

Tibial Cortex Transverse Distraction Combined With Debridement and Vacuum Sealing Drainage for Diabetic Foot Ulcers: Validation of Previous Published Study

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Research Article

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Abstract

Objective: Tibial cortex transverse distraction (TCTD) has been recently reported in treating diabetic foot ulcers. However, there is no further studies verifying the effectiveness. We performed TCTD combined with debridement and vacuum sealing drainage (VSD) for diabetic foot ulcers to test the effectiveness.

Methods: This study includes 25 patients with diabetic foot ulcers from 3 hospitals. The ulcers of all the cases didn't heal for over 3 months. Then we performed TCTD combined with debridement and VSD for them. After the surgery, the patients were regularly followed-up for more than one year.

Results: Among all the patients, one case underwent amputation because of aggravated infections. There were no cases with complication like tibia fractures. Pin-site infections occurred in 2 patients. The infected pin-site healed after changing dressings for 2 weeks. For the rest 22 patients, their ulcers healed at postoperative 8.2 ± 4.5 weeks. The postoperative visual analogue score (VAS) which indicated pain degree, reduced significantly when compared with preoperative VAS.

Conclusions: When combined with other measures like debridement and VSD, TCTD can bring advantages for patients diagnosed with diabetic foot ulcers, and the trauma of this operation remains a factor to be considered.

Type of study/level of evidence: Therapeutic IV.

Introduction

Diabetic foot is one of the serious chronic complications leading to disability and death in diabetic patients.¹ Diabetic foot is also a major cause of non-traumatic amputation. The incidence of diabetic foot is approximately 8.0 % among the hospitalized diabetic patients in China, most of whom are ulcerated with infection.^{1,2} Treatment is difficult and costly, with a huge financial burden on families and society. Diabetic foot formation mechanisms mainly include peripheral nerve and peripheral artery lesions (PAD), in which neuropathy is the main mechanism.^{3,4} PAD is an important factor in the formation of diabetic foot and the main factor leading to amputation. The main symptoms of diabetic foot include sensory abnormalities caused by neuropathy, dry skin, foot deformities. Symptoms associated with PAD include cold, intermittent claudication, resting pain, and foot infection.^{5,6} The core problem of diabetic foot therapy is how to restore blood flow of affected limb, improve microcirculation and oxygen metabolism of ulcer and its adjacent tissues. At present, the vascular lesions of the lower extremity of diabetic foot are mainly treated by vascular surgery, including arterial bypass transplantation, endovascular shaping and stem cell transplantation of the lower extremity, but the vascular lesions of the lower extremity of such patients involve the distal fine arteries, which reduces the clinical efficacy of the above method. Although the treatments of diabetic foot are varied, the final effect is very limited, and some patients inevitably undergo amputation.

Tibial cortex transverse distraction (TCTD) has been recently reported in treating diabetic foot ulcers.^{7,8} Yan et al. conducted a comparative study, which included patients undergoing TCTD (TCTD group) and standard surgical treatment, consisting of debridement, revascularization, local or free flap or skin equivalent, or graft reconstruction along with negative pressure wound therapy (Control group).⁷ They concluded that TCTD substantially facilitated healing and limb salvage and decreased the recurrence of severe and recalcitrant diabetic foot ulcers.⁷ However, the patients in above study came from a single center, and there is no other researchers testing the effectiveness. Therefore, we reported our clinical experience of TCTD to provide reference for other orthopaedic surgeons.

TCTD is designed according to the "tension-stress rule" of Ilizarov technology and is the application of microcirculation reconstruction in the post Ilizarov era. By applying transverse, slow and continuous traction tension to the tibial cadre bone window, stimulating the regeneration of surrounding tissue, promoting the regeneration of bone window and distal microvascular network, improving the ischemia and hypoxia of distal tissue, the problem of tissue ischemic necrosis and neuropathy caused by diabetic foot is fundamentally solved, and the goal of curing diabetic foot is achieved. Although TCTD has been reported to be effective in treating diabetic foot ulcers, we think it should be combined with other measures like debridement and vacuum sealing drainage (VSD). We should not overrate clinical effects of single TCTD. Therefore, we performed TCTD combined with debridement and VSD for diabetic foot ulcers, and reported the clinical outcomes in this study.

