

# A Novel No Foil-to-Skin Contact Technique for Vacuum-assisted Wound Closure in Patients with Sensitive Skin

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**Background:** In some patients with chronic wounds, the surrounding skin is so injured due to various underlying conditions that negative pressure dressing cannot be applied or cannot function properly. Having faced this problem in our everyday practice, we developed a new skin-sparing technique for vacuum-assisted wound closure, which ensures that the peri-wound skin does not come into contact with the transparent adhesive films.

**Methods:** For 9 months (April–December 2022), we performed 32 vacuum wound dressings with the newly developed technique using the 3M ActiV.A.C. Therapy Unit and accessories, and Convatec's VARIHESIVE, avoiding skin contact with the adhesive films.

**Results:** Seven patients with 11 wounds who had sensitive skin or allergy to the conventionally used adhesive films were successfully treated with the new technique. The negative pressure wound dressings remained intact and functioned properly for up to 168 hours without compromising patients' daily activities and therapy.

**Conclusion:** The novel "no foil-to-skin contact" technique for vacuum-assisted wound closure can successfully be incorporated in the treatment of patients in whom conventional negative pressure dressings are otherwise not applicable. (*Plast Reconstr Surg Glob Open* 2023; 11:e5160; doi: [10.1097/GOX.00000000000005160](https://doi.org/10.1097/GOX.00000000000005160); Published online 3 August 2023.)

## INTRODUCTION

Negative pressure wound therapy (NPWT) is a well-established treatment concept for patients with skin lesions of different origin. Its latest version, the vacuum-assisted wound closure, was first introduced and patented in the early 1990s by Louis Argenta (professor of plastic and reconstructive surgery) and Dr. Michael Morykwas (bioengineer) of Wake Forest University of Medicine.<sup>1</sup>

The placement of negative pressure wound dressings is standardized to a great extent. After certain wound preparation (debridement, irrigation with saline/antiseptic agents, hemostasis, and cleansing and drying of the surrounding skin), sterile porous polymer foams are directly applied over the wound bed and fixed with specially

designed adhesive films. A small window is made in the film covering the foam, and a track pad connected to a suction tube is embedded to the foam. The tube is then connected to a pumping device, with a collection canister providing permanent subatmospheric pressure, draining all secretions away from the wound.

Companies offering NPWT products provide instructions on how to use them. However, there are some basic principles, and one of them is that the dressing should be tightly sealed. Otherwise, insufficient negative pressure will be generated, resulting in inadequate drainage of wound exudates. For this purpose, the adhesive films should cover the surrounding skin over at least 3–5 cm.<sup>2</sup>

In most patients, the above-mentioned prerequisites can be achieved easily. However, sometimes adhesive films (foils) may cause allergic reactions or create conditions (excessive heat and moisture) that harm the underlying skin. Whenever complications occur, NPWT must be terminated, compromising the entire wound healing.

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## METHODS

In our efforts to manage the problem of patients' "intolerance" to the conventionally used adhesive films, we developed a novel no foil-to-skin (NOFOTOS) contact technique for vacuum-assisted wound closure. We successfully applied this technique in seven patients over 9 months, performing 32 wound dressings of 11 complex skin lesions on different locations. We used commercially available foams, adhesive foil (which causes trouble when coming into contact with the skin), track pads and tubes, pumping devices with collection canisters (3M ActiV.A.C. Therapy Unit and accessories), hydrocolloid dressings (Convatec's VARIHESIVE), and double-sided adhesive hydrogel strips (3M). Negative pressure applied was  $-125$  mm Hg, at a continuous mode with medium intensity. Because our research involves a modification of well-established and approved treatment technique presenting no additional risks for the patients, and because all data presented are anonymized, no institutional review board approval was required.

## PATIENTS AND METHODS

Using the NOFOTOS technique, we treated for 9 months a group of seven White patients (four men, three women), aged 42–89 (mean 65.3; median 63) years, with a total of 11 wounds in different body regions. (See **table, Supplemental Digital Content 1**, which illustrates the characteristics and outcomes of the patients treated with the NOFOTOS technique. <http://links.lww.com/PRSGO/C697>.)

