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ORIGINAL RESEARCH

Use of a Minimally Invasive Traction Repositor versus Conventional Manual Traction for the Treatment of Tibial Fractures: A Comparative Study from a Tertiary Hospital in China

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Background: Closed reduction and intramedullary nail fixation of tibial fractures may not utilize a fracture table or reduction aids like a femoral distractor, and only manual traction will help aid the reduction process. This study aimed to describe and further investigate the effectiveness of an originally designed minimally invasive traction repositor (MITR) for the treatment of tibial fractures.

Methods: From January 2018 to April 2021, a total of 119 eligible patients with tibial shaft fractures were included and retrospectively assigned to two groups according to different reduction methods: MITR group vs conventional manual traction (CMT) group. The baseline characteristics between the two groups were comparable, including age, gender, BMI, residence, smoking history, drinking history, injury mechanism, fracture type, ASA, method of anesthesia, and surgical delay (all $P > 0.05$). The operation time, fracture reduction duration, intraoperative blood loss, fluoroscopy time, number of intraoperative fluoroscopies, VAS, HSS, fracture healing time, and complications were compared.

Results: All patients completed the follow-ups with an average of 18.5 months (range 12–42 months). The operation time, fracture reduction duration, intraoperative blood loss, fluoroscopy time, and number of fluoroscopies were significantly decreased in the MITR group (all $P < 0.05$). At one month postoperatively, the VAS score was statistically lower in the MITR group (1.8±0.8) than in the CMT group (2.6±1.5). At 6 months postoperatively, the HHS score was statistically higher in the MITR group (90.8±2.3) than in the CMT group (86.4±3.8). We observed no statistical difference in the mean fracture healing time, bone nonunion, implant failure, and infection between the two groups (all $P > 0.05$).

Conclusion: Compared with CMT, MITR facilitates the minimally invasive treatment of tibial fractures and has the advantages of operation time, fracture reduction duration, intraoperative blood loss, fluoroscopy time, number of fluoroscopies, and satisfactory VAS and HSS scores.

Keywords: comparative, intramedullary nail, minimally invasive, tibial fractures, traction repositor

Introduction

Most tibial shaft fractures occur after high-energy trauma and the number of adults who suffer fractures is around 2%.[1,2] Due to its many advantages including less invasive nature, minimal soft tissue dissection, improved biomechanical results, short hospital stay, and early weight-bearing, intramedullary nailing (IMN) has increasingly become the preferred means of treating tibial fractures compared to plates and screws.[3–6]

In clinical practice, closed reduction of a tibial shaft fracture may not utilize a fracture table or reduction aids like a femoral distractor, which differs considerably from that of femur fracture and only manual traction will help aid the reduction process. This implies that not only there is no supporting apparatus specifically for reduction purposes but

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a number of surgical personnel are required. At present, the primary and conventional reduction method for the treatment of the tibial fracture is to remain the flexion position of the affected limb by using curled surgical drapes. However, it still with specific difficulties in immobilizing the affected limb and controlling the fracture broken end until the needle reams through into the intramedullary canal. In other words, due to the lack of effective traction instruments, indirect methods of reducing varus or valgus malalignment were limited. As a result, it is necessary to prolong both the time of intraoperative traction and fracture reduction, as well as the fluoroscopy time if the reduction is difficult. Ultimately, it increases bleeding during operation and raises exposure to radiation injuries.

To the best of our knowledge, effective and persistent traction is the key to minimally invasive treatment for such injuries, as it allows for closed restoration of lower extremity alignment during operation. For these reasons, the authors developed a new reduction tool called the minimally invasive traction repositor (MITR), and then the closed reduction of tibia fractures may be easier with this technique. The objective of this study was to investigate the effectiveness of MITR versus conventional manual traction in treating tibial shaft fractures. We hypothesized that the MITR could reduce the fluoroscopy and operation times, as well as improve clinical outcomes.

