

## Retraction

The article "Studying the impact of the cost-effective Suvidha off-loading dressing in healing neuropathic ulcers in diabetic foot: a case series of 83 cases from South India" is retracted by the Editor-in-Chief, on the request of corresponding author and co-authors.<sup>1</sup> The article is retracted because the authors found some unintended mistakes.

## REFERENCES

1. Bhat SN, Vinoth D. Studying the impact of the cost-effective Suvidha off-loading dressing in healing neuropathic ulcers in diabetic foot: a case series of 83 cases from South India. *Int Surg J* 2020;7:2371-7. DOI: <http://dx.doi.org/10.18203/2349-2902.isj20202851>.

## Case Series

# Studying the impact of the cost-effective Suvidha off-loading dressing in healing neuropathic ulcers in diabetic foot: a case series of 83 cases from South India

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## ABSTRACT

Neuropathic ulcers pose a global burden carrying a risk of amputation of 15-46 times especially in developing countries. These ulcers are mainly managed with offloading techniques. In this study we share our experience of using an easy to use, cost effective method the Suvidha offloading dressings in terms of its acceptability and effectiveness in managing these cases. A prospective case series of 83 patients with mean age 58 years, managed with Suvidha offloading dressing in our institution from 2016 till 2019, excluding patients with ABI less than 0.4 and Wagner 4 and 5. They were reviewed after 6 months/SOS. Ulcer measured 1×1 to 4×4 cm, was present most commonly in the mid foot and least commonly in the lateral aspect of the foot. 53 cases were Wagner grade 2 and 9 cases Wagner grade 3. Forty cases were initially infected, 29 cases had a deformed foot, 5 cases needed interval wound debridement. The duration of ulcer healing was 2 weeks for 1×1 cm great toe ulcer, to 12 weeks for the 4×4 cm mid foot ulcer. All 83 patients were followed up for 6 months. 5 ulcers recurred. The patient satisfaction was measured by a 5-points Likert scale with a mean value of 17.4 out of 20. The Suvidha offloading footwear is a cost effective, easily replicable and efficient dressing requiring only the readily available dressing materials, with good healing rates, good patient satisfaction and adapted for developing countries. The results are comparable with other methods of offloading practiced worldwide.

**Keywords:** Suvidha, Offloading, Diabetes, Ulcer, DFUs

## INTRODUCTION

Ulceration of the lower limb affects 1% of the adult population and 3.6% of people older than 65 years. Leg ulcers are debilitating and painful. They greatly reduce patient's quality of life. Ulcer healing has been shown to restore quality of life. Lower limb ulceration tends to be recurrent and the total annual cost of treating leg ulcers to the NHS has been estimated at £400m.<sup>1</sup> Chronic ulcers ruin the life of patients and increases the burden on health care as a whole. Neuropathic ulcers are formed due to undue pressure leading to breakdown of skin. Various

causes are implicated, but diabetes is the most common cause. The number of diabetics worldwide was estimated at 131 million in 2000. It is projected to increase to 366 million by 2030. Diabetic patients have up to 25% lifetime risk of developing foot ulcers. The annual incidence of diabetic foot ulcers is ~3%.<sup>2</sup> The worldwide prevalence rate of diabetic foot ulcer (DFU) was 6.3%. North America showed the highest prevalence rate of 13.0% compared with Oceania with prevalence rate of 3.0%. Africa showed a prevalence rate of 7.2% which is higher than Asia 5.5%. Europe showed a prevalence rate of 5.1%, Australia has prevalence rate of 1.5%.<sup>3</sup> Belgium

with 16.6%, followed by Canada 14.8% and USA at 13.0%. India showed a prevalence rate of 11.6%.<sup>3</sup> The main problem with the diabetic foot ulcers is that the risk of amputation is 15-46% more compared with non-diabetic patients.<sup>4</sup> This not only adds to the morbidity, but also sets up the vicious cycle of increased pressure on the other limb making it more vulnerable for new onset neuropathic ulcers.

