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Offloading–An Effective Treatment in the Healing of Diabetic Foot Lesions.

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ABSTRACT

Background: To compare the effectiveness of Total contact casts (TCCs), Removable cast walkers (RCWs) and half-shoes to heal diabetic foot lesions. **Methods:** This proposed study was carried out as a prospective, randomized clinical trial in 100 patients diagnosed diabetic foot with superficial non-infected, non-ischemic diabetic plantar foot ulcers. Out of 100 pts, 10 pts did not use any prosthesis and in 90 pts, one of the three offloading modalities was used: Total contact cast (TCC), Removable cast walker (RCW) and half shoes (HS). Outcomes were assessed at wound healing or at 12 weeks, whichever came first. Primary outcome measures included duration of healing of diabetic wounds and also regarding the percent of wounds healed completely after 12 weeks. **Results:** The proportions of healing for patients treated with TCC, RCW, and HS were 85.7, 68.7, and 56.2%, respectively. A significantly higher proportion of patients were healed by 12 weeks in the TCC group when compared with the two other modalities. There was also a significant difference in survival distribution (time to healing) between patients treated with a TCC and both an RCW and half-shoe. The mean number of days to complete wound healing is 30 days for TCC, 52 days for RCW and 60 days for HS. **Conclusion:** The TCC seems to heal a higher proportion of wounds in a shorter amount of time than two other widely used off-loading modalities, the RCW and the half-shoe.

Keywords: Offloading, Total contact cast, Removable cast walker, Half shoes, Diabetic foot.

INTRODUCTION

The rapid rise in the incidence of diabetes, a serious, life-long condition, is of alarming concern to health care professionals. Neuropathic ulcers are the prime precipitant of diabetes-related amputations of the lower extremity.[1] The central goal of any treatment program designed to heal these wounds is effective reduction in pressure (off-loading).[2] Total-contact casts (TCCs) are considered the gold standard of ulcer treatment by many experts in this field.[3-16] In this study we want to discover the clinical effectiveness of various prosthetic devices which off-load ulcer sites to facilitate wound healing.[17] Therefore, the purpose of this study is to prove that using prosthesis for diabetic wounds is better and also to compare the effectiveness of TCCs, removable cast walkers (RCWs), and half-shoes to heal neuropathic foot ulcerations in individuals with diabetes.

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MATERIALS AND METHODS

This proposed study was carried out as a prospective, randomized clinical trial in 100 patients diagnosed diabetic foot; in the department of Surgery, Krishna Institute of Medical Sciences, Karad after getting approval from the Ethics Committee. In this trial, TCC was given to 42 patients, RCW was given to 32 patients and half shoes were given to 16 patients. 10 patients did not use any prosthesis. The diagnosis of diabetes had been made before enrolment and was confirmed either by communication with primary care providers or by reviewing medical records. All the pts had neuropathic plantar diabetic foot ulcer corresponding to grade 1A (superficial, not extending to tendon, capsule, or bone using the University of Texas Diabetic Foot Wound Classification System).[20] Neuropathy was defined as the inability to sense the 10-g Semmes-Weinstein monofilament and a vibration perception threshold .25 V.[18-21] Patients who had active infection, were unable to walk without wheelchair assistance, had wounds in locations on the heel, rear foot, or area other than the plantar aspect of the foot, or had severe peripheral vascular disease (diagnosed by the criteria listed above) were excluded from the study. If patients had more than one plantar wound, the largest wound was used as the index ulcer for inclusion in this study.

The clinical study protocols and the informed consent that each patient was required to sign were approved

by the Institutional Review Board and ethical committee. TCCs were applied using a modification of the technique described by Kominsky.[22] TCCs were changed on a weekly basis or as clinically necessary. RCWs and half-shoes were applied using the directions dispensed with the original packaging. All patients were instructed to use the devices at all times during ambulation. All patients were followed on a weekly basis for device inspection, wound care, and wound debridement. All wounds were surgically debrided as required at each visit. Wounds were measured using a computerized planimetric video wound measurement system. [23]