Methods

Patients and Groups

After approval from the Institutional Review Committee of our hospital and obtained the informed written consent from all patients in accordance with the Declaration of Helsinki (No. W2022-006-1), we performed this study. From January 2018 to April 2021, a total of 119 eligible patients with tibial shaft fractures were included. The participants for this analysis comprised all enrolled patients over 18 years old presenting with acute tibial shaft fractures, who had an admission delay <48 hours, who received IMN fixation, with follow-up time at least 12 months, and patients who have sufficient radiographs available until they are united. Polytrauma patients, patients with pathological or open fractures, adolescents, patients with other risk factors affecting bone healing (osteoporosis or metabolic diseases), and patients with conservative treatment and those without sufficient radiographic follow-up were excluded. A retrospective assignment of patients to two groups was performed randomly on the basis of different intraoperative reduction methods: group A with MITR vs group B with manual traction. All patients involved gave informed consent and all data were anonymized before the analysis to safeguard patient privacy.

Data Collection

Based on the electronic medical record at our institution, we gathered the following data: gender, age, body mass index (BMI, normal with BMI<24 kg/m2, overweight with 24≤BMI<28 kg/m2 and obesity with BMI≥28 kg/m2), residence, smoking history, drinking history, injury mechanism (Low-energy fracture was defined as a fracture caused by fall from standing height, bicycle injury while high-energy fracture as from high height, electronic bike injury, motor vehicle injury, and others), fracture type (stable or unstable according to the AO/OTA classification[7]), ASA, surgical delay, method of anesthesia type (general anesthesia or regional anesthesia), operation time, fracture reduction duration, intraoperative blood loss, fluoroscopy time, and numbers of intraoperative fluoroscopy. Functional outcome evaluation was performed according to the visual analog scores (VAS), Hospital for Special Surgery (HSS) score, and fracture healing time. According to radiographs, fracture healing is demonstrated with a callus bridging in three out of four cortices and has the ability to bear full weight without pain. The participants' clinical and radiographic functional outcomes were evaluated and recorded during the follow-up 3–6–9–12 months. Follow-up began upon enrollment in the cohort, and the endpoint was determined at the latest follow-up visit.

Perioperative Treatment and Surgical Procedure

All patients received the same anesthesia, and all surgeries were performed by the same orthopedic team. All patients received a single dose of a first-generation cephalosporin antibiotic for prophylaxis, or if allergic, the type of specific antibiotic used depended on the surgeon's preference. Preoperative X-rays (both antero-posterior and lateral view) of the injured leg were taken. All operations were performed by the same surgeon (JPZ) in both groups. Partially to fully weight-bearing was encouraged shortly after surgery. Patients or their families were interviewed on a regular basis by either an outpatient review or by telephone.

MITR Group

The patients surgically treated by IMN fixation that were all following international treatment guidelines. Under either general or regional anesthesia, all patients were laid supine and received tibial IMN fixation using the transtendinous approach through a vertical incision in the middle of the proximal end of the tibia. And then, an IMN is inserted and passed down the hollow central cavity (medullary canal) of the bone to fix the fracture in its proper position. The tibia shaft fracture was confirmed anatomically by X-ray fluoroscopy using a C-arm machine. Position of IMN was checked and the wound was closed layer by layer.

The MITR (Chinese patent number: ZL201921961424.9 and ZL201921618950.5) are mainly composed of a retractable and deformable tripod and a calcaneal traction needle for performing distal tibial skeletal traction (Figure 1). In the group A using MITR, the tripod can be adjustable along the tibial axis to accommodate for variable position and deformation of the fractured limb, then the position of the affected limb may be placed stably during the operation to facilitate not only reduction but insertion of the IMN with the calcaneal bone traction, finally the tibia fracture reduction was achieved by this indirect reduction technique without assistant (Figures 2–4).

Conventional Manual Traction Group

There were no differences in surgical position, anesthesia method, and surgery approaches between the conventional group and the MITR group. The tibial fracture was reduced and fixed using IMN by flexing the knee to be as perpendicular to the surgical table as possible with the assistance of curled surgical drapes and at least another personnel. Then, a C-arm X-ray fluoroscopy was used to ensure that the tibia had been anatomically reduced. If the fracture reduction of the tibial was not satisfactory, the reduction should be repeated until it is satisfactory.