As the pressure is implicated in the formation and chronicity of neuropathic ulcers, off-loading of the wound is one of the key elements in treating diabetic (neuropathic) foot ulcers.<sup>5</sup> Several off-loading devices are available, such as walkers, half shoes, orthoses, felted foam, and the total contact cast (TCC), which is seen as the definitive standard therapy.<sup>6</sup> Studies concluded that a TCC healed a higher proportion of neuropathic, non-infected ulcers in a shorter amount of time, with healing rates of ~90%.<sup>7</sup> With total contact cast, in a wide range of ulcers, the majority of patients (76%) showed good response in a relative short time span (median 33 days). Ninety percent of the ulcers healed in a median of 18 days; these results are comparable with the aforementioned randomized controlled trials in which TCC was evaluated.<sup>7,8</sup>

Although a TCC seems a highly attractive off-loading modality and is accepted as the gold standard treatment modality in diabetic foot ulcers, several disadvantages have been reported: new ulcers may occur, daily wound care is not possible, mobility is impaired, costs may be relatively high, and specialized staffs are necessary.<sup>9</sup> In case of prolonged casting, joint rigidity and muscular atrophy have been documented.<sup>10</sup> There are also contraindications to TCC like the presence of peripheral arterial disease (PAD) and/or infection needing daily inspection. In addition, fear of complications and lack of educated staff hamper the implementation of TCC in daily clinical practice.

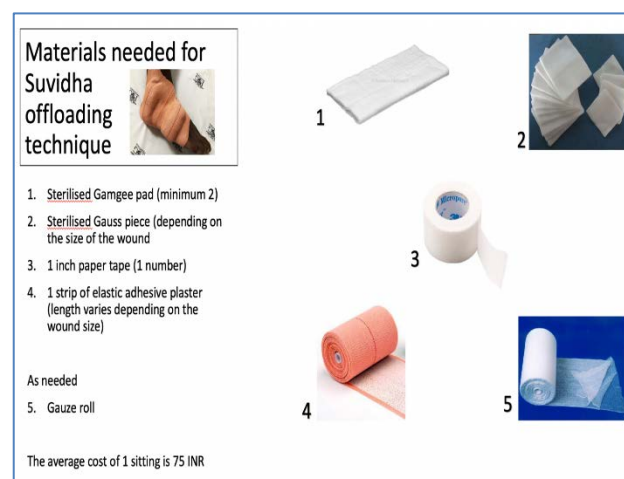
Cost factor can also have an impact, especially in the economically challenged countries, precluding other options for offloading like orthoses, foam foot wear etc. We had developed an offloading dressing technique named as Suvidha offloading dressing (Suvidha implies to comfort/convenience in Hindi) which incorporates the routine materials used for dressing, which is cost-effective and easy to apply. This might be an advantage for patients who do not tolerate the total contact cast and are economically challenged to opt for other options. This offloading dressing is similar to the various other cost-effective methods of offloading practiced in India such as Mandakini technique of offloading and Samadhan system of offloading where a pair of hand-gloves and foam are used as offloading units respectively. We use a rolled-up Gamgee pad instead of a glove which we observed gave good comfort, sturdiness and a good healing rate without compromising much on the patient satisfaction. As Gamgee pad was sterilized and readily available, it was preferred over the gloves. In this study we share our

experience of using the Suvidha offloading dressings in terms of its acceptability and effectiveness. The main objective is to share our experience of a cost-effective, easily replicable and efficient offloading footwear ideal for use in poor resource countries

## CASE SERIES

This prospective study was conducted in PSG Institute of Medical Sciences and Research, Coimbatore, in Tamil Nadu, India from 2016 till 2019. Over this 3 years period, 83 patients were managed with Suvidha offloading dressing. All patients who were having neuropathic ulcer only due to diabetes mellitus, those above 30 years of age, who were unwilling for total contact cast and managed by Suvidha offloading technique by a single surgeon in our institution were included. Those who had peripheral vascular disease (ABI<0.4), ulcers with Wagner grade 4 and 5, those who opted other offloading methods like rocker bottom foot wear, crutches etc. in combination to the Suvidha technique, those with infected ulcers which needed daily wound inspection and those with poor compliance and follow up were excluded. The cost of Suvidha offloading dressing was around 75 Indian Rupees (INR) for each week, with the highest cost of around 900 INR for 12 weeks.

The Suvidha offloading dressing needs the following materials namely 2 sterilized Gamgee pads, a 1-inch paper tape (micropore surgical tape). 2 to 5 gauss pieces depending on the cross section of the wound and an adequate length of elastic adhesive plaster enough to overlap 5 cm of the Gamgee pillars (Figure 1).



