

Observation of Efficiencies of Different Off-loading Methods in Patients with Diabetes Mellitus and Forefoot Ulceration

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Abstract

Objective: Comparison between the groups of diabetic patients using total contact cast, accommodative dressing, a healing shoe, and a walking splint for healing of forefoot ulcers.

Methods: It is a Retrospective Study taking place in the Outdoor Department of General Surgery, Nishtar Hospital Multan, during 1st January 2020 to 15th April 2021.

A total of 164 patients were included in the study. Offloading was done in patients with the help of healing shoe, accommodative dressing which was fitted in a modified surgical shoe, a total contact cast (TCC), walking splint or combined methods that were termed as others. Different variables such as age, location of the ulcer, its depth, length, width and duration along with grading of diabetic foot (Grade I=superficial ulcer, Grade II=deep ulcer, Grade III=deep to the bone ulcer) [30] were used to adjust the overall healing time of the ulcer. Categorical variables were assessed by calculating their frequency and percentage while quantitative variables were assessed by calculating their mean and standard deviation. Chi square test was applied to assess the correlation among different variables. A P value of less than or equal to 0.05 was considered as statistically significant.

Results: Mean healing time was 33.84 ± 14.82 days in Total contact cast group; 26.89 ± 11.05 days in Accommodative dressing group; 32.17 ± 9.06 days in Healing shoes group; 39.96 ± 13.06 days in Walking splint group and 41.54 ± 13.15 days in other treatment modalities group, and the difference was statistically significant ($p < 0.001$). Total 13 ulcers did not heal, one in Total contact cast group; 02 in Accommodative dressing group; 05 in Healing shoes group; 02 in Walking splint group and 03 in other treatment modalities group, and the difference was statistically insignificant ($p = 0.178$).

Conclusion: It can be concluded from the results of the study that use of customized dressings was significantly associated with decreased healing time in forefoot ulcers.

Keywords: Forefoot, Ulcer, Healing, Off-loading, Diabetic Foot, Total Contact Cast, Accommodative Dressings, Walking Splints.

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Introduction

More than 70% of diabetes-related lower-extremity amputations occur due to foot ulceration which is a serious complication.¹ Almost 15% of diabetic

patients were reported to develop ulcerative foot once in the lifetime.² Causes of foot ulcer include loss of sensation and mechanical stress along with the walking stress which may enhance the incidence of injury.³ Areas with highest pressure lead to plantar ulcerations which require removal of stress for healing the wounds.³ There are number of suggested methods for removal of stress for healing foot ulcer.⁴ The total contact cast has been reported to be effective method for reduction of the pressure in case of foot ulcer promoting wound healing.⁵ It is considered as most effective method used for the wound healing and regarded as gold standard in the foot ulcer.⁶ Due to special skills required for the fabrication and time taking method along with apparent risk for secondary injuries, the use of casts

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have not been common. Alternative to the casts which are made custom to fit the ulcerative foot includes healing footwear, foam dressings, walking splints, and accommodative dressings.⁷ These devices are preferred because they offer local pressure over point of high pressure and reduce the pressure at lesion area as compared to prefabricated devices for ulcerations over the foot. Custom made devices include walking splints, custom-modified shoes, and wedged sole shoes proved to effective in the off-loading pressure and healing of wound at the site of ulcer over the foot.⁸

When compared to prefabricated shoes the custom-modified shoes proved to be more helpful in the reduction of pressure at the forefoot.⁸ Studies are not present on the use of accommodative dressings for healing of wound but these are used for reduction of pressure on foot.⁹ Current study revolves around the comparison between the group of diabetic patients using total contact cast and those using alternative custom made devices for pressure reduction such as accommodative dressing, a healing shoe, and a walking splint for healing of fore-foot ulcers.

Methods

Diabetic patients presenting to the outdoor department of General Surgery, Nishtar Hospital Multan with primary complaint of neuropathic ulceration of the forefoot and treatment without surgery during 1st January 2020 to 31st May 2020 were included in the study. It is a retrospective study. Ethical approval for the study was obtained from the Ethical Board of Nishtar Hospital Multan. The sample size for this study was calculated using the reference study by Brike et al.¹⁰ A non probability consecutive type of sampling technique was used. Patients with recurrent diabetic foot ulcer, postoperative lesion, osteomyelitis, ulceration on other parts of the foot (mid-foot, non-plantar, rear-foot), ulcers with abscess formation and ischemic wounds were excluded from the study. Patients were tested for neuropathy with 10g filament of nylon and had loss of sensation. A total of 164 patients were included in the study and their medical records were reviewed retrospectively. Offloading was done in patients with the help of healing shoe, accommodative dressing which was fitted in a modified surgical shoe, a total contact cast (TCC), walking splint or combined methods that was termed as others.

