

**DIFFERENT APPROACHES IN THE MANAGEMENT OF DIABETIC FOOT ULCERS – EXPERIENCE AT A TERTIARY CARE HOSPITAL**

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This study aims to compare the outcomes of the usage of the negative pressure wound therapy (NPWT) using vacuum assisted wound closure / Collagen granules / Offloading techniques with the conventional moist gauze dressing in the treatment of diabetic foot ulcers (DFU).

This is a Prospective, interventional study, that conducted at B.L.D.E (DU)'s Shri B.M.Patil Medical College Hospital and Research Center, Vijayapur over a period of 5 years. The demographic characteristics, type of foot lesions and treatment with different modalities of dressings and outcome were studied. Fifty cases in each group – NPWT/ Collagen granules dressing/ offloading techniques and conventional moist gauze dressings were allocated alternatively.

Two hundred patients were included in the study, saw the gradual increase in the granulation tissue development, but the results were better in other groups than the conventional group and the collagen dressing group had more granulation tissue from first week. There was early recovery among the other groups when compared to the conventional methods. The mean recovery were least in the collagen dressing group. 90% had good outcome in the negative dressing group. The outcome was 92% among the off loading group and 96% good outcome among the collagen group. But the conventional group had only 64% good outcome. And the difference was statistically significant.

In conclusion, the comparison of different methods to treat the diabetic foot ulcer showed that collagen method of dressing to be superior to others followed by offloading and then by topical negative pressure dressing. The conventional method had less favorable and slow outcome.

**Keywords:** negative pressure dressing, collagen dressing, offloading, conventional dressing.

**Introduction**

Diabetic foot ulcers (DFU) are an important cause of disability because of their chronicity and difficulty to treat<sup>1</sup>. The life time risk for a person with diabetes developing foot ulcers is 15%<sup>2</sup>. DFU occurs in diabetic individuals due to its complex involvement of nervous, musculoskeletal, vascular

and immunological systems<sup>3</sup>. Diabetic foot problems can manifest as foot ulcers, infections (cellulitis, osteomyelitis and abscess) or gangrene which might require amputation. Etiopathogenesis of these manifestations can be explained by peripheral neuropathy, peripheral vascular disease asso-

ciated with diabetes which cause ischaemia with impaired angiogenesis. Increased susceptibility to infection is other important cause leading to these manifestations<sup>4</sup>. Minor foot trauma can cause ulcer in diabetics which fails to heal, leading to their chronicity and an indication of lower limb amputation accordingly. Eighty four percent of non traumatic amputations in diabetics are secondary to DFU. One's quality of life is significantly affected with amputation in addition to financial implications<sup>5</sup>. Treatment strategies for DFU should include targeting blood sugar levels at optimum levels along with regular cleaning and dressing, debridement of the wound, offloading principles and control of infection.

Negative pressure wound therapy using vacuum assisted closure, promotes wound healing by four-fold increase in the blood flow in local wound environment, reducing edema, decreasing the bacterial load and thereby promoting the formation and perfusion of granulation tissue which helps in the early closure of the wound bed.

Collagen granules facilitate wound contraction and formation of granulation tissue by recruiting fibroblasts into the ulcer and thus act as effective tool in the healing of diabetic foot ulcers<sup>6</sup>. Collagen granules promote angiogenesis by facilitating migration of fibroblasts and keratinocytes into the ulcer. Collagen is a biomaterial that encourages wound healing through deposition and organization of freshly formed fibers and granulation tissue in the wound bed thus creating a good environment for wound healing.

Around 80% diabetic patients are neuropathic and these patients with any history of foot ulcers have abnormally high pressure under the foot<sup>7</sup>. Offloading techniques have an added advantage in the treatment of plantar aspect foot ulcers, such that, the covering prevents injury from the heat, objects etc. The padding lessens the effect of muscle wasting and gives a soft surface to any hard bony projections, moulding mainly increases the weight bearing area and takes weight off the affected area and rigidity reduces the effect of shearing stress, stabilizes the foot and corrects mobile deformities, ultimately leading to an ulcer free foot.

