

Randomized comparative study between metatarsal head resection and total contact cast in the treatment of diabetic plantar forefoot ulcer

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Objective

The present study assessed and compared the efficacy of metatarsal head resection (MHR) compared with total contact cast (TCC) in the treatment of neuropathic diabetic foot ulcers located at the plantar surface of metatarsal heads.

Materials and methods

Between January 2017 and September 2019, this prospective, randomized, comparative study was performed at Menoufia University –Hospitals. One hundred patients suffering from solitary planter forefoot neuropathic ulceration were assigned into two groups: the first group was treated by MHR and the second group was treated by TCC. Wound healing was the primary outcome while ulcer recurrence and complications were the secondary outcomes of this study.

Results

Baseline patient characteristics were comparable in both groups. Both intention-to-treat and per-protocol analysis were used to evaluate ulcer healing during the treatment period. Percentage of ulcers healed within 12 weeks was 82 and 58% for MHR and TCC groups, respectively ($P < 0.05$). Mean time to heal was significantly shorter in MHR compared with TCC (6.31 ± 1.77 vs 7.48 ± 1.72 weeks, $P < 0.05$). Reduction in ulcer area after 2 weeks was (25.4 ± 9.9 and $17.4 \pm 8.5\%$) in MHR and TCC, respectively ($P < 0.05$). Reduction in ulcer area was (57.7 ± 21.6 and $44.2 \pm 22\%$) in MHR and TCC after 4 weeks of treatment ($P < 0.05$). Complications including infection, deformity, toe ischemia, falls, blister, abrasion, or pressure points were comparable in the two treatment groups.

Conclusion

Being an invasive procedure, MHR offers a safe effective offloading option with higher healing potential and lower recurrence rate compared with TCC as the standard offloading modality.

Keywords:

diabetic foot ulcer, metatarsal head resection, neuropathic ulcer, offloading, total contact cast

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Introduction

Diabetes mellitus (DM) is one of the main problems in health systems and a global public health threat that has increased dramatically over the past 2 decades [1]. Diabetes-related foot ulceration is a serious complication associated with elevated morbidity, mortality, and burden of disease, with a 2.5–10% yearly incidence rate among diabetics [2].

A predominating factor in the development of most diabetes-related foot ulcers is elevated plantar pressure in the presence of neuropathy. Elevated pressure, a measure of tissue trauma, is related to initial ulcer formation, delayed healing, and ulcer recurrence [3]. Effective offloading of pressure as part of a comprehensive management plan is therefore essential for timely healing of plantar foot ulcers [4].

A significant number of offloading devices including total contact casts (TCCs), removable walking braces,

half-shoes, insoles, felt padding, and postoperative shoes are used to reduce high plantar pressures with varying degrees of success [5]. For many years, TCC has been considered the most effective off-loading modality for diabetic foot ulcerations (DFUs) by virtue of its pressure redistribution properties as well as irremovability [6].

The Society for Vascular Surgery commissioned a systematic review to evaluate the different off-loading methods and recommended TCC as the treatment of choice for off-loading foot ulcers [7]. Fitting and preparing of TCC requires considerable time and expertise; some clinicians may be hesitant to

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place a TCC on a neuropathic individual who could be prone to infection, swelling, or abrasion from the cast interior [8]. Patients' compliance and adherence to recommendations for their prescription device is mandatory for ulcer healing and recurrence prevention [9]. One study found that patients used their prescribed removable device for an average of only 29% of their total daily number of steps [10].

Surgical offloading may be indicated in cases of failure or recurrence after nonsurgical offloading options [11]. In low socioeconomic countries as Egypt, the cost of offloading devices and the lack of insurance cover as well as the need for ambulation to make money may affect the Egyptian patients' compliance to offloading devices. In our practice, metatarsal head resection (MHR) was used after failure of offloading devices and revealed encouraging results in ulcer healing, which triggered the need for a randomized, controlled study to evaluate MHR as a primary offloading option for plantar diabetic forefoot ulcers.