Use of walking splint and TCC was done according to

the previously illustrated guidelines¹¹. Healing shoe was a surgical shoe modified with non-polyethylene foam inlay while accommodative dressing was a six inches long adhesive felt which was quarter inch thick and it was attached over the fore-foot by making a cut-out on the ulcerated area. Furthermore accommodative dressing was modified by fitting it into the surgical shoe and with a wedged sole.

Other protocols such as antibiotics for cellulitis and use of moisture retaining dressings in all methods except TCC and accommodative dressings were followed as such. In TCC and accommodative dressings dry type of dressings was used. Changing of accommodative dressings was done weekly and TCC with 1 to 3 intervals while remaining patients were advised to change dressings daily. All patients were followed weekly for debridement of the wound and examination. Nineteen patients were applied with total cast, 39 with accommodative casts, 70 with healing shoes, 25 with walking splints and 11 with other off loading methods.

Ambulation of the patients was not controlled however patients were advised to use walkers etc for weight bearing ambulation. Data was collected by the researcher himself. Which patient will receive which method, was left to the discretion of the clinician. The largest ulcer on the forefoot was assessed for analysis of the outcomes. Different variables such as age, location of the ulcer, its depth, length, width and duration along with grading of diabetic foot (Texas University grading; Grade I=superficial ulcer, Grade II=deep ulcer, Grade III=deep to the bone ulcer)³⁰ were used to adjust the overall healing time of the ulcer.

All the data thus collected was subjected to statistical analysis using SPSS version 23. Categorical variables were assessed by calculating their frequency and percentage while quantitative variables were assessed by calculating their mean and standard deviation. Chi square test was applied to assess the correlation among different variables. A P value of less than or equal to 0.05 was considered as statistically significant.

Results

Patients were divided into five groups depending on their treatment modalities. There were no statistically significant differences in terms of mean age and gender distribution among the groups (p-value 0.072 and 0.088, respectively). Mean ulcer duration was $134.11 \pm$

50.07 days in Total contact cast group; 113.23 ± 41.91 days in Accommodative dressing group; 83.84 ± 33.74 days in Healing shoes group; 111.96 ± 47.93 days in Walking splint group and 101.55 ± 42.68 days in other treatment modalities group, and the difference was statistically significant ($p < 0.001$). Table-I

There were no statistically significant differences

Table 1: Group Characteristics

Group	N	Age, years	Gender, M / F	Ulcer duration, days
Total contact cast	19	52.84 ± 8.86	9 / 10	134.11 ± 50.07
Accommodative dressing	39	58.05 ± 6.65	21 / 18	113.23 ± 41.91
Healing shoes	70	57.71 ± 6.68	26 / 44	83.84 ± 33.74
Walking splint	25	57.24 ± 6.56	8 / 17	111.96 ± 47.93
Others	11	58.54 ± 7.27	8 / 3	101.55 ± 42.68
p-value	-	0.072	0.088	<0.001

observed among the groups in terms of Wagner grade, length of ulcer, width of ulcer and depth of ulcer (p-value 0.464, 0.305, 0.935 and 0.850, respectively). Table-II

Table 2: Ulcer Characteristics

Group	Wagner grade	Length, cm	Width, cm	Depth, cm
Total contact cast	1.95 ± 0.78	2.95 ± 1.26	1.89 ± 0.73	0.82 ± 0.36
Accommodative dressing	1.87 ± 0.80	3.02 ± 1.20	1.95 ± 0.72	0.79 ± 0.37
Healing shoes	1.91 ± 0.77	2.96 ± 1.16	1.98 ± 0.73	0.85 ± 0.38
Walking splint	1.96 ± 0.79	3.01 ± 1.15	1.88 ± 0.72	0.79 ± 0.35
Others	1.91 ± 0.83	2.18 ± 0.98	1.82 ± 0.75	0.91 ± 0.38
p-value	0.464	0.305	0.935	0.850

Mean healing time was 33.84 ± 14.82 days in Total contact cast group; 26.89 ± 11.05 days in Accommodative dressing group; 32.17 ± 9.06 days in Healing shoes group; 39.96 ± 13.06 days in Walking splint group and 41.54 ± 13.15 days in other treatment modalities group, and the difference was statistically significant ($p < 0.001$). Total 13 ulcers did not heal, one in Total contact cast group; 02 in Accommodative dressing group; 05 in Healing shoes group; 02 in Walking splint group and 03 in other treatment modalities group, and the difference was statistically insignificant ($p = 0.178$).

