

Difference between Surgical Offloading and Mechanical Offloading in Treatment of Planter Diabetic Foot Ulcer

*Omar Mohamed Assaed¹, Wesam Amr¹, Hatem Mohammed Abdel Monaem Farg¹, and Mahmoud Abdo Yassin¹

⁽¹⁾ Department of General Surgery, Zagazig University Hospitals, Zagazig, Egypt.

Correspondence to: Omar Mohamed Assaed Abdo Abady.

E-mail: Omar_as3d@yahoo.com, wesam_amr@yahoo.com ORCID <https://orcid.org/0000-0002-4475-7844>, dr.hatem.2009@gmail.com, mahmoudyassin42@yahoo.com

Abstract:

Background: Peripheral neuropathy is a common complication of diabetes. Loss of protective pain sensation results in plantar diabetic foot pressure ulcers due to recurrent shear and tear forces. Offloading the pressure from the sole of the foot is crucial in the healing process of those ulcers. **Objective:** To review different of offloading in the treatment of in the healing of pressure, to evaluate the critical of each modality in the healing process and the safety of each modality. **Patients and Methods:** This prospective non-randomized comparative study which included 30 diabetic patients with chronic non-ischaemic non- healed plantar pressure ulcers; 15 of them was managed by surgical offloading methods and 15 of them with non-surgical (air walker and therapeutic foot shoes). They were followed up for ulcer healing for 6 months. **Results:** In the surgical group 86.7% had a completely healed pressure ulcers while in the non-surgical patients 80% had a healed pressure ulcers at the end of follow up period (6 months). Complications we faced during follow up period were infection, recurrence and non-healing. **Conclusions:** Either surgical or non-surgical modalities could be used without significant difference between them in their outcome. We should tailor the most suitable method for every patient.

Keywords: Diabetes, Peripheral neuropathy, Diabetic Foot

INTRODUCTION

Peripheral neuropathy, when combined with increased plantar pressures plays an important role in the development of diabetes related neuropathic foot ulceration. It is known that insufficient pressure-relief during the treatment of neuropathic foot ulcers leads to delayed wound healing. Most studies agree that the relief of peak pressures on plantar ulceration represents the central point of treatment. Bed rest, wheelchairs and crutches have all been described as ineffective, primarily due to their effect on the quality of life of the patient. The reduction of plantar pressure has been described using various methods with the current recommended

methods being those that off-load the plantar surface of the foot, yet maintain some degree of mobility⁽¹⁾.

Studies showed that raised plantar pressure is a causative factor in the development of plantar ulcers in diabetic patients which is a risk factor of lower extremity amputation. About 50%-86% of lower limb amputations in diabetic patients are preceded by foot ulcers, which are often caused by ill-fitting footwear^(2,3).

Once the skin is ulcerated, it is susceptible to becoming infected, an urgent medical problem. Only two-thirds of foot ulcers will eventually heal^(4,5).

Every year, more than 1 million people with diabetes lose at least a part of their leg as a consequence of the complications of diabetes. This translates into the estimate that every 20 seconds a lower limb is lost due to diabetes somewhere in the world⁽⁶⁾.

Early effective management of DFU as follows: education, blood sugar control, wound debridement, advanced dressing, offloading, advance therapies and in some cases surgery, can reduce the severity of complications, and also can improve overall quality of life of patients especially by using a multidisciplinary team approach⁽⁷⁾.

Offloading is crucial in preventing and healing pressure related plantar diabetic foot ulcers. In the management of diabetic foot ulcers, “offloading” the terminology that means pressure modulation-is most successful when pressure is mitigated at an area of high vertical or shear stress. Common methods to offload the foot include bed rest, wheel chair, and crutch assisted gait but are not practical due to the limitations of the patient’s autonomy and the quality of their life. Offloading orthotic devices allow free mobility of the diabetic foot patients. Alternative modalities of offloading are like total contact casts, felted foam, half shoes, therapeutic shoes, removable cast walkers and finally surgical offloading^(8,9).

Appropriate and efficient off-loading is essential to a successful management of diabetic foot planter ulcers. The aim is to redistribute the pressure over the plantar aspect of the ulcerated diabetic foot, so it can decrease pressure at ulcer site⁽⁹⁾. We performed this study to review different of offloading in the treatment of in the healing of pressure, to evaluate the critical of each modality in the healing process and the safety of each modality..

