Original Article

Effectiveness of Removable Walker Cast in the Healing of Diabetic Neuropathic Foot Ulcer

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Abstract

Background: The elevation of the plantar loading has been implicated in the etiology of plantar foot ulceration in individuals with diabetes mellitus (DM) and peripheral neuropathy. Many strategies are used to reduce this load which are regarded as critical for ulceration healing and commonly called offloading. **Objective:** The objective was to evaluate the effectiveness of the use of a removable cast walker (RCW) in the healing of diabetic neuropathic planter foot ulcerations. **Materials and Methods:** Twenty-nine adult diabetic patients attending Al-Faiyha General Hospital, Basrah city in Iraq, participated in this cross-sectional (randomized selection) prospective study between August 2014 and September 2015. We relied on clinical features for survey a diabetic neuropathy of affected foot and we proved the diagnosis by nerve conduction study. Assessment of vascularity was done clinically and by Doppler ultrasound study. Surgical debridement was done, and the participants were instructed to wear a RCW on the 2nd day post operation. Follow-up was performed weekly, and the outcome was assessed by complete wound healing. **Results:** Twenty-nine patients were included in our study and follow-up program. The mean duration of the neuropathic nonischemic ulcers was 7.1 ± 4.3 months. The healing rate was 62.5%, and we found that the total percentage of healing of the ulcers with 1A and 2A classes was 69.0% with a mean duration of 8.45 ± 2.2 weeks. In addition, we observed that the percentage of patients with diabetic neuropathic foot ulceration with an obvious forefoot deformity was 56.5% of all forefoot ulcers, with a healing rate of 76.9%, whereas those without an obvious foot deformity was 43.5% with a healing rate of 80%. **Conclusion:** RCW is an effective method in the treatment of diabetic neuropathic nonischemic foot ulceration. The healing rate of the ulceration by using this method of offloading mainly depends on the site of planter foot ulcer.

Keywords: Cast, diabetic patients, healing, neuropathic ulcer

Introduction

Diabetic neuropathic foot ulcers are one of the most common precursors to lower limb amputation among persons with diabetes; therefore, effective management of these wounds should have a substantial impact on amputation prevention. Most ulcers result from constant or repetitive pressure applied to the foot while walking. Persons that are insensate due to diabetic peripheral neuropathy lack the innate sensory feedback (e.g., pain) necessary to protect the foot from skin breakdown.[1] In order for a neuropathic ulcer to heal, repetitive pressure must be reduced or eliminated by external mechanisms or devices.[2]

Dr. Paul Brand was the first to widely use total contact casting (TCC) in the mid-1960s to offload the insensate foot in Hansen's disease. It has since been identified as a "Gold Standard" for offloading diabetic foot ulceration within the diabetic foot-care community.[3] However, TCC is underutilized in clinical practice as it is technically difficult and time-consuming to apply, is relatively expensive, and has low patient tolerance.[4]

Because that an alternative offloading methods was introduced in order to overcome this complications such as RCWs which are, as their name implies, cast-like or readymade devices that are removable to allow for self-inspection of the wound and application of topical therapies that require frequent administration.[5]

The aim of this study was to evaluate the effectiveness of the use of a RCW in the healing of diabetic neuropathic planter foot ulcerations.

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Materials and Methods

A total of forty adult diabetic patients with nonischemic, noninfected neuropathic plantar foot ulcers who presented to Al-Faiyha General Hospital, Basrah city in Iraq, participated in this cross-sectional (randomized selection) prospective study between August 2014 and September 2015. Twenty-nine patients were included in this study, and 11 patients were lost to follow-up and hence excluded from the study.

The mean age of the participants was 55.79 ± 7.7 years, with a mean duration of the disease of 11.52 ± 4.0 years. The study included 22 (75.9%) males and seven (24.1%) females. The study inclusion criteria were the presence of a neuropathic plantar foot ulcer with an area graded up to 2A according to the University of Texas (UT) Classification of Diabetic ulcer.[6]

The diagnosis of peripheral neuropathy was based on the clinical signs and symptoms in addition to insensitivity of the foot to a 10-g Semmes-Weinstein monofilament[7] and by a loss of vibration perception which is tested by using 128 Hz tuning fork on the medial malleolus and dorsal aspect of the big toe.[8] Peripheral neuropathy was proved by nerve conduction study; however, we did not include the weight of the patients as a parameter in this study. Exclusion criteria were the absence of two or more pulses on both feet[9] and/or the ankle-brachial pressure index <0.9 or >1.3 and presence of clinical signs of the soft-tissue infection.[10] Both the probe-to-bone maneuver and standard X-ray examination of the foot were used for excluding osteomyelitis.[11] Additional exclusion criteria included the presence of visual problems that could impair balance, an active ulcer on the contralateral foot and previous major amputation of the contralateral limb.