Hence this study was undertaken to compare the outcomes of usage of negative pressure therapy using vacuum assisted closure, collagen granules, offloading techniques with the regular moist gauze

dressings in the treatment of DFU.

### **Aim of study**

To compare the outcomes of usage of negative pressure therapy using vacuum assisted closure/ collagen granules / offloading technique with the conventional moist gauze dressings in the management of diabetic foot ulcers.

### **Patients and methods**

This is a Prospective, Interventional study conducted at B.L.D.E (DU)'s Shri B.M.Patil Medical College Hospital and Research Center, Vijayapur over a period of 5 years from June 2013 to May 2018. Fifty cases in each group – NPWT/Collagen granules dressing/ offloading techniques and conventional moist gauze dressings were allocated alternatively. The demographic characteristics, type of foot lesions and outcome by treatment with different modalities of dressings were studied.

'Primary efficacy end point' includes complete closure of ulcer. 'Secondary efficacy end points' include a reduction in surface area of ulcer over a time to achieve ulcer closure by either skin grafting or secondary suturing.

#### **Inclusion Criteria:**

All cases of diabetic foot ulcers presented to the hospital during the study period with Wagner's grade 1 – 3.

#### **Exclusion Criteria:**

1. Diabetic patient with foot ulcers as a result of electrical, radiation burns and collagen vascular disease.
2. Wagner's grade 4 and 5
3. Patients on chemotherapy or corticosteroids or other immunosuppressive agents.

Ethical clearance was taken from the hospital authorities, before the commencement of study

**Treatment strategies:** Strict hyperglycaemia control using insulin was the foremost important measure taken. Antibiotics were initiated, if signs of infection were evident. Incision and Drainage of abscess was done while superficial skin ulcers were managed conservatively. Debridement of infected lesions was done appropriately and repeated if required.

Procedure for creating NPWT using vacuum assisted closure:

After debridement, glycerin gauze was kept over the wound. Sterile foam were cut to size of wounds

approximately following which they are gently placed on wound area. Perforated drain tube was then located on the top of the foam and the second piece of the foam placed over the top. Adhesive transparent sheet was used to cover foam together with few inches of drainage tube along with healthy skin at surrounding area. Vacuum assisted closure unit which is programmed to produce the required level of negative pressure of wound (50-150mm of Hg) was connected to distal end of drain. Once the

vacuum was switched on, the air was sucked out of the foam causing it to collapse inwards drawing the edges of the wound with it. Fluid within the wound was absorbed by foam which was transported into disposable container within the main vacuum unit.

Then the wound was assessed for decrease in surface area of ulcer, granulation tissue fill up of wound after 7,14,21 and 28 days.( Figure 1)



Figure 1 (Negative pressure wound therapy using vacuum assisted wound closure and outcome.)

**Procedure for Collagen granules dressing:** After thorough debridement of the ulcer, collagen granule dressing was applied to grade 1 to 3 DFU in collagen granules dressing group. Then the wound

was assessed for decrease in surface area of ulcer, granulation tissue fill up of wound after 7,14,21 and 28 days. ( Figure 2)



Figure 2 (Collagen granules dressing and outcome.)

**Procedure for conventional dressing:** After thorough debridement of the ulcer, moist gauze dressing was applied to grade 1 to 3 DFU in conventional dressing group. Then the wound was assessed for decrease in surface area of ulcer, granulation tissue fill up of wound after 7,14,21 and 28 days.

**Offloading technique:** This technique was used in the treatment of the DFU on plantar aspect. After identifying the maximum pressure points using Harris mat technique, individual specialised footwear are prepared and used. Four types of offloading techniques were used in this study with healing

sandals, total contact cast, removable slings and slabs. Then the wound was assessed for decrease

in surface area of ulcer, granulation tissue fill up of wound after 7,14,21 and 28 days. ( Figure 3)



Figure 3 (offloading technique and outcome)

**Results**

The results of all the patients were distributed in different groups where each group had 50 patients. Out of 200 patients, 140 were males and 60 were females. There was no association between age and sex among patients in any group. The mean age of all the groups were included and compared which had shown no statistical difference as in the Table 1. The mean duration of diabetes among patients

treated with different dressings were included and compared found no statistical difference shown in the Table 1.