PATIENTS AND METHODS

A total of 30 diabetic patients with chronic non-ischaemic non- healed plantar pressure ulcers from 33-65 years from 33-65years (15 males, 15 females) attending the Department of general surgery at the zagazig university hospital and Department of Vascular and Endovascular surgery at the National Institute of Diabetes and Endocrinology (NIDE) in the period from July 2019 till September 2019. **Inclusion criteria were;** Informed consent was taken. The demographic data was recorded; age and sex. Diabetic patients with plantar ulcers (possibly pressure related) that failed to heal after 6 months with at least one of the foot pulses (Dorsalispedis or Posterior tibial) easily palpable.

Pre-Procedural:

All patients were subjected to Demographic data taking with special emphasizing on duration of the ulcer, previous treatment or recurrent ulcers, complete clinical examination, The wounds were photographed before intervention. HbA1C, CBC, INR, KFTs, LFTs and serum albumin were done for all patients. Foot x-rays were done for all patients. The modality of the offloading was determined based on presence of osteomyelitis. Fitness for anaesthesia Patient preference.

Operative technique:

Surgical offloading group:

All patients fasted at least 6 hours. Under spinal anaesthesia and complete aseptic condition. The underlying osteomyelitic bone was excised, the hyperkeratotic ulcer edges were curetted and trimmed then approximated or primarily closed with prolene sutures. Follow up X-rays were done before discharge. All patients were ordered not to weight bear until suture release then offloaded by walkers or therapeutic shoes according to protocol of non- surgical group.

Non-Surgical offloading group:

Patients who had Charcot Joint received Air Walker, while other patients received Therapeutic Footwear after curettage and trimming of the hyperkeratotic margins.

Post-procedural:

The ulcers were followed up by measuring their sizes and photographed at a regular basis; once weekly during 1st month, twice monthly till healing occurred then once monthly till the end of follow up period (6 months). HbA1C and foot x-ray were repeated after 3 months from the start. All patients were followed up for 6 months and complications were recorded classified as granulating with ongoing healing progress, complicating in the form of infection, non-healing or recurrence. All dressings were performed depending on the wound status during follow up period.

Statistical analysis

Data were explored for normality by checking the data distribution and using Kolmogorov-Smirnov and Shapiro-Wilk tests. Comparisons between the 2 groups with respect to normally distributed numeric variables were done using the t- test. Non-normally distributed numeric variables were compared by Mann- Whitney test. For categorical variables, differences were analyzed with chi square (χ^2) test and Fisher's exact test when appropriate. Adjustments of p value were done using the Bonferroni method for multiple testing. All p-values are two- sided. P-values ≤ 0.05 were considered significant.

RESULTS:-

In our study 100 cases who had D.F.U.s were assessed for eligibility general surgery at the Zagazig university hospital and Department of Vascular and Endovascular surgery at the National Institute of Diabetes and Endocrinology (NIDE) by the end of September 2019 from 100 assessed cases, 30 cases had included in the study, 70 had excluded due to absence of pedal pulse or case refusal. The flow chart of the cases through the study followed the CONSORT flow diagram had presented in (Fig. 1).

