Received: 14 April 2022 | Revised: 21 July 2022 | Accepted: 23 July 2022

DOI: 10.1111/iwj.13916

ORIGINAL ARTICLE

IWJ WILEY

# An novel and alternative treatment method for large heel ulceration in diabetic patients: Proximal tibial cortex transverse distraction

**Xu Jianda**[1] | **Bai Maosheng**[2] | **Peng Chenjian**[2] | **Yan Xiaojing**[1] | **Wei Changhui**[2] | **Lu Junhao**[2] | **Zhao Jianning**[2] | **Shi Ningwen**[2]

[1]Department of Orthopaedics, Changzhou Traditional Chinese medical hospital, Affiliated to Nanjing University of Traditional Chinese Medicine, Changzhou, China

[2]Department of Orthopaedics, Nanjing Hospital of Chinese Medicine Affiliated to Nanjing University of Chinese Medicine, Nanjing, China

**Correspondence**
Shi Ningwen, Department of Orthopaedics, Nanjing Hospital of Chinese Medicine Affiliated to Nanjing University of Chinese Medicine, Nanjing, 210000, Jiangsu Province, China.
Email: snw1970@163.com

**Abstract**

Heel ulceration in patients with diabetes mellitus (DM) is a major clinical challenge, manifesting with a protracted and uncertain healing process. The prefer treatment of heel ulceration is still controversial. This study aims at describing a newly alternative surgical method with the proximal transverse tibial bone transport technique, as an attempt to achieve wound healing in diabetic patients with large heel ulceration. Retrospective clinical study. A total of 21 diabetic patients with large heel ulceration were enrolled and followed up at least 6 months. The following parameters were assessed: Visual analogue scale (VAS), healing time, ulcer healing rate, ulcer recurrence rate and limb salvage rate. All patients got fully follow-up and achieved wound healing uneventfully. Eighteen patients returned to independent walking without any helper while three patients walked using a crutch. Limb salvage was achieved in all 21 patients (100%). The mean wound area was $67.43 \pm 13.31$ cm$^2$ (range: 46-97 cm$^2$). The mean healing time was $128.62 \pm 16.76$ days (range: 91-160 days). 16 out of 21 patients without calcaneal osteomyelitis achieved ulcer healing with a mean duration of $124.69 \pm 14.42$ days (range: 91–143 days), while the other five patients with calcaneal osteomyelitis were $141.20 \pm 19.12$ days (range: 110-160 days). 2 out of 21 patients got superficial rupture at the previous wounds and healed after outpatient dressing change combined with oral antibiotics. The novel technique described is particularly applicable for large heel ulceration in diabetic patients. It offers a better alternative for achieving wound healing with a favourable encouraging outcome.

**KEYWORDS**

diabetes, healing, heel ulceration, proximal tibial cortex transverse distraction

Xu Jianda and Bai Maosheng are first author and Co-first author.

**Key Messages**

- heel ulceration in patients with diabetes mellitus is a major clinical challenge, manifesting with a protracted and uncertain healing process. It occupies an important component in the patients with nontraumatic lower extremity amputation
- we describe a newly alternative surgical method with the proximal transverse tibial bone transport technique, as an attempt to achieve wound healing in diabetic patients with large heel ulceration.
- the current study shows that the proximal tibial cortex transverse distraction technique is particularly applicable for large heel ulceration in diabetic patients. It offers a better alternative for achieving wound healing with a favourable encouraging outcome

## 1 | INTRODUCTION

Heel ulceration in patients with diabetes mellitus is a major clinical challenge, manifesting with a protracted and uncertain healing process. It's about 15% patients with diabetes mellitus (DM) have got foot ulcerations.[1] Diabetic foot occupies an important component in the patients with nontraumatic lower extremity amputation.[2] Of the patients with heel ulcers, 7% result in amputation and 20% still do not heal until death.[3] Various surgical techniques were reported to achieve limb salvage. However, there is no consensus on prefer or standard protocol, especially in the treatment of heel ulceration exposing the calcaneus. The common perception that 'heel ulcers don't heal' arises due to the apparent lack of progress in treatment.

