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Most Easy on the Pocket Offloading Device Costing <1$ for Rural Diabetic Foot Ulcers

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Abstract

Objectives: The aim of our study is to compare mandakini offloading device suitable for low socio-economic rural population with conventional dressing in the treatment of diabetic foot plantar ulcers.

Methods: From December 2010 to June 2012, 80 patients with diabetic plantar neuropathic ulcer were randomised to Mandakini offloading device (n=40) or Conventional dressing (n=40).

Results: No significant differences between the two groups with respect to baseline ulcer size (4.52 *vs* 4.67 cms). The Number of patients with no necrotic tissue is significantly higher in Test group at 6th week follow up (32 *vs* 8). The number of patients with 75-100% wound filled by granulation tissue is significantly higher in test group at 6th week follow up (32 *vs* 8). The number of patients with no wound surface (Healed ulcer) is significantly higher in test group at 6th week follow up (32 *vs* 10). P value less than 0.001 was the level of significance.

Conclusion: Mandakini offloading device is economical, effective and feasible for rural population.

Keywords: Offloading; Diabetic plantar ulcers; Mandakini offloading device

Key Points

The study was done to give an insight to the depth of diabetic wound management, as it has become a foremost problem in recent era. Offloading is one of the cornerstones of gold-standard treatment in diabetic neuropathic foot ulcer. The study shows the fine efficacy of mandakini offloading device in terms of duration of healing of ulcer, no infection and no recurrence. It is economical, effective and easy to apply.

Introduction

India has the largest number of people with diabetes in the world. Today Indian Diabetic population is about 61.3 millions [1] that means total 122 million foot is at risk of getting Diabetic Foot Ulcer (DFU). It is also expected that this figure in 2025 will reach to 73.5 million [2]. Every 3 sec a new case of diabetes is diagnosed and every 30 sec a lower limb is amputated somewhere due to diabetes [3]. Worldwide, more than 1 million amputations are performed each year with up to 70% of these amputations related to diabetes. Foot problems are common, complex, and costly problem in a patient with diabetes [4-7]. It is a commonest cause of hospital admissions for people with diabetes [8]. It is estimated that 15% of patients with diabetes will develop a lower extremity ulcer during the course of their disease [9]. Diabetic patients are 17 times more likely to develop gangrene of the foot than are persons without diabetes, and gangrene of the lower extremity occurs in 20%-30% of patients with maturity onset diabetes [10]. DFU is basically a pathophysiologic problem in biomechanics of foot. Due to pan neuropathy in diabetes there is altered biomechanics and insensate foot does not appreciate the pressure at planter level and ultimately land up with a diabetic planter ulcer. Offloading is the major solution for healing of this plantar lesions along with adequate blood supply, control of infection, excellent wound care [11,12]. The available Off-loading techniques are: Bed rest, cutout felt pads, crutches, wheelchairs, zimmer frame, temporary shoes, ortho wedge shoes like rocker-bottom wedge design shoes and total contact casting [13-15]. These devices are expensive. Above all procedures have many advantages towards healing, but disadvantages towards patient compliance & cost factor. Indian rural population does not allow their wide usage. It does not permit our patient to take complete bed rest. They have to work for their livelihood. The aim of our study is to compare mandakini offloading device [16] suitable for low socio-economic rural population with conventional dressing in the treatment of Diabetic foot plantar ulcer.

Material and Methods

Interventional study, considering 80 patients with neuropathic diabetic plantar ulcers admitted in R.L. Jalappa hospital and research center Tamaka, Kolar during the period of December 2010 to June 2012.

Definition of study subject

Any patient with Diabetes Mellitus

Inclusion criteria

All patients with DM with neuropathic plantar ulcers

Exclusion criteria

I. Ulcers of Wagener's Grade III, IV and V
II. X-ray showing osteomyelitis
III. Charcot's foot (Photographical)
IV. Ischemic foot ABPI<0.4
V. Patients receiving corticosteroids, immunosuppressive agents, radiation.

