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Pilot-study switchable film dressing & NPWT: A non-interventional, non-placebo-controlled, national pilot study

Michael Schmitz

MCS Medical Consulting, Rotsteinerstr. 18, 56414, Oberahr, Germany

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ABSTRACT

Aim: Negative pressure wound therapy (NPWT) has become an accepted treatment modality for acute and chronic wounds with accelerated healing rates observed. To prevent air from being sucked in from the external environment, the wound and the filler that rests inside or upon the wound are hermetically sealed with an airtight adhesive polyurethane drape that is permeable to water vapour, transparent, and bacteria proof [1]. During the removal of the dressing skin stress occurs. An essential role is shearing force between skin and wound dressing playing [7]. This problem includes missing elasticity, flexibility and to strong adhesion [7,8]. The present study was initiated to evaluate if the switchable formulation of the adhesive ensures a durable and effective occlusion of the dressing and function of the NPWT, but also that the defined adhesion is in the range of patient- and user satisfaction.

Methods: The used film dressing consists of a thin film backing with a non-latex adhesive. Before removal the adhesion is reduced by illuminating the dressing with the UV-A lamp.

Results: 50 patients at a mean age of 71.7 years (SD ± 12.0) with a total of 51 wounds (one patient had two wounds) were included in the study. Wound bed condition (multiple answers possible) was rated as granulation (47), sloughy (33) and necrotic tissue (3). Wound bed condition had improved during the short course of the study with a reduction of sloughy and necrotic tissue.

Wound pain/adjacent to the wound pain was specified with a mean of 3,44 (SD ± 1,4) on the VAS (0 = no pain, 10 = excruciating pain) and was decreasing to a mean of 2,3 (SD ± 1,2) at the final visit (see Table 2 and Fig. 2). The application of the dressing/occlusion with the dressing was rated in mean with 1,02 (1. Visit) and 1,00 (2. Visit) on the 6–point-scale (1 = very good – 6 = insufficient). Significance was calculated as 0,000 for visit 1 (one sample t-test [test value = 3,0]). Reactions on the wound edge/wound surroundings have not been reported. In contrast, a reduction of maceration, redness and dryness of the wound edge/wound surrounding was observed (see Table 1).

Discussion: The clinicians gave favourable scores for the tested film dressing regarding application of the dressing, application of NPWT/connection with the suction, overall satisfaction with the application, tightness of the dressing since the last dressing change, easiness of illuminating the dressing with the UV-A lamp and removal of the dressing after illumination with the UV-A lamp. The overall satisfaction with the product was rated very good. Tolerability such as pain during wearing the dressing and upon removal were given good scores. Existing wound edge and wound surroundings findings like maceration, redness etc. at visit 1 decreased. Skin irritation caused in the use of the film dressing did not occur.

Conclusion: The results confirm that the adhesive ensures a safe and effective occlusion of the dressing and that the strong adhesion enables the NPWT to function according to specification.

The switchable function of the adhesive allows the adhesion of the film dressing to the skin to be reduced when illuminated by the supplied UV-A lamp. The results of the present study show that the reduced adhesion upon illumination enables easy and comfortable removal of the dressing.

1. Aim

Negative pressure wound therapy (NPWT) has become an accepted treatment modality for acute and chronic wounds with accelerated healing rates observed. NPWT is a non-invasive system that creates a localized controlled sub atmospheric (negative) pressure environment.

E-mail address: michael.schmitz64@gmx.de.

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The principle of NPWT involves extending the usually narrowly defined suction effect of drainage across the entire area of the wound cavity or surface using an open-pore filler that has been fitted to the contours of the wound. To prevent air from being sucked in from the external environment, the wound and the filler that rests inside or upon the wound are hermetically sealed with an airtight adhesive polyurethane drape that is permeable to water vapour, transparent, and bacteria proof [1].

Negative pressure wound therapy is indicated for use in all care settings and for a variety of wound types [2].

NPWT assists in wound healing in a number of ways: it drains exudate, contracts the wound edges, alters blood flow in the wound edges, stimulates angiogenesis, reduces tissue oedema, stimulates the formation of granulation tissue, creates a moist environment, and stimulates the wound bed [3,4].