The heel ulcer in diabetic patients usually confers a poor prognosis with a higher risk of major amputation. Many new alternative treatment methods are proposed. Local flaps, island flaps, and local muscle flaps are the most appropriate options for the repair of small defects in the heel. Free flaps or pedicled flaps are other options for the repair of larger defects. However, higher failure rate is found due to large ulcerations, poorer skin abrasion, concurrent severe peripheral vascular disease, and unsuitable recipient vessel.[4] Flap reconstruction in the heel area is almost impossible to supply a bioengineered dressing for functional walking. Cook et al found that the average time of diabetic foot ulcer healing was about 201 days, but with a wide variation in the number of days. No significant difference was found in healing time between patients undergoing vascular intervention before surgery or not.[5]

To our knowledge, few studies were to report the outcome of diabetic patients with large heel ulceration. This study presents 21 diabetic patients with large heel ulceration, who were not eligible for flap surgery. All these patients were treated with proximal transverse tibial bone transport technique, with a good functional closure and avoiding amputation.

## 2 | MATERIALS AND METHODS

This retrospective clinical trial was designed and approved by the Ethics Review Committee of Changzhou Traditional Chinese Medical Hospital, affiliated to Nanjing University of Traditional Chinese Medicine. All methods were performed in accordance with the relevant guidelines and regulations. Written informed consent was obtained.

From May 2017 to December 2021, a total of 21 diabetic patients (12 females and 9 males), ASA II-IV, aged

**TABLE 1** Characteristics of diabetic patients with large heel ulceration

| Variables | Whole population |
|---|---|
| Age | 63.57 ± 4.89 |
| Gender (M/F) | 9/12 |
| BMI | 18.67-28.56 |
| ASA (II/III/IV) | 10/9/2 |
| Diabetes (I/II) | 0/21 |
| Diabetes duration (y) | 7.24 ± 3.51 |
| Hypertension (Y/N) | 12/9 |
| Renal disease (Y/N) | 7/14 |
| Wound area ($cm^2$) | 67.43 ± 13.31 |
| Type of ulcer (neuropathic/arterial insufficiency) | 19/2 |
| calcaneal osteomyelitis (Y/N) | 5/16 |
| Vascular procedures (none/balloon dilatation/vascular stent) | 16/4/1 |
| VSD time (days) | 9.52 ± 3.89 |

53 to 72 (average, 63.57 ± 4.89), BMI 18.67-28.56 (average, 23.93 ± 2.85), unilateral large heel ulcers were enrolled in this retrospective study. The baselines and ulcer characteristics of patients were recorded at first referral (Table 1). The aetiology of the heel ulcers was neuropathic associated with DM in 19 patients. Only two patients got vascular stent (9.5%) and five patients got balloon dilatation (23.8%).

The inclusion criteria were as follows: Wagner grade ≥ 3; the presence of heel ulceration in diabetic patients; area ≥ 3 $cm^2$[26]; the ability to tolerate surgery and anaesthesia. Patients were excluded if they had diabetic foot in other areas; if they had bilateral heel ulcers or multiple ulcers; if they could not tolerate surgery and anaesthesia; if they could not complete full follow-up due to their own subjective or objective reasons.

After the patients were admitted, off-loading was prescribed immediately. The patients routinely wear foot pads on their ankles to prevent pressure sore. Based on the Guidance of International Working Group on the Diabetic Foot, all enrolled patients were managed by a limb salvage protocol including peripheral neurological examination, peripheral vessels evaluation and revascularization, offloading, surgical debridement and vacuum sealing drainage, antibiotic therapy in the case of infection and management of general condition.[7] At the help of endocrinologist, the treatment target of blood glucose fluctuations was <8 mmol/L before meal.

