–S32. DOI: 10.1097/BOT.0000000000000694.
12. Hohmann E, Birkholtz F, Glatt V, et al. The "Road to Union" protocol for the reconstruction of isolated complex high-energy tibial trauma. Injury 2017;48(6):1211–1216. DOI: 10.1016/j.injury.2017.03.018.
13. Menakaya CU, Rigby AS, Hadland Y, et al. Fracture healing following high energy tibial trauma: Ilizarov versus Taylor spatial frame. Ann R Coll Surg Engl 2014;96(2):106–110. DOI: 10.1308/003588414X138245 11650335.
14. Giotakis N, Panchani SK, Narayan B, et al. Segmental fractures of the tibia treated by circular external fixation. J Bone Joint Surg Br 2010;92(5):687–692. DOI: 10.1302/0301-620X.92B5.22514.
15. Paley D. History and science behind the six-axis correction external fixation devices in orthopaedic surgery. Op Techn Orthop 2011;21(2):125–128. DOI: 10.1053/j.oto.2011.01.011126.
16. Pesenti S, Iobst CA, Launay F. Evaluation of the external fixator TrueLok hexapod system for tibial deformity correction in children. Orthop Traum Surg Res 2017;103(5):761–764. DOI: 10.1016/j.otsr.2017.03.015.
17. Kanellopoulos AD, Mavrogenis AF, Kanellopoulos ND, et al. A guide frame for the Taylor spatial frame. J Orthop Trauma 2009;23(7): 537–540. DOI: 10.1097/BOT.0b013e3181a24021.
18. Iobst CA. New trends in ring fixators. J Pediatr Orthop 2017;37(Suppl 2):S18–S21. DOI: 10.1097/BPO.0000000000001026.
19. Manner H, Heubl M, Radler C, et al. Accuracy of complex lower-limb deformity correction with external fixation: a comparison of the Taylor spatial frame with the Ilizarov ring fixator. J Child Orthop 2006;1(1):55–61. DOI: 10.1007/s11832-006-0005-1.
20. Van Niekerk AH, Birkholtz FF, de Lange P, et al. Circular external fixation and cemented PMMA spacers for the treatment of complex tibial fractures and infected nonunions with segmental bone loss. J Orthop Surg 2017;25(2):2309499017716242. DOI: 10.1177/2309499017716242.
21. Fischgrund J, Paley D, Sutter C. Variables affecting time to bone healing during limb lengthening. Clin Orth Rel Res 1994;301(301): 31–37. DOI: 10.1097/00003086-199404000-00006.
22. Hammer R, Hammerby S, Lindholm B. Accuracy of radiological assessment of tibial shaft union in humans. Clin Orth Relat Res 1985;199:233–238.
23. Paley D, Catagni MA, Argnani F, et al. Ilizarov treatment of tibial nonunions with bone loss. Clin Orthop 1989;241(241):146–165. DOI: 10.1097/00003086-198904000-00017.
24. Budiman-Mak E, Conrad KJ, Roach KE. The foot function index: A measure of foot pain and disability. J Clin Epidemiol 1991;44(6): 561–570. DOI: 10.1016/0895-4356(91)90220-4.
25. EuroQol Group. EuroQol–a new facility for the measurement of health related quality of life. Health Policy 1990;16(3):199–208. DOI: 10.1016/0168-8510(90)90421-9.
26. Dite W, Temple VA. A clinical test of stepping and change of direction to identify multiple falling older adults. Arc Phys Med Rehabil 2002;83(11):1566–1571. DOI: 10.1053/apmr.2002. 35469.
27. Blennerhassett JM, Jayalath VM. The four square step test is a feasible and valid clinical test of dynamic standing balance for use in ambulant people post stroke. Arch Phys Med Rehabil 2008;89(11):2156–2161. DOI: 10.1016/j.apmr.2008.05.012.
28. Wall JC, Bell C, Campbell S, et al. The timed get-up-and-go test revisited: measurement of the component tasks. J Rehabil Res Dev 2000;37(1):109–113.
29. Whitaker AT, Gesheff MG, Jauregui JJ, et al. Comparison of PACS and bone ninja mobile application for assessment of lower extremity limb length discrepancy and alignment. J Child Orthop 2016;10(5):439–443. DOI: 10.1007/s11832-016-0761-5.
30. Molepo M, Barnard AC, Birkholtz F, et al. Functional outcomes of the failed plate fixation in distal tibial fractures. Europ J Orthop Surg Traumatol 2018;28(8):1617–1624. DOI: 10.1007/s00590-018-2231-x.
31. Ganger R, Radler C, Speigner B, et al. Correction of post-traumatic lower limb deformities using the Taylor spatial frame. Int Orth 2010;34(5):723–730. DOI: 10.1007/s00264-009-0839-5.
32. Nieuwoudt L, Ferreira N, Marais LC. Short-term results of grade III open tibia fractures treated with circular fixators. SA Orthop J 2016;15(3):20–26. DOI: 10.17159/2309-8309/2016/v15n3a2.
33. Gaskill T, Schweitzer K, Nunley J. Comparison of surgical outcomes of intra-articular calcaneal fractures by age. J Bone Joint Surg Am 2010;92(18):2884–2889. DOI: 10.2106/JBJS.J.00089.
34. Landorf K, Radford JA. Minimal important difference: values for the foot health status questionnaire, foot function index and visual analogue scale. Foot 2008;18(1):15–19. DOI: 10.1016/j.foot.2007. 06.006.
35. SooHoo NF, Samimi DB, Vyas RM, et al. Evaluation of the foot function index in measuring outcomes in patients with foot and ankle disorders. Foot Ankle Int 2006;27(1):38–42. DOI: 10.1177/107110070602700107.
36. Bohannon RW. Reference values for the timed up and go test: a descriptive meta-analysis. J Geriatr Phys Ther 2006;29(2):64–68. DOI: 10.1519/00139143-200608000-00004.
37. Moore M, Barker K. The validity and reliability of the four square step test in different adult populations: a systematic review. Syst Rev 2017;6(1):187. DOI: 10.1186/s13643-017-0577-5.
38. Langford Z. The four square step test. J Physiotherapy 2015;61(3):162. DOI: 10.1016/j.jphys.2015.03.005.
39. van der Merwe L, Birkholtz F, Tetsworth K, et al. Functional and psychological outcomes of delayed lower limb amputation following failed lower limb reconstruction. Injury 2016;47(8):1756–1760. DOI: 10.1016/j.injury.2016.05.027.
40. Ramos T, Ekholm C, Eriksson BI, et al. The Ilizarov external fixator – a useful alternative for the treatment of proximal tibial fractures. A prospective observational study of 30 consecutive patients. BMC Musculoskelet Disord 2013;14(1):11. DOI: 10.1186/1471-2474-14-11.
41. Ramos T, Karlsson J, Eriksson BI, et al. Treatment of distal tibial fractures with the Ilizarov external fixator – a prospective observational study in 39 consecutive patients. BMC Musculoskelet Disord 2013;14(1):30. DOI: 10.1186/1471-2474-14-30.