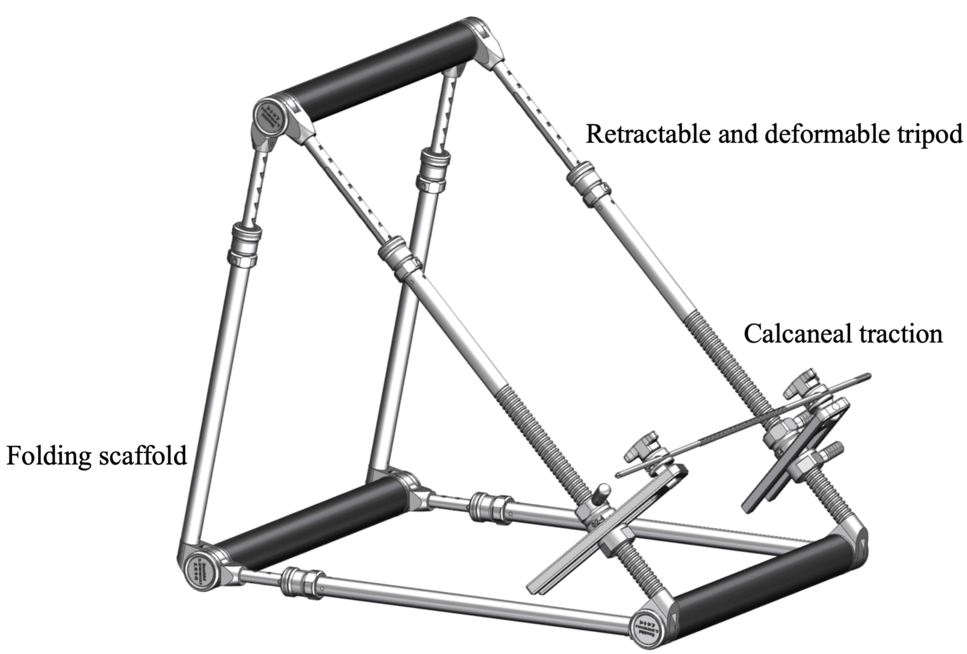

Figure 1 The general view of minimally invasive traction repositor (MITR).

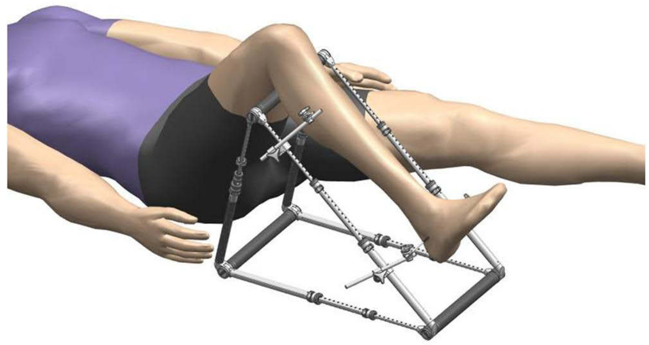

Figure 2 Diagram of device application.