Materials And Methods

Patients

This study was conducted in accordance with the guidelines of the Declaration of Helsinki for Human Research. Informed consent was obtained from all participants, and their rights to privacy were preserved. We conducted a retrospective review on patients having diabetic foot ulcers and undergoing TCTD combined with debridement and VSD between March 2017 and March 2019 at the First Affiliated Hospital of Nanchang University, Jiangxi Provincial People's Hospital Affiliated to Nanchang University and Jiangxi Phenix First Hospital, China.

Preoperative managements

After admission, the patients underwent routine preoperative examination. We evaluated the general condition, adjusted the blood glucose level to less than 10 mmol/L, and performed vascular imaging and ultrasound to understand the patency of the affected limb. If there are more necrotic tissue or serious infection, the necrotic part of foot should be completely removed. Bacterial culture and drug sensitivity test of wound secretion should be carried out. The wound of foot should be covered with VSD, and antibiotics should be applied according to the results of drug sensitivity test.

TCTD surgical technique

We have described the procedure in detail in a previous study (Fig. 1).⁸ After general anesthesia or lumbar anesthesia, the osteotomy area was selected as the medial tibial cortex about 10-20 cm below the knee joint. After positioning, two half nails were used to fix the external fixation frame at the far and near end of the tibial osteotomy area, and then two half nails were placed in the osteotomy area. A long incision about 3 cm was made at the far and near end of the medial tibial osteotomy area to separate the subcutaneous tissue and expose the medial side of the tibia. After drilling, the bone flap was separated from the tibial shaft with a bone knife. After determining the complete free bone flap, we assembled the external fixation device to sutured the incision (Fig. 2). For wounds with large area of infection and more tissue necrosis, we performed intraoperative debridement and covered the wounds with VSD.

Postoperative managements

After surgery, we prescribed continue anti-infection, relieving pain, blood sugar regulation treatment. The dressings of wound were changed and the pin-sites were disinfected regularly. For 3 days after surgery, we stopped using painkillers. Tibial cortex transverse distraction began at postoperative 3-5 day. We carried out 1 mm distraction every day for 14 days in total. Then we reverse-moved the bone mass with 1 mm per day. Approximately 28-30 days were needed to complete the total distraction. After that, X-ray was routinely conducted at every month to analyze the conditions of bone healing. After making sure the bone window was healed, the external fixation frame was removed.

Evaluation indicators

Foot skin temperature, pain visual analogue score (VAS), ankle brachial index (ABI) and wound healing were closely observed during treatment. CTA was conducted to analyze vascular hyperplasia.

Statistical analyses

SPSS version 19.0 (IBM Corp, Chicago, IL, USA) was used to calculate the mean \pm SD of continuous data. T test was used to compared preoperative and postoperative data. Statistical significance was set at $P < 0.05$.

Results

In this study, we totally included 25 consecutive cases (17 males and 8 females) who were diagnosed with diabetic foot ulcers. Their median age was 53 years (range 40–68 years). Their median duration of diagnosing diabetic was 13.2 years (range 6.7–35 years). Cases with left foot ulcers were 13 patients, and cases with right foot ulcers were 12 patients. We classified the foot ulcers according to Wagner stage. Redness, exudation and other infection symptoms occurred during the Wagner 2/3 stage, and dry gangrene at the end of the foot appeared at stage 4. In this study, there were 4 cases of 4 stage, 17 cases of 3 stage, and 4 cases of 2 stage. Computed tomography angiography (CTA) of bilateral lower extremity indicated sub-knee artery occlusion or varying degrees of stenosis, excluding other causes of arterial lesions.

