

# Does fixator-assisted tibial nailing outperform conventional tibial nailing? A multicentre comparative study

Saul Kaplan,<sup>1</sup> Marilize C Burger,<sup>1</sup> Danie Hugo,<sup>1,2</sup> Craig Brown,<sup>1,2</sup> Mathew Alexander,<sup>1</sup> Jeandre D Kotze,<sup>3</sup> Francois Muller,<sup>2</sup> Nando Ferreira<sup>1\*</sup> 

<sup>1</sup> Division of Orthopaedic Surgery, Department of Surgical Sciences, Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa

<sup>2</sup> Khayelitsha District Hospital, Western Cape, South Africa

<sup>3</sup> Paarl Provincial Hospital, Western Cape, South Africa

\*Corresponding author: [nferreira@sun.ac.za](mailto:nferreira@sun.ac.za)

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## Abstract

### Background

There is no local literature evaluating the outcomes of external fixator-assisted tibial nailing. This study aimed to investigate the peri- and postoperative outcomes of tibial nailing using either an unassisted or an external fixator-assisted nailing method, in patients with tibial fractures.

### Methods

A prospective cohort study including skeletally mature (> 18 years) patients with tibial fractures presenting to one of three different hospitals within the Western Cape province of South Africa, and treated with intramedullary nailing, was conducted. Participant demographic, clinical and surgical characteristics were documented perioperatively up until six weeks post-surgery. Differences in operative time, fluoroscopy time, adequacy of reduction, and short-term complications in patients treated with external fixator-assisted versus unassisted tibial nailing were investigated.

### Results

A total of 154 patients with tibial fractures (n = 74 fixator-assisted tibial nails; n = 80 unassisted nails) enrolled in the study. Fixator-assisted tibial nailing was associated with significantly longer operation (median 80, interquartile range [IQR] 60–95 minutes) and fluoroscopy times (median 140, IQR 96–214 seconds) compared to the unassisted group (60, IQR 50–90 minutes and 82.5, IQR 63–121 seconds, respectively) (p < 0.001 and p < 0.001, respectively). No differences were observed in the adequacy of reduction, or prevalence of complications, between groups.

### Conclusion

Comparing fixator-assisted tibial nailing to unassisted tibial nailing, this prospective cohort study suggests that both techniques are comparable when managing tibia fractures in terms of adequacy of reduction and the prevalence of short-term complications. The benefits of fixator-assisted tibial nailing include being relatively easy to apply by all orthopaedic surgeons regardless of surgical experience, maintaining reduction during all steps of tibial nail insertion, reduced need for open fracture reduction, reduced radiation exposure to the surgeon and assistant, and no added risk to the patient.

**Level of evidence:** 2

**Keywords:** tibial fractures, intramedullary nail, suprapatellar, fixator-assisted

## Introduction

Tibial fractures represent the most common long bone injury,<sup>1-3</sup> accounting for approximately 2% of all fractures in adults.<sup>3,4</sup> A 2017 review reported the incidence rate of tibial fractures to be 17 per 100 000 persons each year, with a higher rate reported in males than females.<sup>5</sup> It is imperative that tibial fractures are managed appropriately as the complications, which include nonunion, malunion and surgical-related sepsis, increase the patient's morbidity and are financially costly for the healthcare system.<sup>5</sup>

Tibial fractures are either managed operatively or non-operatively,<sup>6-9</sup> with nonoperative management typically including

Sarmiento bracing or a circular cast.<sup>10-12</sup> The operative management of tibial fractures includes intramedullary nailing, external fixation or plate fixation, with intramedullary nailing being the management of choice for unstable fractures of the tibial diaphysis.<sup>1-3,13,14</sup> Whether managed nonoperatively or operatively, the acceptable reduction of tibial fractures includes coronal angulation of less than 5°, sagittal angulation of less than 5°, rotation of less than 5°, and shortening of less than 1 cm.<sup>7,12</sup> Fractures in the proximal and distal third of the tibia are particularly challenging, with a higher possibility of malreduction than those in the middle of the tibia.<sup>7,15</sup>

