

Application of the Distraction Support in Intramedullary Nailing Treatment for Tibial Shaft Fracture: A Randomized Controlled Study

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Abstract

Purpose The aim of this study is to investigate the effectiveness of using a new distraction support in intramedullary nailing treatment for tibial shaft fracture.

Methods: Patients at the trauma center who underwent the treatment for tibial shaft fractures from July 2013 to December 2018 were enrolled. The patients were randomized in control group(n=43) and distraction support(SD) group(n=42). All operations were performed by the same senior surgeon. The hospital day, blood loss, operative time, infect rate, delayed union rate and malalignment rate(p=0.68) were obtained for the evaluation.

Results: 85 participants were recruited and all cases were achieved the acceptable reduction. The operative time was significantly shorter for DS group than control group (75.3 vs.90.4 p<0.001). Blood loss was significantly lower in the DS group compared to the control group(60.1vs.85.4 p=0.003) . There were no obvious difference about infect rate(p=0.98), delay union(p=0.45), hospital days(p=0.37) and malalignment rate(p=0.68) between the two groups.

Conclusion: Distraction support was effective in intramedullary nailing surgery. The application of distraction support may be a useful method in our future work.

Introduction

Tibial shaft fracture is the most common lower limb fracture, occurring in about 17 per 100,000 persons annually¹. Intramedullary nailing fixation remains the gold choice for unstable tibial shaft fractures in adult². The advantages of intramedullary nailing include soft preservation, restoring alignment and early mobilization^{3,4}. As with most intramedullary nailing techniques, establishing the accurate reduction is the crucial step of the procedure. The reduction need sustain throughout reaming, nail insertion, and placement of interlocking screws.

However, some unstable tibial fractures types including periarticular fracture, segmental and comminuted fracture and accompanying with fibula fracture, are considered as difficult nailing group^{5,6}. Numerous techniques have been described to facilitate fixation, such as reduction clamps⁷, Elastic Bandage Traction Technique⁸, Esmarch technique⁹, external fixators⁶ and sustained traction via fracture table¹⁰. But most of these techniques are difficult to manipulate during the operation. Therefore, our team designed a new distraction support(patent number:201210153980.x) for tibial reduction during surgical process¹¹. In previous study¹², the distraction support has been proved effective in minimally invasive percutaneous plate osteosynthesis of tibial fracture.

Thus, the purpose of this manuscript is to evaluate the effective of this distraction support in intramedullary nailing of tibial shaft fracture.

Materials And Methods

The prospective randomized study was presented in our medical center for the patients who diagnosed with tibial shaft fracture from July 2013 to December 2018. The study was approved by the Ethics Committee of the Affiliated Hospital of Medical College of Ningbo University, and written informed consent was obtained from each patient. All methods were performed in accordance with relevant guidelines and regulations.

Inclusion criteria:(1) closed tibial shaft fracture, (2) adult patients (older than 18 year), (3) treatment with Intramedullary nailing. Exclusion criteria:(1) open fracture, (2) vascular nerve injury,(3)associated intra-articular fracture of tibia, (4) pathological skeletal disease, (5) serious underlying diseases, (6) history of hormone use. After the patients were enrolled in this research, type of treatment was randomized by computer allocation. Each patient received a randomized numbered opaque envelopes. The patients were divided into distraction support group (DS) and control group. All operations were performed by the same surgical team. An Angle greater than 5 degrees indicates malalignment.

Description of the device

As with the previous report¹², the distraction support is a triangular stereoscopic bracket which contains femoral tray, tibial tray and base.(Fig. 1.) In the unfold station, knee joint support locates between femoral tray and tibial tray on the top of the triangle. Anterior nut is in the middle of tibial tray, which adjusts traction power and length during the surgery. Foot support is a square pedal in the distal of tibial tray. The posterior nut in the femoral tray is similar with the anterior one. The range of knee flexion is depended on the choice of groove in the base. The pivot allows femoral tray, tibial tray and base to be folded in the same plane which facilitates antisepsis and storage.

Surgical treatment

Under adequate anaesthesia, the patient was positioned supine on a radiolucent fracture table. The distraction support was positioned beneath the operative limb. A sterile drape was placed on the knee joint support, which creating the barrier between the popliteal fossa and support. A sterile ankle strap was used to secure the ankle to tibial tray. The appropriate knee flexion was achieved by matching the suitable groove in the base. Simultaneously regulating the anterior nut on each side of tibial tray, persistently traction was applied to the fracture. The reduction was confirmed by fluoroscopy(Fig. 2). In conventional group, reduction was achieved by sustained traction from two assistants. All surgery adopt the same protocol of the transtendinous approach. 3.2 mm tibial guide wire was drilled into medullary space after lengthening incisional opening in the proximal tibia. Reaming was adopted when guide wire arrived the distal medullary space. The surgeon reamed 1 mm larger than the chosen nail's diameter. Then, an appropriate intramedullary nail was inserted, which was confirmed by fluoroscopy. With oriented pin, Locking screws were fixed through stab incisions, both proximally and distally. Lastly, The distraction support was then removed. The incision was closed in a layered manner.