We followed up all the patients, with a mean time of 13.2 months (range, 12–24 months). Among all the patients, one case underwent amputation because of aggravated infections. There were no cases with complication like tibia fractures. Pin-site infections occur in 2 patients. The infected pin-site healed after dressing changing for 2 weeks. For the other 22 patients, their ulcers healed at postoperative 8.2 ± 4.5 weeks. The postoperative VAS which indicated pain degree, reduced significantly when compared with preoperative VAS (preoperative 6.25 ± 0.34 VS postoperative 3.42 ± 0.35 , $P < 0.05$). The skin temperature after the surgery was significantly improved (preoperative 35.27 ± 0.25 VS postoperative 36.62 ± 0.27 , $P < 0.05$). The postoperative ABI (0.55 ± 0.07) was significantly improved ($P < 0.05$) when compared with preoperative ABI (0.41 ± 0.09). CTA indicated the formation of collateral circulation appeared, the superficial artery of the lower extremity became thicker and thicker than before operation and intertwined into a net. A typical case is shown in Fig. 3.

Discussion

Diabetic foot is a serious complication of diabetes. The conditions are complex and serious, and the treatment methods are diverse but the effect is often not ideal. The lower extremity artery lesions of diabetic foot are distributed in stages, and the lower knee artery is more likely to be involved, such as anterior tibial artery, posterior tibial artery, peroneal artery and so on.^{4,6} These sub-knee arteries have the characteristics of small diameter, hard plaque texture, not easy to fully dilate blood vessels, as well as distance from the heart, small arterial pressure, and poor distal inflow, easy to form thrombus after dilatation, resulting in blood microcirculation disorders.^{3,4} Tissues lack of adequate nutrition, and ulcers are difficult to heal. The effect of reconstructing blood microcirculation below knee, especially foot, is not accurate, so the clinical application in diabetic foot therapy is limited.

TCTD technology can stimulate the regeneration of peripheral tissue by applying transverse, slow and continuous traction tension to the bone window of tibial cadre.^{7,8} It promotes the regeneration of bone window and distal microvascular network, improve the ischemia and hypoxia of distal tissue, and fundamentally solve the problems of ischemic necrosis and neuropathy caused by diabetic foot, so as to cure diabetic foot.^{7,8} In this study, one case underwent amputation because of aggravated infections. There were no cases with complication like tibia fractures. Pin-site infections occur in 2 patients. The infected pin-site healed after dressing changing for 2 weeks. For the other 22 patients, their ulcers healed at postoperative 8.2 ± 4.5 weeks. The VAS reduced significantly when compared with preoperative VAS. Therefore, TCTD combined with debridement and vacuum sealing drainage could produce good clinical effects.

For the treatment of Wagner stage 3/4 diabetic foot, TCTD has some limitations. The external fixation needs to be fixed for nearly 3 months, it affects the daily life of patients to some extent. After fixing the external fixation frame, the common complication is nail infection. Long-term nail care is needed to prevent nail infection and affect the surgical effect. If the direction and rate of the external fixation frame change, it will have adverse consequences, since the treatment requires high compliance. Therefore, we should communicate effectively and fully with the patients and their families before operation, inform the

perioperative treatment process and nursing matters needing attention, and prevent the patients from having too high expectations and many reasons leading to the interruption of treatment and the occurrence of surgical complications. In addition, transversal bone movement of the tibia only reconstructs the blood flow of the foot, promotes wound healing, and does not treat diabetes, so there is a possibility of recurrence.

In conclusion, when combined with other measures like debridement and VSD, TCTD can bring advantages for patients diagnosed with diabetic foot ulcers, and the trauma of this operation remains a factor to be considered.

Abbreviations

TCTD: tibial cortex transverse distraction

VSD: vacuum sealing drainage

VAS: visual analogue score

PAD: peripheral artery lesions

Declarations

Funding

There was no funding.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

This study was approved by the ethics committee of Jiangxi Provincial People's Hospital. All study methods were in accordance with the Declaration of Helsinki. Informed consent was obtained from all individual participants included in the study.

Availability of data and material

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

Zhi-Qiang Fan participated in the design of this study. Zhi-Qiang Fan and De-Wu Liu performed the data analysis, collected the important background information, drafted the manuscript. All authors read and approved the final manuscript.

Ethical Publication Statement

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this study is consistent with those guidelines.

Conflicts of Interest Statement

None of the authors has any conflict of interest to disclose.

