

Original Article

Role of customised negative-pressure wound therapy in the integration of split-thickness skin grafts: A randomised control study

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ABSTRACT

Background: Split-thickness skin grafting (STSG) is a time-tested technique in wound cover, but many factors lead to suboptimal graft take. Role of custom-made negative-pressure wound therapy (NPWT) is compared with conventional dress in the integration of STSG and its cost is compared with widely used commercially available NPWT. **Materials and Methods:** This is a parallel group randomised control study. Block randomisation of 100 patients into one of the two groups (NPWT vs. non-NPWT; 50 patients each) was done. Graft take/loss, length of hospital stay post-grafting, need for re-grafting and cost of custom-made negative pressure wound therapy (NPWT) dressings as compared to widely used commercially available NPWT were assessed. **Results:** Mean graft take in the NPWT group was $99.74\% \pm 0.73\%$ compared to $88.52\% \pm 9.47\%$ in the non-NPWT group ($P = 0.004$). None of the patients in the NPWT group required second coverage procedure as opposed to six cases in the non-NPWT group ($P = 0.035$). All the patients in the NPWT group were discharged within 4–9 days from the day of grafting. No major complication was encountered with the use of custom-made NPWT. Custom-made NPWT dressings were found to be 22 times cheaper than the widely used commercially available NPWT. **Conclusions:** Custom-made NPWT is a safe, simple and effective technique in the integration of STSG as compared to the conventional dressings. We have been able to reduce the financial burden on the patients as well as the hospital significantly while achieving results at par with other studies which have used commercially available NPWT.

KEY WORDS

Negative-pressure wound therapy; skin transplantation; wounds and injuries

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INTRODUCTION

Wounds requiring reconstruction are usually large with extensive soft-tissue loss caused by trauma, infections, burns, diabetic foot ulcers, pressure sores, etc. These situations often lead to considerable distress to the patients and have a negative impact on the physical, emotional, social and economic aspects of their lives.^[1,2]

One of the principal tools of a reconstructive surgeon is the split-thickness skin graft (STSG), which is a simple yet versatile technique for reconstruction of cutaneous defects. The major causes of skin graft loss are the formation of blisters or hematomas under the graft which interfere directly with serum imbibition and revascularisation, lack of proper apposition of graft to its bed and infection of the graft. Thus, further interventions are required for successful coverage of such wounds.^[3]

The efficacy of negative-pressure wound therapy (NPWT) in wound care was initially described by Morykwas *et al.*^[4] in the United States in 1997. It has also been used to optimally prepare the wound surface for graft acceptance and to enhance graft take.^[5-7]

Commercially available NPWT has become popular, but despite its presence in the market for two decades, the main reason for its limited usage is its cost, and alternatives have been keenly sought.^[8] Patients who attend to our hospital belong to low socioeconomic strata as such they cannot afford the cost of commercially available NPWT dressing. However, we wanted to provide our patients the benefit of this new wound care concept as such we devised a custom-made NPWT.

Objectives

- To determine its feasibility and safety
- Whether custom-made NPWT improves the skin graft take
- Whether custom-made NPWT shortens hospital stay
- Need for secondary wound coverage procedures
- Cost-effectiveness.

MATERIALS AND METHODS

This was a parallel group randomised control study conducted from January 2013 to December 2015 in our department. The research was conducted according to the principles of the Declaration of Helsinki after

obtaining clearance from the Institution's Ethical Committee.

A total sample size of 100 patients was considered to be sufficient to detect a difference of 10% in graft take between the two groups with a power of 90% with 95% confidence. After informed consent, all the enrolled 100 patients with wounds ready to be grafted due to varied aetiologies were subjected to detailed history, systemic and local examination followed by routine investigations and wound swab cultures. Patients aged below 10 years, ones with psychiatric disorders and those who refused consent were excluded from the study [Supplementary Figure 1].