Intramedullary nailing can be technically challenging and is performed through either the infrapatellar approach or the

suprapatellar approach. The infrapatellar approach was first described by Küntscher in the 1940s.<sup>16</sup> With advances in the intramedullary nailing technique, the semi-extended tibial nailing technique was described by Tornetta et al. in the early 1990s.<sup>16,17</sup> The semi-extended approach was later modified by Cole et al. to the suprapatellar approach with the knee in a semi-extended position.<sup>18</sup>

Intramedullary nailing of the tibia via a suprapatellar approach reportedly makes it easier to acquire an adequate reduction when compared to tibial nailing via an infrapatellar approach.<sup>1,4,19</sup> The suprapatellar approach also appears to be superior to the infrapatellar approach with regard to operative time, the incidence of anterior knee pain, and technical difficulty in obtaining the correct entry point.<sup>13,14,20,21</sup> The semi-extended position allows for improved management of proximal third metaphyseal tibial fractures as it mitigates the deforming forces on the proximal fragment during deep knee flexion needed for infrapatellar nail insertion.<sup>1,18</sup> Intraoperative imaging is also easier to obtain in a semi-extended position.<sup>4</sup> Due to the above reasons, the suprapatellar approach is gaining popularity among orthopaedic trauma surgeons.

When performing intramedullary nailing of tibia fractures, numerous adjuncts have been employed to aid in fracture reduction. These include blocking screws, modified external fixators, ankle distractors, traction frames, commercial reduction tools, and circular fixator-based reduction devices.<sup>3,6,15,22,23</sup> Fixator-based devices facilitate obtaining and maintaining fracture reduction during insertion of the tibial nail and are then removed once the tibial nail has been inserted. Current evidence suggests that external fixator-assisted tibial nailing results in less fluoroscopy time and more ease in obtaining fracture reduction.<sup>3,6,13,24</sup> The use of an additional device during surgery could, however, lead to increased complications and total surgical time.<sup>15</sup> Prospective investigations evaluating the benefit of external fixator-assisted tibial nailing are lacking.

This study aimed to investigate the peri- and postoperative outcomes of tibial nailing, using either an unassisted or an external fixator-assisted nailing method, in patients with tibial fractures.

## Methods

A prospective cohort study was conducted, enrolling skeletally mature (> 18 years of age) patients presenting with tibial fractures to the orthopaedic departments of three designated

hospitals during the period October 2022 to December 2023. Inclusion criteria stipulated clinical informed consent for operative management involving intramedullary nail fixation. No specific exclusion criteria were applied. Ethical approval and hospital board approvals were secured from all participating institutions. Informed consent for participating in the research study was obtained from all participants. Human and animal rights were always protected.

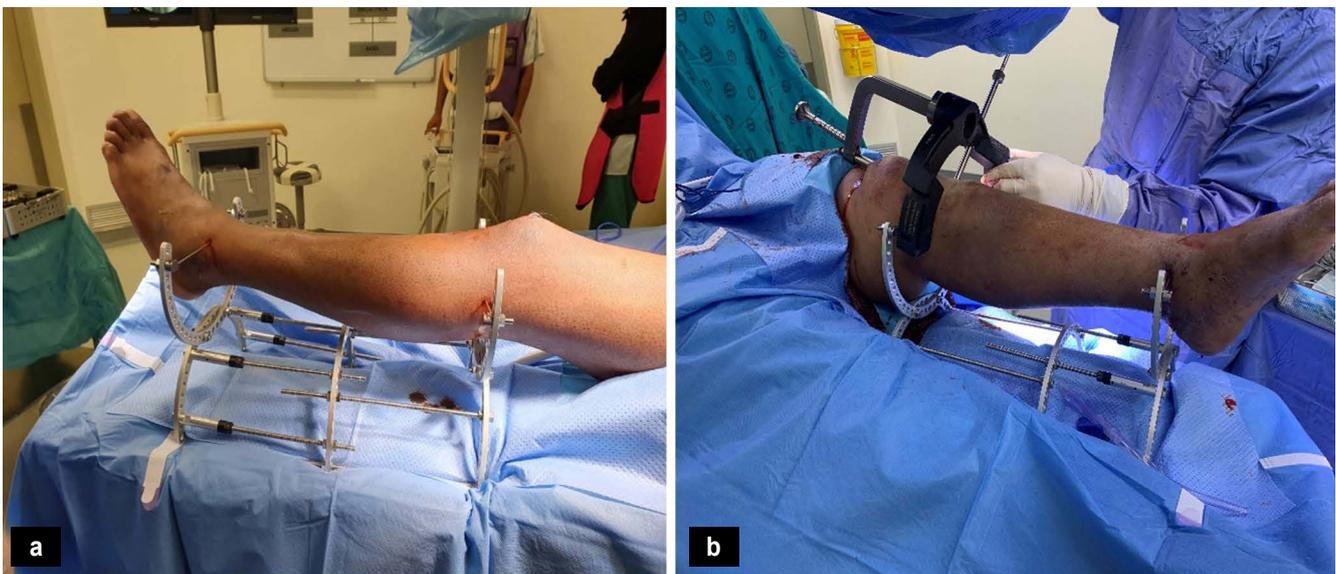
Demographic and clinical variables were recorded at the time of recruitment. All participants received the same preoperative workup, intraoperative care (apart from the nailing technique) and postoperative rehabilitation. Intramedullary nailing was performed via the suprapatellar approach in all cases, using either an unassisted or external fixator-assisted technique. The decision as to which nailing technique to use was left to the treating surgeon. Surgical variables were documented by the operating surgeon on a specifically designed data collection form, and included operative time, fluoroscopy time, the reduction technique used, adequacy of reduction obtained, as well as any intraoperative complications experienced. The reduction technique was classified as either closed reduction, mini-open reduction or extensive open reduction. The tibial fractures were classified according to location, morphology (AO classification), and either as open or closed injury. If the fracture was classified as open, it was then further classified according to the Gustilo-Anderson classification.