First-generation cephalosporin was administered to each patient pre-operatively and 24 hours postoperatively. Exercise was encouraged after operation immediately and weight-bearing walk was allowed after 4–6 weeks. The follow up was appointed at 1,3,6,9 and 12 months postoperatively.

Statistics

Statistical analysis was performed by SPSS software package (version 19). Shapiro-Wilk tests was used to assess normality and F test was adopted to measure variance homogeneity. Continuous variables are presented as mean \pm standard deviations and compared via independent samples t-tests. Skewed variables are given as median and compared via Wilcoxon signed-rank tests. $P < 0.05$ indicated statistics significance.

Results

A total of 132 tibial shaft fracture patients were received treatment in our medical center. 92 patients were prospectively randomized into control group and DS group. 7 patients were lost during the follow up due to moving or other personal reasons. At last, 85 patients finished the study and complete data was collected (control group 43 and SD group 42). The flowchart was shown in Fig. 3.

The detail demographics was given in the Table.1. there was no significant difference in age, sex, mechanism of injury, fracture location, classification between two groups. The major results were shown in the Tabel.2. The average hospital day was 10.2 ± 3.1 days in control group, while 9.4 ± 2.7 days in SD group ($P > 0.05$). Operative time (75.3 ± 10.5) was much less in DS group than that (90.4 ± 15.5) in control group ($p < 0.001$). Blood loss was significantly lower in the DS group (60 ± 27.2) compared to the control group (85.4 ± 25.4) ($p < 0.001$). After surgery, there were 2 patients in control group and 3 patients in DS group developed with superficial infection. Modified anti-infection treatment was adopted and all patients got healed. Delay union occurred in 7 patients who were required to use crutches until half a year after surgery. Finally, no nonunion was founded. Apex anterior deformity occurred in 2 patients in the DS group and 2 patients in the manual reduction group. Valgus malalignment occurred in 3 patients treated with DS-assisted nailing and in 4 patients treated without DS assistance. Accordingly, the incidence of malalignment between the 2 groups was not statistically significantly. ($p = 0.68$) (Table.3.)

Discussion

Tibial intramedullary nailing is considered as the optimal treatment for tibial shaft fracture in adults¹³. As the critical process, reduction often determines the success or failure of surgery, especially in cases of unstable fracture. To our knowledge, three type of reduction techniques are commonly used in clinical practice. First is manual traction. Although simple and convenient, it increases the physician's workload and radiation time¹⁴. Second, traction table is another technique. The concern is that calcaneal traction may increases the risk of contamination of the operative area¹⁵. Last is external fixation assistive technology. It is an invasive operation that requires a long time of fixation and high technical

requirements, which is limited to popularize use^{16,17}. Therefore, our team developed a closed reduction distraction support for tibial fractures to maintain the stability during reduction.

Distraction support is the closed reduction assistive equipment. By changing the different positions of the anterior tray in the clamping groove of the bottom frame, the knee joint flexion Angle can be adjusted to meet the needs of closed reduction of fracture and intraoperative intramedullary nail operation. According to the average lower limb length in Chinese, we set the base length of the front and rear tray as 32 cm and 30 cm. By rotating the anterior nut, the tray can be extended to achieve the axial reduction of fracture. The adjusting range is from 0 cm to 18 cm. In order to reduce the damage to nerve and vessels, 2 mm was set as the minimum adjustment unit. The sagittal angulation deformity can be corrected by changing the position of ankle support, which could be moved perpendicular to the anterior tray through connection holes. Due to the delicate design, the distraction almost has no negative affect on the anterior and lateral fluoroscopy during surgery.

We believe that distraction support is an effective technique to aid and maintain anatomic reduction in intramedullary nailing treatment of tibial shaft fracture. It has many advantages over other reduction technique. This technique can reduce unnecessary invasive procedures and reduce the number of X-ray exposures. In most cases, after one or two attempts, the guide wire passes smoothly through the fracture to the distal tibia. This greatly reduces the operative time and improves the operation efficiency. It can maintain the position after reduction and reduce the secondary damage caused by repeated reduction, especially multi-stage fractures. This can also significantly reduce the amount of blood loss during the operation. Meanwhile, fine-tuning operation can be adjusted to precise reduction, avoiding secondary neurovascular injury caused by excessive traction¹⁸. Iatrogenic injuries are associated with delayed union and nonunion of tibial shaft fractures¹⁹. This may be the cause of impaired blood supply to the tibial fracture region. Therefore, the surgeon must be more vigilant in avoiding any distraction of the tibial fracture site²⁰. Adjusting the shelf length and the position of lower limbs not only correct the shortening of fracture, but also eliminate the angulation and rotation deformity.