The selected patients underwent screening for a period of one to two weeks, to stabilize the wound and institute appropriate medical and surgical line of treatment like diabetic control. Control of infection

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by initiating appropriate antibiotic based on culture sensitivity report, surgical debridement, correction of anemia and correction of other medical illness. After the initial screening period the eligible patients were divided randomly in to test group and control groups.

Test group

The Mandakini offloading device was applied to the patients (NO MCR CHAPPALS) (Figure 8). Dressing was changed once a week and review was done weekly till 4-6 weeks.

Control group

The conventional dressing was applied to the patient (WITH MCR CHAPPALS). Dressing was changed as and when required and review was done weekly till 4-6 weeks. The wound response was evaluated weekly using a visual score [17], both in case of Mandakini offloading device and conventional dressing.

The score for the percentage of wound covered by slough and nonviable (necrotic) tissue are-

1. = 76-100% wound covered with nonviable tissue.
2. = 51-75% wound covered with nonviable tissue.
3. = 26-50% wound covered with nonviable tissue.
4. = 11-25% wound covered with nonviable tissue.
5. = 0-10% wound covered with nonviable tissue.
6. = No necrotic tissue.

The score for the percentage of wound covered by granulation tissue are-

1. = No granulation present.
2. ≤ 25% of wound covered by granulation tissue.
3. = 25-74% of wound covered by granulation tissue.
4. = 75-100% of wound covered by granulation tissue.

The reduction of wound size and area measured in cm^2.

The final parameters and wound characteristics of the two randomized groups were analyzed and compared.

- Mandakini offloading device is compared with conventional dressing.
- The selected patient was given a educational material called "20 Steps Toward Foot Health for People with Diabetes" in their own language [18].
- Treatment of selected patients was done with bed side surgical debridement and a conventional topical antiseptic is applied when required.

Statistical Analysis Used

Chi Square Test and Fisher Exact Test [19,20]

Study design

An Interventional study, considering 80 patients

Duration of study

December 2010 to June 2012

Ethical clearance

Done No.DMC/KLR/MEU/IEC-CER/233

Results

Age distribution

Most of the patients fell in the age group between 40 to 70 years. The Mean ± SD for test group is (57.85 ± 13.88) and control is (57.60 ± 12.22), so age distribution is statistically similar between the two groups with p=0.539 (Table 1, Figure 1).

Sex distribution

The male and female ratio of the test group is 60%:40% and the control group is 62.5%:37.5%. Hence Sex distribution is statistically similar between the two groups with p=0.818 (Table 2, Figure 2).

Size of the ulcers

The mean size of the ulcer was 4.5 cm. The mean ± SD of the size of ulcer in test group (4.525 ± 2.47) and in control group (4.675 ± 2.43)

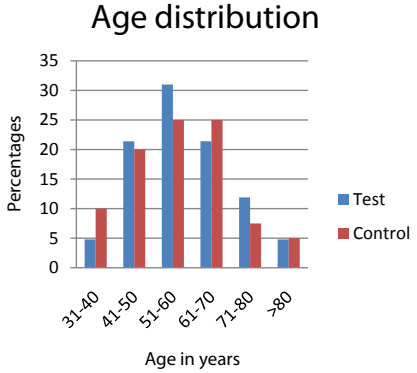


Figure 1: Age distribution in test group and control group.

Age in years	Test group		Control group	
	No	%	No	%
31-40	2	4.8	4	10.0
41-50	9	21.4	8	20.0
51-60	13	31.0	10	25.0
61-70	9	21.4	10	25.0
71-80	5	11.9	5	7.5
>80	2	4.8	3	5.0
Total	40	100.0	40	100.0
Mean ± SD	57.85 ± 13.88		57.6 ± 12.22	
Inference	Inference Age distribution is statistically similar between the two groups with **P=0.539**			

Table 1: Age distribution in test group and control group.

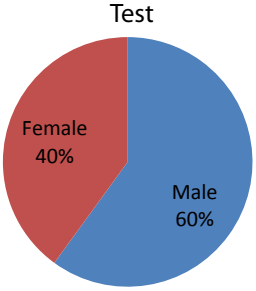


Figure 2: Sex distribution in test group and control group.