The wounds were prepared by debridement, serial saline/betadine dressing or by NPWT until fit for grafting [Figure 1a]. STSG of intermediate thickness was harvested, fenestrated and sutured to the recipient site. Once the graft was fixed, block randomisation of the patient into one of the two groups (NPWT vs. non-NPWT; 50 patients each) was done by computer-generated numbers. Allocation concealment was done by sealed envelope method.

Negative-pressure wound therapy group

The STSG was covered with a single layer of paraffin gauze dressing, followed by two sheets of autoclave sterilised locally available open cell polyurethane foam (cut to fit the contour of the wound) with a fenestrated tube between the two layers and covered with a transparent adhesive dressing (iodrape) creating a vacuum seal after bringing the tube out through a hole made in the adhesive dressing and securing the tube to the opening with iodrape pieces [Figure 2a]. While applying customised NPWT on hairy areas such as head and neck, groin and sacrum, hair was shaved/trimmed for 3–5 cm around the wound for adequate seal with



Figure 1: (a) Healthy granulating wound, (b) complete graft take on the 4th post-operative day while removing the negative-pressure wound therapy dressing, (c) stable graft at follow-up

iodrape. Besides, prior tincture benzoin application helps in better adherence of iodrape in these areas. No differences exist in application of customised NPWT over limbs as compared to flat surfaces such as trunk. The patient was transported to the recovery room and back to the ward. After arrival in the ward, before connecting the tubing to the wall mounted suction [Figure 2b], vacuum regulator was adjusted to the desired negative pressure level (125 mmHg) by occluding the outlet of the canister with the thumb. After connecting the tubing to the canister, further titration of pressure was done if required. The tubing has to be of sufficient wall thickness so that it does not collapse when exposed to high negative pressures and some bending.

Non-negative-pressure wound therapy group

The STSG was covered with a single layer of paraffin gauze dressing, followed by tie over bolster dressing. Supplementary Plaster of Paris slab was used in extremity wounds.

Post-operative care

After the intervention, patients were confined to bed and allowed limited movement only for personal hygiene. Patients in the NPWT group were kept on continuous suction for 4 days. No extended wound care was performed in both the groups until 4th post-operative day when all wounds were uncovered and assessed and photographs were taken [Figure 1b and c]. NPWT was not applied again after 4th post-operative day in any case.

Outcome

The main outcome was the percentage and the area in cm² of skin graft take and graft loss. It was assessed with the help of digital photographs which were taken from a

distance of 40 cm from the wound with a single camera and analysed with the Adobe CS₃ software by a third person who was blinded to group allocation.

Other outcomes that were assessed are:

- Length of hospital stay after grafting
- Requirement for re-grafting the same site
- Cost of custom-made NPWT dressings as compared to widely used commercially available NPWT.

Statistical analysis

Data were analysed using SPSS for Windows IBM Corp., Released 2011. IBM SPSS statistics for Windows, version 20.0. IBM Corp., Armonk, NY, USA. Categorical outcomes in the two groups were compared using Yates-corrected Chi-square test. Continuous outcome measures were compared using Mann–Whitney U-test. All *P* values were two-sided, and a *P* < 0.05 was considered statistically significant.

RESULTS

Baseline demographics of the patients are shown in Table 1. Trauma was the leading cause of wounds, and ankle and foot was the most common site (52.83%) in both the groups [Table 1]. Around one-third of the

Table 1: Demographics of the patients, aetiology and distribution of wounds

Variable	NPWT group (n=50)	Non-NPWT group (n=50)
Age (mean±SD)	39.5±16.2	40.1±17.4
Sex		
Male	36	39
Female	14	11
Cause of wound (%)		
Trauma	28 (56)	26 (52)
Diabetes	10 (20)	7 (14)
Burn	6 (12)	8 (16)
Post-fasciotomy	2 (4)	3 (6)
Post-infective	3 (6)	3 (6)
Frostbite	1 (2)	3 (6)
Site of wound (%)		
Scalp	2 (3.7)	-
Neck	-	2 (3.8)
Chest	-	2 (3.8)
Upper limbs	6 (11.1)	2 (3.8)
Thigh	2 (3.7)	14 (26.9)
Leg	8 (14.8)	12 (23)
Ankle and foot	36 (66.6)	20 (38.5)
Total number of wounds	54 (100)	52 (100)