The unassisted nailing technique may be considered the more conventional technique by which the operating surgeon inserts a dedicated tibia-locking intramedullary nail with the use of manual distraction at the fracture site to aid reduction without the use of reduction devices.

The fixator-assisted nailing technique used a simple custom-built circular external fixator consisting of 5/8 rings and threaded rods (*Figure 1*).

A 1.8 mm tensioned fine wire is inserted in the proximal tibia just anterior to the fibula head under fluoroscopic guidance. Care is taken to ensure that the fine wire is inserted perpendicular to the mechanical axis of the tibia in the coronal plane, and parallel to the theatre floor. Prior to inserting the second fine wire, rotational alignment of the tibia is clinically corrected.

A second 1.8 mm tension wire is inserted into the distal tibia, under fluoroscopic guidance, just anterior to the fibula and approximately 1 cm proximal to the ankle joint. The fine wire is inserted perpendicular to the mechanical axis of the tibia in the



**Figure 1.** a) A custom-built circular external fixator applied to a tibia fracture to aid in reduction prior to inserting a tibial intramedullary nail via a suprapatellar approach; b) a tibial nail being inserted after a circular external fixator is applied

coronal plane, and parallel to the theatre floor. The fine wires are then attached to the external fixator frame, and the wires tensioned to 100 kg. Longitudinal traction is then applied to the tibia by distracting the fixator construct. Once adequate distraction has been achieved to reduce the fracture, the frame is secured to maintain the distraction. Coronal plane translation is corrected by sliding the bone fragments on the reference wires while slight anterior or posterior pressure is used to correct apex-anterior or -posterior angulation. The tibial nail is then inserted via a standard suprapatellar approach. The external fixator is removed once the nail is inserted, and proximal and distal locking screws are inserted.

All participants followed a standard postoperative protocol, which included outpatient follow-up at two weeks and six weeks post-surgery. The surgical and trauma wounds were assessed for any signs of fracture-related infection (FRI). FRI was diagnosed according to the consensus criteria proposed by Metsemakers et al.<sup>25</sup>

Postoperative full-length anteroposterior and lateral radiographs at six weeks follow-up were used to assess alignment, radiological signs of union and hardware failure. For fractures in the distal third of the diaphysis, the lateral distal tibial angle (LDTA) and the anterior distal tibial angle (ADTA) were used to measure angular deformity in the coronal and sagittal planes. For fractures in the proximal third, the medial proximal tibial angle (MPTA) and posterior proximal tibial angle (PPTA) were used. For midshaft fractures, the anatomical axis lines of the tibia were used. If coronal angulation of more than 5° or sagittal angulation of more than 5° was measured, the fracture was classified as malreduced. Any complications encountered were recorded.