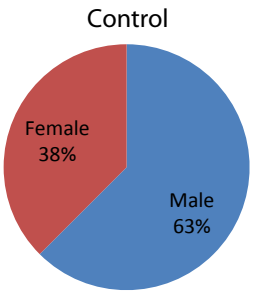


Figure 2a: Sex distribution in test group and control group.

Sex distribution	Test group		Test group	
	No	%	No	%
Male	24	60.0	25	62.5
Female	16	40.0	15	37.5
Total	40	100.0	40	100.0
Inference	Sex distribution is statistically similar between the two groups with **P=0.818**			

Table 2: Sex distribution in test group and control group.

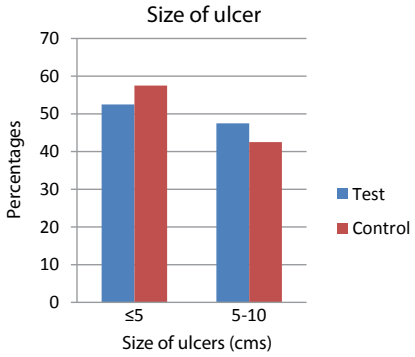


Figure 3: Size of the Ulcers in test group and control group.

is statistically similar between the two groups with p=0.785 (Table 3, Figure 3).

Grade of ulcers

Most of the patients had Grade I and II ulcers in both test and control groups. The grade of ulcer is statistically similar between the two groups p=0.648 (Table 4, Figure 4).

Presence of necrotic tissue or slough

Number of patients with No Necrotic tissue are significantly higher in Test group at 3rd week follow up (p=0.178), at 4th week (p ≤ 0.001), at 5th week (p ≤ 0.001), at 6th week (p ≤ 0.001) when compared to Control group as per the Chi-Square/Fisher Exact test (Table 5, Figures 5a and 5b).

Presence of granulation tissue

Number of patients with 75-100% wound filled are significantly higher in Test group at 3rd week follow up (p=0.009), at 4th week (p=0.002), at 5th Week (p=0.063), and at 6th week (p ≤ 0.001) when compared to Control group as per the Chi-Square /Fisher Exact test (Table 6, Figures 6a and 6b).

Wound surface area

Number of patients with no wound surface (Nil) are significantly higher in Test group at 3rd week follow up (p=0.104), at 4th week (p=0.118), at 5th Week (p ≤ 0.001), and at 6th week (p ≤ 0.001) when compared to Control group as per the Chi-Square/Fisher Exact test (Table 7, Figures 7a and 7b).

Size of the ulcers in cms	Control group n=40		Test group n=40	
	No	%	No	%
≤ 5	21	52.5	23	57.5
5-10	19	47.5	17	42.5
Mean ± SD	4.675 ± 2.43		4.525 ± 2.47	
Inference	Size of the ulcers is statistically similar between the two groups with **P=0.785**			

Table 3: Size of the Ulcers in test group and control group.

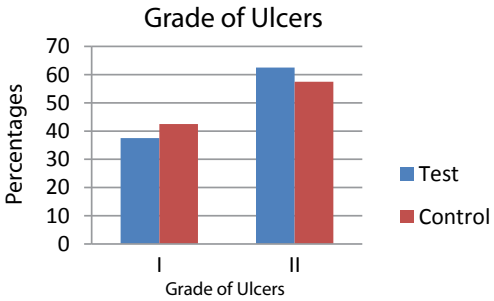


Figure 4: Grade of ulcer in test and control group.

Grade of Ulcers	Control group n=40		Test group n=40	
	No	%	No	%
I	15	37.5	17	42.5
II	25	62.5	23	57.5

Table 4: Grade of Ulcers in test group and control group.