This article has some limitations. The sample size of this study is limited, which is likely to cause the deviation of the results. Therefore, large sample data is needed to study the safety and effectiveness of long-term follow-up.

In conclusion, The distraction support technique is safe, effective and suitable for clinical application in patients with tibial shaft fracture in this study. We hope that a large sample multi-centre randomized study will confirm the reliability and safety of this technique which will be widely used in clinical practice, especially in primary medical institutions in future.

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Tables

Table.1 Demographic Information

	Control group (n=43)	DS group(n=42)	<i>p</i>
Male	25/43	28/42	0.42
Age(years)	40±10.3	38±9.8	0.51
Mechanism of injury			
Traffic accident	23	24	0.74
High- energy fall	10	8	0.64
Slip	5	4	0.75
others	5	6	0.72
Location			
p/3	10	11	0.75
m/3	13	8	0.23
d/3	20	23	0.45

^a p/3: proximal third, ^b m/3 middle third, ^c d/3 distal third

Table.2.Major results of two groups

	Control group (n=43)	DS group(n=42)	<i>P</i>
Hospital day(d)	10.2±3.1	9.4±2.7	0.37
Operative time(mins)	90.4±15.5	75.3±10.5	<0.001
Blood loss	85.4±25.4	60.1±27.2	0.003
Infection	2	3	0.98
Delayed union	5	2	0.45

Table.3.Alignment Following Intramedullary Nailing

Variable	Overall (n=85)	Control group (n=42)	DS group (n=43)	<i>P</i>
No. of patients with malalignment (>5 deg)	8	5	3	0.68
No. of patients with valgus malalignment	7	4	3	0.97
No. of patients with apex anterior malalignment	4	2	2	1.00

Figures

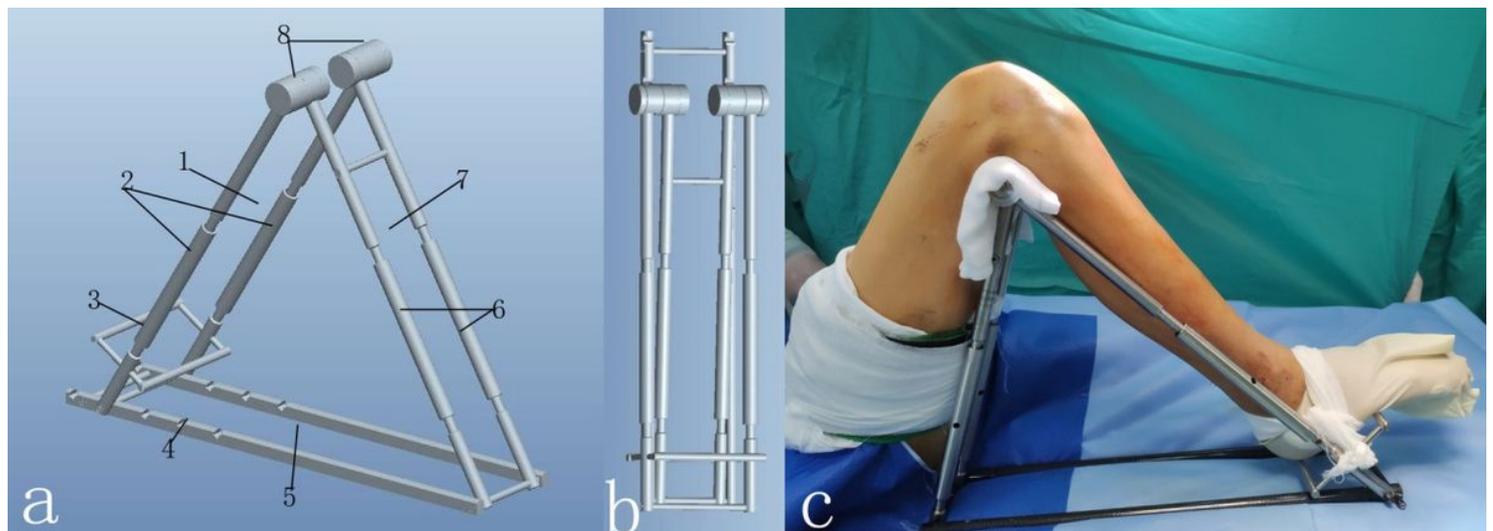


Figure 1

Schematic diagram of distraction support: an illustration of unfolded distraction support 1:Front cradle 2:Front adjustable nut 3:Foot support 4:Groove 5:Bottom cradle 6:Rear adjustable nut 7:Rear cradle 8:Knee joint support(a). an illustration of folded distraction support(b). The affected extremity was fixed to the closed reduction surgical device for tibial fracture in flexion position via the foot-ankle fixed-traction band(c).



