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The Effectiveness of Three Layers Foam Dressing as an Offloading Technique in Treating Diabetic Foot Ulcer – Comparative Study

[1]Amal Safar Al Thebati, [2]Nora Mohammed AL-Ouda, [1]Sahar Masri Al khaldi, [3]Asmaa Doghether Al sofyani, [4]Mohamed Al Saeed

[1]King Faisal Hospital,[2]Taif, Prince Sultan Military Medical City – Riyadh, [3]Ministry of Health, Taif, [4]Department of surgery, Taif University

ABSTRACT

Background and aim of the work: and aim of the work: More than 25% of Saudi Arabia population are diabetics, about 20% of the will develop ulcer in their feet. Offloading is the cornerstone in prevention or healing of plantar neuropathic foot ulcers. This study aimed to investigate the effectiveness of use of three layers elastic foam as an off-loading modality in patients with diabetic non infected neuropathic ulcers in term of the speed of healing progress and comparing that with removable walking boat off-loading techniques.

Patients and methods: this prospective double-blind, randomized, controlled clinical trialwas done in diabetic foot care clinics at King Abdul Aziz specialist Hospital, King Faisal general Hospital and Prince Mansour military Hospital, Taif, Saudi Arabia from January 2014 to October 2016.Diabetic patients with non infected neuropathic plantar ulcers after debridement of at least 2 weeks were included in the study. Ischemic ulcers are excluded from the study. Patients who met the inclusion criteria of this study weresubdevided randomized into 2 groups, the felted foam dressings group; in which the three layers felted foam was applied around the ulcer. Control group the removable walking boat was used. In both groups the ulcer was covered with saline soaked dressing to be changed daily.

Results:47 patients were enrolled in the study (23 in felted foam group and 24 in the removable walking boat group). There was no significant difference in the demographics, ulcer size, duration of diabetes, and clinical and laboratory data between both groups ($P > 0.05$). The mean duration of complete healing of the ulcer was highly significantly shorter in felted foam group than in the removable walking boat group ($P < 0.001$). In both groups the duration of healing was negatively correlated with the patient age, the level of HbA1c,andthe ulcer size ($P < 0.05$).

Conclusions: the three layers felted foam is effective, simple, and less expensive offloading technique and it superior to removable walking boat in promoting the complete healing of neuropathic diabetic foot ulcers.

Keywords: neuropathic plantar ulcer, three layer felted foam, removable walking boat.

INTRODUCTION

It is generally accepted that (besides infection control and revascularization, when necessary) pressure relief is the most important measure in the treatment of diabetic foot ulcers[(1,2)].The use of felted foam dressings is a promising but not yet well-standardized technique for the treatment of neuropathic diabetic foot ulcers and may have some advantage over total contact casting or removable walking boat techniques [(1-4)].This study aimed to investigate the effectiveness of use of three layers elastic foam as an off-loading modality in patients with diabetic non infected neuropathic ulcers in term of the speed of healing progress and comparing that with removable walking boat off-loading techniques.

PATIENTS AND METHODS

This prospective double-blind, randomized, controlled clinical trial was done in diabetic foot care clinics at King Abdul Aziz specialist Hospital, King Faisal general Hospital and Prince Mansour military Hospital, Taif, Saudi

Arabia from January 2014 to October 2016 after approval of the ethical committee. Diabetic patients with non infected neuropathic plantar ulcers after debridement of at least 2 weeks were included in the study. Ischemic, neuro-ischemic ulcers or infected ulcers were excluded from the study. Patients who met the inclusion criteria of this study were randomized and subdevided into 2 groups without interference from the treating team, one group to receive the felted foam off loading treatment and in the other group the removable walking boat was used. Complete clinical history and physical examination was done included the inspection of the foot and the palpation of the peripheral pulses. Peripheral diabetic neuropathy was evaluated by measuring the vibration perception threshold with the calibrated tuning fork, fundus examination, and complete organ profile were performed. Patients with neuroischemic or

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ischemic diabetic foot ulcers were excluded from the study. The felted foam dressings group; in which the three layers felted foam (about 9 mm thickness) was measured exactly to fit the plantar aspect of the foot and an aperture was cut from the felted foam at the exact location of the ulcer, allowing clear visualization of the ulcer. Hypoallergic elastic non-woven fabric was wrapped around the foot and the felted foam pad to secure the felted foam which was kept dry all times and the ulcer was covered with sponge soaked in saline to be changed daily. Control group the removable walking boat was used. The primary outcome is to compare the time required of healing in both groups. The secondary outcome is to find a correlation between the time required of ulcer healing with duration of diabetes, level of Hb A1c, presence of nephropathy or and retinopathy. We recorded the changes in the ulcers every week after the onset of the treatment.

Statistical analysis: SPSS program, version 20.0(SPSS Inc., Chicago, IL, USA) was used. The data were expressed in number and percentage (qualitative) whereas, the quantitative data were expressed as means ±SD. The significance between 2 means was tested by Student's t test. The chi-square test (X^2) and Fisher exact (FE) tests were used to differentiate between two groups. $P<0.05$ was considered as statistically significant. Pearson and Spearman's correlation tests were used to correlate between each parameter and different variants in the same group to find significant differences.

