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Comparative Study Between Conventional Dressing and Dressing With Off Loading Technique in the Management of Diabetic Foot Plantar Ulcers

Dr. Shishira S. Ranade[1], Dr. B. J. Sharath Chandra[2], Dr. P. B. Thrishuli[3]

[1]Senior Resident, Affiliated to JSS Medical College, A constituent of JSS University- Mysore, Karnataka, South India

[2]Professor and Unit Chief, Affiliated to JSS Medical College, A constituent of JSS University- Mysore, Karnataka, South India

[3]Associate Professor, Affiliated to JSS Medical College, A constituent of JSS University- Mysore, Karnataka, South India

Abstract: ***The basic etiology of neuropathic diabetic foot wounds involves pressure in conjunction with cycles of repetitive stress, leading to failure of skin and soft tissue integrity. The central tenet of any treatment plan addressing neuropathic diabetic foot wounds is the appropriate debridement of nonviable tissue coupled with adequate pressure relief (off-loading).***

Keywords: Off Loading, Diabetic Foot, Plantar Ulcers, Mandakini Device.

1. Objectives of the Study

1.1 Aims and objectives

a) To compare the effectiveness of the OFF LOADING technique with the conventional dressing in the management of diabetic plantar foot ulcers.
b) To compare the outcome, amputation rates between the OFF LOADING technique and the conventional dressing in the management of diabetic plantar foot ulcers.

Inclusion Criteria
Patients with type 1 and type 2 diabetes mellitus, having the ulcers in the plantar aspect of the foot, involving not more than half the surface.

Exclusion Criteria
a) Diabetic foot ulcers with osteomylitis.
b) Diabetic ulcers with peripheral vascular disease.
c) Plantar ulcers other than diabetic ulcers, like Hansen disease.
d) Large ulcers involving more than half of the plantar surface of the foot(to get sufficient surface for off loading)

2. Methodology

All cases reporting to JSS under the study period satisfying inclusion and exclusion criteria were studied. The study comprises minimum of 50 patients as a study group, and minimum of 50 patients as a control group, with diabetic foot ulcers secondary to type 1 andtype2 diabetes mellitus, admitted to JSS Hospital, Mysore during the study period i.e. from Nov 2010 to Nov 2012.

These variables were compared between the two group:
1) Pain scale- visual analog scale.
2) Duration of hospital stay.
3) Total no. of dressings done during the hospital stay.
4) Total no. of days antibiotics given
5) Morbidity rate-Rate of amputations.
6) Mortality rates.
7) Total expenditure for the patient.

3. Mandakini off Loading Device

Many OFFLOADING devices are expensive.7 A simple OFF LOADING technique used in this study is a device made of “used pair of gloves” and a ‘dynaplast adhesive plaster.’ Fore foot plantar ulcers are attended by applying the device proximal to the lesion and the Hind foot ulcers are attended by applying the device distal to the lesion. ulcers involving more than half of the plantar area were excluded from the study in order to provide adequate space for applying the device.

Figure 1: Used pair of gloves which is rolled

Figure 2: Gloves rolled in an adhesive plaster

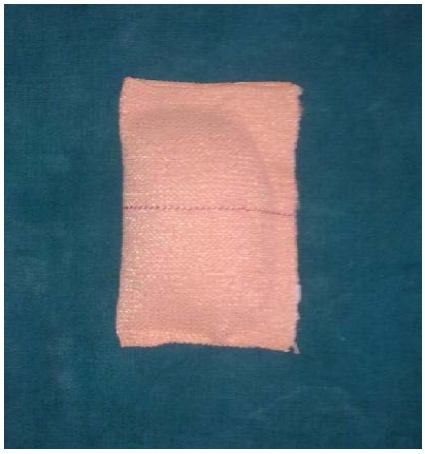


Figure 3: Device is ready for off loading

Figure 4: Applying the device in a patient with plantar ulcer

4. Statistical

a) Descriptive statistics
The Descriptives procedure displays univariate summary statistics for several variables in a single table and calculates standardized values. Variables can be ordered by the size of their means. In the present study descriptive statistics were calculated for individual statements as well as the total scores for each component.

b) Crosstabs (Contingency coefficient test)
The Crosstabs procedure forms two-way and multiway tables and provides a variety of tests and measures of association for two-way tables. The structure of the table and whether categories are ordered determine what test or measure to use.

c) Independent samples t test
The Independent-Samples T Test procedure compares means for two groups of cases. Ideally, for this test, the subjects should be randomly assigned to two groups, so that any difference in response is due to the treatment (or lack of treatment) and not to other factors. All the statistical calculations were done through SPSS 16.0 (2007) for windows.