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Figures

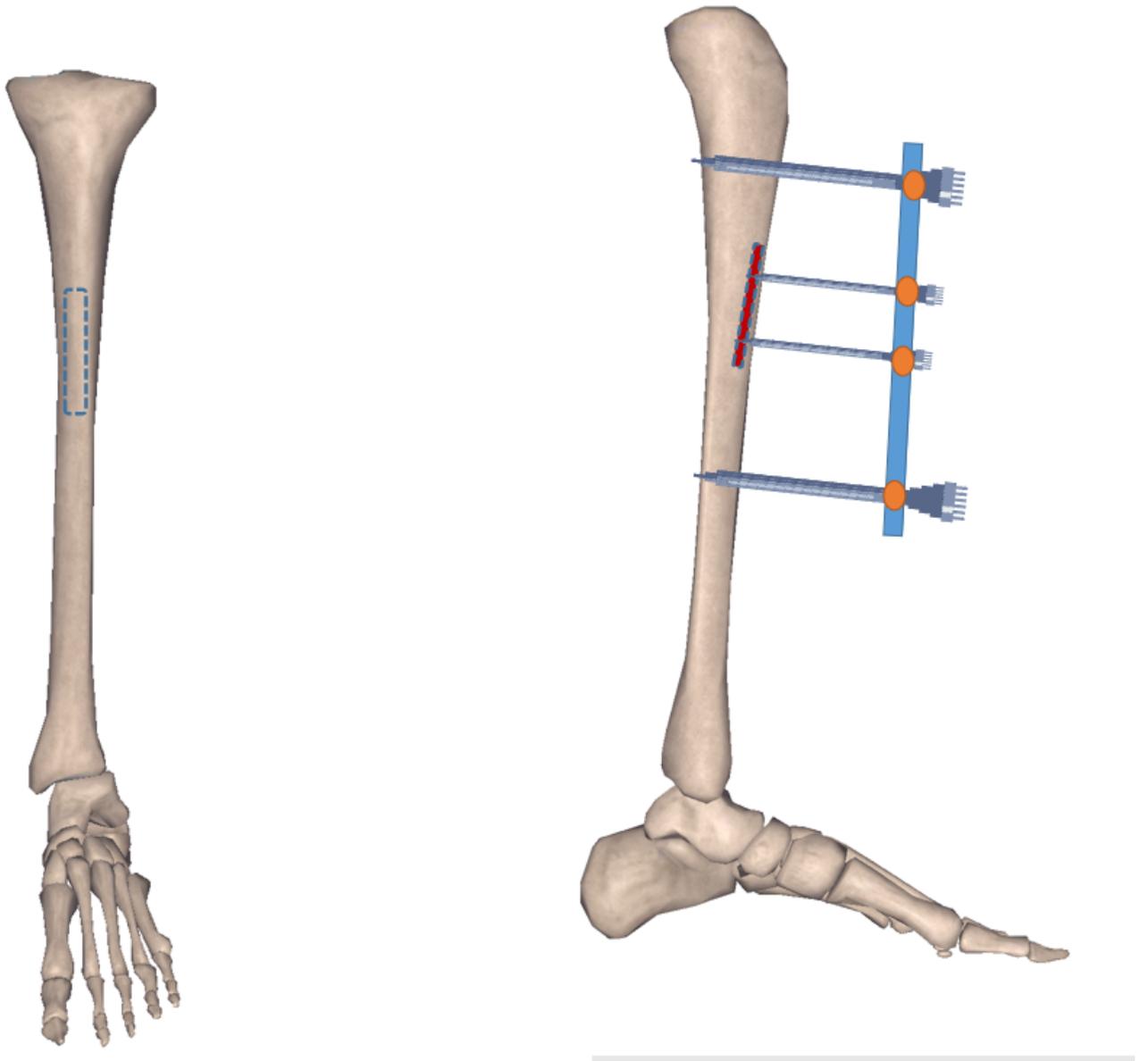


Figure 1

Surgical Schematic of tibial cortex transverse distraction procedure.



Figure 2

Intraoperative photo of tibial cortex transverse distraction.



Figure 3

A typical patient diagnosed with diabetic foot ulcers and underwent tibial cortex transverse distraction combined with debridement and vacuum sealing drainage. (a) Preoperative wound. (b) Wound after debridement and vacuum sealing drainage. (c) Fresh wound after vacuum sealing drainage (c, d) The wound healed after tibial cortex transverse distraction