RESULTS

47 patients were enrolled in this study (23 in felted foam group and 24 in the removable walking boat group). Table 1 shows no significant difference in the demographics, ulcer size, duration of diabetes, and clinical and laboratory data between both groups ($P > 0.05$). The mean duration of complete healing of the ulcer was highly significantly shorter in felted foam group than in the removable walking boat group ($P < 0.001$). Comparing the mean duration of healing in both groups below and above the median values of the level of HbA1cand the ulcer size; significant negative correlations were found. The duration of healing is not significantly correlated with gender, age of the patient, or duration of diabetes.

DISCUSSION

Absence of sensation in neuropathic patient which prevent the patient to respond to noxious stimuli, neuropathic changes in the plantar muscles resulting in structural foot deformity due to, such as hammertoes, bunions, metatarsal deformities will lead to imbalanced distribution of pressure load and stress during ambulation and finally will end in pressure necrosis and ulceration[1].In this study all patients had diabetic neuropathy.

Various off loading modalities have been used for the relief of the plantar load at the ulceration site which is one of the most important factors in the outcome of neuropathic foot ulcerations[2-4]. Felted foam padding has been used for a long time for redistribution of foot pressure; however, to date, there are little published controlled studies describing outcomes associated with this padding technique[1]. In our study we compared the felted foam technique as a loading modality with the removable walker.

In contrast to other methods for pressure relief, such as total contact cast or football dressings, felted foam enables daily dressing changes and can be used in patients with smaller infections[5].In this study the dressing covering the ulcer have been changed daily. However, the removable cast walker offers several advantages over total contact cast as it can be easily removed for self-inspection of the wound and application of topical therapies, in addition, patients can sleep more comfortably (as in felted foam dressing) when wearing these devices than those with total contact cast or football dressing[6-8].

Holmes and Timmerman concluded in their study that, felted foam pads, when properly positioned, can be an inexpensive and effective means of reducing plantar pressure in the shoe[9].Hayda *et al*. reported similar findings[10]. Zimny*et al*. evaluated the effects of felted foam on wound healing in diabetic neuropathic ulcers compared with a standard method of offloading and they suggested that it may be a useful alternative in treating neuropathic foot ulceration, especially in patients who are unable to avoid weight-bearing[11]. In our study, the ulcers of all patients treated with felted foam healed completely within a mean period of about 20 weeks which was highly significantly shorter than in the removable walking boat group ($P < 0.001$). However, Fleischli *et al*. found in their study that total contact cast and removable walkers achieved the best reduction of plantar pressures at the site of

neuropathic ulcerations followed by the felted foam dressing and surgical shoe[12]. The difference with our results may be related to the ulcer characteristics and the methodology used.

A strong association between HbA1c which is standard measure of glycemia over 2–3 months and healing of neuropathic foot ulcer is unclear; however, Christman *et al*. in their study suggested that glycemia, as assessed by HbA1c, may be an important biomarker in predicting wound healing rate in diabetic patients[13]. In adherence to their findings, we verified in our study that the duration of healing of the ulcers were significantly correlated to the level of HbA1c and in turn to the glycemic control.

Margolis *etal*. in their study reported that the factors which may contribute to neuropathic ulcer healing, were ulcer surface area, ulcer duration, and the race of the patient with no relationship with age and sex [14-16].The results of the previous study were in accordance of our results; but, we didn't correlate the healing rate with duration of the ulcer or the race of the patient.

Mrdjenovich found in his study that for successful outcomes several factors must be integrated which include; the increase in oxygen to the ulcer, decrease infection, maintain good glycemic control, with adequate pressure and strain relief[17].These findings were in accordance with the results of our study; however, we excluded from this study infected and ischemic ulcers.

CONCLUSIONS: the three layers felted foam is effective, simple, and less expensive offloading technique and it superior to removable walking boat in promoting the complete healing of non infected neuropathic diabetic foot ulcers.

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Table 1: Patient characteristics

	Group I (felted foam treatment)	Group II (removable boat walkers)	P value
Total number	23	24	
Sex (%) Male Female	 14 (61) 9 (39)	 16 (66.7%) 8 (33.3%)	 NS NS
Age: Mean ±SD (years): Male Female	 61.6 ± 12.7 58.7 ±13.4	 60.3 ± 11.8 56.6 ± 14.1	 (NS) (NS)
Mean duration of diabetes (years)	14.9±3.7	15.2±3.1	0.89 (NS)
Control of diabetes: Oral hypoglycemic Insulin Dietary control	 10 (43) 9 (39%) 4 (28%)	 12 (50) 7 (29) 5 (21)	 (NS) (NS) (NS)
Smokers Neuropathy Mean toe pressure Mean Hb A1 C percentage before treatment	19 (82.6%) 23 (100) 58.7±8.6mm Hg 9.7±2.4	16 (66.6) 24 (100) 57.4±6.5mm Hg 9.1±2.6	(NS) (NS) (NS) (NS)
Mean ulcer size (cm)	10.1±2.3	9.7±1.9	P > 0.05 (NS)
Mean duration of ulcer healing (years)	20.4±4.6	38.9±9.2	P< 0.001 (HS)

NS; non significant, Hs; highly significant

Figure 1: Shows the application of the felted foam and the plantar ulcers before and after healing