## 2.1 | Preoperative evaluation

Neuropathy was evaluated and defined as unable to fell a 10-g Semmes-Weinstein hairs using monofilament test (Neurotips).[8] Ischemia with inadequate limb perfusion was defined as the absence of palpable dorsalis pedis (DP) and posterior tibial (PT) pulses and/or an ankle brachial pressure index less than 0.9.[9]

Vascular patency in all patients was evaluated using CT angiography or diagnostic angiography prior to surgery intervention. Patients with severe artery stenosis were re-evaluated by a vascular surgeon for revascularization to restore foot perfusion.[10] The revascularization procedures were to open all occluded arteries or revascularize the wound-related artery with stenting or balloon dilation if needed preoperatively. After evaluation, the patients received low molecular weight heparin Sodium (Sanofi Winthrop Industrie, France, 0.6 mL:6000AxaIU) for thromboprophylaxis once daily post-operatively until discharge. Patients were treated with Clopidogrel for at least 1 month after discharge.

X film, three-phase CT bone scanning, and magnetic resonance imaging (MRI) were regularly used to evaluate the presence and severity of infection. Probe-to-bone test was also routinely performed to aid the diagnosis of osteomyelitis. Deep tissue specimens were routinely sent for microbiological culture and drug sensitivity testing as our initial assessment (Figure 1).

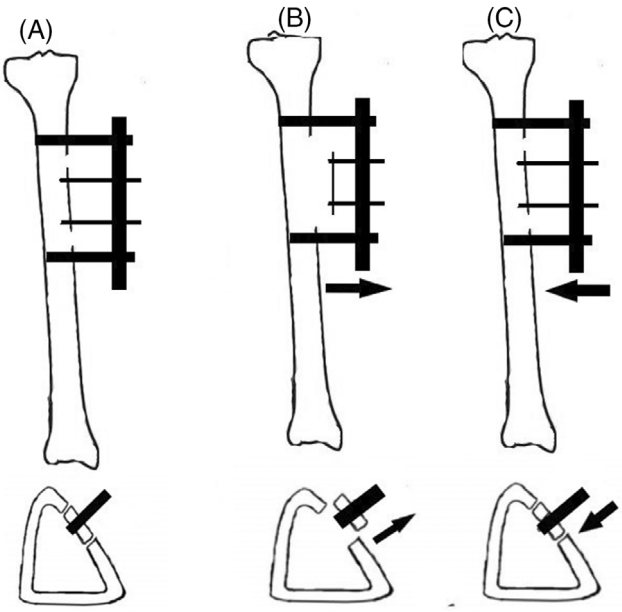


**FIGURE 1** The schematic diagram of proximal tibial cortex transverse distraction. (A) Schematic diagram of tibial cortex transverse distraction. The corticotomy fragment was a vertical rectangular area (about length 5 cm, width 2 cm) located at the medial upper tibia. A special monoliteral external fixator was used for the transverse distraction. (B) Regular distraction (C) Reverse distraction

## 2.2 | Surgical method

The surgeries were performed under lumbar spinal anaesthesia or general anaesthesia without a tourniquet. And patients were positioned dependent on the need of operations. The corticotomy fragment was a vertical rectangular area (about length 5 cm, width 2 cm) located at the medial upper tibia, about the junction of the upper 1/3 and middle 1/3. A special monoliteral external fixator (Figure 2) was used for the transverse distraction. This fixator had a special designed linking device, permitting the corticotomy fragment lift or descend by rotating the knob clockwise or counterclockwise. The maximum distraction height was 15 mm between the distracted cortex fragment and the tibia shaft. Based on the appropriate positioning, two half pins with the special designed linking device were screwed into the corticotomy fragment for distraction, while another two half pins were screwed into distal and proximal tibial shaft for fixing external