### Statistical analysis

To detect a minimum clinically important difference (MCID) in theatre time of 10–15 minutes, and based on preliminary data from two previous unpublished studies (mean surgical times of 69.3 ± 20.4 minutes and 77.0 ± 23.8 minutes), a total sample size of 36–78 participants per group is needed. This calculation assumes 80% power and an alpha level of 0.05.

Data was analysed using STATISTICA software (v14, TIBCO Software). Categorical data are described as frequencies and counts, while continuous data are described as means and standard deviations, or medians with interquartile ranges (IQR), depending on data distribution. Given the non-randomised allocation of treatment procedures, baseline differences in demographics

were investigated. In addition, differences in outcomes between treatment groups were investigated using independent t-tests, Mann-Whitney U tests (depending on distribution) or chi-square/Fisher's exact tests. An alpha level of 0.05 was considered statistically significant.

### Results

A total of 154 participants (n = 113, 73% male) with a mean age of 35.6 ± 12.6 years were included (Table I). No differences in baseline demographics between participants in the fixator-assisted and unassisted groups were observed (Table I).

The most common mechanism of injury was pedestrian–vehicle accidents (PVA) in both the fixator-assisted (61%) and unassisted (41%) groups, followed by falls (23% and 16%, respectively), with significantly different distributions between all mechanisms of injury between the groups (p = 0.006) (Table II). The tibial fractures in both groups were classified according to location, morphology (AO classification), and either as open or closed injury. If the fracture was classified as open it was then further classified according to the Gustilo-Anderson classification. Patients treated with the fixator-assisted method mostly had distal third injuries (49%) compared to middle third fracture locations in the unassisted group (54%) (p = 0.001). The distribution of AO classification and fracture type was also significantly different between the groups (p = 0.048 and 0.006, respectively). The groups were, however, comparable according to the Gustilo-Anderson classification (p = 0.103) (Table II).

A difference in the rank of the surgeons performing the surgery was observed (p < 0.001), with the majority of the unassisted surgeries performed by registrars (88%, n = 70), compared to medical officers who performed most of the fixator-assisted surgeries (54%, n = 40). A difference in the median time to surgery was also observed (p = 0.044) (Table III). The groups were, however, comparable when the time to surgery was grouped as less than seven days and more than seven days. A difference in reduction technique (p = 0.047) between the two groups was also observed, with more open and mini-open reductions observed in the unassisted group. When considering only the subgroup that had closed fractures, 70% (n = 7) of those operated after seven days required open reduction before inserting the tibial nail compared to those operated within seven days (30%, n = 3). This finding was, however, not statistically significant (p = 0.343, data not shown).

**Table I:** Demographic characteristics of all participants with tibial fractures, as well as those in the fixator-assisted and unassisted groups

Demographic variable	All patients	Fixator-assisted	Unassisted	p-value
	n = 154	n = 74	n = 80	
<b>Age (years)</b>	35.6 ± 12.6	37.1 ± 13.1	34.3 ± 12.1	0.171
<b>Sex</b>				
Male	73.4 (113)	75.7 (56)	71.3 (57)	0.587
Female	27.0 (41)	24.3 (18)	28.8 (23)	
<b>Comorbidities</b>				
Yes	18.2 (28)	17.8 (13)	19.0 (15)	> 0.999
No	80.5 (124)	82.2 (60)	81.0 (64)	
<b>Alcohol use</b>				
Yes	55.2 (85)	57.5 (42)	55.8 (43)	0.870
No	42.2 (65)	42.5 (31)	44.2 (34)	
<b>Tobacco use</b>				
Yes	60.4 (93)	54.8 (40)	68.0 (53)	0.132
No	37.7 (58)	45.2 (33)	32.1 (25)	

Non-missing data is described as mean ± standard deviation, or as frequency (count) with the total number of participants indicated in parentheses

**Table II:** Clinical characteristics of all patients with tibial fractures, as well as those in the fixator-assisted or unassisted groups