All patients were admitted to the hospital 1 day before operation; full history taking and systemic and regional examinations were performed. Laboratory investigations were requested which included hematological (complete blood count, blood group) and biochemical (blood sugar, blood urea, serum creatinine, hemoglobin A1c [HbA1c], and total serum protein) parameters, C-reactive protein, erythrocyte sedimentation rate, and radiological study of both feet. Doppler ultrasound study and nerve conduction study of the lower extremities were done followed by treatment with a surgical debridement to remove all nonviable tissues to expose the entire surface lesion,[12] which was done under regional anesthesia (ankle block), and all patients passed smoothly without any postoperative complications.

We instructed the participants to wear a RCW on the 2nd day post operation. Follow-up was performed weekly for up to 12 weeks, and the outcome was assessed by complete wound healing (defined as complete epithelialization). On each visit, regular investigations such as blood sugar and radiological examination were done.

Data analysis was done using Statistical Package for the Social Sciences version 20 (SPSS, IBM, Chicago, IL, USA).

Results

The different demographic parameters for the patients are summarized in Table 1 and are as follows:

Twenty-nine patients were included in our study and follow-up program, with 22 males (75.9%) and seven females (24.1%). The minimum age of the patients was 39 years and the maximum was 70 years, with a mean age of 55.79 ± 7.7 years. The minimum duration of diabetes was 4 years and the maximum duration was 21 years, with a mean duration of 11.52 ± 4.0 years. The minimum duration of the ulcers was 3 months and the maximum was 24 months, with a mean duration of 7.1 ± 4.3 months. The minimum HbA1c was 6.9%, whereas the maximum level was 11%, with a mean level of 9.4%. According to UT-Classification, there were 13 patients (44.8%) with 1A class and 16 (55.2%) with 2A class. There were 13 participants (56.5%) in this study with an obvious forefoot deformity, whereas there were ten

Table 1: Demographic parameters

Sex	
Male	22 (75.9)
Female	7 (24.1)
Age (years)	
Minimum	39
Maximum	70
Mean±SD	55.79±7.7
Duration of DM (years)	
Minimum	4
Maximum	21
Mean±SD	11.52±4.0
Ulcer duration (months)	
Minimum	3
Maximum	24
Mean±SD	7.1±4.3
HbA1c (%)	
Minimum	6.9
Maximum	11
Mean±SD	9.4
Ulcer UT-classification	
1A	13 (44.8)
2A	16 (55.2)
Forefoot deformity	
Yes	13 (56.5)
No	10 (43.5)
Total	23 (100)
Ulcer location	
Forefoot	23 (79.3)
Midfoot	1 (3.4)
Heel	5 (17.3)
Total	29 (100)
Smoking habit	
Smoker	16 (55.2)
Nonsmoker	10 (34.5)
Ex-smoker	3 (10.3)

SD: Standard deviation, DM: Diabetes mellitus, HbA1c: Glycated hemoglobin, UT: University of Texas

participants (43.5%) without an obvious forefoot deformity. The neuropathic foot ulcers were most commonly located in the forefoot which were 23 (79.3%) ulcers, whereas there were five (17.3%) ulcers in the heel and the least number of ulcers was located in the midfoot which was one ulcer (3.4%). Sixteen patients (55.2%) were nonsmokers, ten (34.5%) were smokers, and three patients (10.3%) were ex-smokers.

Table 2 shows the relationship between the plantar foot ulcers and the age groups of patients. This study found that the number of patients with diabetic neuropathic foot ulcers in the first age group (31–40 years) was one (3.4%), in the second age group (41–50 years) was seven (24.0%), and the third age group (51–60 years) was twelve (41.4%), and in the fourth age group (61–70 years) was nine (31.0%). However, we found that the foot ulcers were most commonly occurred between (51 and 70 years), which represented 72.4% of all ulcers.