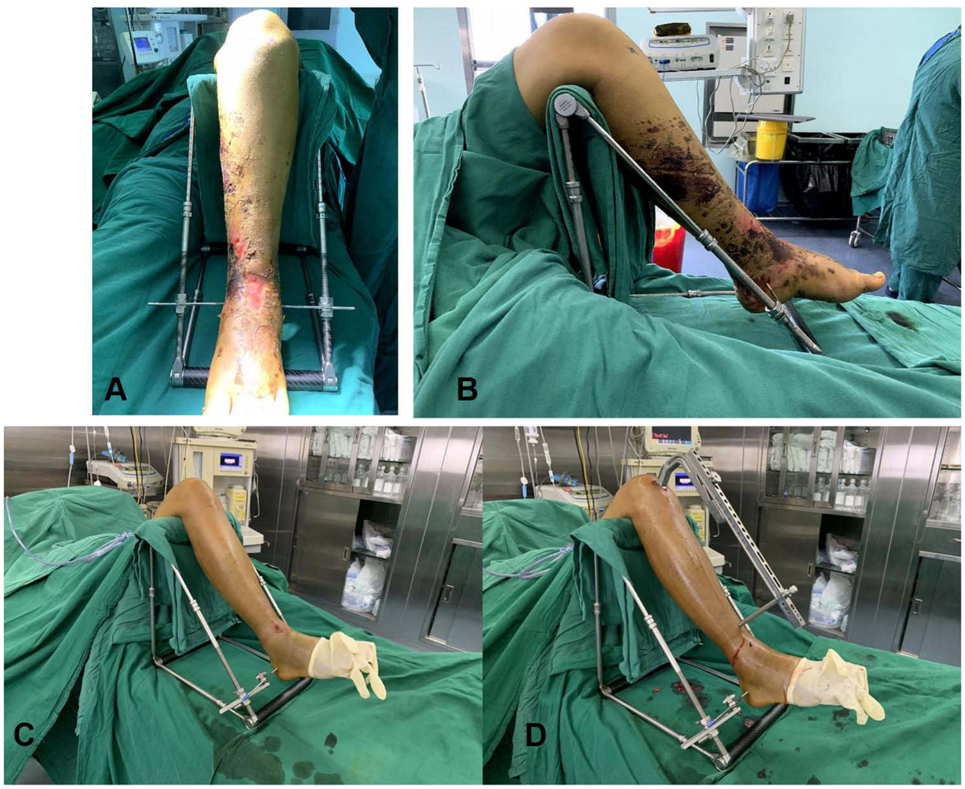

Figure 3 Intraoperative view of minimally invasive traction repositor (MITR) application. A 20-year-old female patient with comminuted fracture of the left tibia. (**A**) Anteroposterior view. (**B**) Lateral view. A 48-year-old male patient with distal third fracture of the right tibia. (**C**) The MITR is connected and applied to the affected limb. (**D**) The minimally invasive incision for closed reduction of the tibia fracture and intramedullary nail insertion.

Postoperative Rehabilitation

Exercises for quadriceps function were initiated immediately after surgery. Within two weeks after surgery, the knee was passively flexed continuously to a 90° flexion and full weight-bearing walking was performed. Active flexion and extension of the knee were achieved 4 weeks after surgery.

Statistical Analysis

Kolmogorov–Smirnov test was used to determine the normality of continuous variables. To calculate group mean differences, Student-t tests were applied to numerical variables that satisfy normality. Data was presented as mean ± standard deviation. In nonnormally distributed data, median and interquartile range (IQR) are reported using the Mann–Whitney *U*-test. We reported categorical variables as proportions and analyzed differences through chi-square and