Distribution of cases by type of offloading – Healing sandals were used in 35 patients, total contact slab in 10 patients, Removal sling in 3 patients and Total contact cast in 2 patients.

When the reduction in the size of the ulcer with

Table 1 (Mean and SD values of Age, Duration of diabetes, Days of healing compared with various types of dressings)

PARAMETERS	OFFLOADING		COLLAGEN		CONVENTIONAL		p value		
	MEAN	SD	MEAN	SD	MEAN	SD			
Age	58.9	13.2	56.0	11.8	60.2	11.4	58.9	13.2	0.396
Duration of diabetes in years	9.8	7.3	8.1	5.4	7.9	5.4	7.7	5.7	0.294
Days of healing	37.9	18.8	32.6	10.2	22.1	6.8	58.4	21.9	<0.001*

various types of dressings are compared in the study, we found that the ulcer size took longer time to reduce in conventional dressings than others as shown in the Table 3, which was statistically significant in the weeks 3 and 4.

Primary efficacy end point – secondary intention healing was achieved in maximum number for the ulcers treated with offloading technique and 2 patients required secondary suturing and skin grafting was done in four patients to establish the secondary efficacy end point.

On the contrary, in the topical negative pressure

group, skin grafting was done for wound closure in twenty five patients when compared to conventional group, in which only fifteen patients needed skin grafting to establish secondary efficacy end point.

The study saw the development of the granulation tissue and saw there was gradual increase in the granulation tissue development as the weeks pass by but the results are better in other groups than the conventional group and the collagen dressing group had more granulation tissue from week 1 (Table 2).

**Table 2** (Granulation tissue at week 1, 2, 3 and 4 compared with various types of dressings)

DURATION (WEEKS) AND GRANULATION (%)		OFFLOADING		COLLAGEN		CONVENTIONAL		p value
		N	%	N	%	N	%	
1st WEEK	0-33%	33	66	0	0	34	68	<0.001*
	33%-66%	14	28	0	0	16	32	
	66%-100%	3	6	50	100	0	0	
	Total	50	100	50	100	50	100	
2nd WEEK	0-33%	11	22	0	0	1	2	<0.001*
	33%-66%	17	34	0	0	33	66	
	66%-100%	22	44	50	100	16	32	
	Total	50	100	50	100	50	100	
3rd WEEK	0-33%	0	0	0	0	0	0	<0.001*
	33%-66%	15	30	0	0	15	30	
	66%-100%	35	70	50	100	35	70	
	Total	50	100	50	100	50	100	
4th WEEK	0-33%	0	0	0	0	0	0	<0.001*
	33%-66%	2	4	0	0	0	0	
	66%-100%	48	96	50	100	50	100	
	Total	50	100	50	100	50	100	
FOLLOW UP	Good	45	90	46	92	48	96	<0.001*
	Satisfactory	5	10	4	8	2	4	
	Total	50	100	50	100	50	100	

**Table 3** (Distribution of patients according to reduction in the size of ulcer and type of wound closure in various types of dressings)

	DURATION	TOPICAL NEGATIVE	OFFLOADING	COLLAGEN	CONVENTIONAL	p value
Reduction in the size of the Ulcer (%)	1week	20%	10%	15%	10%	0.122
	2weeks	40%	35%	30%	18%	0.006*
	3weeks	65%	50%	55%	25%	<0.001*
	4weeks	90%	75%	80%	60%	<0.001*
Type of wound closure	Secondary intention healing	20	44	33	25	<0.001*
	Secondary suturing	5	2	4	10	<0.001*
	Skin grafting	25	4	13	15	<0.001*
	Total	50	50	50	50	

Similarly when the mean days of healing among the different method were compared, we found there was association. There was early recovery among the other groups when compared to the conventional methods. The mean recovery days were less in the collagen dressing group (Table 1).