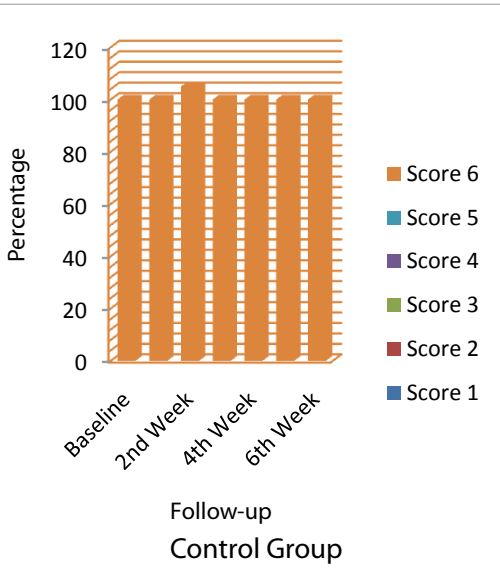


Figure 5: The bar chart shows gradual regression of necrotic tissue in test and control groups.

Discussion

The number of patients studied was 80 and randomly divided in to test group (40) and control group (40). Both the test and control groups were matched regarding their age, diabetic status, nutritional status, and grade of ulcer. In addition, there were no significant differences between the two groups with respect to baseline ulcer size (p=0.785) and amount of nonviable tissue/slough. The Number of patients with no necrotic tissue is significantly higher in Test group at 3rd week follow up (p=0.178), at 4th week (p ≤ 0.001), at 5th week (p ≤ 0.001) and at 6th week (p ≤ 0.001) when compared to Control group. There is minimal loss of viable tissue in the test group compared to that of control group this is because the number of bed side surgical debridement required is less and done superficially to remove dead tissue only. The number of patients with 75-100% wound filled by granulation tissue is significantly higher in Test group at 3rd week follow up (p=0.009), at 4th week (p=0.002), at 5th Week (p=0.063), at 6th week (p ≤ 0.001) when compared to Control group.

The number of patients with no wound surface (Nil) is significantly

Study period	Control group Visual score of slough covering the ulcer						Test group Visual score of slough covering the ulcer					
	1	2	3	4	5	6	1	2	3	4	5	6
Baseline	21 (52.5)	12 (30)	6 (15)	1 (2.5)			23 (57.5)	10 (25.0)	7 (17.5)			
1st Week	15 (37.5)	11 (27.5)	7 (17.5)	7 (17.5)			20 (50.0)	9 (22.5)	5 (12.5)	3 (7.5)	3 (7.5)	
2nd Week	9 (22.5)	10 (25)	8 (20)	4 (10)	11 (27.5)		6 (15.0)	17 (42.5)	7 (17.5)	5 (12.5)	5 (12.5)	
3rd Week	7 (17.5)	13 (32.5)	7 (17.5)	10 (25)	3 (7.5)		2 (5.0)	12 (30.0)	9 (22.5)	8 (20.0)	9 (22.5)	
4th Week	5 (12.5)	15 (37.5)	6 (15)	7 (17.5)	7 (17.5)			1 (2.5)	14 (35.0)	8 (20.0)	9 (22.5)	8 (20.0)
5th Week		9 (22.5)	13 (32.5)	9 (22.5)	9 (22.5)				6 (15.0)	7 (17.5)	7 (17.5)	20 (50.0)
6th Week		5 (12.5)	15 (37.5)	7 (17.5)	5 (12.5)	8 (20)				3 (7.5)	5 (12.5)	32 (80.0)
Inference	Number of patients with No Necrotic tissue are significantly higher in Test group at 3rd week follow up (P=0.178), at 4th week (P ≤ 0.001), at 5th Week (P ≤ 0.001), at 6th week (P ≤ 0.001) when compared to Control group as per the Chi-Square/Fisher Exact test											

Figures in brackets are percentages

Visual score:

1. 76-100% wound covered with nonviable tissue
2. 51-75% wound covered with nonviable tissue
3. 26-50% wound covered with nonviable tissue
4. 11-25% wound covered with nonviable tissue
5. 0-10% wound covered with nonviable tissue
6. no necrotic tissue

Table 5: Presence of necrotic tissue or slough in test group and control group.