## DESCRIPTION OF TECHNIQUE

After adequate preparation of the wound bed and edges, self-adhesive hydrocolloid dressings were placed

## Takeaways

**Question:** When adverse reactions to standard adhesive drapes occur, vacuum-assisted wound closure would be interrupted.

**Findings:** Vacuum dressings could be arranged in a way that would not cause any adverse reactions.

**Meaning:** Our technique enables vacuum-assisted wound closure in patients where conventional vacuum dressings are not applicable.

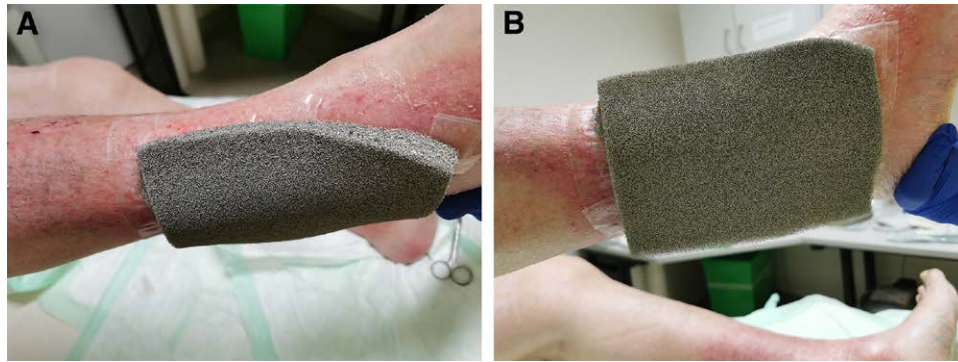
around the wound covering (0.5–1 cm) of the surrounding skin. The outer perimeter of the hydrocolloid coverage was purposefully arranged in a rectangular shape, which would facilitate the further placement of the entire dressing. Then, the inner side of the hydrocolloid dressings was cut around the wound edges so that the whole wound bed became free, leaving the peri-wound skin protected. Because the hydrocolloid dressings were unable to provide hermetic seal, we surrounded them, again in rectangular manner, with double-sided adhesive hydrogel strips (**Fig. 1**).

The above-mentioned steps prepared the "base" for the placement of the foam. The hydrocolloid dressings protected the wound edges and the surrounding skin. The double-sided adhesive hydrogel strips provided a water- and airtight seal and protected the outer perimeter of the peri-wound skin, which would be needed for the vacuum dressing.

The next step included foam fixation. We used rectangularly shaped polyurethane foam, which could be used in its full thickness or could be halved along its longitudinal axis. It is of crucial importance to properly define



**Fig. 1.** First steps of the wound dressing application. A, Anterolateral view of patient 1's mixed etiology ulcer with multiple lymphatic fistulas on the right leg. When this photograph was taken, the previous conventional NPWT had already temporarily been stopped (over a period of 3 days) because the patient developed a local allergic reaction to the conventionally used adhesive films. Instead, various silver-coated dressings were applied, but unfortunately we were unable to create a dry sterile medium for the wound healing. A window was cut around the wound contours on the inner side of the hydrocolloid dressing. The outer side deliberately covered not only the wound edges but also part of the surrounding skin. Double-sided adhesive hydrogel strips had already been placed around the hydrocolloid dressings. B, The wound and the dressing seen from the posterolateral aspect.