Four patients in the NPT group and two patients in the non-NPT group had two wounds each, while rest of the patients had one wound each. SD: Standard deviation, NPWT: Negative pressure wound therapy



Figure 2: (a) Locally available disposables used for customised negative-pressure wound therapy: Polyurethane foam, iodrape and tubing, (b) Wall mounted canister connected to hospital central suction

wounds in both the groups (36 [33.96%]) were prepared for STSG by NPWT pre-operatively while conventional betadine-saline dressing was used in the remaining wounds. Area and percentage of graft take/loss was calculated after assessment of wounds on the 4th post-operative day [Table 2]. The mean difference in the percentage of graft take was 11.22% with 95% confidence interval of 5.75–16.69.

None of the patients in the NPWT group required second coverage procedure as opposed to six cases in the non-NPWT group who had to undergo second-stage grafting for adequate wound cover ($P = 0.035$).

All the patients in the NPWT group were discharged within 4–9 days from the day of grafting. In the non-NPWT group, 40% cases had to stay beyond 9 days, and the maximum duration of hospital stay post-grafting was 22 days.

No major complication was encountered with the use of custom-made NPWT. Minor complications included maceration in six patients and pain on the removal of NPWT in nine patients which was managed by thorough cleaning, analgesics and infiltration of xylocaine through tubing 10 min before dressing change.

For analysing cost of dressing using handcrafted as compared to commercially available dressing, wounds were divided into three groups depending on the maximum dimensions of the wound [Table 3].

DISCUSSION

In a short span of 20 years, since NPWT has come into vogue, it has been used for the integration of STSG for wounds of varied aetiologies. More than half of the wounds in both the groups of our study were caused by trauma (28 cases [56%] in the NPWT group and 26 cases [52%] in the non-NPWT group). Diabetes (10 cases [20%]) and burns (8 cases [16%]) were the second leading causes of wounds in NPWT and non-NPWT groups, respectively. Trauma was the leading cause of wounds in the series presented by Moisidis *et al.*^[9] and Jeschke *et al.*^[10] as seen in our study while Llanos *et al.*,^[3] Scherer *et al.*^[11] and Kamolz *et al.*^[12] reported the use of NPWT over graft mostly in burns.

Other causes of wounds reported in literature for which NPWT has been used for the integration of STSG include diabetic wounds,^[13] hidradenitis cystica and amputation stump wounds,^[5] wounds following excision of irradiated extremity sarcomas,^[14] necrotising fasciitis and associated pubic bone osteomyelitis,^[15] Fournier's gangrene,^[16] chronic leg ulcers,^[17] over punch grafts after excision of melanoma feet^[18] and over radial forearm free flap donor sites.^[19] NPWT has also been used for securing skin grafts to microvascular free flaps^[20] and for the vulvovaginal reconstruction with skin grafts.^[21] Role of NPWT has also been reported in single-stage approach to stabilise skin grafts on the skull after outer table bone was removed.^[22]

Table 2: Mean area of wound, mean graft take and loss among the two groups

Variable	Mean±SD		P
	NPWT group*	Non-NPWT group*	
Area of wound grafted (cm ²)	93.78±74.12 (12.62-327.40)	135.68±122.82 (17.34-516.65)	0.137
Graft take (%)	99.74±0.73 (96.60-100.00)	88.52±19.47 (13.40-100.00)	0.004
Graft loss (%)	0.26±0.73 (0.00-3.40)	11.47±19.47 (0.00-86.60)	0.004