Clinical characteristic	All patients	Fixator-assisted	Unassisted	p-value
	n = 154	n = 74	n = 80	
<b>Mechanism of injury</b>				
Assault	13.0 (20)	6.8 (5)	18.8 (15)	0.006
PVA	50.6 (78)	60.8 (45)	41.3 (33)	
Fall	19.5 (30)	23.0 (17)	16.3 (13)	
MVA	7.1 (11)	1.4 (1)	12.5 (10)	
MBA	3.2 (5)	1.4 (1)	5.0 (4)	
GSW	6.5 (10)	6.8 (5)	6.3 (5)	
<b>Fracture location</b>				
Proximal third	11.0 (17)	11.0 (8)	11.4 (9)	0.001
Middle third	39.6 (61)	24.7 (18)	54.4 (43)	
Distal third	38.3 (59)	49.3 (36)	29.1 (23)	
Segmental	9.7 (15)	15.1 (11)	5.1 (4)	
<b>AO classification</b>				
42A1	13.6 (21)	13.5 (10)	13.8 (11)	0.048
42A2	23.4 (36)	31.1 (23)	16.3 (13)	
42A3	14.3 (22)	10.8 (8)	17.5 (14)	
42B2	19.5 (30)	13.5 (10)	25.0 (20)	
42B3	10.4 (16)	6.8 (5)	13.8 (11)	
42C2	11.0 (17)	16.2 (12)	6.3 (5)	
42C3	7.8 (12)	8.1 (6)	7.5 (6)	
<b>Fracture type</b>				
Open	42.2 (65)	31.1 (23)	52.5 (42)	0.006
Closed	57.8 (89)	68.9 (51)	47.5 (38)	
<b>Gustilo-Anderson classification</b>				
N/A	57.8 (89)	68.9 (51)	47.5 (38)	0.103
Type 1	7.8 (12)	6.8 (5)	8.8 (7)	
Type 2	20.8 (32)	14.9 (11)	26.3 (21)	
Type 3A	12.3 (19)	8.1 (6)	16.3 (13)	
Type 3B	1.3 (2)	1.4 (1)	1.3 (1)	

Non-missing data is described as frequency (count) with the total number of participants indicated in parentheses. PVA: pedestrian-vehicle accident; MVA: motor vehicle accident; MBA: motorbike accident; GSW: gunshot wound

A significant difference in the operative time and the fluoroscopy time between the two groups was observed ( $p < 0.001$  and  $p < 0.001$ , respectively), with an increased time observed in the fixator-assisted group. Interestingly, the main difference is in fractures of the distal segment (80 [60–95] and 60 [50–90] respectively;  $p = 0.031$ ).

Adequate reduction was achieved in the majority of patients in both groups, with no difference in distribution ( $p = 0.428$ ) between the groups (*Table III*). Similarly, no difference in the distribution of complications between groups was observed, with each group experiencing three complications of fracture-related infection.

The majority of distal third fractures were treated by medical officers using the fixator-assisted technique ( $p < 0.001$ ). Similar to the whole cohort, the fixator-assisted method was mostly performed with a closed reduction technique ( $p = 0.031$ ), had a greater operative time ( $p = 0.031$ ) and greater fluoroscopy time ( $p = 0.002$ ) than the unassisted group (*Table IV*).

## Discussion

Intramedullary nailing is the management of choice for treating tibial fractures,<sup>1-3,13,14</sup> and there are multiple techniques described to aid

in obtaining adequate fracture reduction. These techniques include blocking screws, blocking wires, modified external fixators, ankle distractors, traction frames, and commercial reduction tools.<sup>15,22</sup> The current published data suggest that external fixator-assisted tibial nailing decreases operative time and fluoroscopy time, and makes it easier to obtain fracture reduction.<sup>3,6,13,24</sup> This study aimed to investigate the peri- and postoperative outcomes between tibial nailing using either an unassisted or an external fixator-assisted nailing method, as chosen by the treating clinician when treating tibial fractures in our patient population.