Figure 2

Process of surgery with distraction support in radiographs. Anteroposterior and lateral fluoroscopy shows before reduction of the tibial and fibula fractures when the affected extremity was fixed on the distraction support(a,b). Anteroposterior and lateral fluoroscopy reveals a good reduction of the tibial and fibula fractures by modulating both anterior nuts on each side of tibial tray(c,d). The guide wire and intramedullary nail pass smoothly through the fracture and reach distal medullary space (e,f). With oriented pin, Locking screws are fixed through stab incisions, both proximally and distally(g,h).

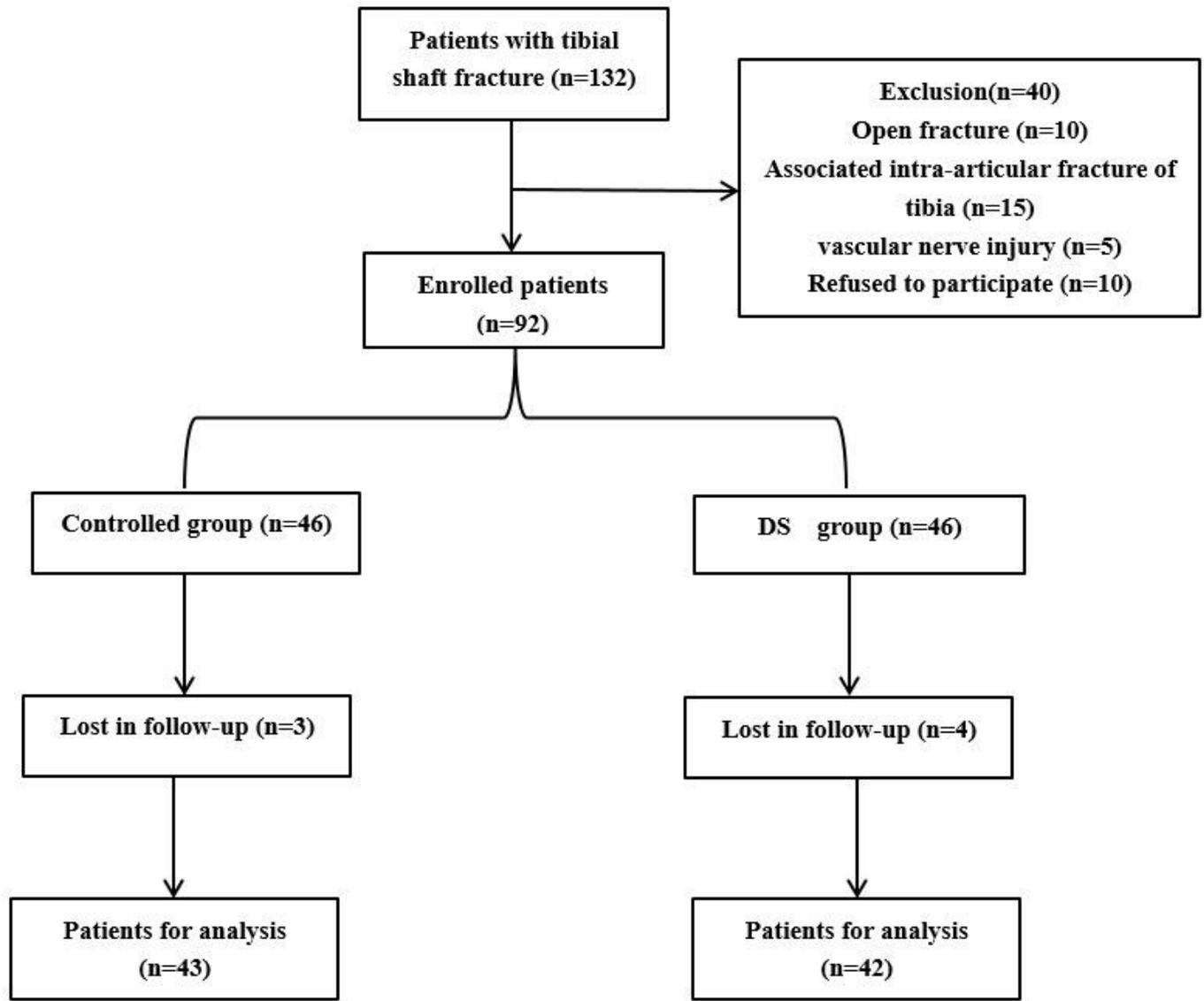


Figure 3

The flowchart