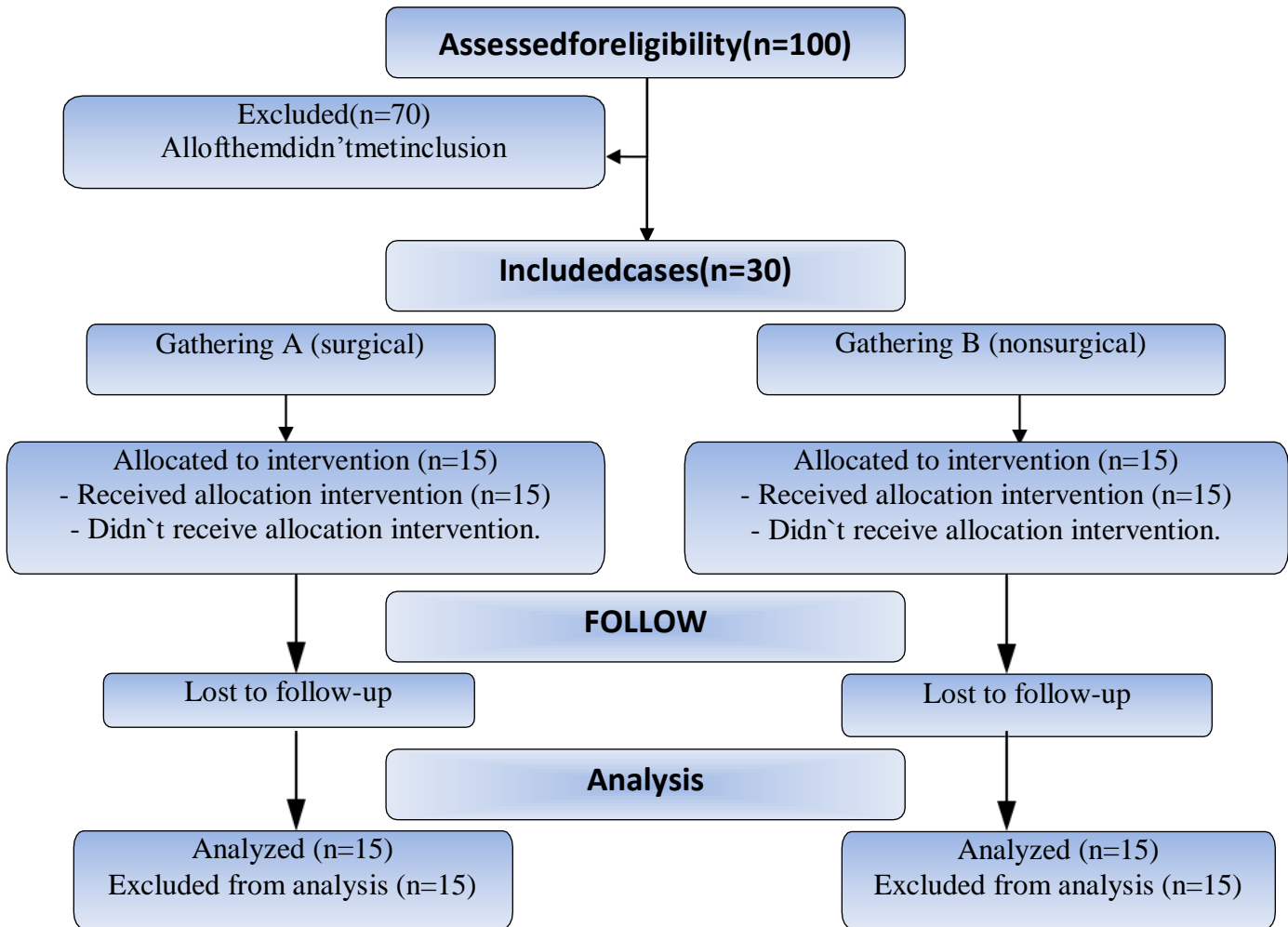


Fig. (1):CONSORTFlowdiagramofthestudy.

Table (1): Demographic Data of Studied Cases.

Data		SurgicalGroup(n=15)	NonsurgicalGrou p (n=15)	P valu e
Age		43±4.2	45±3.5	>0.05
Sex	Male	10	9	
	Female	5	6	
Smokingstatus	Yes	9	8	
	No	6	7	
Descriptivcharacteristicsofdiseasegatherin gs				
Duration ofdiabetes		1.3±0.8	1.4±1.4	>0.05

Woundduration(months)	4.3±5.7	5.6±6.2	>0.05
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Table 1; showed that there were no significant difference between both groups regarding Demographic Data. There were no significant difference between both groups as regard Duration of diabetes or Wound duration.

Figure 2; showed that there is no significant difference between both groups regarding Characters of Ulcer.