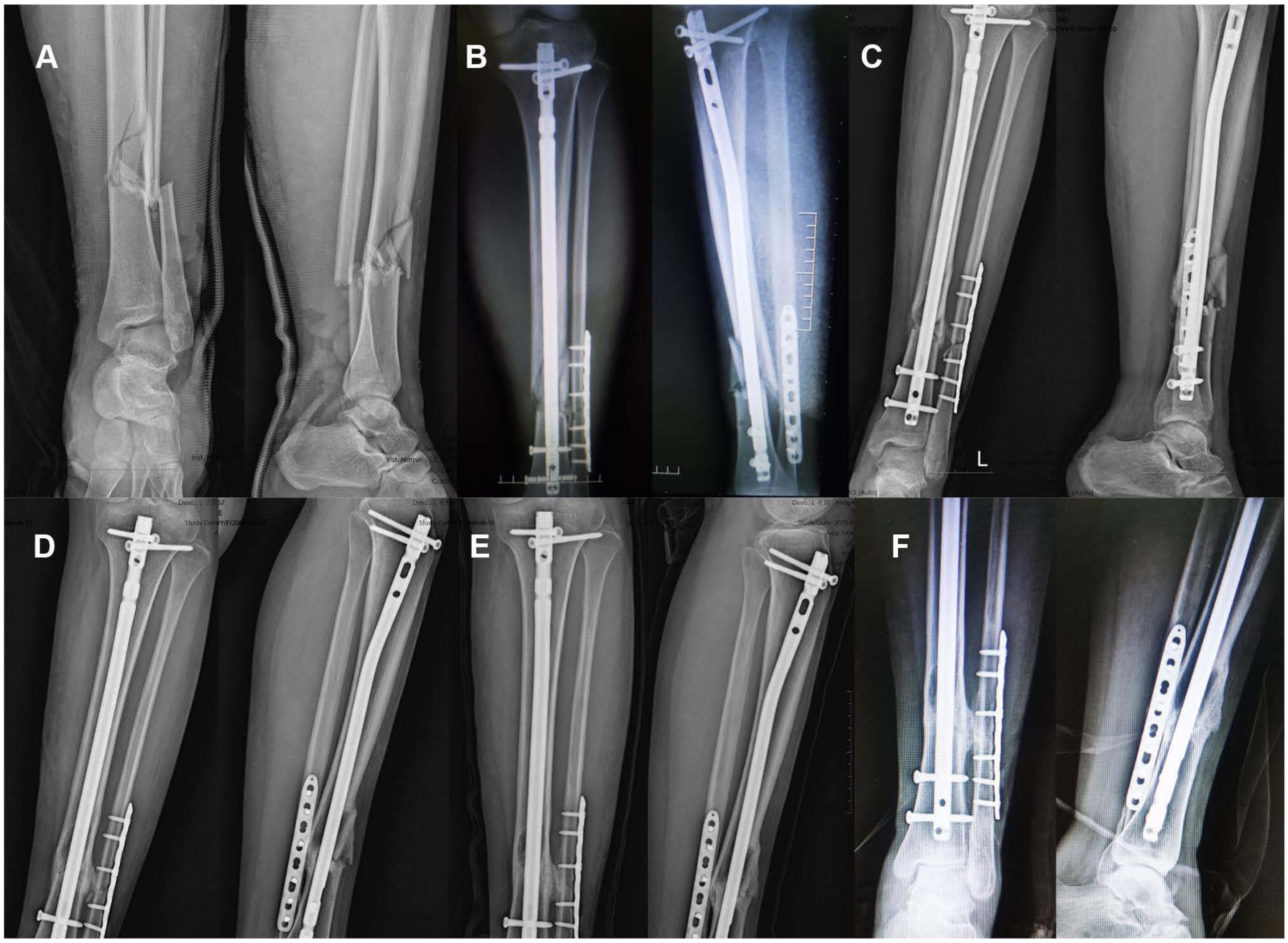

Figure 4 Anteroposterior and lateral X-ray films of a 20-year-old female patient with comminuted fracture of the left tibial. (**A**) Before surgery. (**B**) Immediately after surgery. (**C**) 1 month after surgery. (**D**) 3 months after surgery. (**E**) 6 months after (**F**) 12 months after surgery.

Fisher's exact tests. Operation time, fracture reduction duration, intraoperative blood loss, fluoroscopy time, number of intraoperative fluoroscopies, VAS at 1-month post-operation, HHS score at 6-month post-operation, bone nonunion, infection, and implant failure were recorded and compared between the two groups. All data analyses were performed using IBM SPSS Statistics for Windows, version 26.0 (IBM, Armonk, NY, USA). The level of significance was set at $p < 0.05$.

Results

The baseline characteristics of patients in the two groups are summarized in Table 1. In the MITR group, there were 19 (59.4%) males and 13 (40.6%) females with an average age of 53.2 years old. The mechanism of injury was divided into low-energy (17 cases, 53.1%) and high-energy (15 cases, 46.9%). The mean surgical delay was 2.5 days. While in the conventional manual traction group, there were 63 (72.4%) males and 24 (27.6%) females with an average age of 48.5 years old. The mechanism was divided into low-energy (51 cases, 58.6%) and high-energy (36 cases, 41.4%). The mean surgical delay was 4 days. The baseline characteristics between these two groups were comparable, including age, gender, BMI, residence, smoking history, drinking history, injury mechanism, fracture type, ASA, method of anesthesia, and surgical delay (all $P > 0.05$, Table 1).

