

## Quantitative evaluation of exudate leakage through adhesive wound dressings in experimental pig skin model

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### Abstract

The leakage of wound exudate onto the surrounding skin, resulting in the maceration of the healthy peri-wound skin, was evaluated semi-quantitatively using commonly used adhesive wound dressings and a pig skin model. In this skin model, we prepared a 6-mm-diameter skin defect wound (i.e., hole) into which 2 round filter papers were inserted. We then applied 6 types of adhesive wound dressings to the holes. We flipped the skin over and dripped 20  $\mu$ L or 40  $\mu$ L of 1% gentian violet solution onto the filter papers from the back surface of the pig skin model 8 times every 30 minutes. We observed that more leakage occurred in the wound dressing designed for a small to moderate amount of exudate. Moreover, we found no clear relationship between the type of adhesive contact layer and the degree of adhesion to the wound margin. These observations indicate that exudate leakage and periwound skin maceration can be prevented through sufficient and rapid exudate absorption by wound dressings. Therefore, wound dressings that absorb wound exudate sufficiently and rapidly while maintaining moisture on the wound surface must be selected and applied in the clinical setting to prevent/reduce wound exudate leakage onto the surrounding skin and avoid periwound skin maceration.

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### Introduction

An appropriately moist environment facilitates the healing of skin defect wounds<sup>1-5)</sup>. However, the healthy periwound skin should be kept dry instead of moist, as this leads to skin maceration resulting in delayed healing and wound enlargement<sup>6,7)</sup>. In a wound with excessive exudate, conventional dressings such as ointment and gauze adhere poorly to the periwound skin, allowing the exudate to spread to the healthy periwound skin and resulting in maceration. Among the wound dressings commercially available in recent years, those that absorb exudate and prevent leakage onto the periwound skin while adhering to it sufficiently are considered to be effective in preventing periwound skin maceration.

Although there are concerns of exudate leakage onto the periwound skin and its subsequent maceration, to the best of our knowledge, there have been no studies to date regarding the quantitative or semi-quantitative comparison of exudate leakage and the resulting periwound skin changes with the application of different wound dressings. In this study, we applied various adhesive wound dressings and semi-quantitatively evaluated the amount of exudate leakage onto the healthy periwound skin, which determined the degree of its maceration, using a pig skin model. We also discuss the differences in the type of contact layer and the structure of the absorbing layer of the various wound dressings used.

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## Materials and Methods

We purchased pieces of excised skin (skin strips) with the hair clipped (10 cm×10 cm) containing a small amount of subcutaneous tissue that were collected from the trunk of a 2-year-old or 3-year-old female pig (200–300 kg ; referred to as ‘Onuki’). Full-thickness skin defect wounds (6 mm diameter) were made using a disposable punch (6 mm ; Maruho Co., Ltd., Osaka, Japan). A skin strip was attached to a frame made of a corrugated board. Various adhesive wound dressings were then attached to the skin surface (Fig. 1).

Two round filter papers (6 mm diameter ; #2, Toyo Roshi Kaisha, Ltd., Tokyo, Japan) were inserted into the holes of the full-thickness skin defect wounds. The skin was then flipped over and 20  $\mu$ L or 40  $\mu$ L of 1% gentian violet solution was dripped onto the filter papers from the back surface of the pig skin model 8 times every 30 minutes.

We applied 6 types of wound dressings : (1) ALLEVYN Adhesive, a polyurethane foam using acryl adhesive (hereinafter referred to as “A”) ; (2) ALLEVYN Gentle Border (“G”) and (3) Mepilex Border (“B”), polyurethane foams using silicone on the adhesive surface ; (4) Versiva XC, with hydrofiber in the absorptive layer and hydrocolloid in the adhesive layer around the absorption area (“V”) ; (5) ALLEVYN Thin, a self-adhesive polyurethane foam (for dermal defects ; absorbs less exudate) (“U”) ; and (6) Mepilex Lite, a polyurethane foam using silicone adhesive (for dermal defects ; absorbs less

exudate) (“L”). Five dressings from each of the wound dressing groups were used.

For wound dressings U and L, which have low to moderate exudate absorption capacities and are indicated only for partial thickness dermal defect in the Japanese health insurance system, 20  $\mu$ L or 40  $\mu$ L of 1% gentian violet solution was dripped 8 times every 30 minutes. For the other wound dressings, which are designed for full-thickness skin defects and have a high exudate absorption capacity, 40  $\mu$ L of 1% gentian violet solution was dripped 8 times every 30 minutes. A total of 40 dressings consisting of 5 dressings per group were used.