**Figure 1: Materials needed for Suvidha offloading dressing.**

For wounds without recent infection, the method of application is as follows as shown in (Figure 2). The wound is initially cleaned and made sure that it is not currently infected. Making the offloading Gamgee pad pillars - the Gamgee pad is rolled or folded to form a small "pillow" which is 1 cm to 1.5 cm in thickness. This

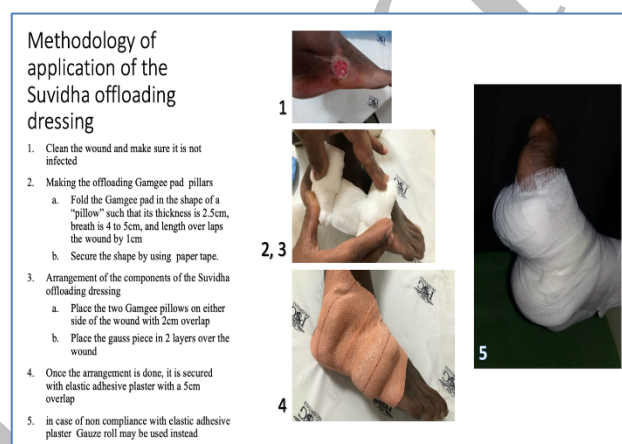
is important because the Gamgee pads will flatten over time. The breadth is 5 cm. The length of the pillow depends on the length of the wound with a 2cm overlap. The Gamgee pad after rolling into a pillow shape of 1cm to 1.5 cm thickness, is held in shape with paper tape. This pillow is used as an offloading unit. One to two such pillars are made depending upon the location of plantar ulcer (Figure 2).

**Method of application of the Suvidha offloading dressing** - one to two Gamgee pillows are placed one on either side of the wound to act as offloading pillars. The wound is covered with 2 layers of gauss piece as needed and the arrangement is secured with an elastic adhesive plaster overlapping the Gamgee pillars by 5cm on all sides (Figure 2). The leg may or may not be encircled.

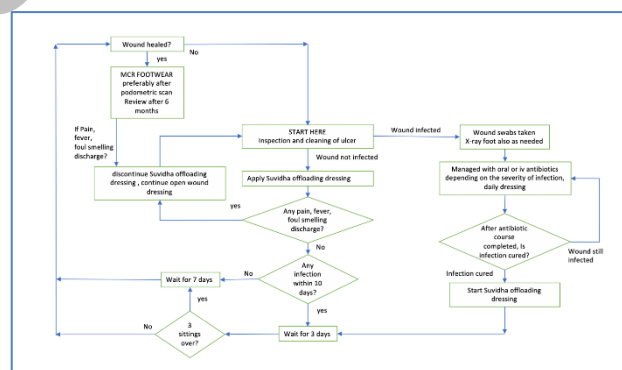
In case of non-availability of materials, gauze roll can be used instead of elastic adhesive plaster and sterile gauss stacked to 1.5 cm instead of Gamgee pad (Figure 6). **Duration of dressing and follow-up.** The dressing is changed once in 7 days. **Precautions taken** - all patients are instructed not to wet the dressing, to keep it dry and clean. They are mainly instructed regarding the need for immediate wound inspection if within the 7 days period they develop fever, pain, swelling or foul-smelling discharge. In such case, the dressing is removed, the wound is thoroughly inspected. If there is evidence of infection, the dressing is discontinued and the wound is managed as a case of infected ulcer as described below. **Review** - after 7 days, the dressing is removed, wound is inspected and re-debrided if needed. If the wound is still not healed, the offloading dressing is reapplied. And the patient is asked to review after 7 days. If the wound is healed, a custom made offloading MCR footwear to prevent recurrence of ulcers are advised. The customized MCR sandals were made preferably after a podometric scan noting the pressure zones with the help of PMR department at our institution.

In case of infected ulcers- swabs are taken for pus culture and sensitivity; radiograph of the foot is taken to rule out osteomyelitis and the wound is then thoroughly debrided. Depending on the severity of infection, oral or iv antibiotics are given as per the sensitivity and daily dressing is done. When the wound infection is under control, the Suvidha offloading dressing is done once in 3 days for initial 2 to 3 sittings. Once the wound is non-infected, it is changed once in 7 days till ulcer heals. If during the course of healing, pain occurs, the dressing is removed, wound is then inspected. If there is evidence of infection, the wound is debrided, antibiotics are administered, and daily dressing is done till wound infection settles. This is followed by Suvidha offloading once in 3 days dressing and then once healed, once in 7 days. Once ulcer is healed, customized MCR footwear is prescribed (preferably after a podometric scan) and patient is asked to follow-up once in 6 months for 1 year and as needed thereafter (Figure 3).

The data of the 83 patients who were managed with Suvidha offloading technique collected were age, sex, initial size of the ulcer, Wagner's grade of diabetes, location of the ulcer in the foot, whether the wound was initially infected, presence of deformed foot due to history of previous debridement or toe amputations, the need for interval wound debridement, the duration needed for ulcers to heal, whether podometric scan was done, recurrence of ulcer after 6 months if any and finally patient satisfaction which was measured using Likert scale during the prescription of the MCR footwear. The data was tabulated in excel worksheet, and the mean values were calculated. The distribution of data by is illustrated in (Table 1). There was no comparison group.