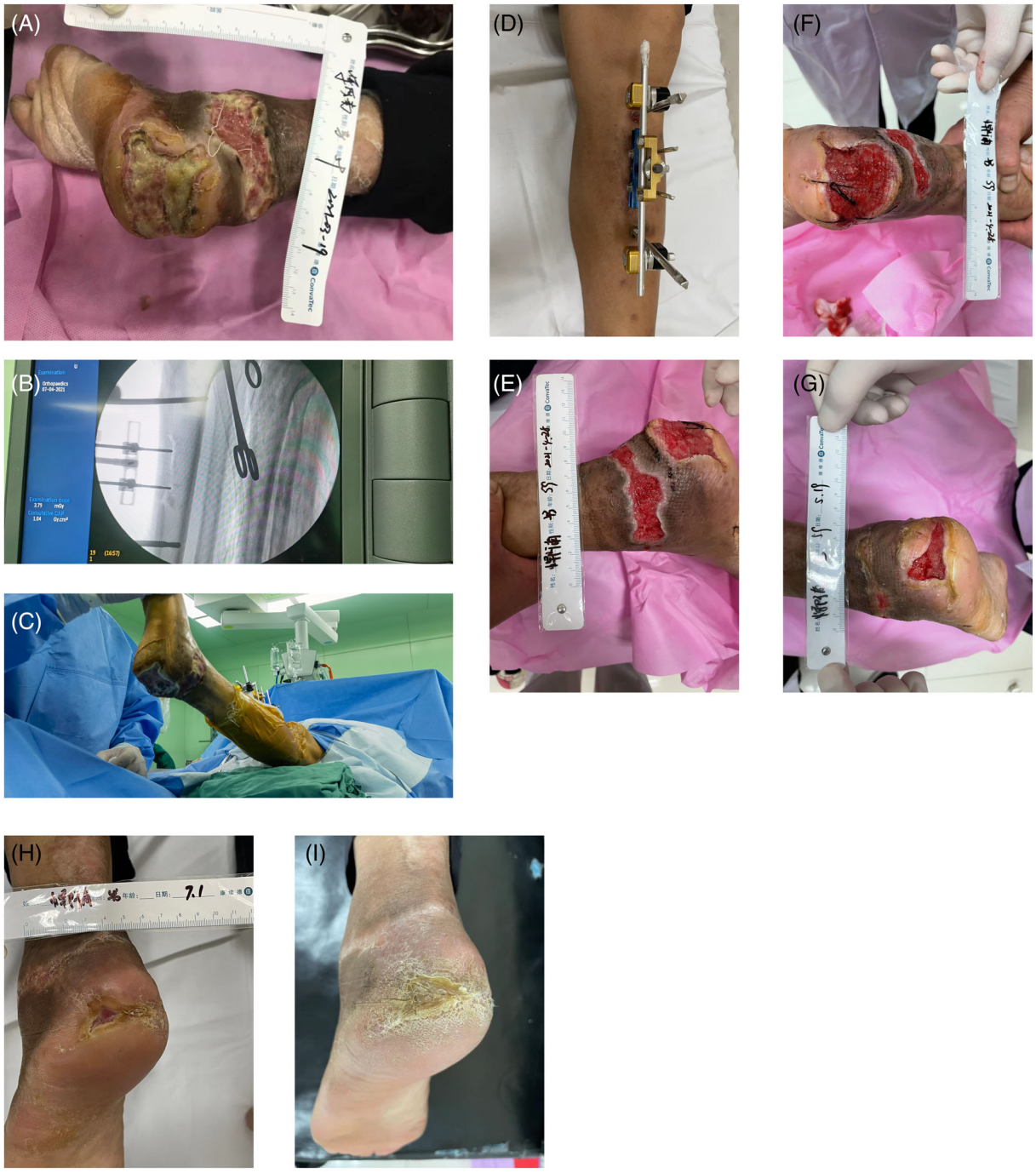


**FIGURE 2** A 62 year male diabetic patient with large heel ulceration. (A) The large heel ulceration (2 wounds: 52 × 63 $mm^2$, 37 × 83 $mm^2$). (B) Intraoperative fluoroscopy showed the corticotomy fragment was achieved. (C and D) A special monoliteral external fixator was used for the transverse distraction. This fixator had a special designed linking device, permitting the corticotomy fragment lift or descend by rotating the knob clockwise or counterclockwise. (E and F) 5 weeks postoperatively, the wound became smaller and covered with fresh granulation tissue. (G) 8 weeks postoperatively, one wound healed and the other one became much smaller. (H) 14 weeks postoperatively, only a little wound existed. (I) 16 weeks postoperatively, the diabetic foot ulcer completely healed. And the patient walked freely with the healed foot.

fixator. And then, a longitudinal arc incision was made across the corticotomy fragment. The subcutaneous tissue was sharp separated to protect blood supply. In order to minimally disrupt periosteal blood supply, several discontinuous incisions (2-4 mm) were made in periosteum for subperiosteal osteotomy. The fragment was separated with a small bone knife. And then, the external fixator was installed with incision sutured. The position

of external fixator and corticotomy site were assessed by postoperative radiographs.