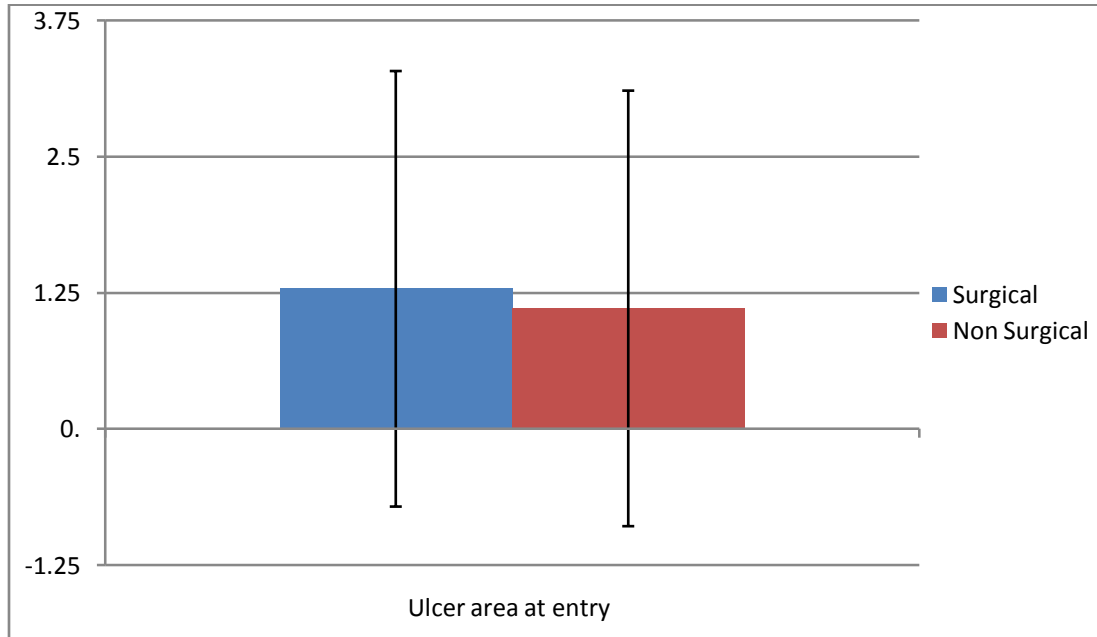


Fig. (2): Ulcer area at entry group.

C. Outcome, End result of study:

At the end of the Follow up period (6 months) there is no significant difference between two groups in number of patients who had healed wounds. 13 of the 15 surgical offloading patients (86.7%) had a completely healed pressure ulcer with range of healing between 4-14 weeks. In non-surgical patients; 12 of 15 (80%) had a healed pressure ulcer with range between 3-23 weeks. There is significant difference in mean duration of healing between two groups.

Figure 3; showed that there were no significant difference between both groups as regard Characters of Ulcer.

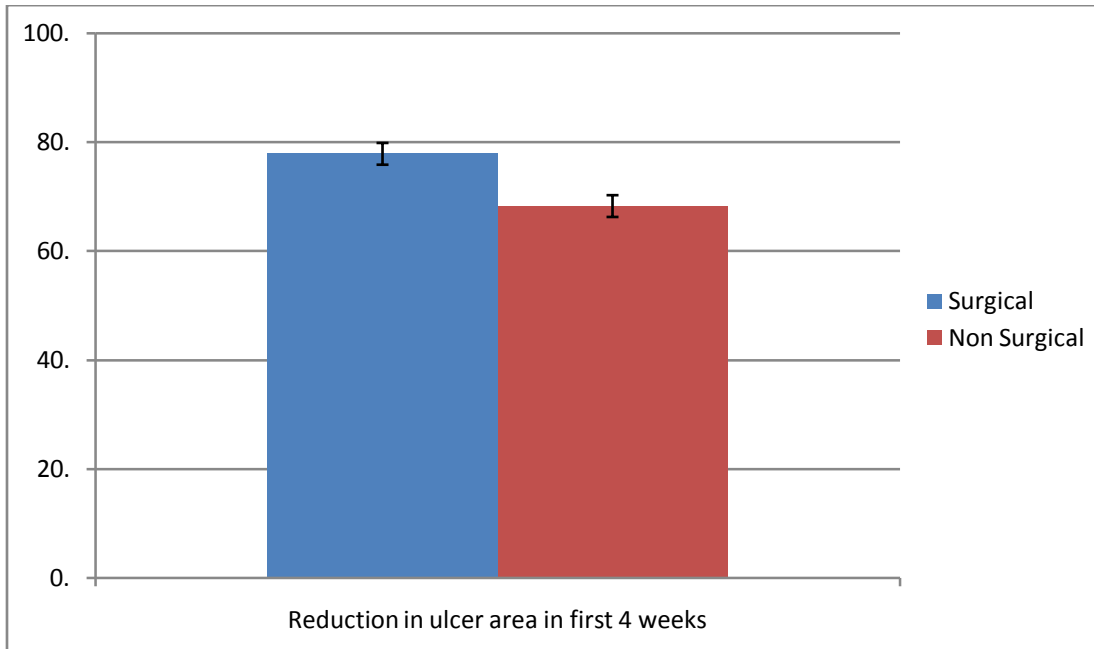


Fig. (3): Reduction in ulcer area in first 4 week

The following table shows that there is significant difference between both groups regarding in offloading device or Peak pressure reduction in device figure 4.