Distal tibia fractures are inherently more difficult to nail due to the widening of the medullary canal distally, and as a result, the nail loses its ability to aid in fracture reduction employing its tight endosteal fit. The more distal the tibia fracture, the more difficult it is to gain stability of the distal fragment, which increases the risk of rotational, translatory and angular deformity.<sup>19,26</sup> For this reason, additional techniques to obtain fracture reduction are sometimes required when nailing distal third tibial fractures. These additional techniques include the addition of blocking screws or wires which are placed under fluoroscopy guidance; as a result, the overall operative and fluoroscopy time is increased. The main finding of this study is that fixator-assisted tibial nailing was the technique

**Table III:** Surgical characteristics of all patients with tibial fractures, as well as those in the fixator-assisted or unassisted groups

Surgical variables	All patients	Fixator-assisted	Unassisted	p-value
	n = 154	n = 74	n = 80	
<b>Surgeon's rank</b>				
Medical officer	30.3 (46)	54.1 (40)	10.0 (8)	< 0.001
Registrar	60.5 (92)	29.7 (22)	87.5 (70)	
Consultant	9.2 (14)	16.2 (12)	2.5 (2)	
<b>Time to surgery (days)</b>	5.0 (3–9)	6 (3–13)	4.5 (3–7)	0.044
Less than 7 days	69.5 (107)	62.2 (46)	76.3 (61)	0.079
More than 7 days	30.5 (47)	37.8 (28)	23.8 (19)	
<b>Reduction technique</b>				
Closed	77.9 (120)	86.5 (64)	70 (56)	0.047
Mini-open	18.2 (28)	10.8 (8)	25 (20)	
Extensive	3.9 (6)	2.7 (2)	5 (4)	
<b>Operative time (min)</b>	70 (52–90)	80 (60–95)	60 (50–90)	< 0.001
Proximal third	67.5 (57.5–90) (16)	65 (57.5–90) (8)	70 (55–90) (8)	0.916
Middle third	60 (50–77.5) (56)	70 (60–75) (17)	60 (45–85) (39)	0.063
Distal third	75 (55–90) (58)	80 (60–95) (35)	60 (50–90) (23)	0.031
Segmental	100 (60–120) (15)	100 (80–120) (11)	90 (49–150) (4)	0.895
<b>Fluoroscopy time (sec)</b>	98 (73–162)	140 (96–214)	82.5 (63–121)	< 0.001
Proximal third	141 (101.5–166) (16)	153 (137–257) (7)	121 (95–150) (9)	0.186
Middle third	81.5 (61–122) (54)	139.5 (104.5–234) (12)	74.5 (53–95) (42)	< 0.001
Distal third	98 (79–177) (47)	173 (95–197) (25)	90 (64–101) (22)	0.002
<b>Segmental</b>	117.5 (96–138) (14)	99.5 (95–138) (10)	133 (121.5–152) (4)	0.257
<b>Adequate reduction</b>				
Yes	96.1 (148)	94.6 (70)	97.5 (78)	0.428
No	3.9 (6)	5.4 (4)	2.5 (2)	
<b>Complications</b>				
Yes	3.9 (6)	4.0 (3)	3.8 (3)	> 0.999
No	96.1 (147)	96.0 (71)	96.2 (76)	

Non-missing data is described as median (IQR) or frequency (count) with the total number of participants indicated in parentheses

of choice when managing distal third tibial fractures. This could potentially suggest that the surgeons found it easier to obtain reduction of these fractures using fixator-assisted distraction through the correctly placed fine wires which are perpendicular to the mechanical axis of the tibia. Once reduction was achieved, the external fixator was able to maintain length and rotational stability until it was removed after nail insertion and locking screw placement. Most of the fixator-assisted tibial nailing was also performed by more junior surgeons (medical officers), which might potentially be an indication that the fixator provided the junior surgeon with the ability to reduce the tibia fracture and insert the tibial nail with more ease. However, future studies should attempt to objectively measure the reasons of clinicians to utilise one approach over the other.

It was notable that more patients were treated by means of open reduction of their tibial fractures when utilising the unassisted tibial nailing technique. An interesting, albeit non-significant, observation was 70% of the closed fractures required open reduction if they were treated more than seven days after the initial injury. While the sample size of the subgroup in this study was too small to make meaningful inferences, future studies should interrogate this finding further. It appears that the fixator-assisted tibial nailing technique reduces the need for open fracture reduction, subsequently

preventing the fracture site from being exposed to the external environment, thus potentially decreasing the risk of fracture-related infections and wound complications. However, future research should provide evidence for these hypotheses.