Afterwards, all nonviable tissues including all infected and necrotic tissues were aggressively debrided until reaching the healthy tissue. The debrided specimens were sent for microbiological culture and drug sensitivity testing. Appropriate antibiotherapy was initiated based on the culture results. Usually, broad spectrum antibiotic therapy was applied first, and then adjusted according to the results of culture. If osteomyelitis of calcaneus was diagnosed, bone debridement was performed in addition. Following the debridement, vacuum sealing drainage (VSD) was used and changed every 3 or 4 days until the wound was covered with healthy granulation to skin level.

Daily dressing changes were applied to protect pin-site from infections. The tibial cortex transverse distraction (1 mm every day) was adjusted at a rate of 0.25 mm every 6 hours after 2 to 3 days postoperatively. After reaching the maximum distraction height, the reverse direction distraction began with the same speed. Some patients could not tolerate the pain from distraction, the speed could be changed to 1 mm every 2 or 3 days and back to the initial speed gradually. The distraction procedure continued until the ulcer healed or the corticotomy fragment healed and was unable to distraction. And then, the external fixator was removed. The external fixators were removed about 1 week after the ulcer healed.

Saline was used for wound dressing change to avoid the stimulation of disinfectant to fresh granulation. The bone responding to the region of osteomyelitis was removed directly. After wound lavage, vaseline gauze was used to cover the wound to keep the wound moist and promote granulation growth. And the size of wound gradually reduced until healing. Necessary bedside wound debridement was used to promote healing. Patients were discharged when the wound condition was fresh enough for just dressing change and decline of inflammatory markers was evident. The duration of antibiotic therapy depended on the results of bacterial culture results, degree of osteomyelitis or soft tissue infection, and healing procedure. The dressing change frequency and outpatient follow-up time were determined according to the individual conditions.

The earlier active range of motion (ROM) exercises were initiated for the ankle joint. The ulcer location determined the patient's weight-bearing time and intensity. If the ulcer is at the stress position of the heel, weight bearing is forbidden. If not, partial weight bearing with crutches was allowed after VSD was removed. Full weight beating was not permitted until the wound healed and the fat pad fibrosed to the calcaneus.

### 2.3 | Study clinical parameters

Healing time was defined as the time from operation to healed heel ulcer.

Healing was defined as the ulcer completely epithelialize and not reoccurred.[11]

Deep ulcers were defined as full-thickness skin lesions extending to the tendon or bone.

Ulcer duration was defined as the time from onset of ulcer to admission.

Duration of DM was defined as the time from diagnosis to admission.

Wound area was estimated by multiplying the two greatest diameters of the lesion at right angles. Depth was assessed by visual inspection, as well as by probing if indicated.[12]

### 2.4 | Statistics

SPSS V.24.0 (SPSS Inc., Chicago, Illinois) was employed for statistical analyses. The normality of distribution for continuous numeric variables was assessed by Kolmogorov–Smirnov test. According to normally distributed or not, the variables were presented as means with SD, and otherwise as medians with inter-quartile ranges (95% confidence intervals, 95% CI). $P < .05$ was considered statistical significant.

## 3 | RESULTS

The mean wound area was $67.43 \pm 13.31$ cm$^2$ (range: 46-97 cm$^2$). The mean duration of VSD was $9.52 \pm 3.89$ days (range: 7-20 days). All patients got fully follow-up and achieved wound healing uneventfully. The mean healing time was $128.62 \pm 16.76$ days (range: 91-160 days). 16 out of 21 patients without calcaneal osteomyelitis achieved ulcer healing with a mean duration of $124.69 \pm 14.42$ days (range: 91-143 days), while the other five patients with calcaneal osteomyelitis were $141.20 \pm 19.12$ days (range: 110-160 days).