After dripping, the back surface of the skin was covered with cling wrap used for foods (Saran Wrap, Asahi Kasei, Tokyo, Japan), and the skin was inverted after 5 minutes so that the wound dressing would be located on the top side. One hour after the last dripping, the wound dressing was removed and evaluated.

The primary endpoint was assessment of the skin area stained by the pigment from the gentian violet that leaked onto the pig skin surface. The pigment distribution in the wound dressing was also observed on a cross-sectional view. The site on the pig skin surface stained with the pigment from the leakage of gentian violet was digitally scanned at 600×600 DPI with DocuCentre-IVC6680 (Fuji Xerox, Ltd., Tokyo, Japan) to prepare still images.

All sites that were punched to prepare full-thickness 6-mm-diameter skin defect wounds appeared black on the still images. Each still image was dichotomized at a

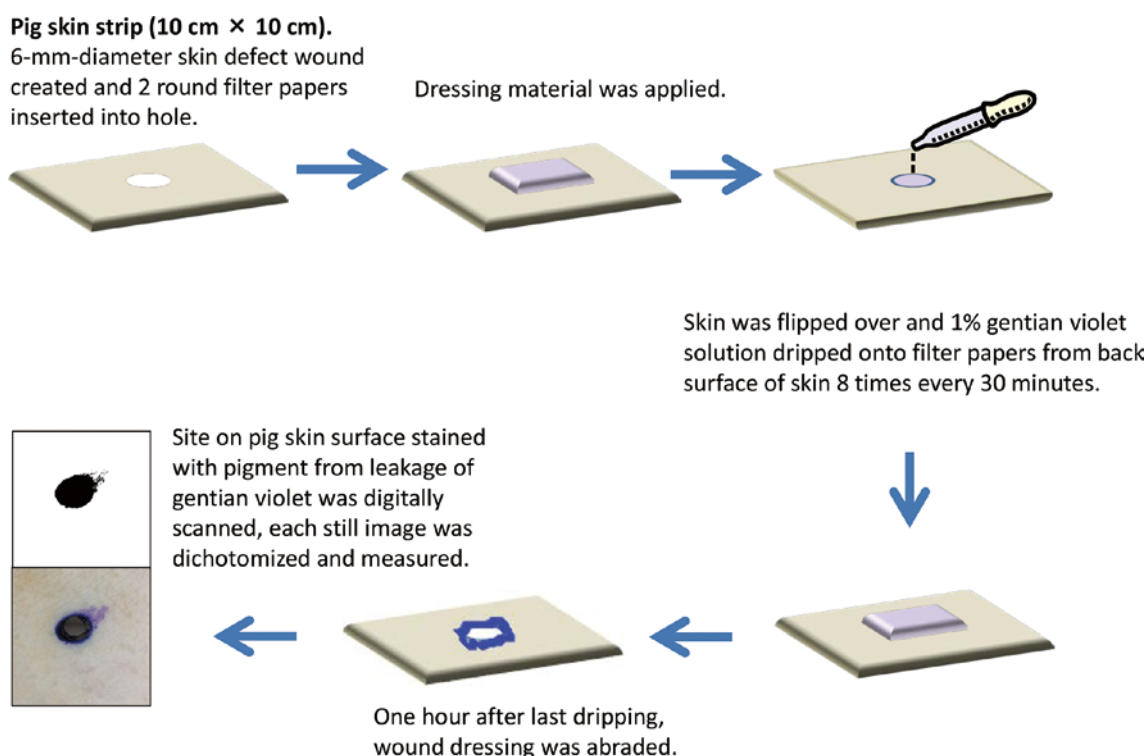


Fig. 1 Experimental method

threshold value of 100 out of 256 gradation levels by a desktop computer, and the amount of stain was calculated on the basis of the proportion of black pixels. Thereafter, the number of pixels equivalent to the punched area was subtracted to obtain the number of pixels equivalent to the area of the leakage of 1% gentian violet. The area of leakage on the back surface of the pig skin was measured in a similar manner.

All experiments were conducted in a room with the temperature and humidity set at 25°C and 56%, respectively. For statistical analyses, the Kruskal-Wallis test was used for multiple comparisons using Microsoft Excel (Microsoft Co., Washington, USA). A *P*-value of <0.05 was considered to indicate a statistically significant difference.