Figures in parentheses indicate range. NPWT: Negative pressure wound therapy, SD: Standard deviation, * $P < 0.05$ was considered statistically significant

Table 3: Cost difference between custom-made negative-pressure wound therapy dressings and widely used commercially available negative-pressure wound therapy dressings

Serial number	Size of dressing/wound	Total number of dressings used	Cost of single commercial NPWT dressing* (INR)	Total cost of commercial NPWT dressings (INR)	Cost of single custom-made NPWT dressing** (INR)	Total cost of custom-made NPWT dressings (INR)
1	Small (10 cm × 7.5 cm)	36	7563	272,268	336	12,096
2	Medium (18 cm × 12.5 cm)	44	9075	399,300	385	16,940
3	Large (26 cm × 15 cm)	29	11,440	331,760	540	15,660
Total				1,003,328		44,696

*MRP of widely used commercially available NPWT dressings in Jammu and Kashmir. The cost includes adhesive draping, polyurethane foam and connecting tube, **Cost of custom-made NPWT dressing. The cost includes adhesive draping (incise drape/iodraper), locally available half inch thick medium density open cell polyurethane foam with pore size of 400–600 μ available as 6×3 feet sheet cut to desired size and autoclaved and connecting tubing. NPWT: Negative-pressure wound therapy, INR: Indian Rupee, MRP: Mediscor Reference Price

Wounds are generally irregular in shape, so the calculation of wound size becomes a difficult task. We used the tracing of the wound (initial and final stage). This tracing along with a scale was photographed, and the wound area and area of graft take and graft loss were calculated using computer software Adobe Photoshop CS3. Llanos *et al.*^[3] used AutoCAD software for calculation of wound size, whereas Mouës *et al.*^[1] used Adobe Photoshop for same purpose.

Both the groups were comparable with no statistically significant difference ($P = 0.137$) as far as the size of wound was concerned. NPWT has been used over STSG for the coverage of wounds ranging from small to large sizes. The mean wound sizes of the two groups of our study were $93.78 \pm 74.12 \text{ cm}^2$ in NPWT and $135.68 \pm 122.82 \text{ cm}^2$ in non-NPWT groups, respectively. Many studies have reported similar mean wound size as ours^[14] while some have reported smaller^[3,23] and larger^[10,11,22] wounds.

Non-standard/custom-made NPWT has been used over STSG by Llanos *et al.*,^[3] Petkar *et al.*,^[24] and Dorafshar *et al.*^[25] with comparable results.

Assessment of post-operative graft take/graft loss (area and percentage)

Mean graft take in the NPWT group was $99.74\% \pm 0.73\%$ compared to $88.52\% \pm 9.47\%$ in the non-NPWT group, difference was statistically significant ($P = 0.004$). Mean graft loss in the NPWT group was $0.26\% \pm 0.73\%$ compared to $11.47\% \pm 19.47\%$ in the non-NPWT group which also turned out to be statistically significant ($P = 0.004$).

Several studies have reported statistically significant difference in the quality and quantity of graft take using NPWT over graft as compared to conventional dressing, similar to our results.^[3,6,9-12,24-27] Furthermore, significant difference in the mean graft loss between the two groups has been reported by Llanos *et al.*^[3] concordant to our results.

Several postulates suggest why negative pressure dressings may improve graft survival.^[4] First, an important aspect to successful graft take is maintaining good apposition between the graft and the wound surface. By design, continuous negative pressure dressings provide a uniform distribution of negative pressure and apposition between the graft and the wound bed in most cases, even if the surface contour is irregular.^[22,28] This becomes particularly important for patients with traumatic injuries

necessitating skin grafting as these grafts are often in irregularly contoured regions such as the hand, wrist and ankle. Second, accumulation of hematoma or seroma under the graft contributes to graft loss. The negative pressure dressing provides continuous removal of wound fluid, which prevents the accumulation of hematoma or seroma while maintaining graft to wound apposition.^[5,28] Third, desiccation is detrimental to wound healing^[29] and is reduced with the occlusive nature of the NPWT dressing, in which a moist environment is maintained. Last, infection contributes to graft loss. NPWT has been associated with lower bacterial counts at wound sites,^[4] and this reduction in the local bacterial flora may enhance graft survival.