The average follow-up time for patients was 18.5 months (range 12 to 42 months). The operative time, fracture reduction duration, intraoperative blood loss, fluoroscopy time, and number of fluoroscopies were significantly decreased in the MITR group compared with that in the conventional manual traction group (all $P < 0.05$, Table 2). At one month postoperatively, the VAS score was statistically lower in the MITR group (1.8±0.8) than in the conventional group (2.6

Table 1 Comparisons of Patient Demographics and Injury-Related Data Between Two groups[§]

Characteristics	Group A With MITR (n=32)	Group B With Manual Traction (n=87)	*P* value*
Age, years	53.2 ± 18.8	48.5 ± 19.0	0.230
Gender, no. (%)			0.173
Male	19 (59.4%)	63 (72.4%)	
Female	13 (40.6%)	24 (27.6%)	
BMI group, no. (%)			0.859
Normal (BMI<24 kg/m2)	11 (34.4%)	34 (39.1%)	
Overweight (24 ≤ BMI < 28 kg/m2)	18 (56.3%)	44 (50.6%)	
Obesity (BMI ≥ 28 kg/m2)	3 (9.4%)	9 (10.3%)	
Residence, no. (%)			0.269
Rural	18 (56.3%)	39 (44.8%)	
Urban	14 (43.8%)	48 (55.2%)	
Smoking history, no. (%)			0.349
Yes	20 (62.5%)	46 (52.9%)	
No	12 (37.5%)	41 (47.1%)	
Drinking history, no. (%)			0.110
Yes	12 (37.5%)	47 (54.0%)	
No	20 (62.5%)	40 (46.0%)	
Injury mechanism, no. (%)			0.591
Low-energy fracture	17 (53.1%)	51 (58.6%)	
High-energy fracture	15 (46.9%)	36 (41.4%)	
AO/OTA classification, no. (%)			0.760
A	18 (56.3%)	55 (63.2%)	
B	10 (31.3%)	24 (27.6%)	
C	4 (12.5%)	8 (9.2%)	
ASA, no. (%)			0.423
1	18 (56.3%)	37 (42.5%)	
2	8 (25.0%)	31 (35.6%)	
3	5 (15.6%)	12 (13.8%)	
4	1 (3.1%)	7 (8.0%)	
Method of anesthesia type, no. (%)			0.488
Regional anesthesia	21 (65.6%)	51 (58.6%)	
General anesthesia	11 (34.4%)	36 (41.4%)	
Surgical delay	2.5 (1, 4)	4 (2, 4)	0.257

Notes: [§]Values are presented as the number (%). Age is presented as the mean ± standard deviation. Surgical delay is presented as the median and interquartile range (IQR). *The differences between the groups were not statistically significant for all parameters.
Abbreviations: MITR, minimally invasive traction repositor; BMI, body mass index; ASA, American Society of Anesthesiologists.

Table 2 Comparisons of Operation-Related Data and Outcomes Between Two groups[§]

Characteristics	Group A With MITR (n=32)	Group B With Manual Traction (n=87)	*P* value
Operation time, (min)	67.0±12.2	72.7±13.4	0.039*
Fracture reduction duration, (min)	10.9±2.7	19.3±6.3	<0.001*
Intraoperative blood loss, (mL)	200 (100, 200)	400 (200, 500)	<0.001*
Fluoroscopy time, (min)	15.4±3.7	20.9±5.5	<0.001*
Times of fluoroscopy	14.0±2.6	23.1±7.6	<0.001*
VAS	1.8±0.8	2.6±1.5	<0.001*
HSS	90.8±2.3	86.4±3.8	<0.001*
Fracture healing time, (week)	19.8±3.8	19.8±3.9	0.968
Postoperative complications			
Bone nonunion, no (%)	0 (0.0%)	3 (3.4%)	0.563
Implant failure, no (%)	1 (3.1%)	2 (2.3%)	1.000
Infection, no (%)	1 (3.1%)	3 (3.4%)	1.000

Notes: [§]Values are presented as the mean ± standard deviation. Postoperative complications are presented as the number (%). Intraoperative blood loss is presented as the median and interquartile range (IQR). *P<0.05, statistical significance.
Abbreviations: MITR, minimally invasive traction repositor; VAS, visual analog scores; HSS, Hospital for Special Surgery score.