None patient required low limbs amputation, and the limb salvage was achieved in all 21 patients (100%). Eighteen patients resumed their preoperative independent walking without any helper while three patients walked using a crutch.

Two out of 21 patients got superficial rupture at the previous wounds and healed after outpatient dressing change combined with oral antibiotics. Only one patient had pin-site infections and healed after local debridement and dressing changes.

## 4 | DISCUSSION

The heel ulcers are often thought to be the most challenging type of diabetic foot.[13] In present study, we confirmed that proximal transverse tibial bone transport technique offers a better alternative for large heel ulceration with a favourable encouraging outcome. Also, no serious complication was found.

### 4.1 | Anatomical and biomechanical characteristics for heel ulcer to heal

The heel acts as an important biomechanical structure of the foot and has a higher surface pressure when under load. It transmits the body weight to the forefoot during standing, while to the ground during walking.[14] Due to the distinctive anatomical characteristics, the sole skin acts as a shock absorbing pad. The subcutaneous tissue has many small loculi filled with fluid fat under tension. If the ulcers reach the deep layer, the small interlinked loculi and fluid fat make deeper sepsis difficult to manage.[15] Furthermore, the heel vasculature has a relatively low resting blood perfusion pressure. Unlike other areas of the body, the lower blood perfusion pressure fails to supply enough conducive to wound healing. The thickness of subcutaneous fat and heel pad usually decreases with age and diabetes mellitus. Off-loading has been regarded as a critical procedure for ulcer healing, which can achieve a weight redistribution.[16] So, off-loading provides a good environment for wound healing without sustained pressure. In our institute, off-loading was prescribed immediately after admitted and modified according to the required during the course of treatment.

People with diabetes are more likely to have stiffer heel pads, and the changed mechanical property made the heel more vulnerable to trauma and ulceration.[17] In contrast to lesions confined to the toe or forefoot, heel ulcer (>3 $cm^2$) was harder to heal with a significantly longer healing time.[18] These wounds often fail to heal, despite a palpable pulse at the ankle, seemingly good pedal perfusion and aggressive wound care. The potential reasons explained included distal neuropathy, peripheral artery disease, local repeated trauma, calcaneous osteomyelitis, and limited soft tissue around calcaneous.[19]

### 4.2 | The potential theory mechanism of proximal tibial cortex transverse distraction

In 1960seconds, Professor Ilizarov proposed a new biological theory 'distraction regeneration'. The concept of 'in situ tissue regeneration, natural repair and reconstruction' has the advantage of better clinical prognosis with less minimal trauma. It pointed out that a certain tension produced by slowly and continuously stretch could stimulate tissue growth activity and regeneration. The technique of tibia cortex transverse distraction originated in 1980s after the angiogenesis and neovascularization in the surrounding tissues was found accompanied with distraction osteogenesis.[20] The blood flow and the number of functional capillaries were redistributed in local calluses and surrounding soft tissues, which promote tissue regeneration.[21,22]

Tibial cortex transverse distraction increases local neovascularization and microvascular perfusion for wound healing of diabetic foot. The blood flow, higher density of small vessel, and volume were confirmed by CT perfusion.[23] Zhu et al report that tibial cortex transverse distraction successfully treated a patient with lymphoedema, and it reduced the edema of limb slowly but steadily in following 6 months postoperatively.[24] This technique improved the function of lymph system effectively as blood circulation.

### 4.3 | Revascularization of lower extremity vessels

Oxygen, bound to haemoglobin in red blood cells, diffuses across vessel wall to tissue cells via the interstitial fluid. The oxygen gradient ensures effective diffusion of oxygen for wound healing. An adequate supply of Oxygen and energy is critical for the control of infection and tissue repair. Angiogenesis is fundamental for a normal and complete blood supply.