5. Results

Figure 5: Example; Hind foot plantar ulcer

Figure 6: After 3 weeks of OFF LOADING

Figure 7: After 6 weeks of OFF LOADING

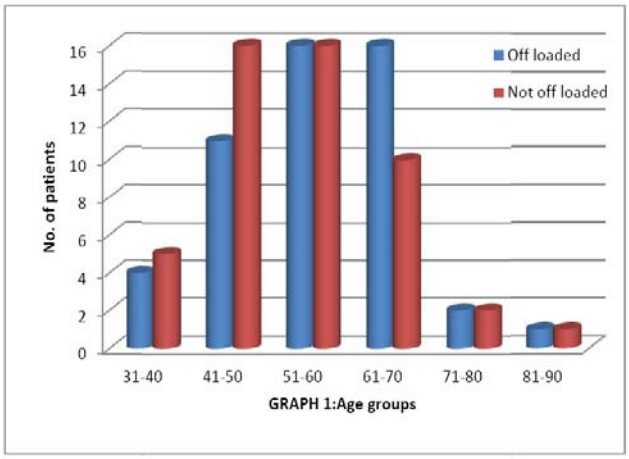
1) Age Distribution

Out of 50 patients who were off loaded, maximum number of patients were between 51 to 70 years of age (32 patients) and among not off loaded patients maximum number of patients were between 51 to 60 years of age (16 patients).

Table 1: Age Distribution

Age in Yrs	Off loaded	Not off loaded
31-40	4	5
41-50	11	16
51-60	16	16
61-70	16	10
71-80	2	2
81-90	1	1

GRAPH 1: AGE DISTRIBUTATION



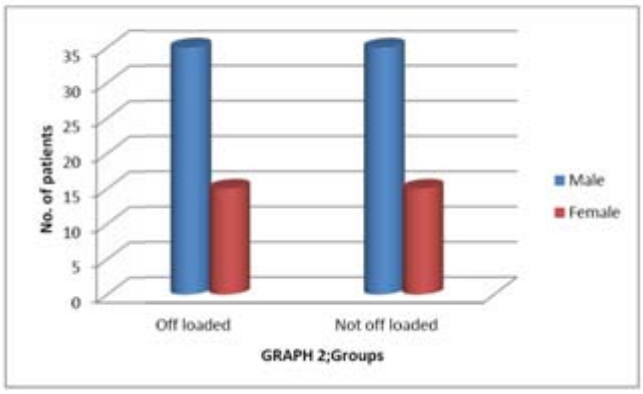
2) Sex Distribution

Of 100 patients 70 male and 30 female patients were chosen for study purpose. The groups were further equally divided comprising 35 males and 15 females in each group, i.e. off loaded and not off loaded groups.

Table 2: Sex Distribution

SEX	Off loaded	Not off loaded
Male	35	35
Female	15	15

GRAPH 2: SEX DISTRIBUTION



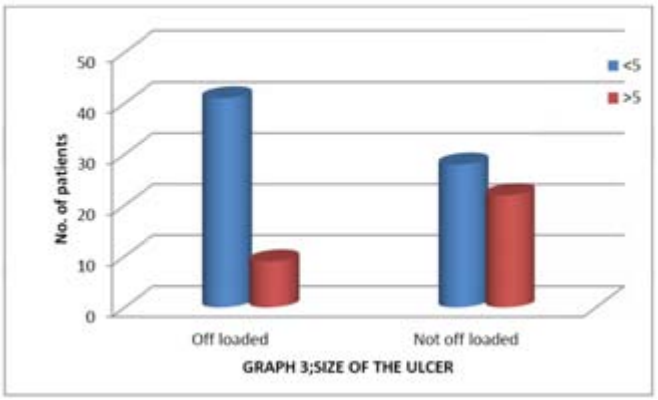
3) Comparision of Size of the Ulcer

Among the patients who had undergone off loading 41 patients presented with size less than 5 cms, compared to 28 patients of not off loaded group