Study period	Control group Visual score of granulation tissue covering the ulcer				Test group Visual score of granulation tissue covering the ulcer			
	1	2	3	4	1	2	3	4
Baseline	23 (57.5)	13 (32.5)	4 (10.0)		23 (57.5)	13 (32.5)	4 (10.0)	
1st Week	23 (57.5)	9 (22.5)	8 (20.0)		23 (57.5)	9 (22.5)	8 (20.0)	
2nd Week	17 (42.5)	16 (40.0)	6 (15.0)	1 (2.5)	9 (22.5)	18 (45.0)	10 (25.0)	3 (7.5)
3rd Week	12 (30.0)	14 (35.0)	10 (25.0)	4 (10.0)	1 (2.5)	22 (55.0)	11 (27.5)	6 (15.0)
4th Week	12 (30.0)	12 (30.0)	10 (25.0)	6 (15.0)		14 (35.0)	18 (45.0)	8 (20.0)
5th Week		14 (35.0)	16 (40.0)	10 (25.0)		8 (20.0)	12 (30.0)	20 (50.0)
6th Week		12 (30.0)	20 (50.0)	8 (20.0)			8 (20.0)	32 (80.0)
Inference	Number of patients with 75-100% wound filled are significantly higher in Test group at 3rd week follow up (P=0.009), at 4th week (P=0.002), at 5th Week (P=0.063), and at 6th week (P ≤ 0.001) when compared to Control group as per the Chi-Square/Fisher Exact test							

Figures in brackets are percentage

Visual score:

1. = no granulation present
2. ≤ 25% of wound
3. = 25-74% of wound filled
4. = 75-100% of wound filled

Table 6: Presence of granulation tissue in test group and control group.

Study period	Control group			Test group		
	Wound Surface area (cm2)					
	5-10	1-5	Nil	5-10	1-5	Nil
Baseline	30 (75.0)	10 (25.0)		31 (77.5)	9 (22.5)	
1st Week	30 (75.0)	10 (25.0)		30 (75.0)	10 (25.0)	
2nd Week	30 (75.0)	10 (25.0)		25 (62.5)	15 (37.5)	
3rd Week	28 (70.0)	12 (30)		20 (50.0)	18 (45.0)	2 (2.5)
4th Week	22 (55.0)	16 (40.0)	2 (2.5)	17 (42.5)	15 (37.5)	8 (20.0)
5th Week	16 (40.0)	18 (45.0)	6 (15.0)	2 (2.5)	18 (45.0)	20 (50.0)
6th Week	2 (2.5)	28 (70.0)	10 (25.0)	2 (2.5)	6 (15.0)	32 (80.0)
Inference	Number of patients with No Wound surface (Nil) are significantly higher in Test group at 3rd week follow up (P=0.104), at 4th week (P=0.118), at 5th Week (P ≤ 0.001), and at 6th week (P ≤ 0.001) when compared to Control group as per the Chi-Square /Fisher Exact test					

Table 7: Wound Surface Area in test group and control group.

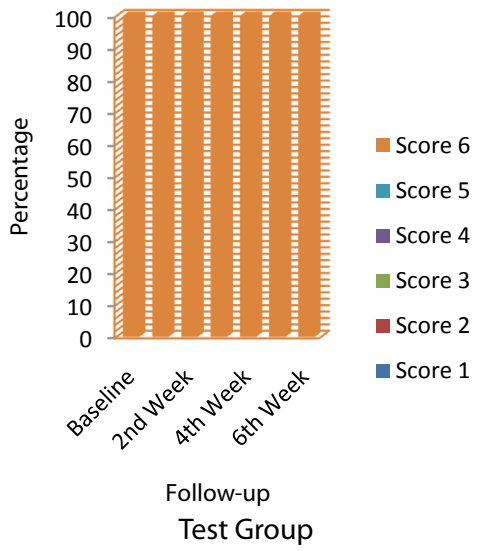


Figure 5a: The bar chart shows gradual regression of necrotic tissue in test and control groups.