Materials and methods

Study design

This study was designed as a single-center, non-blinded, randomized, controlled trial at the Department of Vascular Surgery, Menoufia University. Adult diabetic patients with solitary planter forefoot neuropathic ulceration were recruited.

To be eligible to participate: patients needed to provide informed consent, be at least 18 years old, have a documented diagnosis of type 1 or type 2 DM, have a documented diagnosis of neuropathic ulceration of the forefoot, and have normal physical activity.

Patients were excluded if they had: clinical manifestations of peripheral arterial disease, active infection, cardiac insufficiency, diabetic coma, hepatic insufficiency, moderate to grave renal impairment, hemoglobin less than 100 g/l, antecedents or suspicion of malignant diseases, or psychiatric disorder that compromise treatment or revaluations. Active infection at the wound site was distinguished by the presence of cardinal signs of redness, warmth, swelling, tenderness or pain, and purulent secretions. This study was approved by our Institutional Ethics Committee.

The control variables including age, sex, type, and time of evolution of DM, and current treatment (oral hypoglycemic drugs or insulin) were recorded. Ulcer site, size, time of evolution (in weeks), and stage

according to University of Texas Wound Classification [12] were documented. Peripheral neuropathy was defined as loss of protective sensation, confirmed in each participant by the inability to sense a 10-g Semmes-Weinstein monofilament [13].

After written informed consent, eligible patients were randomized using a computerized list into two groups: the first was treated by MHR (the MHR group) and the second group was treated by foot offloading using the TCC (the TCC group).

Interventions

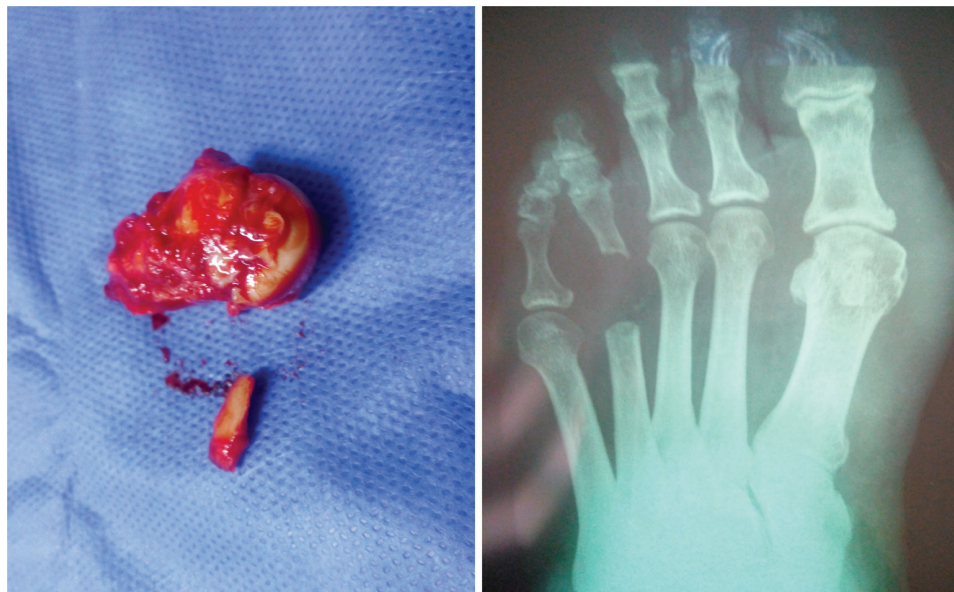
Metatarsal head resection (MHR group)

All procedures were performed under local anesthesia. An incision was performed on the dorsal aspect of the foot opposite the plantar ulcer and extending from the base of the toe to the distal third of the metatarsal shaft. Metatarsal head was resected along with adjacent articular surface of the tarsal bone (Fig. 1). Finally, the incision was left open. The plantar ulcer was debrided and kept open. Postoperative antibiotic was prescribed prophylactically. Patients were allowed to bear weight, ambulate when they feel comfortable, and were not restricted in their daily activities. All patients were fitted with protective footwear. Patients were scheduled for weekly follow-up visits at the outpatient clinic.