### Results

The area of pigment leakage onto the pig skin surface was significantly larger for wound dressing L, which has a low exudate absorption capacity, than for all the other wound dressings. The mean number of pixels at 600 dpi was  $216,375 \pm 38,590$  (mean  $\pm$  SD) for wound dressing L. For the polyurethane foam wound dressings (A, G, and B), which are designed for full-thickness skin defects, the level of exudate absorption was high. The mean number of pixels was  $13,333 \pm 3,727$ ,  $13,273 \pm 1,068$ , and  $14,622 \pm 7,360$  for wound dressings A, G, and B, respectively. For wound dressing V, which has hydrofiber as the absorption layer and hydrocolloid as the adhesive layer, the area of pigment leakage onto the periwound skin was small. The mean number of pixels was

$14,829 \pm 6,165$  for wound dressing V. Although wound dressings A and G are made of the same polyurethane foam, the adhesive material for dressing A is acryl adhesive, whereas that for dressing G is silicone adhesive. The area of pigment leakage onto the periwound skin for wound dressings A and G was not significantly different (Fig. 2).

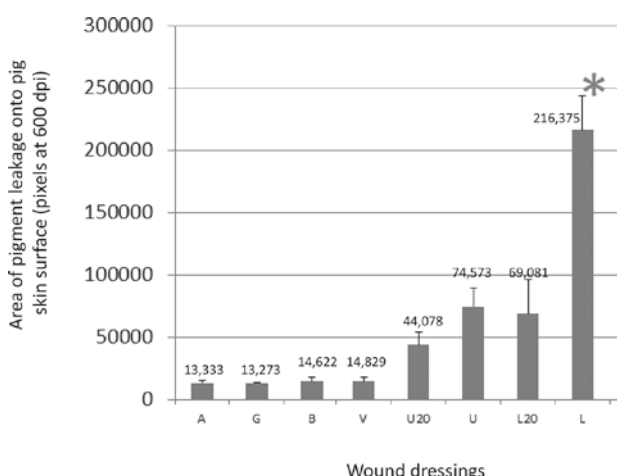
### Discussion

We investigated the amount of leakage from a wound onto the periwound skin, and compared the differences in the area of leakage according to the type of adhesive wound dressing used in a pig skin model.

It has been previously reported that chronic leakage of exudate onto the periwound skin causes the horny layer to absorb water and expand, leading to maceration of the healthy periwound skin. This causes softening of the horny layer and a decrease in the amount of intercellular lipids, resulting in damage of the healthy periwound skin<sup>8)9)</sup>. The cytoplasmic projections that connect the cells in the basal and spinous cell layers, and resistance and barrier function against external force decrease in the horny layer and entire epidermis<sup>10)</sup>, resulting in delayed healing and enlargement of the wound<sup>6)7)</sup>. Although anatomical locations, tension forces, shear in the wounds, mobility of the wound area, and other factors are involved in the development of maceration, leakage of exudate is a major cause of maceration. Therefore, the reduction of exudate leakage onto the healthy periwound skin prevents maceration, and eventually avoids delayed healing and wound enlargement.

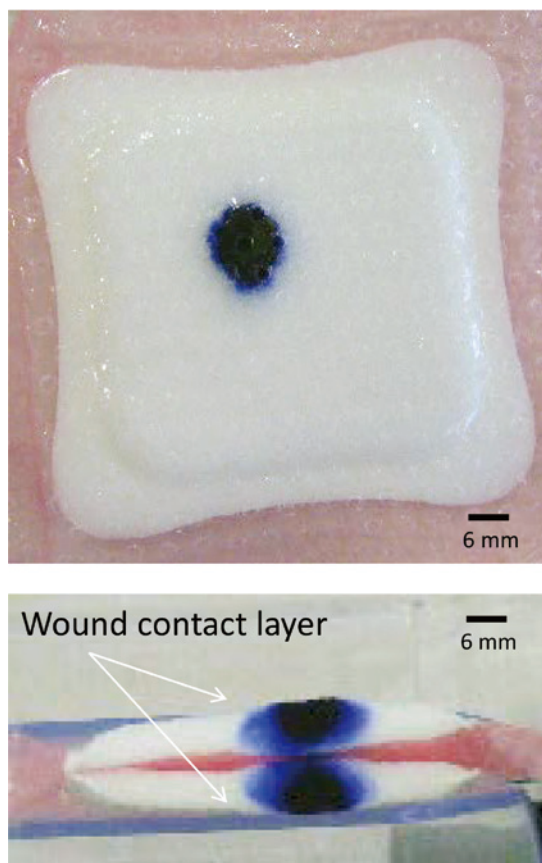
In recent years, adhesive wound dressings have been commonly selected for convenience by patients and healthcare professionals. Good wound dressings (a) minimize adhesion to the wound surface and newly formed epithelium; (b) cause no damage upon removal; (c) facilitate wound healing; (d) securely adhere in place; and (e) prevent exudate leakage from wounds onto the healthy skin, thereby minimizing the risk of periwound skin maceration<sup>11)</sup>.