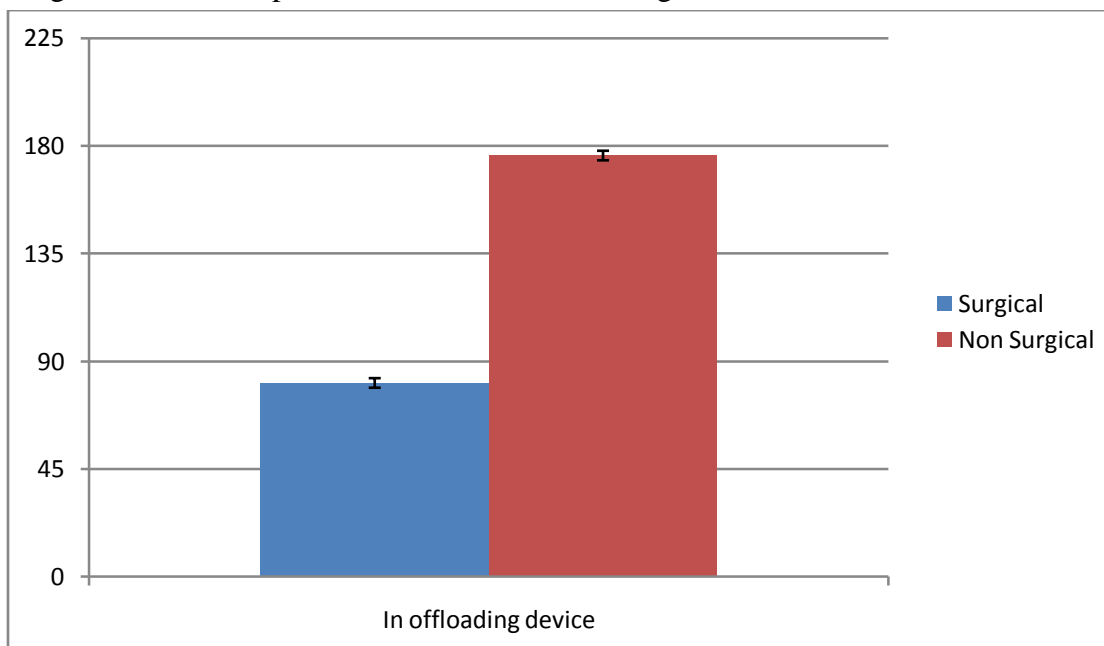


Fig. (4): Mean In offloading device.

Figure 5; showed that in surgical group, there were 2 with SAE, 3 with new ulcer, 1 with Falls due to device, 3 with Blister due to device, 3 with Abrasion due to device, 3 with Pressure point due to device, 2 with infection, 1 case recurrence occurred, 2 cases no

healing has been achieved. In Nonsurgical group, there were 1 with SAE, 4 with new ulcer, 2 with Falls due to device, 3 with Blister due to device, 3 with Abrasion due to device, 2 with Pressurepoint due to device, no infection occurred in all case, 2 case recurrence occurred, 3 cases no healing has been achieved.

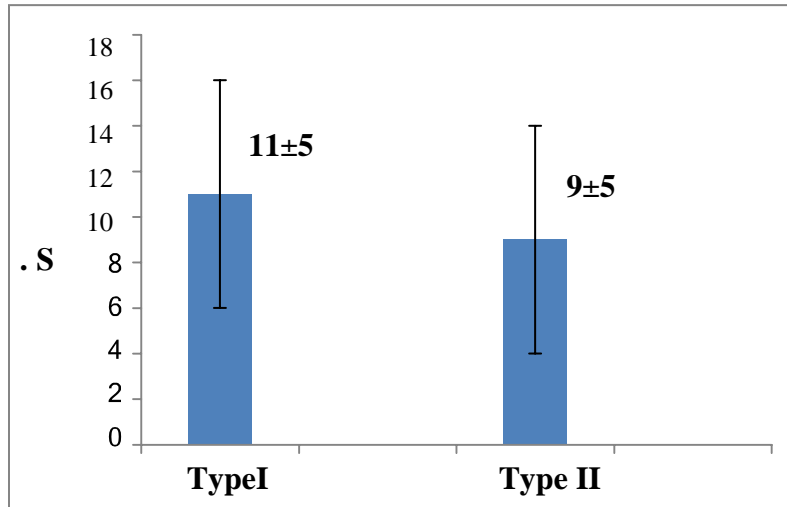


Fig. (5): SAE complication of studied group.