**Fig. 2.** Foam fixation. A, The foam, seen from the anterolateral aspect, was placed over the free wound bed and at the base of the wound dressing, and allowed to remain fixed for the further steps of the procedure. B, The posterolateral view of the foam and wound dressing.

the length and width of the foam to cover the whole free wound bed, the hydrocolloid dressings, and the inner half of the gel strips. We measured the sides of the rectangle formed by the double-sided adhesive hydrogel strips (the outer perimeter of the dressing) and used the following formulas:

$$L_f = L_{op} - 2 \times \frac{1}{2} \times W_{hs} = L_{op} - W_{hs}$$

and

$$W_f = W_{op} - 2 \times \frac{1}{2} \times W_{hs} = W_{op} - W_{hs},$$

where:

$L_f$  is the length, and  $W_f$  is the width of the foam.

$L_{op}$  is the length, and  $W_{op}$  is the width of the outer perimeter of the dressing.

$W_{hs}$  is the width of the hydrogel strips.

Because we utilized 3-cm-wide strips ( $W_{hs} = 3\text{ cm}$ ):

$$L_f = L_{op} - 3\text{ cm};$$

$$W_f = W_{op} - 3\text{ cm}.$$

The foam was applied over the free wound bed and the basis of the wound dressing without assistance to hold it in place, because it attached to the upper side of the double-sided adhesive hydrogel strips (Fig. 2). For further fixation of the foam and to provide tight hermetic seal in the periphery of the wound dressing, we placed strips of conventionally used adhesive film over the double-sided adhesive hydrogel strips and the foam. These strips should not touch the skin. Their outer edge should coincide with the outer edge of the double-sided adhesive hydrogel strips. The adhesive film was placed over the center of the foam, an adequate opening was made, and a track pad was applied. The pad was then connected to the pumping device (Fig. 3).

Depending on wound localization, easily removable secondary dressing with normal gauze, white bandage, or tube bandage could also be applied. This may serve as



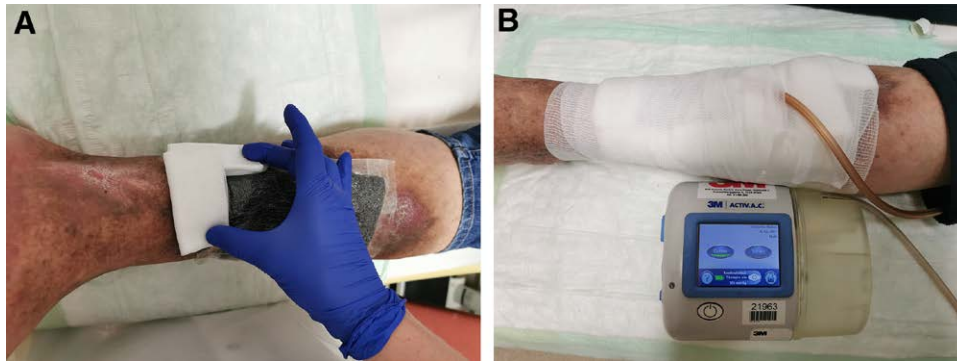
**Fig. 3.** The hermetically sealed vacuum dressing. The adhesive films came nowhere into contact with the skin and functioned well up to 168 hours.

additional fixation of the entire wound dressing and prevent its unintentional removal by patients or health-care professionals (Fig. 4). In our patient with an abdominal wound, the dressing remained intact and functioned well up to 168 hours without it.

## RESULTS

The NOFOTOS technique was successfully incorporated in the wound treatment of all seven patients. The vacuum dressings remained tightly sealed for up to 168 hours with a negative pressure of 125 mm Hg. The vacuum wound dressing allowed our patients to perform their daily activities, including physiotherapeutic exercises. No leakage alarms or defect functioning were detected. All our patients benefitted from the NWTP: the microbial contamination was consecutively reduced or eliminated, the lymphatic fistulas dried up, adequate granulation tissue formation was achieved in the wound bed, and the peri-wound skin recovered completely. No allergic reactions or skin injuries related to the wound dressings were observed. Patients 1, 2, and 3





**Fig. 4.** Optional secondary dressing. A, Patient 2. After the vacuum wound dressing was applied and tight seal secured, it was surrounded by gauzes. B, A normal white bandage was applied over the vacuum dressing and gauzes to prevent the unintentional removal of the wound dressing. The secondary dressing could easily be removed, so that the sensitive or injured peri-wound skin could be treated with different dermatological products, which accelerated healing of the skin.

underwent a split-thickness skin graft surgery. Patient 4 was transferred to another facility with no ability to perform NPWT to receive their substitution treatment and was lost to follow-up. In patient 5, NPWT was interrupted because of diverse socioeconomic factors. Patient 6 underwent a delayed primary wound closure. In patient 7, the lymphatic fistula dried up, and the wounds healed by secondary intention.