Total contact cast (the TCC group)

Before applying TCC; ulcer was irrigated with normal saline; hypertrophic margins and necrotic tissue were debrided; and sterile dressing was applied to the ulcer. We preferred to postpone application of cast for 24 h after debridement in few cases to avoid risk of bleeding beneath the cast. At first interdigital padding was applied. Stockinette was placed over the foot, extending to the knee. The stockinette was pulled forward to cover the toes, folded ~2–4 inches over the dorsum of the foot, and secured with a plastic tape. Adhesive foam was folded to cover the toes completely, with the top and bottom sticking to the stockinette, and the excess was trimmed from each side. Cotton padding was applied over the stockinette. Extra padding was applied over the malleoli and over the shin of the tibia. The patient was placed in a prone position with the leg flexed at the knee, and the foot placed in a neutral position with the ankle as close to 90° as possible. Three rolls of 4-inch-plaster wrapped the foot and leg from distal to proximal ending 1 inch distal to the fibular head. The cast was molded to the exact contour of the leg and foot to provide maximum contact. Two rolls of 3-inch fiberglass were applied in the same manner to strengthen the cast. Weight-bearing was allowed only after the cast had cooled

Figure 1



Resected metatarsal head.

Figure 2



Total contact cast.

and hardened (Fig. 2). Cast shoes were supplied, and the patients were scheduled for cast renewal on a weekly basis at the outpatient clinic.

The wound size was evaluated before initiation of treatment and during weekly follow-up. The elliptical method described by Shaw *et al.* [14] and the mathematical formulae described by Johnson [15] were used for wound measurement. Wound healing rate, defined as absolute area healed per day, was recorded in both groups.

Follow-up and outcomes

Patients were followed for 12 weeks or until ulcer healing, whichever came first. After complete ulcer

healing, forefoot offloading shoes (Fig. 3) were prescribed for patients and were followed up monthly for 6 months for recurrence.

The primary outcome was the percentage of complete wound healing, defined as epithelization and complete closure of the lesion without secretion or the need for dressing, at 12 weeks. Secondary outcomes were ulcer recurrence or presence of complications like skin breakdown, new ulcer, infection, gangrene, or joint problem. Cast treatment was terminated when there was no reduction in size or depth of the wound after 6 consecutive weeks, when an infection developed, or when the patient had discomfort with the cast; these cases were defined as cast failure.

Statistical analysis

Statistical analysis was performed using SPSS version 24.0. (IBM Corp., Armonk, New York, USA). Discrete variables were presented as numbers (counts) and percent. Continuous variables presented as mean and SD. Student's *t*-test was used for intergroup comparisons to test the significance of difference between two different variables. A *P* value of less than 0.05 was considered statistically significant. For the percentage of ulcers healed, an intention-to-treat and per-protocol analysis was performed. The per-protocol analysis included only those patients who completed follow-up in the allocated group. Dropout, if present, was taken into account in the intention-to-treat analysis of all randomized patients. Patients whose ulcer was amputated were not included in the intention-to-treat analysis. Ulcer healing as a function

Figure 3



Forefoot offloading shoe.

Table 1 Baseline patient demographic criteria and medical history data

	MHR group	TCC group	<i>P</i> value
Number of patients	50	50	
Sex (male/female)	29/21	24/26	0.423
Age (years)	49.4±7.1)	51.7±6.8)	0.1
Type of diabetes			
Type I/type II	7/43	4/46	0.524
Duration of DM	13.2±5.1	11.7±5.9	0.176
Weight	89.1±4.6	87.8±5.2	0.188
Height	171.1±6.8	169.5±6.4	0.228
BMI	30.53±2.2	30.61±2.9	0.87
Ulcer area at entry (cm ²)			
Range	0.95–6.7	0.78–6.4	0.11
Mean±SD	3.54±1.1	3.21±0.95	
Small (<2.5 cm ²)	18	23	0.41
Large (>2.5 cm ²)	32	27	0.41
Depth of the ulcer at entry			
University of Texas Grade 1A	29	36	0.2
University of Texas Grade 2A	21	14	0.2
Metatarsal head 1	15	13	0.82
Metatarsal head 2–4	29	32	0.68
Metatarsal head 5	6	5	1.0

DM, diabetes mellitus; MHR, metatarsal head resection; TCC, total contact cast.

of time was presented using Kaplan–Meier plots and was tested using log-rank analysis.