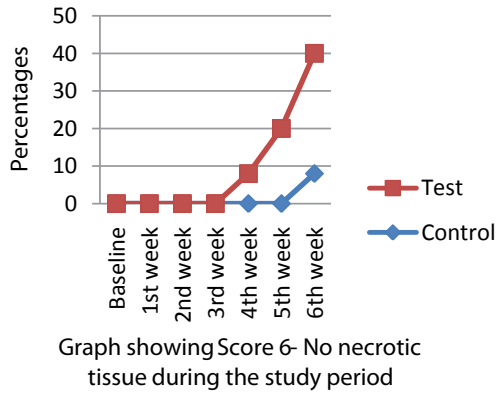


Figure 5b: A comparative line diagram showing presence of necrotic tissue or slough in control and test group in each week.

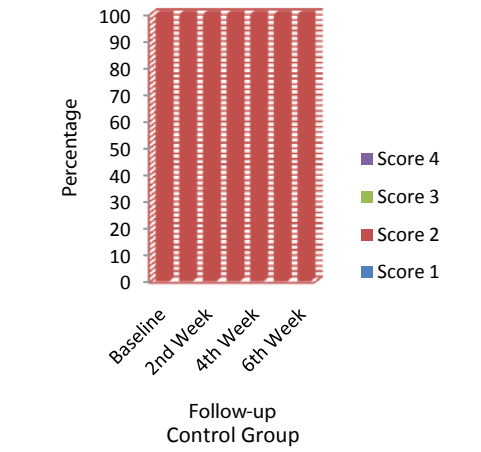
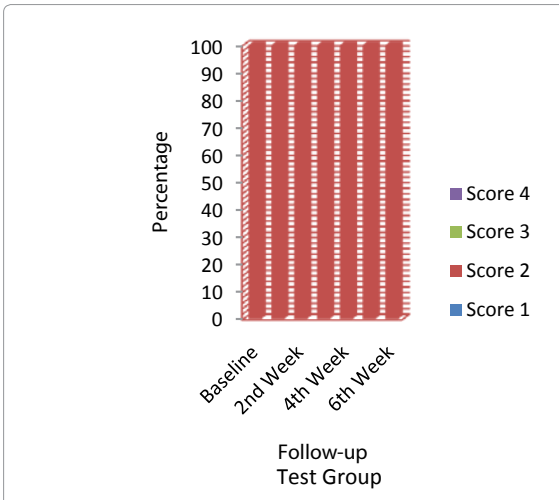


Figure 6: The bar graph shows the gradual progress of granulation tissue in control and test groups in each week.



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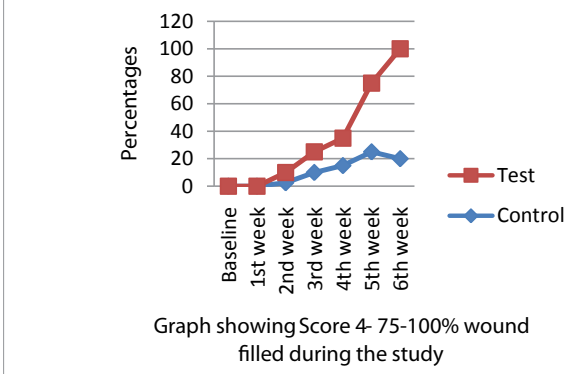

Figure 6b: Line diagram showing comparative study of gradual progress of granulation tissue in control and test groups in each week.

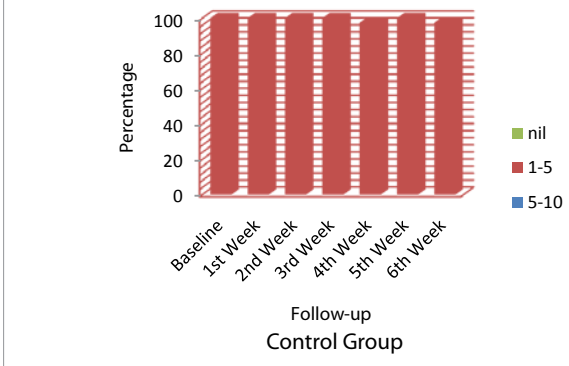

Figure 7: The bar diagram showing shrinking of wound surface in control and test groups in each week.