±1.5). At 6 months postoperatively, the HHS score was statistically higher in the MITR group (90.8±2.3) than in the conventional group (86.4±3.8). Table 2 also shows no statistical difference in the mean fracture healing time between the two groups (19.8±3.8 min for MITR group vs 19.8±3.9 min for the conventional group).

Three patients (all in the conventional group) developed nonunion, of which one was atrophic and was treated with bone grafting and exchange nails and union was achieved after 14 weeks. Two other nonunion patients had an oligotrophic nonunion, accompanied by distal interlocking screw breakage five to nine weeks after surgery. Among the MITR group, one had a distal interlocking screw break at eight weeks after surgery. Unions were all achieved 12–17 weeks after re-inserting the distal interlocking screws. In terms of infections, four patients (one in MITR group A and three in the conventional group) were infected superficially and none were infected deeply. The wound infections were all treated with antibiotics and incisional drainage or debridement, and they were all resolved without complications. Despite these differences, postoperative complications including bone nonunion, implant failure, and infection did not differ significantly between the two groups. A detailed description of operation-related results and data is presented in Table 2.

Discussion

An intramedullary nailing procedure is the primary treatment option for most surgeons when treating a tibial shaft fracture.[8–10] In the present study, we put forward a novel minimally invasive traction repositor (MITR) which might facilitate the closed reduction of tibial fractures and compared the surgical and clinical outcomes with the conventional manual traction method. With the MITR, not only could the fracture be reduced, but it could also be kept in anatomical placement without additional personnel. Based on our results, anatomic or nearly anatomic reductions of the tibial fractures were easily achieved. This technical procedure offered the advantages of shorter operative time, fracture reduction duration, intraoperative blood loss, fluoroscopy time, and numbers of fluoroscopy during surgery, as well as better VAS and HHS scores after surgery. Compared with the conventional method, the application of this novel technique was safe without increasing the risk of postoperative complications. After all fractures had healed, all patients demonstrated satisfactory postoperative clinical functional improvement.

Clinical analysis of OTA/AO type C comminuted tibial fractures has shown that the soft tissue damage and the severe fracture pattern pose a clinical challenge and are associated with a high complication rate, specifically fracture nonunion.[11–13] Studies on long-term results have shown that less invasive operations can lead to improved knee function and stability.[12,14] Biz et al[15,16] conducted two retrospective studies to analyze the medium-long-term clinical and radiographic results of the three other surgical osteosynthesis techniques used for the treatment of tibial fractures: open reduction internal fixation (ORIF), minimally invasive plate osteosynthesis (MIPO), and external fixation. They revealed and demonstrated that early radiographic features may be predictive for pain perceived by patients at mid-term follow-up and the radiographic outcomes were inversely proportional to the fracture comminutions and statistically different between internal and external osteosynthesis, but comparable between ORIF and MIPO techniques. Unfortunately, tibial fracture surgery procedures cannot easily be controlled for alignment and stability, especially when minimally invasive surgery is needed. Then, in order to complete the IMN fixation, an open reduction is necessary if the guiding wire cannot pass through the distal fracture site,[17] which would seriously compromise the blood supply to the fragments, thus resulting in oligotrophic nonunion. While some surgeons prefer to use IMNs augmented with poller screws to treat tibial plateau fractures, which may assist in reducing deformity in the axis and reducing fractures more effectively by directing the IMN during insertion.[18–20] Numerous studies reported nonunion,[21] coronal malalignment,[22] sagittal malalignment,[23] complication of superficial[24]/deep infection,[22,25–27] and the need for secondary surgical procedures[21] in the treatment of difficult reduction tibial shaft fractures. It still remains controversial whether this is the best surgical approach when you take into account the increased difficulty of fracture reduction and the poor postoperative results. The overall incidence of adult patients who experience nonunion tibial shaft fractures varies between 2% and 10%[14] and that in severe comminuted fractures is reported as high as 25%.[28] Accordingly, a considerable number of patients with tibial shaft fractures treated with IMN will not heal their fractures one year postoperatively.[13]