Results

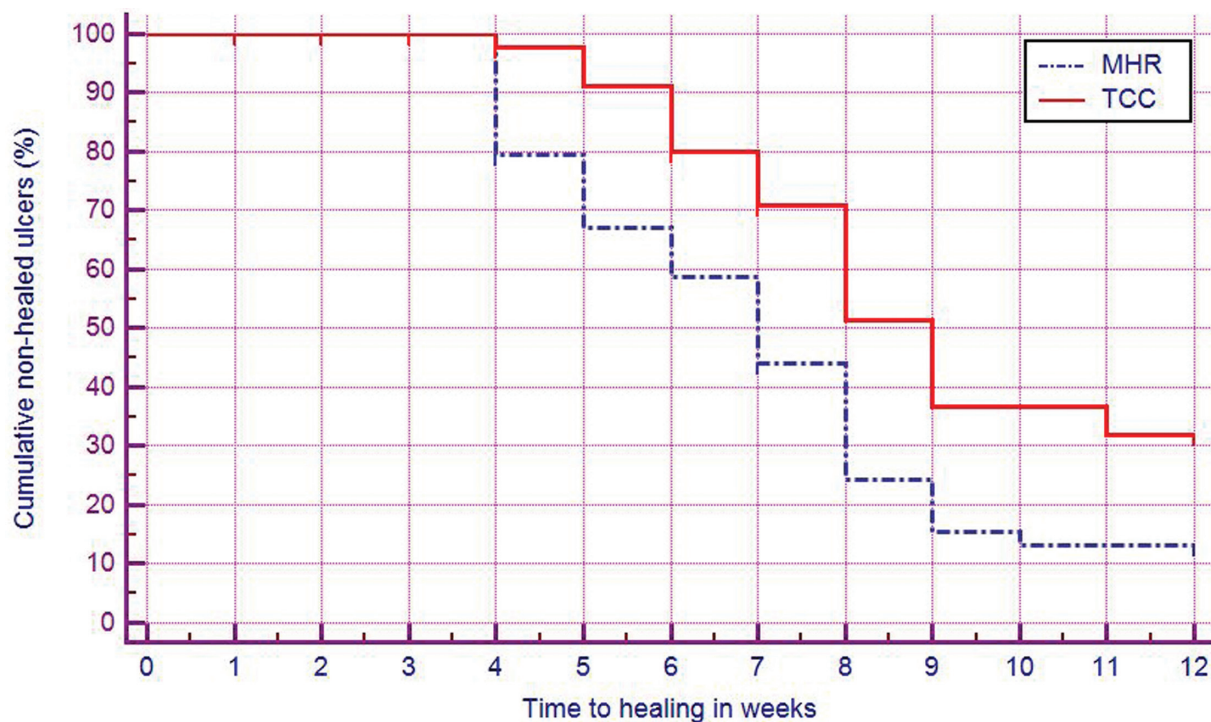
Between January 2017 and September 2019, according to the eligibility criteria, 100 patients were included in this study. Baseline patient characteristics are shown in Table 1 with no significant differences between treatment groups for demographic criteria and medical history data. The ulcers site, grade, and initial mean baseline surface area were comparable between the two treatment groups.

In the TCC group, eight patients discontinued treatment during the 12-week initial period. Two

patients withdrew in the second week and another three patients in the third week due to intolerability to cast. Three patients escaped treatment at the seventh and eight weeks after alleging no satisfactory results according to their opinions. In the MHR group three patients, two patients in the third week, and one in the fifth week discontinued follow-up.