## DISCUSSION

Vacuum-assisted wound closure, with its multiple variations, proved its efficiency in various studies in the past 30 years. Benefits of NPWT arise from four primary (macro- and microdeformation, fluid removal, and alteration of the wound environment) and multiple secondary mechanisms of action.

Macrodeformation (induced wound shrinkage) results from the application of deformational forces on the wound edges. Vacuum causes the foam pores to collapse and pulls the wound edges together. Animal studies showed that when a negative pressure of  $-125$  mm Hg is applied, the foam shrinks by approximately 80%.<sup>3</sup>

The term “microdeformation” is used to describe the changes that appear in the foam and the tissues when vacuum is applied. The beneficial effects on wound healing are explained by the complex interplay of mechanical (compression and tension), shear, and hydrostatic forces, as well as gravity. As a result, a signaling intercellular cascade is activated, which upregulates the process of granulation. Microdeformation causes localized tissue hypoxia, and the decreased levels of tissue oxygen promote the neoangiogenesis.<sup>4</sup>

Fluid evacuation is another important primary mechanism of action of the vacuum-assisted wound closure. The excessive accumulation of fluids in skin lesions inhibits wound healing by means of mechanical compression on cells and tissues. When the pressure in the interstitium becomes too high, cell proliferation is inhibited by the decreased build-up of intrinsic tension. As excessive fluids are removed from the wound, the hydrostatic compression

on the capillaries is decreased, their lumen expands, and the distance that the immune and recovery cells should traverse *per diffusionem* to reach the target tissues is shorter. NPWT also decreases the burden on the lymphatic vessels (the main “evacuators”) and gradually increases their density at the wound edges.<sup>5</sup>

Finally, vacuum alters the wound environment. With the removal of the excessive fluid containing electrolytes and proteins, the osmotic and oncotic gradients on the surface of the skin lesion are stabilized. The components of the vacuum dressing isolate the wound from the non-sterile environment and help maintain it clean and moist.<sup>5</sup>

The secondary effects of NPWT include promotion of neurogenesis, hemostasis, cellular proliferation, differentiation, and migration as well as modulation of the inflammatory processes and alteration of the so-called bio-burdens in the wounds.<sup>3</sup>

## MEDICAL ADHESIVE-RELATED SKIN INJURIES

Medical adhesive-related skin injury (MARS) occurs when the superficial cutaneous layers are removed by a medical adhesive. They manifest as erythema, skin trauma, or skin lesions persisting longer than 30 minutes after adhesive removal. MARS also includes reactions, such as contact or allergic dermatitis, maceration, and folliculitis. It seems that when the skin-to-adhesive attachment is stronger than the skin-cell-to-skin-cell attachment, separation of the epidermal layers from the dermis is noted when the adhesive is removed.<sup>6,7</sup>

## MARS AND VACUUM-ASSISTED WOUND CLOSURE

The exact incidence of MARS remains unknown. Although medical adhesives are frequently used, there is little awareness of MARS among health-care professionals, who either do not know of its existence, do not recognize it, or do not feel obliged to report it. There are limited data from clinical studies in small patient

populations where the incidence of MARSII reached up to 54%. Type IV allergic reactions develop more often in patients with leg ulcers (incidence 40%–80%, when compared with 2%–9% in the general population), where the peri-wound skin (especially if macerated) is more susceptible to contact eczemas. This phenomenon could probably be explained with the insufficient venous and lymphatic drainage. The information on the incidence of MARSII in patients undergoing vacuum-assisted wound therapy is even scarcer and limited exclusively to single case reports.<sup>8</sup>