All the patients that participated in this study had a noninsulin-dependent DM, eight patients (27.6%) were on oral hypoglycemic drugs, eleven patients (37.9%) on insulin therapy, and ten patients (34.5%) on both oral hypoglycemic drugs and insulin therapy [Table 3].

The study showed that ten patients (34.4%) with diabetic foot ulcers had DM for <11 years, whereas 19 patients (65.6%) had DM for 11 years or more [Table 4].

For statistical purposes, we divided the age of the patients into four groups and observed that in the first group (31–40 years), there was one patient with nonhealed ulcer; in the second age group (41–50 years), there were five (71.9%) patients with healed ulcers, and two (24.1%) patients were not healed; in the third age group (51–60 years), there were nine (75.0%) patients with healed ulcers and three (25.0%) patients were not healed, and in the fourth age group (61–70 years), there were six (66.7%) patients with healed ulcers and three (33.3%) patients were not healed. However, the results were not statistically significant ($P = 0.16$) [Table 5].

Table 6 shows the relationship between sex of the patients and the UT-Classification, and we found that there were eight male patients (36.4%) with 1A class and 14 (63.6.%) with 2A class, whereas there were five (71.4%) females with 1A class and two (28.6%) with 2A class.

We found that six females (85.7%) that participated in this study were healed and one (14.3%) was not healed, whereas 14 (63.6%) males were healed and eight (36.4%) were not healed. The results were not statistically significant ($P = 0.224$) [Table 7].

This study also showed the relationship between the healing rate and the site of neuropathic ulcers, and it had been observed that the number of patients with healed ulcers in the forefoot was 18 (78.3%), and there were only five patients (21.7%) with nonhealed ulcers, whereas two patients (40%) had their ulcers healed in the heel area, and there were three patients (60%) with nonhealed ulcers, while the only patient with midfoot ulcer did not show any evidence of healing ($P = 0.034$) (significant) [Table 8].

Table 2: Age distribution

Age (years)	Patients, *n* (%)
31-40	1 (3.4)
41-50	7 (24.0)
51-60	12 (41.4)
61-70	9 (31.0)
Total	29 (100.0)

Table 3: Type of treatment

Type of treatment	Patients, *n* (%)
Hypoglycemic drug	8 (27.6)
Insulin	11 (37.9)
Mixed	10 (34.5)
Total	29 (100)

Table 4: Duration of diabetes and ulcer distribution

Duration of DM (years)	Ulcers, *n* (%)
<5	1 (3.4)
5-10	9 (31.0)
11-15	14 (48.3)
16-20	4 (13.8)
20-25	1 (3.4)
Total	29 (100.0)

DM: Diabetes mellitus

Table 5: Healing to age distribution

Healing	Age (years) (%)				Total (%)
	31-40	41-50	51-60	61-70	
Healed	0 (0.0)	5 (71.9)	9 (75.0)	6 (66.7)	20 (69.0)
Not healed	1 (100.0)	2 (24.1)	3 (25.0)	3 (33.3)	9 (31.0)
Total	1 (100.0)	7 (100.0)	12 (100.0)	9 (100.0)	29 (100.0)

Table 6: Sex and University of Texas-classification

Sex	UT-classification (%)		Total (%)
	1A	2A	
Male	8 (36.4)	14 (63.6)	22 (100.0)
Female	5 (71.4)	2 (28.6)	7 (100.0)
Total	13 (44.8)	16 (55.2)	29 (100.0)

UT: University of Texas

Table 7: Healing to sex distribution

Healing	Sex (%)		Total (%)
	Male	Female	
Healed	14 (63.6)	6 (85.7)	20 (69.0)
Not healed	8 (36.4)	1 (14.3)	9 (31.0)
Total	22 (100.0)	7 (100.0)	29 (100.0)

P=0.224 (NS). NS: Not significant

The total number of planter neuropathic ulcers with 1A class according to UT (UT-Classification) was 13 (44.8%), the number of healed ulcers was ten (76.9%), whereas the number of nonhealed ulcers was three (23.1%), and the total number of ulcers with 2A class was 16 (55.2%), the number of healed ulcers was ten (62.5%) and six (37.5%) ulcers were not healed. The results were not significant ($P = 0.229$) [Table 9].