Both intention-to-treat and per-protocol analysis were used to evaluate ulcer healing during the treatment period. According to intention-to-treat analysis, the percentage of ulcers healed in 12 weeks was 82% for the MHR group and 58% for the TCC group with significant statistical difference between the two groups ($P=0.015$), which was confirmed by the per-protocol analysis of both

Figure 4



Cumulative nonhealed ulcers at 12 weeks.

Table 2 Ulcer healing parameters and complications

	MHR group	TCC group	P value
N	50	50	
12 weeks dropout	3	8	0.199
Ulcer healed (%) after 12 weeks			
Intention-to-treat analysis	41 of 50 (82%)	29 of 50 (58%)	0.015
Per-protocol analysis	41 of 47(87.2%)	29 of 42 (69%)	0.042
Time to healing (weeks)	6.31±1.77	7.48±1.72	0.007
Reduction in ulcer area after 2 weeks			
Intention-to-treat analysis (50/48)	25.42±9.95%	17.47±8.53%	0.001
Per-protocol analysis (47/42)	26.38±9.42%	18.33±8.73%	0.001
Reduction in ulcer area after 4 weeks			
Intention-to-treat analysis (48/45)	57.72±21.65%	44.19±22%	0.003
Per-protocol analysis (47/42)	58.63±20.93%	45.83±21.83%	0.006
Healing rate after 4 weeks	7.16 mm ² /day	5.13 mm ² /day	0.01
Adherence to offloading shoes [n (%)]	18 (43.9)	15(51.75)	0.93
Recurrence [n (%)]	1 (2.4)	5 (17.25)	0.02
Complications			
Infection	5	1	0.2
Complications due to device ^a	0	0	1
Toe ischemia	0	0	1
Deformity	4	0	0.11

MHR, metatarsal head resection; TCC, total contact cast. ^aFalls, blister, abrasion, pressure points.

groups ($P=0.042$). Cumulative nonhealed ulcers during the initial 12-week treatment period is shown in Fig. 4 with significant difference between the two groups ($P=0.002$). Time to heal was significantly shorter in the MHR group (6.31 ± 1.77 weeks) compared with (7.48 ± 1.72 weeks) for the TCC group ($P=0.007$).

Reduction in ulcer area (RUA) was evaluated in both groups after 2 and 4 weeks of treatment. After 2 weeks, RUA was 25.4 and 17.4% in the MHR group and TCC group, respectively ($P=0.001$). RUA was 57.7 and 44.2% in the MHR group and the TCC group after 4 weeks of treatment ($P=0.003$), with significantly faster healing rate in the MHR group

Figure 5



Sample cases before and after treatment.

Figure 6



Sample cases before and after treatment

(7.16 mm²/day) than the TCC group (5.13 mm²/day) (Table 2).

Sample cases before and after treatment, from both groups, were elicited in the following figures (Figs 5–10).

Out of the 41 patients with healed ulcers in the MHR group, 18 (43.9%) patients were adherent to the prescribed offloading shoes for the 6-month follow-

up period., while in TCC group, 15 out of 29 patients (51.75%) were adherent to the prescribed offloading shoes for the same period ($P=0.93$). Ulcer recurrence during the 6 months follow-up period among patients nonadherent to their prescribed offloading shoes was detected in one (2.4%) patient and five (17.25%) patients in the MHR group and TCC group, respectively ($P=0.02$) (Fig. 11). Patient adherent to their prescribed offloading shoes showed no ulcer recurrence in both groups during the 6-month

Figure 7



Sample cases before and after treatment.

Figure 8



Sample cases before and after treatment.

follow-up period. In nonadherent patients one out of 23 patients had recurrence in the MHR group with no significant difference between adherent and nonadherent patients ($P=1.0$), while in the TCC group, five out of 14 patients had recurrent ulcers in nonadherent patients with significant statistical difference between adherent and nonadherent patients ($P=0.016$). Complications including infection, deformity, toe ischemia, falls, blister,

abrasion, or pressure points were comparable in the two treatment groups (Table 3).

Discussion

DFU represents one of the common and challenging problems in modern vascular surgery practice, being diabetic you have a 12–25% life-time risk to develop a DFU [16]. Although the development of DFU is

Figure 9



Sample cases before and after treatment.