Patients with diabetes mellitus usually have peripheral arterial disease, which affect more distal calf arteries with longer arterial occlusions. The hypoxic blood flow results in tissue breakdown and tissue necrosis, which triggers the inflammatory immune response. And the poor nutrient delivery and loss of peripheral nerve sensation accelerate skin breakdown with poor healing.[25] Most authors proposed that the peripheral arterial disease or revascularization failure was independent risk factors of major amputation in patients with diabetic foot.[16,26]

Vascular patency in all patients was evaluated using CT angiography or diagnostic angiography prior to surgery intervention. Patients with severe artery stenosis were re-evaluated by a vascular surgeon for revascularization to restore foot perfusion. And transverse tibial bone transport technique acts as a stimulus to wound healing by accelerating angiogenesis. In earlier stage of healing, the residual cellular debris or microorganisms trigger sharply release of inflammatory factors (such as neutrophils, leucocytes and macrophages). They will

increase oxygen uptake and engulf the bacteria, which promote wound healing.[27]

## 4.4 | Systemic therapy of the general and local conditions

The diabetic foot is not just a peripheral foot problem, we must be aware that it needs complex management of severe comorbidities to improve prognosis.[28] Meloni et al managed diabetic individuals with ischemic heel ulcers with a preset multidisciplinary limb salvage protocol, and concluded that the concomitant comorbidities were independent risk factors of prognosis.[29]

Many variables were found influencing the prognosis of patients with heel ulcers. Peripheral revascularization is mandatory in patients with ischemic diabetic foot unlcers for wound healing.[30] Poor foot perfusion, especially the posterior tibial artery below the ankle, was related with worse outcome.[19] Vascular patency in all patients was evaluated using CT angiography or diagnostic angiography prior to surgery intervention. Patients with severe artery stenosis were re-evaluated by a vascular surgeon for revascularization to restore foot perfusion. Grüneboom et al studied the closed circulatory systems in murine long bones and found that trans-cortical capillaries were a central component and traverse cortical bone perpendicularly.[31] In order to minimally disrupt periosteal blood supply, several discontinuous incisions (2-4 mm) were made in periosteum for subperiosteal osteotomy.

The ulcer size and depth played an important role in ulcer healing.[32] This present study indicates that the outcome for large heel ulceration is better than the previous literatures reported results. Nevertheless, the healing time was 128.62 ± 16.76 days, longer than the 126 days in an unselected patients with diabetic foot ulcers.[33] Transverse Tibial Bone Transport Technique offered a better alternative for extensive heel ulceration with a favourable encouraging outcome.

Calcaneal osteomyelitis was related with higher probability of delayed healing. Once the diagnosis of osteomyelitis or deep tissue infection was established, surgical debridement became inevitable to achieve infection control. In this study, five patients with calcaneal osteomyelitis had delayed healing time in this study (141.20 ± 19.12 vs 124.69 ± 14.42). Paisley et al have reported a 33% healing rate at 30 weeks in diabetic heel ulceration with calcaneal osteomyelitis in comparison to 94% in those without osteomyelitis.[34]

## 4.5 | Complications

In present study, none serious complication was found. 2 out of 21 patients got superficial rupture at the previous wounds and healed after outpatient dressing change combined with oral antibiotics. Only one patient had pin-site infections and healed after local debridement and dressing changes. Fan et al assess the complications of 30 patients with tibial cortex transverse distraction from four centres and found that this technique could be performed for diabetic foot ulcers safely. However, a standard operative procedure was needed to reduce potential complications.[35]

## 4.6 | Limitations

There were some important limitations about this present study. It's just a descriptive retrospective research, and none control group was set. Nevertheless, our results are encouraging and more future research are needed. Furthermore, the small sample size makes some bias. And the vascular patency was not re-evaluated after revascularization.

The current study shows that the proximal tibial cortex transverse distraction technique is particularly applicable for large heel ulceration in diabetic patients. It offers a better alternative for achieving wound healing with a favourable encouraging outcome.

## CONFLICT OF INTEREST

The authors declare that they have no competing financial and non-financial interests.

## DATA AVAILABILITY STATEMENT

All data generated or analysed during this study are included in this published article and are available from the corresponding author on reasonable request.

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**How to cite this article:** Jianda X, Maosheng B, Chenjian P, et al. An novel and alternative treatment method for large heel ulceration in diabetic patients: Proximal tibial cortex transverse distraction. *Int Wound J*. 2023;20(3):732-739. doi:10.1111/iwj.13916