**Figure 2: Method of application of Suvidha offloading dressing.**



**Figure 3: Flowchart for management of Suvidha offloading dressing.**

A total of 83 patients were selected who met the inclusion and exclusion criteria. The minimum and maximum age noted in this study were 37 and 88 years respectively. The mean age was 58 years, there were 52 males and 31 females. The smallest size of the ulcer was in the great toe of 1×1cm size, the largest ulcer was 4×4 cm in size in the mid foot (Figure 4). The location of ulcers was as follows. 10 patients had ulcers in the base of the great toe (Figure 5), 12 cases were in the heel, 5 cases were in the lateral aspect of the foot (Figure 7), 6 were in the great

toe (Figure 5E), 23 were in the meta tarsal region (Figure 8) and 27 were in the mid foot region and 11 of them had a deformed foot (Figure 4). The diabetic ulcers were limited to a maximum Wagner grade 3 only. 21 cases had Wagner grade 1, 53 cases had Wagner grade 2 and 9 cases had Wagner grade 3 ulcers. 40 cases were infected initially before applying the Suvidha offloading dressing and were having once in 3 days dressing for the initial 3 settings (Figure 8). 29 cases had a deformed foot (Figure 4 and 8) due to previous surgery and amputations. Totally 5 cases needed interval wound debridement and thereby the total ulcer healing time for them was not calculated. The duration of ulcer healing was minimum 2 weeks for the 1×1 cm size great toe ulcer (Figure 5) and the longest was 12 weeks for the 4×4 cm mid foot region ulcer (Figure 4). 28 patients did not do the podometric scan as they were not affordable.



**Figure 4: Mid foot ulcers.**



**Figure 5: Base of great toe ulcer.**



**Figure 6: Alternatives in case of shortage of materials.**



**Figure 7: Ulcer in the lateral aspect of foot.**



**Figure 8: Meta tarsal ulcer, in a deformed foot which needed multiple debridement. Patient had recurrence after 6 months.**

All 83 patients were followed up for 6 months, where 5 cases had recurrent ulceration (Figure 8). During the time of review however, the patients were seen by 5 different surgeons during their routine shift. The patient satisfaction was measured by the Likert scale (Figure 9). The lowest was 10 (3 cases) and the highest was 20 (20 cases) with a mean value of 17.4. The Data was compared as per the location of the ulcer as depicted in (Table 1).

Table 1: Comparing the parameters of the diabetic foot ulcers based on location of ulcer.

Location of ulcer	Number of cases with ulcers present in this region	Mean age	Size range	Most common wagner's grade	Number of ulcers initially infected	Number of deformed foot due to previous surgery	Number of cases needing interval wound debridement	Mean Time required for the ulcer to heal (weeks)	Number of cases where podometric scan was done	Number of recurrent ulcers	Mean Likert scale
Great toe	6	49	1×1 to 1×3	2	none	1	none	2.33	1	none	20
Base of great toe	10	56	1×1 to 3×3	2	1	1	none	3.8	5	none	17.3
Meta tarsal region	23	63	1×2 to 3×4	2	10	10	none	7.3	17	2	17.3
Lateral aspect of foot	5	55	1×1 to 2×2	2	1	0	0	3.2	2	none	18.6
Mid-foot	27	57	2×2 to 4×4	2	22	11	4	8.6	21	3	16.5
Heel	12	60	1×2 to 4×3	2	6	6	1	6.2	9	none	17.8

Likert scale used to evaluate the patient satisfaction in Suvidha technique					
The Suvidha offloading dressing is	Strongly disagree (1 point)	Disagree (2 points)	Undecided (3 points)	Agree (4 points)	Strongly agree (5 points)
1. Cheap and affordable					
2. Comfortable to wear					
3. Easy to maintain					
4. Easy technique to master if needed					
<b>Total</b>					<b>20 points</b>

Figure 9: Likert 5 points scale - maximum score of 20 points.

## DISCUSSION

The management of diabetic foot offloading was present from early times. The methodology however was different. Total contact cast is considered gold standard with a good success rate i.e. 90% of the ulcers were healed in a median time of 18 days, however it is evident that only 2% of the patients comply to it.<sup>7,8</sup> In our case study, the mean healing time was variable to the site of the ulcer with the minimum time taken for the great toe as 2 weeks, and the maximum of 5 weeks for mid-foot ulcers. The most common Wagner's grade noted was 2<sup>nd</sup> grade.