The airtight seal is created using commonly a film dressing [5]. Films are an extremely versatile dressing type that can be effectively used in the treatment of many superficial wounds, such as skin grafts, surgical wounds and superficial burns; they provide an optimal moist environment to promote healing, act as a barrier to bacteria, and afford protection from urine and faecal contamination [6].

During the removal of the dressing skin stress occurs. An essential role is shearing force between skin and wound dressing playing [7]. This problem includes missing elasticity, flexibility and to strong adhesion [7,8].

In the EWMA-Document “Pain at wound dressing changes” there was complete agreement that gauze was the product which most often caused pain at dressing changes (mean rank = 1.0), followed by knitted viscose (3.1), film dressings (3.2), paraffin tulle (3.5) and low adherent dressings (4.8). Foam dressings and hydrocolloids were ranked equally (mean rank = 6.5). Hydrogels (mean rank = 9.5), hydrofibre (9.2), alginates (7.3) and soft silicones (7.2) were assessed as the products least likely to cause pain at dressing changes [9].

When removing a patient’s dressing, every attempt should be made to avoid unnecessary manipulation of the wound and to prevent further damage to the delicate healing structures within the wound and surrounding skin [9].

Film dressings are long-time used in combination with negative pressure wound therapy (NPWT) in combination with wound fillers (PU-foam or antimicrobial non-adherent gauze).

The film dressing should ensure a durable and lasting occlusion of the wound to guarantee a proper function of the NPWT. Beneath that reasoned in the frequent number of dressing changes the film dressing should be easy to remove to avoid shearing forces and damage to the intact skin.

Dressings constructed with so-called switching adhesive have lately been developed. They offer two adhesive levels, one (strong) during clinical use and one (reduced) for the removal process. The switching between the two levels is done by illumination with a UV-A lamp. The switching process is done by the nurse and is completed within seconds.

The present study was initiated to evaluate if the switchable formulation of the adhesive ensures a durable and effective occlusion of the dressing and function of the NPWT, but also that the defined adhesion is in the range of patient- and user satisfaction. Illumination of the film dressing with the UV-A lamp irreversibly switches the adhesion from strong to weak and guarantees a painless/comfortable removal of the dressing.

2. Methods

The pilot study evaluated suitability for use as well as user and patient satisfaction during use of the tested film dressing in the use with NPWT for routine wound care of wounds of various aetiologies.

The used film dressing consists of a thin film backing with a non-latex adhesive. The dressing is breathable, allowing good oxygen and moisture vapor exchange. It is waterproof and impermeable to liquids and bacteria. An intact dressing protects the site from outside contamination. The dressing has been applied and removed by healthcare professionals. Before removal the adhesion is reduced by illuminating the dressing with the UV-A lamp. Dressing change frequency was depending on the patient and wound condition and was at the discretion of the clinician. For wound cleansing and dressing application the centres current protocol was used. Patients with venous leg ulcers received compression treatment according to the current standard. Patients with pressure ulcers received standard prevention measures and those with diabetic foot ulcers received off-loading and other relevant prevention measures.

1-week observation per patient was assessed. Study duration was 1 week (+/- 2 days). Evaluations took place during the 3 planned visits at day 0, 3–4 and 7 ± 2 days. Baseline evaluation included patient age, gender, duration of the wound and health status. All unexpected adverse and serious events observed by or reported to the investigators were evaluated. The intensity, duration and causal relationship to the evaluated dressing was rated for all adverse events.

An approval of an ethical committee was submitted and given (Ethics committee FEKI Freiburg, feki-code 0218/1098 05. February 2018)

3. Results

3.1. Demographic and baseline characteristics

N = 50 patients at a mean age of 71.7 years (SD ± 12.0) with a total of 51 wounds (one patient had two wounds) were included in the study, 46 of them finalized the 1-week study period. Gender distribution was 25 males (49%) and 26 (51%) female patients.

Mean wound age was measured with 6,5 months (SD ± 6,6).