When Cost effectiveness related to dressings other than supportive treatment is compared - NPWT costs around Rs 900, collagen dressing group costs around Rs 1,200; whereas Offloading technique group costs around Rs 800 and conventional dressing costs around Rs 300.

The different dressing methods were compared to see the outcome as shown in (Table 2). Ninety percent had good outcome in the topical negative dressing group. The outcome was 92% among the off loading group and 96% good outcome among the collagen group. But the conventional group had only 64% good outcome. And the difference was statistically significant.

## Discussion

The mean age among the negative pressure dressing group is comparable to the study done by Nain et al<sup>4</sup>. Mean age of subjects in study group was  $61.33 \pm 7.63$  years and also to the multicentre randomized study by Blume et al, which had mean age as 58 years<sup>8</sup>. The study by Joseph et al had mean age of 52 years<sup>9</sup>. The sex wise distribution in the negative pressure dressing group was found

to have majority males (76%) than females. This is comparable to studies by Blume et al<sup>8</sup>, and Nain et al<sup>4</sup>, with 78.5% and 79% respectively.

Pressure offloading of diabetic plantar foot ulcers facilitates faster granulation tissue fill up. The mean age of the patients in years in the offloading dressing was found to be  $53.3 \pm 11.7$ . This mean was found to be in accordance with the mean age of patients in study by Lindy Begg et al<sup>10</sup> which was  $57.2 \pm 12.9$  years and slightly lower when compared to  $65.6 \pm 9.9$  years as per study David Armstrong et al<sup>11</sup>.

The mean age and sex distribution among the patients of collagen dressing had no association. But the mean age were similar to the study by Veves A et al<sup>12</sup>, which was 58 years and the current study had same age mean. The sex majority saw males to be more in percentage who were 70% and this percentage was higher among studies by Veves A et al<sup>12</sup> and Holmes et al<sup>6</sup>. The study showed no association with mean ages among different study groups. So the study had taken almost all similar age groups.

Rate of granulation tissue formation in our study was 46.6% in TNP group on 14 th day and 83.3% in TNP group on 28 th day these findings were comparable to the studies done by Joseph, et al who had 81.56% of granulation tissue formation in vacuum group after 2 week. In a study done by Tauro et al<sup>13</sup> had 71.43 % granulation tissue for-

mation in vacuum group. The study by Blume et al<sup>8</sup> showed a 95% of granulation tissue formation. The current study had shown association for healing with different methods.

The percentage of healing seen in few of the studies were Meuller et al<sup>14</sup> which showed 90% with mean and SD 42±29 days, Birke et al 2002<sup>15</sup> saw 81% for duration of 45.5±43.4 days and Miyan et al<sup>7</sup> had 95% with range of 34- 45 days.

The percentage of reduction in surface area after 4 weeks in Topical negative pressure therapy group, offloading group, collagen group showed note worthy decrease in the size of ulcer with respect to conventional group. Studies conducted by Bireke et al 2002<sup>15</sup>, Veves A et al<sup>12</sup> showed almost similar results.

The current study found significant association between granulation tissue formation at different weeks and also there was increasing percentage of granulation tissues in vacuum assisted dressing and collagen dressing as compared to off loading as the granulation tissue was 66-100% from the 1st week. The conventional dressing also showed granulation tissue at par with the vacuum and col-

lagen dressing and more than as compared off loading dressings. The results show that early care and optimal foot care to be factors for better healing which is similar findings in the study by Hilde Smith-Strøm et al<sup>16</sup>.

When the cost effectiveness is considered, though the collagen group costs around Rs 1200 without including the supportive treatment, offered good results when compared to conventional dressings. The mean duration of healing and length of hospital stay in collagen dressing group is least when

## Conclusion

The comparison of different methods to treat the diabetic ulcer showed that collagen method of dressing to be superior to others followed by offloading and then by topical negative pressure dressing. The conventional method had less favourable and slow outcome.

## Authership & conflict of interest

This is to verify authership of this article and there is no conflict of interest in any way.

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