Various other offloading techniques were introduced in India such as the Bohler iron plaster cast, Samadhan system of offloading, similarly, Mandakini offloading device, has a mean wound healing time of 4.83 weeks.<sup>11</sup> Several other offloading techniques namely cast shoes, modified shoes with insoles, in-shoe orthoses, surgical offloading techniques like Achilles tendon lengthening (ATL), silicone injections, tissue augmentation, metatarsal head resection, osteotomy/arthroplasty/ostectomy/exostectomy, external fixation; flexor tendon transfer or tenotomy, crutches/canes/wheelchairs, bracing (patella tendon bearing, ankle-foot orthoses); (non-)removable walkers; offloading dressings; felted foam/padding; callus debridement; walking exercise; and gait modification are available.<sup>12</sup> This systematic review showed that the evidence to support the use of footwear and offloading interventions has improved substantially in several areas over the last years but is still small or non-existent in other areas. The best available evidence is for the use of non-removable devices, either TCC or walkers renders irremovable, for the healing of neuropathic plantar forefoot ulcers. Additionally, high-quality recent evidence supports the use of therapeutic footwear that has a demonstrated reduction in plantar pressure and that is consistently worn by the patient to prevent plantar foot ulcer recurrence.<sup>12</sup> All the patients in our study were prescribed customized MCR foot wear after the ulcer healed to prevent recurrence. Despite advising the need for a podometric scan to better prescribe the foot wear, 28 out of 83 patients were not

affordable to do it. The recurrence however was noted in 5 cases all of whom had done the podometric scan but failed to use recommended foot wear.

The Wagner's grade of ulcer in our study, was not found to have a significant impact on ulcer healing rates, as most of the ulcers had a Wagner's grade 2, which differed widely in the stages of healing. A study by Samyon et al concluded that healing times were not significantly different for each grade of the Wagner ( $p=0.1$ ) or the university of Texas (UT) system ( $p=0.07$ ), but there was a significant stepwise increase in healing time with each stage of the UT system ( $p<0.05$ ), and stage predicted healing ( $p<0.05$ ) i.e. increasing stage, regardless of grade, is associated with increased risk of amputation and prolonged ulcer healing time. The UT system's inclusion of stage makes it a better predictor of outcome.<sup>13</sup>

The location of the ulcer in this study however was noted to have varying healing times especially with deformed foot. The great toe ulcers had the fastest mean healing time of 2 weeks with only 1 of the 6 cases with deformed foot. The longest healing time of 8 weeks, and the longest mean healing time of 5 weeks were noted in the mid-tarsal region where all cases had deformed foot due to prior surgeries. According to Younis et al, the prevalence of DFU was 7.02%, of which 4.5% of the ulcers were on the planter and 2.6% on the dorsal surface of the foot; 8.5% of the persons had bilateral foot ulcers and 0.4% subjects had Charcot deformity.<sup>14</sup>

The overall cost of the Suvidha offloading technique was minimum of 75 INR for a single dressing to maximum about 900 INR for 12 weeks healing ulcers which required no interval wound debridement.

The patient satisfaction is the ultimate aim for any offloading dressing given the vast array of options available to the patient. Kendra et al commented that there are few data on the impact of offloading regimens on patient satisfaction in diabetic foot populations. Given that offloading is one of the cornerstones of gold-standard neuropathic foot ulcer treatment, the paucity of research on patient satisfaction with these modalities is a large gap in the literature.<sup>15</sup> In our study we used the 5 points Likert scale (score 0 to 20) (Figure 4) to grade the patient's satisfaction. The minimum score was 10 for a heel ulcer of 3x3cm heel ulcer in a deformed foot. The maximum score was 20. The mean score overall was 17.4, the maximum mean scores of 20 was for the ulcers in the great toe region.

### Limitations

Thick Gamgee pads 10x10cm or larger may not be readily available especially in rural setup. Elastic adhesive dressing may not be available in many smaller hospital setups, use of regular dressing instead may lead to displacement of offloading device and ailure of the

dressing. Maintaining a clean and dry dressing for 1 week is cumbersome. Need for strict follow-up as the wound can get infected if it is not regularly inspected.

### CONCLUSION

The Suvidha offloading footwear is a simple, affordable and cost-effective dressing requiring readily available dressing materials with good healing rates and good patient satisfaction, comparable with other methods of offloading practiced worldwide. This technique is easy to learn and simple to practice by surgeons treating diabetic foot ulcers in developing countries.

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