Underlying disease (either individually or in combination) was in 11 cases a chronic venous insufficiency, in 9 cases pressure (pressure ulcers), in 14 cases some diabetes mellitus, in 26 cases a surgical procedure (postsurgical wound healing disturbance) and three others.

Wound size in mean was measured with 25,74 cm^2 [6,6 cm length (SD ± 3,7) and 3,9 cm width (SD ± 2,3)] and 1,4 cm depth (SD ± 1,3).

Wound volume was reduced to a mean of 15,08 cm^2 size and 0,8 cm wound depth at the last visit.

The patients wound characteristics are shown in Table 1, Fig. 1. Wound bed condition (multiple answers possible) was rated as granulation (47), sloughy (33) and necrotic tissue (3).

Wound bed condition had improved during the short course of the

Table 1
Physician scored wound characteristics during the study period.

Day of treatment/ visit	Scale used	Visit 1: Day -30 to day 0 screening and baseline	Visit 2 Day 7 ± 2 days 1st dressing change	Visit 3 Day 14 ± 2 days 2nd dressing change
Wound size Mean	cm^2	25,74 **cm^2**	22,32 **cm^2**	15,08 **cm^2**
Wound depth Mean	cm	**1,4 cm**	**1,1 cm**	**0.8 cm**
Exudate	Light	**0**	0	5
production N	Moderate	**35**	41	36
	Severe	**16**	5	3
Wound edge/	No findings	26	26	31
wound	Maceration	12	7	2
surrounding	Redness	8	5	1
	Dryness	1	0	0
Wound bed	Black necrotic tissue	3	1	0
condition	Yellow tissue	33	18	12
	Granulation tissue	47	49	44

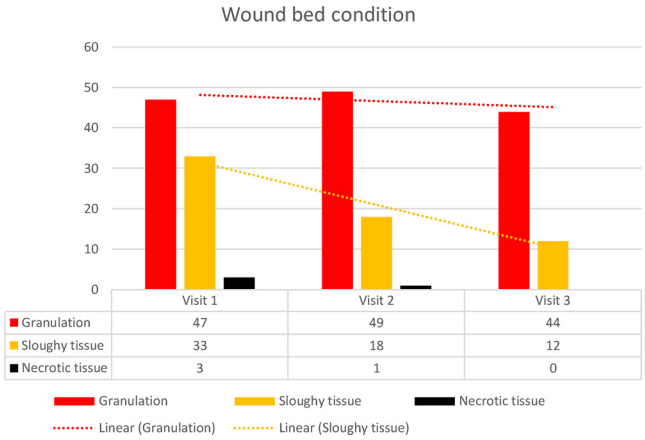

Fig. 1. Evaluation of wound bed condition during the study.

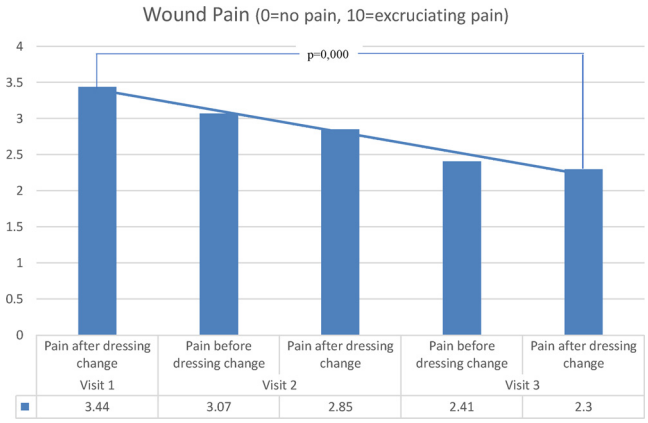

Fig. 2. Evaluation of wound pain during the study.