higher in Test group at 3rd week follow up (p=0.104), at 4th week (p=0.118), at 5th week (p ≤ 0.001) and at 6th week (p ≤ 0.001) when compared to Control group. In test group, ulcers healed in 32 patients during follow up for 6 weeks. Among these, 2 patients in 3 weeks, 6 patients in 4 weeks, 12 patients in 5 weeks and 12 patients in 6 weeks. In 8 patients ulcer was not healed but, size of the ulcer decreased during the follow up period. No patients among the test group has secondary

infection 40 patients were applied conventional dressing. Among these, ulcer healed in 10 patients during follow up for 6 weeks. Among these, 2 patients in 4 weeks, 4 patients in 5 weeks and 4 patients in 6 weeks In 30 patients ulcer was not healed but, size of the ulcer decreased during the follow up period. This study demonstrated that Offloading along with bed side surgical debridement had cumulative effect in reduction of slough, increase granulation tissue and faster wound bed preparation (Figures 8a and 8b). The test group patients had increased growth of the granulation tissue along with epithelisation which is generally correlated with the development of a granulating wound bed. All this are done with visual score so it cannot be determined whether there was an increase in granulation tissue production resulting from the treatment or that more granulation was visible after debridement. But patients in test group produced better results than the control group. The ulcer also healed faster and has less recurrence rate due to offloading. The study was done to give an insight to the depth of diabetic wound management, as it has become a foremost problem in recent era. Offloading is one of the cornerstones of gold-standard treatment in diabetic neuropathic foot ulcer.

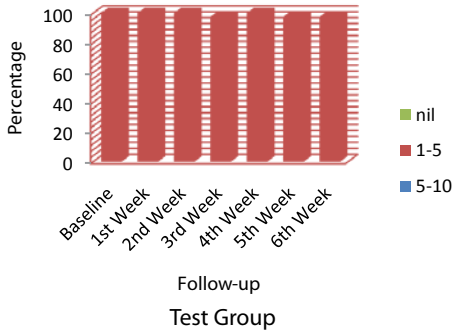

Figure 7a: The bar diagram showing shrinking of wound surface in control and test groups in each week.

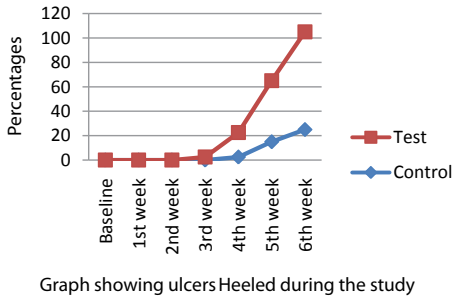

Figure 7b: The comparative line diagram showing shrinking of wound surface in control and test groups in each week.

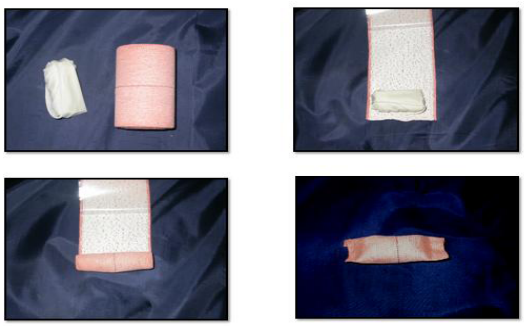

Figure 8: Method to prepare mandakini offloading device [7].

Figure 8a: Healed ulcer after using offloading during weekly follow up.

Figure 8b: Healed ulcer after using offloading during weekly follow up.

The study shows the fine efficacy of mandakini offloading device in terms of duration of healing of ulcer, no infection and no recurrence. It is economical, effective and easy to apply. It is ideal offloading device for low socio-economic rural population in developing countries. It reduces the duration of healing of ulcer when compared to conventional dressing. It completes the criteria to be called as ideal offloading device.

Acknowledgement

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