Table 1: Showing number of patients with different prosthesis

	No of cases	Percentage
Prosthesis used	90	90%
Non removable		
Total contact cast (TCC)	42	42%
Removable		
Removable cast walker (RCW)	32	32%
Half shoes (HS)	16	16%
Prosthesis not used	10	10%

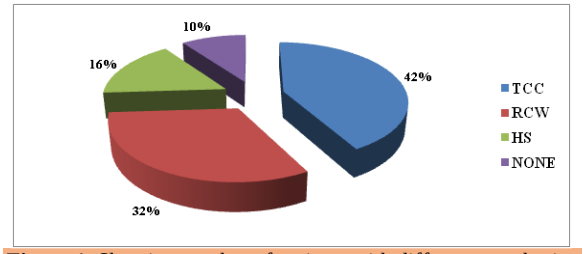

Figure 1: Showing number of patients with different prosthesis

Outcomes were assessed at wound healing (defined as complete epithelialisation) or at 12 weeks, whichever came first. Primary outcome measures included proportion of complete wound healing at 12 weeks.

RESULTS & DISCUSSION

The pts were followed for 12 weeks and the response of the prosthesis was noted [Table 1, Figure 1]. Out of 42 pts who used TCC, 30 pts got healed completely and therefore the proportion of wound healing came out to be 85.7 %. Out of 32 pts who used RCW, 22 pts got healed completely which came out to be 68.7 % and the number of pts who got healed with HS were 9 out of 16, which came as 56.2 %. The pts who did not use any offloading prosthesis got healed only 3 out of 10 and that is 30 % [Table 2].

At 12 weeks, the proportion of healing was significantly higher in the TCC group than in the patients treated with the two other modalities (85.7 vs 68.7 vs 56.2)

Table 2: Showing percent of wounds completely healed with different prosthesis

Prosthesis	No of patients	No of wounds healed	Percentage
TCC	42	36	85.7 %
RCW	32	22	68.7 %
HS	16	9	56.2 %
None	10	3	30 %

Among patients healing within the 12-week period, the mean number of days to complete wound healing is 30 days for TCC, 52 days for RCW and 60 days for HS. The mean days for the pts who did not use any prosthesis is 70 days [Table 3, Figure 2]. The mean time to healing was significantly shorter in patients treated with the TCC compared with those treated with RCW and half-shoe.

Table 3: Showing mean days to complete healing with different prosthesis

Prosthesis	No of patients	Mean days to complete healing
TCC	42	30
RCW	32	52
HS	16	60
None	10	70

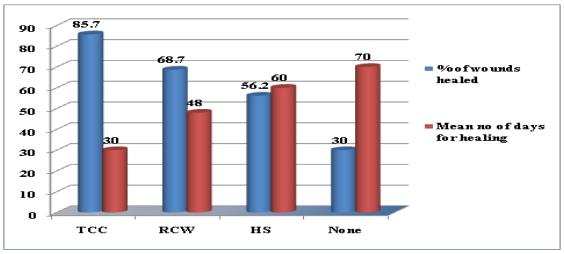

Figure 2: Showing percent of wounds healed completely with mean no of days

The result of this study suggests that, use of Offloading and Prosthesis is always better than not using any prosthesis with regards to the duration of healing of diabetic wounds and also regarding the percent of wounds or the pts healed completely. Among the different types of prosthesis used the Total contact cast (TCC) is better than other types of prosthesis like Removable cast walker (RCW) or Half shoes (HS) with respect to percent of wounds healed completely and also the mean duration of wound healing. The TCC heals a higher proportion of wounds in a shorter amount of time than two other widely used off-loading modalities, the RCW and the half-shoe. Additionally, it seems that patients are less active when treated with the TCC than with the half-shoe. This reduction in activity and ability to aggressively off-load the plantar aspect of the foot may partially explain the success of the TCC. As noted earlier, TCCs are considered by most diabetic foot specialists to be the gold standard off-loading modality for treatment of wounds on the sole of the foot. [3]

CONCLUSION

In conclusion, this study suggests that there are significant differences in wound healing based on the off-loading device selected. The central tenets of healing the non-infected, non-ischemic diabetic wound have and will continue to be appropriate debridement and pressure reduction.

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