Table 3: Size of the Ulcer

SIZE OF THE ULCER IN cms	Off loaded	Not off loaded
<5	41	28
>5	9	22

GRAPH 3: SIZE OF THE ULCER



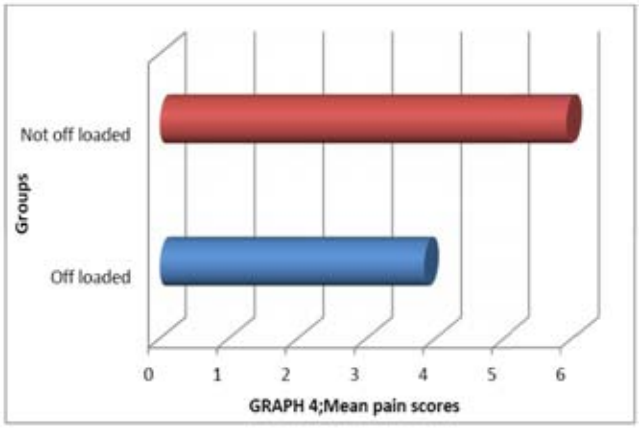
4) Comparison of Pain Scale

Among the patients who have undergone offloading the mean score on the pain scale was 3.84,compared to 5.92 for patients who had not undergone off loading. The results showing statistical significance with p value being 0.000.

Table 4: Painscale

	PAIN SCALE
Off loaded	3.84
Not off loaded	5.92

GRAPH 4: PAIN SCALE



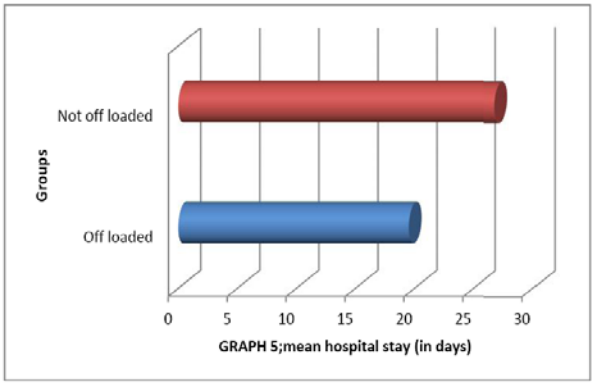
5) Comparison Of Duration Of Hospital Stay

Among the patients studied, the mean duration of hospital stay for the patients who has undergone off loading was 19.52 days, compared to 26.84 days for the non off loaded group. The results showing statistical significance with p value being 0.002.

Table 5: Duration of Hospital Stay

Off loaded	19.52
Not off loaded	26.84

GRAPH 5: DURATION OF HOSPITAL STAY



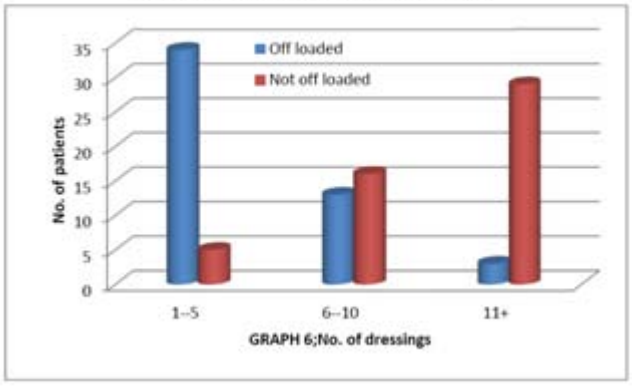
6) Comparison of Total Number of Dressings Done

Among the patients studied, of the off loaded group 34/50(68%) required 1 to 5 dressings, whereas among the patients who had not undergone off loading 29/50(58%) required more than 10 dressings showing a statistically significant value p=0.000.