Various panels of wound experts gather regularly to create standardized guidelines for the prevention and treatment of MARSII. Particular attention is paid to the proper risk evaluation before the use of adhesives and skin protection.<sup>9–11</sup>

In patients undergoing vacuum-assisted wound therapy, MARSII occurs because of at least two reasons: (1) skin contact to the adhesive substances of the fixation films and (2) excessive accumulation of fluids under the adhesive films. The adhesive drapes contain often acrylic or silicone compounds, which can cause allergic/irritative skin reactions. They could also create excessively humid environment underneath because of the accumulated heat with subsequent local hyperhidrosis and skin maceration. The resultant moist microclimate provides an excellent environment for microbial reproduction, especially in mobile areas such as natural folds and joints. As excessive fluid accumulates under the adhesive film, the film can partially detach itself from the skin and compromise the hermetic seal and the functioning of the entire dressing. Thus, more fluids (wound exudates) come to this area and intensify the above-mentioned pathologic changes. When adhesive drapes are removed, superficial cutaneous lesions may occur.<sup>8,10,12</sup>

There are several strategies for the prevention of MARSII. The guidelines for primary and secondary prevention include selection of suitable patients and appropriate wound products, the use of skin barriers and means for harmless removal of the adhesive drapes, adequate education of health-care professionals and patients, etc. However, this article focuses on the tertiary prevention: What must be done to treat the consequences of MARSII, and to ensure successful NPWT?

### BENEFITS OF NOFOTOS

The first thing to do when a harmful factor is detected is to eliminate the exposure. That is probably the most important characteristic of NOFOTOS; it eliminates the necessity of exposing the skin to the adhesive substances in the drapes, and thus, provides it with the opportunity to regenerate.

We applied hydrocolloid dressings, which protect the wound edges and a minimal area of the peri-wound skin. They are made of gel-forming materials mixed with elastomers and adhesives, and consist of two layers. The inner layer is self-adhesive and contains a hydrophilic polymer matrix with dispersed cellulose, gelatin, and pectin, and the outer layer consists of a thin polyurethane foil.

Gelatin is a highly purified collagen-derived animal protein extensively used in the food and pharmaceutical industry. Pectin is a carbohydrate found in fruits. Cellulose is a polysaccharide and the most abundant biopolymer on Earth, synthesized by bacteria, plants, and animals. Incorporated in a polymer matrix, they build the inner layer of the hydrocolloid dressing, which touches the skin. When this layer encounters fluids, a change in the physical state occurs, and a gel is formed. This provides optimal moisture for the wound healing and the intact skin, and promotes autolytic debridement. The gel also possesses the ability to capture cell debris. The outer layer of the hydrocolloid dressings represents a barrier to pathogenic microorganisms and protects the wound from the environment.

Hydrocolloid dressings are semipermeable to water and gas vapors, and impermeable to fluids and bacteria. They maintain acidic pH, which impedes bacterial growth. Hydrocolloid dressings can safely be removed from the skin without causing much pain.<sup>11,13–15</sup>

The double-sided adhesive strips represent the peripheral part of the wound dressing. They use hydrogels to adhere to different surfaces and contain a significant volume fraction of water and small amounts of polymers. Because of the low density of polymers, adhesive hydrogels are soft and deformable. Upon contact with the skin, adhesion normally occurs by means of physical and chemical interactions (covalent bonds, intermolecular interactions, etc). Hydrogels adhere to implants and synthetic materials and can be used as drug carriers and vectors. They are biocompatible, biodegradable, nonimmunogenic, and minimally invasive. Some hydrogels also exert hemostatic and antimicrobial effects.