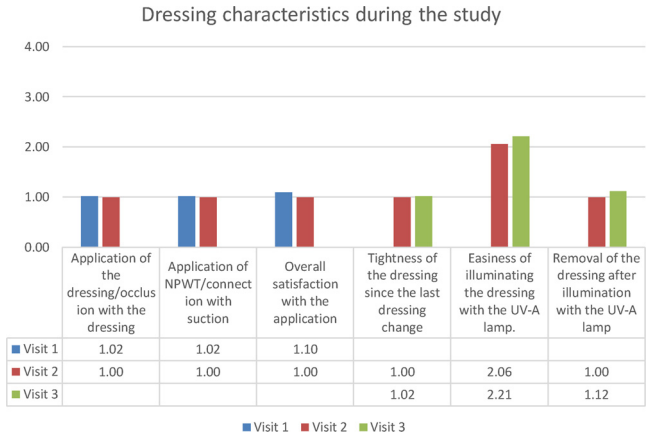

Fig. 3. Dressing haracteristics during the study.
All parameters scored on a 6–point- scale, 1 = very good – 6 = insufficient.

study with a reduction of sloughy and necrotic tissue.

Level of exudation was assessed to be severe in 16 cases, moderate in 35 cases. At the end of the study, level of exudate was reduced (3 severe, 36 moderate and 5 light).

Wound pain/adjacent to the wound pain was specified with a mean of 3,44 (SD ± 1,4) on the VAS (0 = no pain, 10 = excruciating pain) and was decreasing to a mean of 2,3 (SD ± 1,2) at the final visit (see Table 2 and Fig. 2).

3.2. Results and Analysis of primary parameter

Adhesion (Table 2, Fig. 3):

The application of the dressing/occlusion with the dressing was rated in mean with 1,02 (1. Visit) and 1,00 (2. Visit) on the 6–point-scale (1 = very good – 6 = insufficient). Significance was calculated as 0,000 for visit 1 (one sample *t*-test [test value = 3,0]).

The application of NPWT/connection with suction was rated in mean with 1,02 (1. Visit) and 1,00 (2. Visit) on the 6–point-scale (1 = very good – 6 = insufficient). Significance was calculated as 0,000 for visit 1 (one sample t-test [test value = 3,0]).

3.3. Results and Analysis of secondary parameters

3.3.1. Painless/comfortable removal

At baseline, pain was measured with a mean of 3,44 (SD ± 1,45), during the study period pain decreased to a mean of 2,30 (SD ± 1,23) (VAS 0 = no pain, 10 = excruciating pain). Significance was calculated as 0,000 (paired *t*-test). At each dressing change, pain level after dressing change was rated lower compared to the pain level before dressing change. Overall, pain level decreased over the study period.

The easiness of illuminating the dressing with the UV-A lamp (Table 2, Fig. 3) was rated in mean with 2,06 (2. Visit) and 2,21 (3. Visit) on the 6–point-scale (1 = very good – 6 = insufficient). Significance was calculated as 0,000 for visit 2 and 0,001 for visit 3 (one

Table 2
Dressing characteristics during the study period.

Day of treatment/visit	Scale used	Visit 1: day 0 screening and baseline	Visit 2 Day 3-4 ± 2 days 1st dressing change	Visit 3 7 ± 2 days n 2nd dressing change
Pain before dressing change mean (SD)	10–point-scale 0 = no pain – 10 = excruciating pain)	–	3,07	2,41
Pain after dressing change mean (SD)		3,44	2,85	2,30
Application of the with the dressing mean (SD)	6-point-scale, 1 = very good – 6 = insufficient	1,02 (SD ± 0,14)	1,00 (SD ± 0,00)	–
Application of NPWT/connection with suction mean (SD)	6-point-scale, 1 = very good – 6 = insufficient	1,02 (SD ± 0,14)	1,00 (SD ± 0,00)	–
Overall satisfaction with the application mean (SD)	6–point- scale, 1 = very good – 6 = insufficient	1,10 (SD ± 0,47)	1,00 (SD ± 0,00)	–
Tightness of the dressing since the last dressing change Mean (SD)	6–point- scale, 1 = very good – 6 = insufficient	–	1,00 (SD ± 0,00)	1,02 (SD ± 0,15)
Easiness of illuminating the dressing with the UV-A lamp.	6–point-scale, 1 = very good – 6 = insufficient	–	2,06 (SD ± 0,31)	2,21 (SD ± 1,41)
Removal of the dressing after illumination with the UV-A lamp mean (SD)	6–point-scale, 1 = very good – 6 = insufficient	–	1,00 (SD ± 0,00)	1,12 (SD ± 0,63)

sample *t*-test [test value = 3,0]).