Figure 10

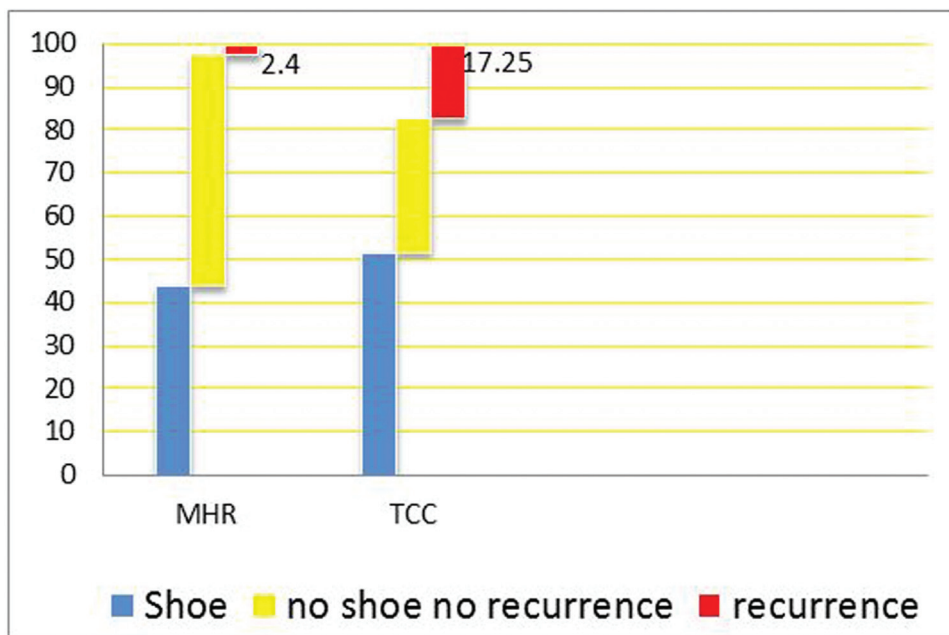


Sample cases before and after treatment.

multifactorial, diabetic peripheral neuropathy is considered the leading cause of DFU and is the causative factor in 35–45% of all DFUs [17]. High plantar pressure with repetitive plantar trauma represents a key component in the pathogenesis of neuropathic foot ulceration, accordingly diabetic foot offloading is considered a cornerstone in diabetic foot management [18].

From numerous off-loading modalities, TTC and surgical offloading with MHR were evaluated in this study. The role of surgical offloading using MHR and the TCC in the treatment of neuropathic plantar ulceration were separately evaluated in many studies; however, there are few studies that conducted a randomized, comparative evaluation of both offloading modalities as we did in this study.

Figure 11



Ulcer recurrence.

Ulcer healing was the primary outcome of this study; three parameters were used to evaluate the ulcer potentiality to heal: the cumulative nonhealed ulcers at 12 weeks, the mean time to heal, and the RUA at 2 and 4 weeks. To avoid bias in the evaluation of ulcer healing parameters between the two treatment groups, both Intention-to-treat and per-protocol analyses were used in this study. MHR showed significantly higher ulcer healing percentage after the initial 12 weeks period compared with TCC. RUA at 2 and 4 weeks, and the mean time to heal were also significantly faster in the MHR group.

According to the clinical practice guidelines of the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine, TCC is now considered the treatment of choice for planter neuropathic ulceration; on the other hand, there is debate about the role of surgical intervention in offloading such ulcers [7].

Some authors reported that surgical interventions including MHR may have only limited additional value in ulcer healing compared with nonsurgical treatment and should be considered only after the failure of nonsurgical treatment [19,20]. Cavanagh and Bus had a similar recommendation against the surgical offloading interventions for its inferiority compared with conservative treatment [4].