Table 6: Number f Dressings

NO.OF DRESSINGS	Off loaded	Not off loaded
1--5	34	5
6--10	13	16
11+	3	29

GRAPH 6: NUMBER OF DRESSINGS



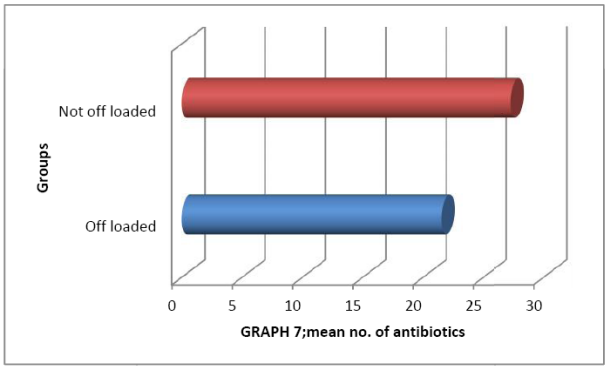
7) Comparison of Total Number of Days Antibiotics Were Administered

Among the patients studied, for the patients who had undergone off loading, the main duration of antibiotics administered was 21.5 days compared to 27.2 days for the patients who had not undergone off loading, the value being significant with p=0.034.

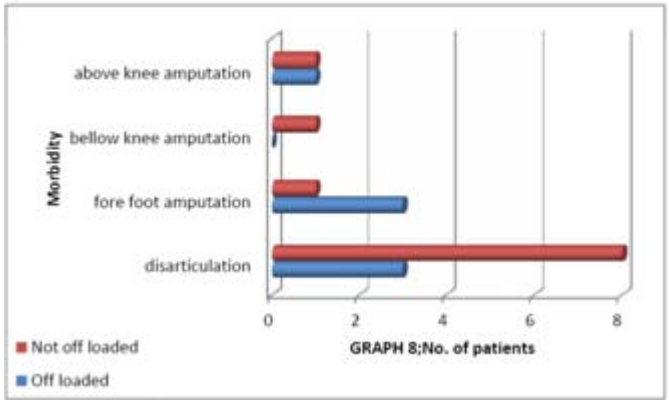
Table 7: No. of Days Antibiotics Given

Off loaded	21.52
Not off loaded	27.24

GRAPH 7: NO.OF DAYS ANTIBIOTICS GIVEN



GRAPH 8: MORBIDITY RATES



8) Comparison of Morbidity

Among the patients who had undergone off loading 7 patients(14%)required further disarticulations/ amputations to control the disease, where as among the non offloaded

group 11 (22%) patients required further disarticulations/ amputations; p=0.31.

Table 8: Morbidity Rates

MORBIDITY	Off loaded	Not off loaded
disarticulation	3	8
fore foot amputation	3	1
bellow knee amputation	0	1
above knee amputation	1	1

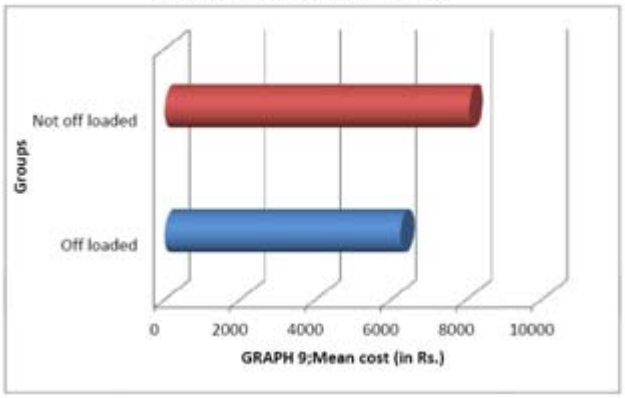
9) Comparison of Cost Effectiveness

Among the patients studied the mean cost of hospital stay for the off loaded group was 6249.62,where as it was 8062.52 for the non off loaded group. p=0.012.