Wound closure at 12 weeks was observed in 95% of Total contact cast group; 95% of Accommodative dressing group; 77% of Healing shoes group; 76% of Walking splint group and 64% of other treatment modalities group, and the difference was statistically significant ($p = 0.028$). Table-III

Table 3: Comparison of Healing Time

Group	Healing time, days	Not healed, N	Closed at 12 weeks, %
Total contact cast	33.84 ± 14.82	1	95%
Accommodative dressing	26.89 ± 11.05	2	95%
Healing shoes	32.17 ± 9.06	5	77%
Walking splint	39.96 ± 13.06	2	76%
Others	41.54 ± 13.15	3	64%
p-value	<0.001	0.178	0.028

Discussion

This study was conducted for determination of effectiveness of alternative methods of off-loading the pressure from the different grades of ulcerative foot^[30]. when compared these devices to the total contact casts for the purpose of healing of wound. Findings of the studies suggested that the diabetic patients with forefoot ulcer in which custom made devices (an accommodative dressing, fit in a modified surgical shoe, healing shoe, or walking splint) were used had better rates of wound healing by off-loading pressure than those in which total contact cast was used. Clinicians selected of the method of off-loading, which required different factors to be considered such as preference of patient, severity of symptoms, patient's mobility, compliance of patient to the method, and time required for fabrication. Time required for healing may also be affected by these factors and use of different types of topical dressings for different methods of off-loading may also effect the healing. These uncontrolled factors were the major limitations in this study while identifying the most effective off-loading method.

Different aspects such as area of ulcer, age of patient, and duration of ulcer were taken under account before selection of the methods of off-loading. However for off-loading of plantar ulcers total contact cast was regarded as gold standard method by the authors. As our study included the diabetic patients of young age and total contact cast was used for ulcer located at metatarsal area only. For toe ulcer the healing shoe was a preferred method of offloading. In this study combination of accommodative dressing and modified surgical shoe were used but studies must determine

the effect of each method separately in ulcer healing.

Our study revealed that the healing progress was 24% in 12 weeks which is much higher than the studies in which no customized method was used with standard wound care for off-loading.¹² Implementation gap between off-loading techniques used in both studies, or poor professional training for use these techniques lead to this difference in the outcomes. These findings highlight the requirement of effective off-loading methods that can be used by the medical related personals managing foot ulcer including nurses, podiatrists and physical therapists.

In a study done by David et al.,¹³ findings suggested that total contact cast was more effective in wound healing and require less time for healing as compared to the other off-loading methods including removable cast walker and half shoe. In other studies it was reported that by the use of total contact casts time required for healing of ulcer was only 6-8 weeks.¹⁴ High percentage of wound healing was reported in descriptive and randomized clinical trials by the use of total contact cast than that of topical growth factors, bioengineered tissue, or special dressings.^{15,16,&18}

Current study involved the analysis of different off-loading methods used for ulcer healing in diabetic patients in order to determine the most effective method for meeting the requirements at different levels of population and clinical disciplines and settings. Accommodative dressing and the healing shoe were two off-loading methods used in this study providing custom relief to the ulcer area, needed simple fabrication thus require less training and less time to apply it over the ulcerative foot as compared to total contact cast. For prevention from further injury and effective off-loading care must be taken while applying any technique. Less difference of the healing time by the use of different techniques used by two different clinicians in this study supported the general effectiveness of these methods.

Conclusion

It can be observed from the results of the study that use of accommodative dressings like customized dressings was significantly associated with decreased healing time in forefoot ulcers.

Conflict of Interest: *None*

Funding Source: *None*

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Authors Contribution

M.A: Conceptualization of Project

M.I: Data Collection

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Z.I.M: Statistical Analysis

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K.H.Q: Writing of Manuscript