La Fontaine *et al.* [21] also had concluded that surgical intervention for DFUs should be considered for

Table 3 Relationship between ulcer recurrence and adherence to offloading shoes

	MHR [n (%)]		TCC [n (%)]		
	Recurrence	Non	Recurrence	Non	
Shoe	0	18 (43.9)	0	15 (51.75)	0.93
Non	1 (2.4)	22 (53.7)	5 (17.25)	9 (31)	0.02
	1.00	0.016			

MHR, metatarsal head resection; TCC, total contact cast.

patients who have failed proper offloading and wound care, or who have recurrent ulcers with appropriate preventative care, if appropriate, after proper optimization has been completed.

On the other hand, there are many studies in the literature that support our results about the effective role of MHR in diabetic ulcer offloading and neuropathic planter ulcer healing. In a study by Patel and Wieman [22], mean planter pressure was measured before and after MHR and revealed mean planter pressure reduction following resection with no significant transfer of pressure to adjacent metatarsal heads. In a study by Griffiths and Wieman [23], the ulcers healed within a mean of 2.4±1.6 months after MHR with rare postoperative complications.

In another study by Wieman *et al.* [24], 88% of the ulcers healed using this technique, and the healing was relatively more rapid than would be expected from the historical norms. The study by Piegass *et al.* [25] demonstrated that surgical treatment of neuropathic ulcers is an effective approach compared with

conventional treatment in terms of the healing rate (95.5 vs 79.2%), healing time (46.73 ± 38.94 vs 128.9 ± 86.6 days), and complications (4.5 vs 12.5%).

In a case-control model by Armstrong *et al.* [26], patients in the surgery group healed significantly faster than those in the standard therapy group (60.1 vs 84.2 days) with no significant difference in the proportion of patients receiving an incident amputation in the follow-up period. Another study by Motamedi and Ansari [27] showed that wound healing occurred more efficiently in the MHR group than in the medical group and recommended MHR as a better choice of treatment because it results in fewer ulcer recurrence, patient morbidities, and complications.

Ulcer recurrence and complications were the secondary outcomes in this study. No ulcer recurrence was detected in both groups among patients adherent to their prescribed offloading shoes. On the other hand, ulcer recurrence was significantly lower in the MHR group compared with the TCC group among patients neglecting offloading shoes. Analyzing recurrence within the same group according to adherence to offloading shoe revealed significantly higher recurrence in nonadherent than adherent patients within the TCC group, while no difference was detected within the MHR group indicating prophylactic efficacy of MHR against recurrence.

Many studies supported our results about the protective effect of MHR against ulcer recurrence. Giurini *et al.* [28], retrospectively analyzed 34 pan-MHRs in patients with diabetes and a forefoot ulcer and reported that 97% of the ulcers healed and remained ulcer free for an average of 20.9 months. A randomized, controlled study with low risk of bias on 41 patients compared surgical excision of the ulcer with removal of bone segments underlying the lesion to conservative treatment (i.e. relief of weight-bearing and regular dressing) and found a significant reduction in ulcer recurrence at 6 months follow-up in the surgical group: 14 vs 41% ($P < 0.01$) [25].

Another retrospective cohort study by Armstrong *et al.* [29], including 50 patients demonstrated a lower recurrence rate at 6 months follow-up of single MHR compared with conservative treatment ('aggressive off-loading'): 5 vs 28%, $P = 0.04$. Another retrospective cohort study with low risk of bias including 92 patients also demonstrated lower recurrence rates at 1 year follow-up of pan-MHR

compared with conservative treatment: 15.2 vs 39.1%, $P = 0.02$ [26].

On the other hand, in a study by Molines-Barroso *et al.* [30], 119 patients with diabetes who underwent resection of at least one metatarsal head were analyzed prospectively to assess reulceration in the other metatarsal head and reported a 41% recurrent ulceration (transfer lesions) during a median follow-up period of 13.1 months.

High recurrence rate was also reported by Sanz-Corbalan *et al.* [31] after MHR because of a relatively high rate of peak pressure being transferred to an adjacent metatarsal head and causing a secondary ulceration during the 6-month follow-up period.

Conclusion

Being an invasive procedure, MHR offers a safe and effective offloading option with higher healing potential and lower recurrence rate compared with TCC as the standard offloading modality.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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