This study also described the relationship between the type of treatment used to control the level of glucose in diabetic patients and the healing of ulcers; this relationship is summarized in Table 10 and is as follows:

In this study, 11 (37.9%) patients were on insulin therapy; eight (72.7%) of them were healed and three (27.3%) were not. Eight (27.6%) patients were on oral hypoglycemic therapy; three (37.5%) of them were healed and five (62.5%) were not. Ten (34.5%) participants were on mixed therapy (insulin and oral hypoglycemic drugs); nine (90.0%) of them were healed and one (10.0%) was not ($P = 0.137$, not significant).

In this study, the number of healed forefoot ulcers in patients with an obvious forefoot deformity was ten (76.9%), whereas the number of healed forefoot ulcers without an obvious forefoot deformity was eight (80.0%) ($P = 0.32$, not significant) [Table 11].

In this study, we found that no healing of ulcer was obtained before 5 weeks of treatment, whereas there were 12 patients (41.4%) healed between 5 and 8 weeks, eight patients (27.6%) healed between 9 and 12 weeks, and nine patients (31.0%) were not healed, as shown in Table 12.

We found that the minimum time taken by ulcers in order to heal was 6 weeks, whereas the maximum time was 12 weeks, and the mean duration of off-loading time was 8.45 ± 2.2 weeks, as shown in Table 13.

Table 8: Healing to ulcer site

Healing	Site of ulcer (%)			Total (%)
	Forefoot	Midfoot	Heel	
Healed	18 (78.3)	0 (0.0)	2 (40.0)	20 (69.0)
Not healed	5 (21.7)	1 (100.0)	3 (60.0)	9 (31.0)
Total	23 (100.0)	1 (100.0)	5 (100.0)	29 (100.0)

P=0.034 (S). S: Significant

Table 9: Healing to University of Texas-classification of ulcer

Healing	UT-classification (%)		Total (%)
	1A	2A	
Healed	10 (76.9)	10 (62.5)	20 (69.0)
Not healed	3 (23.1)	6 (37.5)	9 (31.0)
Total	13 (100.0)	16 (100.0)	29 (100.0)

P=0.229 (NS). NS: Not significant, UT: University of Texas

Table 10: Healing to type of diabetes treatment

Healing	Treatment (%)			Total (%)
	Insulin	Oral	Mixed	
Healed	8 (72.7)	3 (37.5)	9 (90.0)	20 (69.0)
Not healed	3 (27.3)	5 (62.5)	1 (10.0)	9 (31.0)
Total	11 (100.0)	8 (100.0)	10 (100.0)	29 (100.0)

Table 11: Healing and forefoot deformity

Healing	Forefoot deformity (%)		Total (%)
	Yes	No	
Healed	10 (76.9)	8 (80)	18 (78.3)
Not healed	3 (23.1)	2 (20.0)	5 (21.7)
Total	13 (100.0)	10 (100.0)	23 (100.0)

P=0.32 (NS). NS: Not significant

Table 12: Average time of off-loading of all ulcers

Healing	Off-loading time (weeks) (%)				Total (%)
	<5	5-8	9-12	>12	
Healed	0 (0.0)	12 (60.0)	8 (40.0)	-	20 (100.0)
Not healed	-	-	-	9 (100.0)	9 (100.0)
Total	0 (0.0)	12 (41.4)	8 (27.6)	9 (31.0)	29 (100.0)

Table 13: Off-loading time of healed

	Minimum (weeks)	Maximum (weeks)	Mean (weeks)±SD
Off-loading time	6	12	8.45±2.2

Discussion

There are many types of off-loading strategies used for the treatment of diabetic neuropathic foot ulceration to decrease the incidence of lower limb amputations, but which of these strategies are more suitable remains unclear.

In this study, we evaluated the efficacy of using RCW in the treatment of diabetic neuropathic foot ulcers on forty patients. However, 11 patients were excluded because they were lost to follow-up. The remaining 29 patients completed the study. The mean age of patients was 55.7 ± 7 years and 75.9% were males, with a mean duration of DM of 11.52 ± 4 years.