The removal of the dressing after illumination with the UV-A lamp (Table 2, Fig. 3) was rated in mean with 1,00 (2. Visit) and 1,12 (3. Visit) on the 6–point-scale (1 = very good – 6 = insufficient). Significance was calculated as 0,000 for visit 3 (one sample *t*-test [test value = 3,0]).

The overall satisfaction with the application (Table 2, Fig. 3) was rated in mean with 1,10 (1. Visit) and 1,00 (2. Visit) on the 6–point-scale (1 = very good – 6 = insufficient). Significance was calculated as 0,000 for visit 1 (one sample *t*-test [test value = 3,0]).

The overall satisfaction with the product was rated in mean with 1,00 on the 6–point-scale (1 = very good – 6 = insufficient).

3.4. Tolerability results

Reactions on the wound edge/wound surroundings have not been reported. In contrast, a reduction of maceration, redness and dryness of the wound edge/wound surrounding was observed (see Table 1).

3.5. Safety evaluation

There were no serious adverse events (SAE) ore adverse advents (AE) observed.

4. Discussion

NPWT is an adjunctive healing method for selected surgical wounds at high risk for complications, acute wounds, and certain chronic wounds after failure of primary intention healing. The negative pressure is applied until granulation tissue develops or the local conditions allow an additional surgical procedure (e.g., skin graft or flap). Sub atmospheric pressure is applied to the surface of a wound that is sealed off by a film dressing and connected via a tube to a suction pump and drainage collection system [10]. An airtight seal is created using a film dressing [5].

Films are an extremely versatile dressing type that can be effectively used in the treatment of many superficial wounds, such as skin grafts, surgical wounds and superficial burns; they provide an optimal moist environment to promote healing, act as a barrier to bacteria, and afford protection from urine and faecal contamination [6].

During the removal of the dressing skin stress occurs. An essential role is shearing force between skin and wound dressing playing [7]. This problem includes missing elasticity, flexibility and to strong adhesion [7,8].

When removing a patient's dressing, every attempt should be made to avoid unnecessary manipulation of the wound and to prevent further damage to the delicate healing structures within the wound and surrounding skin [9].

The present study was initiated to evaluate if the switchable formulation of the adhesive ensures a durable and effective occlusion of the dressing and function of the NPWT, but also that the defined adhesion is in the range of patient- and user satisfaction. Illumination of the film dressing with the UV-A lamp irreversibly switches the adhesion from strong to weak and guarantees a painless/comfortable removal of the dressing.

The number of patients and the types of wounds treated with the film dressing during the 1-week study period is a representative sample that provided meaningful clinical data on clinical performance of the tested film dressing.

The clinicians gave favourable scores for the tested film dressing regarding application of the dressing, application of NPWT/connection with the suction, overall satisfaction with the application, tightness of the dressing since the last dressing change, easiness of illuminating the dressing with the UV-A lamp and removal of the dressing after illumination with the UV-A lamp.

The overall satisfaction with the product was rated very good.

Tolerability such as pain during wearing the dressing and upon removal were given good scores. Existing wound edge and wound surroundings findings like maceration, redness etc. at visit 1 decreased. Skin irritation caused in the use of the film dressing did not occur.

5. Conclusion

The results confirm that the adhesive ensures a safe and effective occlusion of the dressing and that the strong adhesion enables the NPWT to function according to specification.

The switchable function of the adhesive allows the adhesion of the film dressing to the skin to be reduced when illuminated by the supplied UV-A lamp. The results of the present study show that the reduced adhesion upon illumination enables easy and comfortable removal of the dressing.

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Ethical statement

An approval of an ethical committee was submitted and given (Ethics committee FEKI Freiburg, feki-code 0218/1098 05. February 2018).

Conflict of interest

None declared.

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