Most of the adhesive hydrogels already approved by the health authorities in the USA and Europe contain fibrin-, gelatin-, poly-ethylene glycol, and cyanoacrylate. The double-sided adhesive hydrogel strips are easy to handle. They stick tightly to various surfaces and tissues when a pressure of approximately 1 kPa (~7.5 mm Hg) is applied for 5 seconds. Additionally, hydrogels can resist tearing energy of up to 4000 J m<sup>-2</sup>.<sup>16</sup>

Both hydrocolloid wound dressings and double-sided adhesive hydrogel strips are flexible, which makes NOFOTOS easy to apply in different body areas: on even and curved surfaces. In the standard vacuum-assisted wound dressings, the foam should be cut so that it resembles the contours of the wound, which is not necessary here. The hydrocolloid dressing is easier to cut along the wound edges because it is thinner and partially transparent. This allows wound managers to quickly cut the foam to a proper size and apply it over the dressing. Because the foam sticks to the gel strips, there is no need of assistance to hold it in place before the final fixation with the normal foil is performed. The rectangular foam shape provides a wide surface for even fixation of the track pad.

In the NOFOTOS technique, both the wound and the peri-wound skin are subjected to subatmospheric pressure. Through the foam lying over the hydrocolloid dressings and the double-sided adhesive hydrogel strips, vacuum



**Fig. 5.** Lateral view of another mixed etiology ulcer on the left leg of patient 1. After the removal of the vacuum dressing, peripheral depression was observed (best seen on the right part of the photograph).

is exerted on the intact skin around the lesion; that is, it can also benefit from its wound healing properties with no danger for the cutaneous integrity. Furthermore, it probably improves the lymphatic drainage, performing local lymphatic massage.

After the removal of the entire vacuum dressing, in our patients we observed a mild depression around the whole perimeter of the wound at the place of the double-sided adhesive hydrogel strips, which suggests that the pressure there was higher than the one over the foam and hydrocolloid dressing. This may ensure a better sealing effect in the periphery of the dressing (Fig. 5).

There is limited information in the published literature on patients with MARSIs undergoing NPWT with alternative techniques for the placement of vacuum wound dressings. During the Russian–Afghan war, the Russian doctor Bagautdinov developed a technique for NPWT in patients with allergy to adhesive drapes. The method was published in 1986 in the Russian medical literature. Its use outside Russia was published for the first time in 2017. In the Bagautdinov method, sterile petroleum and antiseptic is smeared over the peri-wound skin, and conventional adhesive drapes are applied with consequent hermetic seal. This technique also corresponds entirely to the current guidelines concerning the prevention and treatment of MARSIs. However, large areas of the surrounding skin must be covered by petroleum and adhesive film to fix the dressing, which is not necessary with NOFOTOS.<sup>6,17</sup>

The “jelly VAC” represents another interesting attempt to relieve MARSIs. Here, ultrasound jelly is placed under plastic wrap (soaked in povidone-iodine) to isolate the peri-wound skin from it and achieve additional sealing. This technique allows a continuous control of the surrounding skin because of its transparency. NOFOTOS provides this advantage too, since the double-adhesive strips are transparent and there is no need of additional preparation of the drape.<sup>18</sup>

## CONCLUSIONS

According to our experience, the NOFOTOS technique may enable continuing NPWT even in patients with MARSIs. It is in fact a technique that can be used to treat both chronic and acute wounds, with the primary defects being almost always chronic, and the lesions that occur within MARSIs being always acute. NOFOTOS could be a safe alternative to the techniques for vacuum-assisted wound closure in patients showing allergic reactions to adhesive drapes, meeting the requirements of the contemporary guidelines. However, further clinical studies are needed to prove or negate its benefits. With the implementation of NOFOTOS in the practice, a cost-effective analysis can be done. This method requires the use of additional materials, but the time needed for first placement and dressing changes are shorter. Moreover, no assistance is needed to hold the components of the dressing during fixation. The combined advantage of reduced procedure time and less manpower needed could be of great benefit nowadays, with the staff shortage observed worldwide.

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## DISCLOSURES

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