There are several problems associated with reduction by curled surgical drapes, which is currently the most common treatment for tibial fractures. Firstly, one cannot confirm and maintain whether curled surgical drapes produce satisfactory results. Secondly, an IMN should be inserted only after fracture reduction with curled surgical drapes to prevent both surgery and intraoperative fluoroscopy from being negatively affected. Finally, the reduction of the fracture may not be performed effectively due to the soft and slippery characteristics of the curled surgical drapes. Based on these, it may also be responsible for the high incidence of postoperative complications following tibial fracture. Therefore, it is imperative that we explore a promising traction device that might help to facilitate the closed reduction during the surgery procedure and improve fracture healing.

In contrast to conventional manual traction, the novel traction device called MITR could generate a tremendous longitudinal force on the distal end of the tibia. Because of the obstruction caused by the tripod, a similar counterforce was created. It was possible to keep the lower limb in traction from the beginning of the surgery until the end. A traction force generated by the MITR was more efficient, symmetrical, and sustained than a conventional manual traction. In short, by means of skeletal traction the malalignment could be easily corrected in a closed way, and shorten the operative time, the fracture reduction period, fluoroscopy time, intraoperative blood loss, and number of fluoroscopies during surgery based on our results, the postoperative complication rates were not increased by this procedure, which provides safety and ethical advantages for clinical applications.

Furthermore, there were two benefits to this novel technique over conventional fracture reduction with curled surgical drapes. Firstly, knee pain is common in patients who undergo IMN fixation for tibial shaft fractures.[29,30] In the present study, the average VAS at 1 month postoperative was 1.8 in MITR group, which is significantly lower than that of the conventional manual traction group with 2.8 (P<0.001). Secondly, although we did not observe the faster fracture healing process in the MITR group, the application of MITR resulted in a higher HSS score (90.8 vs 86.4, P<0.001).

Several limitations should be acknowledged in our study. Firstly, a relatively small number of patients with tibial shaft fractures were included in this study. Secondly, due to the low number of participants included, we were unable to conduct more stratified analyses or perform advanced analyses such as multiple regression. Nevertheless, the purpose of our study was first to describe and then evaluate a novel technique which was developed within our department. Another strength is the homogeneity of the patients examined in the study, all having acute closed fractures and not exposed or pathological fractures requiring different treatments.[31] And the specific cohort of patients received the same surgery with IMN and in this study, all operations were performed by the same surgeon (JPZ), thus eliminating the effects of possible confounding variables, which alleviates to some extent the selection bias. Additionally, with the short duration of follow-up in our study, averaging 18.5 months (range: 12 to 42 months), we did not discuss the present of osteoarthrosis which is a whole joint pathology involving cartilage, synovial membrane, meniscus, subchondral bone, and infrapatellar fat pad that might influence the clinical outcomes in tibial fracture patients at different follow-up.

Conclusions

Compared with curled surgical drapes reduction, our retrospective cohort study suggests that the MITR in the treatment of tibial fracture has the following advantages: (1) shorter operation time and fracture reduction duration, (2) less intraoperative blood loss, fluoroscopy time, and number of fluoroscopies, and (3) better VAS and HHS scores after surgery. Further long-term large-sized prospective randomized trials are needed to evaluate the efficacy of this novel technique.

Abbreviations

IMN, Intramedullary nail; MITR, minimally invasive traction repositor; VAS, visual analog scores; HSS, Hospital for Special Surgery score; BMI, body mass index; ASA, American Society of Anesthesiologists.

Data Sharing Statement

The data used to support the findings of this study are available from the corresponding author (Junfei Guo) upon request.

Ethics Approval and Consent to Participate

This study was approved by the institutional review board of the Third Hospital of Hebei Medical University in accordance with the Declaration of Helsinki (No. W2022-006-1). Informed written consent from all patients were obtained.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors have no relevant financial or non-financial interests to disclose in this work.

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