Table 9: Mean Cost in RS

Off loaded	6249.62
Not off loaded	8062.52

GRAPH 9: MEAN COST IN RS



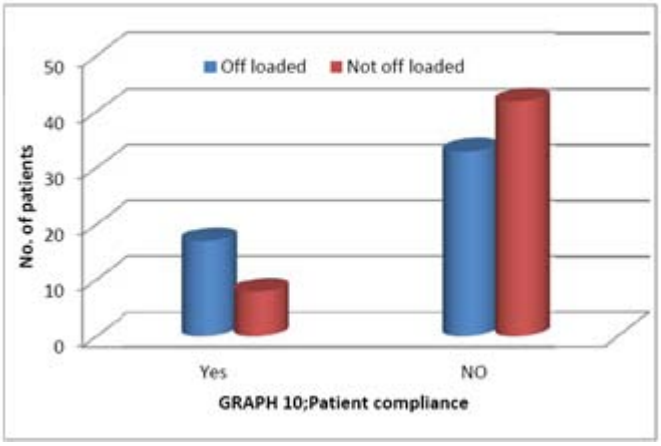
10) Comparison of Compliance

Among the patients studied in the off loaded group 17/50(34%) were compliant with the type of dressing done, where as only 8/50(16%) among the non off loaded group were compliant with the type of dressing done, with the value showing significance; p=0.038.

Table 10: Patient Compliance

PATIENT COMPLIANCE	Off loaded	Not off loaded
Yes	17	8
NO	33	42

GRAPH 10: PATIENT COMPLIANCE



6. Discussion

This is a prospective comparative study, comparing 100 diabetic patients with plantar ulcers,50 of whom had undergone off loading dressing and 50 of whom had undergone conventional dressing.

1) In the present study Patients who had undergone off loading had a significantly lesser score on the pain scale (mean = 3.84) compared to (mean= 5.98) among the non off loaded group, with p value p=0.000. Sunil v Kari in his study using 'mandakini off loading device' for off loading the diabetic foot plantar ulcers, concluded that pain experienced by the patient in off loaded group is much less, and patients were more compliant compared to not off
loaded group.7 My study with p=0.000
2) In the present study patients who had undergone off loading had a significantly shorter duration of stay (mean- 19.52 days) compared to those who had undergone conventional dressing (mean-26.84days), values showing significance, p=0.002. Study conducted by Gayle E.Reiber et al showed that mean length of hospital stay was around 20.6 days for diabetic patients with foot ulcers.
3) In the present study Patients who had undergone off loading 34/50 (68%) patients required 1-5 dressings compared to 29/50 (58%) patients who required more than 10 dressings, values showing statistical significance, p=.000. Sunil v Kari in his study concludes that, number of dressings used for off loading the diabetic plantar ulcers were significantly lesser.
4) The total expenditure of hospital stay for patients who had undergone off loading was significantly lesser (mean- 6249.62) compared to the conventional dressing group (mean- 8062.52), value showing significance, p=0.012.Sunil V. Kari in study mentioned that, total expenditure for off loaded patients was much lesser, as the total length of the hospital stay and number of dressings used were also low, and hence he recommends that using off loading technique, for diabetic plantar ulcers is economical. P=0.012

7. Conclusion

This study which compares off loading technique of dressing to the conventional technique for plantar ulcers in diabetic

patients using a simple off loading device has shown that patients undergoing off loading technique had significantly lesser pain, shorter duration of hospital stay, lesser number of dressings, required lesser doses of antibiotics, with a better compliance and lesser economic burden on the patient. Hence our study favors the off loading technique for plantar ulcers in diabetic patients as this technique is more tolerable, more compliant with shorter hospital stay and lesser economic burden on the patient.

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Author Profile

Dr. Shishira S Ranade, MS in surgery, working as a senior resident in the department of General surgery .J S S HOSPITAL, MYSORE. Affiliated to JSS medical college, A constituent of JSS University- Mysore, Karnataka, South India

Dr. B. J. Sharath Chandra, MS in surgery working as a professor and unit chief in the department of General surgery .J S S HOSPITAL,MYSORE. Affiliated to JSS medical college, A constituent of JSS University- Mysore, Karnataka, South India.