A study done by Piaggesi *et al*. in 2007 showed that the mean age of patients was 59.8 ± 8.2 years, with a mean duration of DM of 14.7 ± 11.1 years; however, this study was designed to compare between removable and irremovable cast walkers and they found that the healing percentage of ulcers with (RCW) was 85% with a mean duration of 6.7 ± 3.4 weeks.[13]

In this study, we observed that the healing percentage of the first age group (31–40 years) was 0.0%, in the second age group (41–50 years) was 71.9%, in the third age group (51–60 years) was 75.0%, and in the fourth age group (61–70 years) was 66.7%. We believe the low percent of healing in younger age group to be because they are more active than older age groups. However, the relationship

between the age of patients and healing of ulcers was not statistically significant ($P = 0.16$).

Regarding the relationship between the sex of the patients and the healing rate, we found that there was 85.70% healed ulcer in females, whereas in males, the healing rate was 63.6%, and these results were nonsignificant ($P = 0.224$) and are in line with a study done by Margolis *et al*. who used a different method of off-loading, and they found that 51.5% of healed ulcers were in females and 47.5% of healed ulcers were in males.[14] Owing to our cultural traditions, most of the females in our society are confined to home and have less activity and weight bearing compared to males who, most of the time, are away from home engaged in work or other activities.

The planter foot ulcers in this study were most commonly located in the forefoot (79.3%); the heel ulcers represent 17.3% and the least number of the ulcers was located in the midfoot (3.4%). The healing rate of the forefoot ulcers was 78.3%. These results are not in line with the study done by Gutekunst *et al*. who compared between the effectiveness of total contact cast (TTC) and RCW and observed that the RCW provides greater reduction in the key loading variables of peak pressure, pressure-time integral, maximum force, and force time integral in the forefoot region of the foot, a frequent site of diabetic foot ulceration. However, this finding of lower healing proportions (41.6%) in the RCW despite greater load reductions reinforces the importance of compliance in ulcer healing in the diabetic neuropathic foot.[15]

The percentage of planter neuropathic ulcers with 1A class according to UT-Classification was 44.8%, with a healing rate of 76.9%, whereas the percentage of ulcers with 2A class was 55.2%, with a healing rate of 62.5%; however, we found that the total percentage of healing of the ulcers with 1A and 2A classes was 69.0% with a mean duration of 8.45 ± 2.2 weeks. The results in this study seem to be comparable to the result of Faglia *et al*. who observed that the healing percentage of the ulcers was 72.7% with a mean duration of 5.6 ± 0.6 weeks of using RCW.[16] Another study was done in 2005 by Armstrong *et al*. who showed that the healing percentage of diabetic nonischemic neuropathic ulcers was 51.9%, with a mean duration of 8.2 ± 2.1 weeks; however, this study was compared between instant RCW and RCW.[17]

The rate of ulcer healing in this study was reported to be 72.7% with insulin therapy alone and 90% with mixed treatment by insulin and oral hypoglycemic drugs in contrast to only 37.5% in those using oral hypoglycemic drugs alone to control the glycemic status, and this result seems to be in line with Pendsey who found that insulin is an important factor in the healing of diabetic foot ulcers.[18]

We did not utilize local insulin application to the ulcer in this study, but a study done in China by Wu *et al*. in 2009 showed that topical application of insulin can promote the synthesis of wound collagen, accelerate the wound angiogenesis, and speed up the wound healing in aging DM rats.[19]

In this study, the number of healed forefoot ulcers in patients with an obvious forefoot deformity was ten (76.9%), whereas the number of healed forefoot ulcers without an obvious forefoot deformity was eight (80.0%); however, these results are not statistically significant ($P = 0.32$) and are in agreement with the study done by Birke *et al*. who observed that the use of the RCW in the treatment of diabetic neuropathic forefoot ulcer was less effective than shoe modification in a patient with fixed forefoot deformity because accommodation of deformity was limited by RCW; however, they depended on measuring pressure at the site of previously healed ulcer.[20]

Conclusion

RCW is an effective method in the treatment of diabetic neuropathic nonischemic foot ulceration. The healing rate of the ulceration by this method of offloading mainly depends on the site of ulceration in the planter aspect of the foot, in which the forefoot ulcers have a higher rate of healing. The effect of foot deformity in neuropathic forefoot ulceration can be eliminated by using RCW. Patient education and compliance is a cornerstone for the successfulness of this type of off-loading strategy.

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Conflicts of interest

There are no conflicts of interest.

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