Another, not surprising, finding of this study was that fixator-assisted tibial nailing took significantly longer than unassisted tibial nailing when considering all tibial fractures regardless of the fracture location. Interestingly, when considering operative time specific to fracture location, no difference was observed between the two techniques for proximal or middle-third fractures. Fixator-assisted nailing of the distal third fractures, however, took longer than unassisted techniques. Similarly, fluoroscopy time mirrored the findings of total operative time, with more fluoroscopy time required for fixator-assisted approaches. Both middle and distal fractures required more fluoroscopy time, while proximal and segmental fractures were comparable between the two techniques. This same observation was noted by Mehta et al., who reported that using the STORM commercial reduction device to aid reduction of distal third tibial fractures before tibial nail insertion resulted in longer operative and fluoroscopy time when compared to manual fracture distraction, although the clinical outcomes in both groups were comparable.<sup>27</sup> In contrast, an earlier study by Jackson et al. found that there was comparable operative and fluoroscopy

**Table IV:** Clinical and surgical characteristics of all patients with distal third tibial fractures, as well as those in the fixator-assisted or unassisted groups

Clinical and surgical characteristics	All patients	Fixator-assisted	Unassisted	p-value
	n = 59	n = 36	n = 23	
<b>AO classification</b>				
42A1	27.1 (16)	27.8 (10)	26.1 (6)	0.192
42A2	28.8 (17)	38.9 (14)	13.0 (3)	
42A3	7.8 (4)	8.3 (3)	4.4 (1)	
42B2	16.9 (10)	11.1 (4)	26.1 (6)	
42B3	16.9 (10)	11.1 (4)	26.1 (6)	
42C3	3.3 (2)	2.8 (1)	4.4 (1)	
<b>Surgeon's rank</b>				
Medical officer	40.7 (24)	61.1 (22)	8.7 (2)	< 0.001
Registrar	52.5 (31)	33.3 (12)	82.6 (19)	
Consultant	6.8 (4)	5.6 (2)	8.7 (2)	
<b>Time to surgery (days)</b>				
Less than 7 days	59.3 (35)	58.3 (21)	60.9 (14)	> 0.999
More than 7 days	40.7 (24)	41.7 (15)	39.1 (9)	
<b>Reduction technique</b>				
Closed	79.7 (47)	88.9 (32)	65.2 (15)	0.031
Mini-open	18.6 (11)	8.3 (3)	34.8 (8)	
Extensive	1.7 (1)	2.8 (1)	0 (0)	
<b>Operative time (min)</b>	75 (30–195)	80 (45–195)	60 (30–110)	0.031
<b>Fluoroscopy time (sec)</b>	98 (79–177) (47)	173 (95–197) (25)	90 (64–101) (22)	0.002
<b>Adequate reduction</b>				
Yes	93.2 (55)	94.4 (34)	91.3 (21)	0.639
No	6.8 (4)	5.6 (2)	8.7 (2)	
<b>Complications</b>				
Yes	5.1 (3)	5.6 (2)	4.4 (1)	> 0.999
No	94.9 (56)	94.4 (34)	95.7 (22)	

Non-missing data is described as median (IQR) or frequency (count) with the total number of participants indicated in parentheses

time between fixator-assisted tibial nailing and conventional tibial nailing using manual traction.<sup>6</sup>

Complications following tibial nailing result in increased morbidity for the patient, including prolonged pain and potential disability. Complications further consume substantial healthcare resources, which is detrimental in a resource-limited healthcare system.<sup>5</sup> In terms of adequacy of reduction and the number of complications observed, we report no difference between fixator-assisted nailing and unassisted techniques. These findings are comparable to the results of a study by Zha et al. who compared the use of a minimally invasive traction retractor versus conventional manual traction for the treatment of tibial fractures at a tertiary hospital in China.<sup>3</sup>

It is evident from the available literature that fixator-assisted tibial nailing is not detrimental to patients, with the only downfall being that it slightly increases the operative time and fluoroscopy time when managing distal third tibial fractures. This can be justified as it appears that fixator-assisted tibial nailing is valuable in preventing the need to open these fractures to obtain reduction, which is beneficial in decreasing the risk of postoperative fracture-related infections and wound complications. This time difference may decrease and become insignificant as an orthopaedic surgeon performs more of the fixator-assisted tibial nailing technique for distal third tibial fractures. Unfortunately, the current literature may not reflect the true difference between fixator-assisted and conventional tibial nailing of distal third tibial fractures, either

because the studies consist of too few patients or the surgeries were performed by multiple surgeons with some having little experience performing fixator-assisted tibial nailing.