DISCUSSION:

This study has the advantage of being prospective which may have a positive impact on the outcome. However, we acknowledge some limitations such as; limited time, small sample size, non-randomization and limited financial resources **Finestone et al.**⁽¹⁰⁾ showed that cure rate is likely to be about 90 % in the surgical group and the non-surgical compliant group while in our study the cure rate was 86.7 % for surgical group and 80 % for non-surgical group. This slight difference may be related to the higher sample size of their study which was 100 individuals (40 in the surgical group & 60 in the non-surgical).

In the same study, recurrence in the surgical group and non-surgical group was 20 % and 50 % respectively with in a follow up period of two years, while in our study recurrence rate was 6.7 % in the surgical group and 13.3 % in the non-surgical group but within a follow up period of 6 months⁽¹¹⁾.

Offloading was a crucial therapy approach for the management of diabetic foot ulcers and total contact casts were shown to be the most effective devices to facilitate ulcer healing. However, they have more issues -less compliance and influence quality of life- compared to removable boots⁽¹²⁾.

An RCT including 41 patients showed higher healing rates and shorter time to healing of forefoot plantar ulcers for a combination of surgical excision, debridement, removal of bone segments underlying the lesion, and surgical closure when compared with conservative offloading treatment (initial debridement and medication of ulcer, relief of weight-bearing and

regular dressings), 95 % in 47 days versus 79 % in 129 days ($p < 0.05$), although conservative offloading did not involve the current standard of care (TCC)⁽¹³⁾.

A retrospective cohort research encompassing 50 patients with intractable plantar ulcers indicated that fifth metatarsal head removal was as successful as unloading treatment, both 100 % healing rate, but resulted in shorter time to healing (maximum 5.8 vs. 8.7 weeks).

Healing time was 5.8 ± 2.9 weeks vs. 8.7 ± 4.3 weeks in the control group who received standard wound care that consisted of wound dressing changes, offloading, and weekly debridement, while in our study healing time was 7 ± 3 weeks in the surgical group vs. 11 ± 6 weeks in non-surgical group significantly fewer patients re-ulcerated during the 6 month follow-up after resection of the fifth metatarsal head (4.5 % versus 27.8 %).

No significant differences were identified in proportion of patients diagnosed as having an infection during follow-up (18.2 % versus 22.2%; $P = .8$), while in our study infection was only in the surgical group (20 % ; p value = 0.046).

Age of patients who experienced major amputation (4.5% versus 11.7%; $P = 0.4$), whereas in our study there was no amputations during follow up period⁽¹⁴⁾.

A retrospective cohort research analysed 92 patients with numerous plantar forefoot ulcers and revealed that those treated with Panmetatarsal head resection healed considerably faster (mean 60.1 vs. 84.2 days, $p = 0.02$) than those treated with conservative offloading⁽¹⁵⁾.

Results of six non-controlled investigations of patients treated with single or pan metatarsal head excision after failed conservative treatment indicated between 88% and 100% recovery compared between detachable cast walker with removable partial shoe, included one experiment with 50 participants. There was no statistically significant difference between detachable cast walkers and temporary therapy shoes in the number of neuropathic, plantar foot ulcers healed (p value = 0.78). Reported time to recovery, in the detachable cast walker group was 6 weeks compared with 9 weeks in the temporary therapeutic shoe group with a follow up period of 12 weeks while the follow up in our trial was 6 months⁽¹⁶⁾.

Compared felted foam adhered to a temporary half-shoe that transported eight to the heel, showing 12 cases of disease from 61 patients in a follow up period of 10 weeks or at least till healing happened which had greater than our results that had zero disease in non- method.

CONCLUSION:

Either surgical or non-surgical modalities could be used without significant difference between them in their outcome. We should tailor the most suitable method for every patient. We recommend conducting randomized controlled reviews on a larger number of cases to reach better results.

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