Need for second-stage grafting

None of the patients in the NPWT group required second coverage procedure as opposed to six cases in the non-NPWT group who had to undergo second-stage STSG for adequate wound coverage which is a statistically significant difference ($P < 0.05$).

Initial graft survival with NPWT reduces the need for repeated grafting, which may eliminate costly repeated surgical expense and hospital stay.^[6] Many studies have reported significant reduction in the reoperation rates in the grafts covered by NPWT as found in our study^[3,6,11] while Moisidis *et al.*^[9] reported no need for regrafting any case in either of the two groups. Home-made devices are more effective at preventing reoperation, and patients report less pain on dressing change.^[30]

Hospital stay in days from grafting to discharge

Expediting the patients discharge to home offers a cost-effective advantage to both hospital and patient. In our study, all the patients in the NPWT group were discharged within 4–9 days from the day of grafting. In the non-NPWT group, 10 cases (40%) had to stay beyond 9 days, and the maximum duration of post-grafting hospital stay was 22 days. Length of post-STSG hospital stay was significantly reduced in the NPWT group ($P = 0.034$), thus reducing the burden on the hospital workforce, resources and infrastructure and enabling their better utilisation.

Llanos *et al.*^[3] noted that the mean post-grafting hospital stay was 8 days (range 7–13 days) in the negative pressure group versus 12 days (7–23 days) in the control group which was statistically significant ($P = 0.001$) and is in agreement with our study. Scherer *et al.*^[11] noted that the

post-STSG length of hospital stay was 14 ± 10 days in the NPWT group compared to 19 ± 15 days in the non-NPWT group which was not significant.

No major complications were encountered in our study with the use of custom-made NPWT. Safety of home-made NPWT has been reported by many studies.^[3,24,25]

Cost

The cost of custom-made NPWT which was used in our study was around 22 times cheaper than the widely used commercially available NPWT.

Cost of home-made vacuum dressing for an average-sized wound was INR 448 per dressing in the study conducted by Petkar *et al.*^[24] almost same as our custom-made medium-sized dressing. Dorafshar *et al.*^[25] reported that the combined equipment and labour costs were four times lower when a hospital devised and built system was used than when a commercial system was used for delivery of NPWT (USD 25.4/day compared to 110.6/day). The cost of equipment used for one indigenously crafted dressing reported by Andreassen and Madsen^[31] (16 €) is 10 times cheaper than the commercial method. Rozen *et al.*^[26] reported cost of dressing as \$557 over 5 days compared to \$3180 for commercial counterpart (5–6 times more) with net saving of \$2603 per patient.

There are definite advantages of the commercially available NPWT dressing such as no need to assemble the dressing material, good negative pressure regulation, effluent management is better and the patient can be ambulatory. However, for optimal utilisation of NPWT in wound care, its affordability is a very important factor, especially in developing countries.

CONCLUSIONS

Custom-made NPWT is a safe, useful, simple and effective technique in the integration of STSG as compared to the conventional dressing. It decreases the need for secondary wound coverage procedures and leads to a reduction of the days of hospital stay with all the benefits to the patient and the hospital. We have been able to reduce the financial burden on the patients as well as the hospital significantly while achieving results at par with other studies which have used commercially available NPWT. More of such cost-effective methods and studies are required to provide the benefit of NPWT to underprivileged poor patients of developing countries as

the cost of the widely used commercially available NPWT makes its use restricted to only those who can afford its huge cost.

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Conflicts of interest

There are no conflicts of interest.

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