Although not within the scope of the research question, an interesting and important observation from this study was that frame-assisted tibial nailing allowed for sustained distraction at the fracture site throughout the tibial nailing procedure until released at the end of the nail insertion. This allowed the surgeon and assistant to stand away during fluoroscopy and limit radiation exposure, which has dose-dependent health risks. Another benefit was that there was less effort required by the surgeon and assistant to maintain reduction during reaming and insertion of the tibial nail. The ability to maintain distraction throughout reaming prevents eccentric reaming, decreasing the risk of malreduction when inserting the tibial nail. These observations were noted in previous studies.<sup>3,6,7</sup>

The strengths of this study include the prospective cohort design ensuring that data is accurate and complete. The findings suggest that fixator-assisted tibial nailing is comparable to unassisted tibial nailing with the exception that operative time and fluoroscopy time is increased when managing distal third tibia fractures. The fixator-assisted tibial nailing technique does not independently ensure the adequacy of reduction when managing tibial fractures with a tibial intramedullary nail.

The limitations of this study include the heterogeneity between the fixator-assisted nailing and unassisted nailing groups in terms of their baseline characteristics, and the inherent selection bias that this introduces to the study. However, the findings of this pragmatic study can potentially guide the focus of potential future randomised controlled trials. The surgeries were performed by multiple surgeons with a range of levels of experience, from junior medical officers to specialist orthopaedic surgeons, in a real-world setting following a pragmatic approach. However, tibial fractures are very common in our setting and all surgeons are competent in managing these injuries using intramedullary nailing. Finally, while the cohort is powered to detect large differences, the study was not powered to detect smaller differences in subgroup analyses; therefore, findings should be interpreted with caution.

## Conclusion

Comparing fixator-assisted tibial nailing to unassisted tibial nailing, this prospective cohort study suggests that both techniques are comparable when managing tibia fractures in terms of adequacy of reduction and the prevalence of short-term complications. The benefits of fixator-assisted tibial nailing include that it is relatively easy to apply by all orthopaedic surgeons regardless of surgical experience; it maintained reduction during all steps of tibial nail insertion; reduced need for open fracture reduction; reduced radiation exposure to the surgeon and assistant; and there was no added risk to the patient. Further long-term large-sized prospective randomised trials are needed to better evaluate the benefits of fixator-assisted nailing vs unassisted tibial nailing.

## Ethics statement

The authors declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010. Ethical approval for this study was obtained prior to commencement of data collection from the Health Research Ethics Committee Stellenbosch University. The ethics reference number is S22/09/172.

All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Informed consent was obtained from all individual participants included in the study. The authors affirm that human research participants provided informed consent for publication.

## Declaration

The authors declare authorship of this article and that they have followed sound scientific research practice. This research is original and does not transgress plagiarism policies.

## Author contributions

SK: study conceptualisation, study design, data capture, data analysis, first draft preparation, manuscript preparation, manuscript revision

MCB: study conceptualisation, study design, data analysis, first draft preparation, manuscript preparation, manuscript revision

DH: study conceptualisation, data capture, manuscript revision

CB: study conceptualisation, data capture, manuscript revision

MA: data capture, manuscript revision

JDK: data capture, manuscript revision

FM: data capture, manuscript revision

NF: study conceptualisation, study design, data analysis, first draft preparation, manuscript preparation, manuscript revision

## ORCID

Kaplan S  <https://orcid.org/0009-0003-2185-9914>

Burger MC  <https://orcid.org/0000-0003-2831-4960>

Hugo D  <https://orcid.org/0000-0003-2336-3085>

Brown C  <https://orcid.org/0000-0002-0633-8227>

Alexander M  <https://orcid.org/0000-0002-7904-7519>

Kotze JD  <https://orcid.org/0009-0009-6650-6622>

Muller F  <https://orcid.org/0009-0006-1606-393X>

Ferreira N  <https://orcid.org/0000-0002-0567-3373>

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