In the present pig skin model, wound dressings with a low absorption capacity allowed the pigment to spread largely to the periwound skin. It is therefore considered that dressing materials that can sufficiently absorb exudate from the wound surface at a speed equivalent to that of exudation are required to prevent exudate leakage onto the periwound skin and its maceration. On the other hand, L showed a relatively low capacity for absorption of exudate and adhesion to the wound margin, suggesting that there would be an increased risk of transversal spread of exudate and subsequent maceration of the periwound skin with this type of dressing. Figure 3 shows pigment absorption with a wound dressing in which the amount of leakage onto the periwound skin was small.



**Fig. 2** Area of pigment leakage onto pig skin surface in each dressing material

Area of pigment leakage onto pig skin surface was significantly larger in wound dressing L (*p*<0.05) than in the other dressings. More exudate leakage was observed in wound dressing designed for small to moderate amount of exudate. L20 and E20: 20  $\mu$ L of 1% gentian violet solution was dripped every 30 minutes instead of 40  $\mu$ L.



**Fig. 3** Longitudinal section of dressing material G  
Pigment did not spread over surface of wound dressing, but was superiorly absorbed, indicating that amount and speed of absorption were sufficient. This absorption condition was observed in wound dressings A, G, B, and V.

Here, the pigment did not spread over the surface of the wound dressing, but was superiorly absorbed, indicating that amount and speed of absorption were sufficient. Such absorption was observed in wound dressings A, G, B, and V.

In this study, we found no clear relationship showing that the degree of adhesion between the wound margin and the wound dressing is a contributing factor to leakage onto the periwound skin. However, as wound dressings A, G, and B have adhesive force and sealing characteristics in the wound margin, they are considered to have adhered sufficiently to the pig skin surface and prevented pigment leakage to the skin surface.

Interestingly, there was no difference in the extent of pigment leakage to the periwound skin among the wound dressings with adhesive and sealing characteristics. These wound dressings include those with silicone adhesive, which can have many contact points to the wound (G and B)<sup>12)</sup>, those with acryl adhesive, which is inferior to silicone (A), and those with no adhesion between the wound margin and the wound dressing and an adhesive surface composed of hydrofiber (V). Although V

reportedly absorbs exudate quickly and extensively<sup>13)14)</sup>, and induced less maceration of the periwound skin owing to the relatively less amount of exudate, a lack of moisture at the wound surface was also evident.

We excluded hydrocolloid wound dressing in this study, since hydrocolloid gelatinization, which is observed clinically, would not have occurred as the body surface temperature could not be reproduced sufficiently in this pig model. We tested a hydrocolloid wound dressing in a preliminary study, but the results showed that prevention of leakage onto the periwound skin was inferior with this type.

The limitations of this study were that there is no positive control in this model, and that the surface of the wound and the shape of the wound edge are relatively smooth and flat. This condition may be different from wounds in clinical practice, which may affect the results. Another limitation of this study model was that the viscosities of the 1% gentian violet solution and clinical wound exudate may be different; the gentian violet solution should be less viscous and easier to escape the wound adhesive layer. Our results did not contradict the clinical usefulness of silicone adhesive for exudate leakage, which leads to maceration of the wound margin. The experimental skin condition was also different from that which would be encountered in a clinical setting: there was no motion involved, stress distribution, capacity of adherence, or external pressure over each dressing.

The present results suggest that exudate leakage onto the periwound skin and the resulting maceration of the wound margin can be prevented by using a wound dressing that absorbs exudate from the wound maximally and rapidly. Therefore, in selecting a wound dressing, it is important to choose a material that maintains wound surface moisture, provides adhesion to the wound margin in order to prevent exudation on the periwound skin surface<sup>15)16)</sup>, and possesses rapid and strong exudate absorbing properties.

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### Conflict of interest disclosure

All authors declare that they have no conflict of interest associated with this study.

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## 豚皮モデルを用いた粘着性創傷被覆材による滲出液の漏出の定量的評価

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【要旨】 適切な湿潤環境により創治癒は促進されるが、創周囲の健常皮膚への浸出液の漏れにより周囲が浸軟し治癒の遷延や創の拡大をもたらすことがある。今回我々は、種々の粘着性創傷被覆材を用いて創周囲の皮膚への浸出液の漏れを量的に評価した。

ブタの皮膚を用いて 6 mm 大の皮膚欠損創を作成し、6 つの異なる粘着性創傷被覆材で創を被覆した。皮膚の後面から 20  $\mu$ L または 40  $\mu$ L の 1% メチルバイオレット液を 30 分おきに 8 回滴下し皮膚に浸透させた。1 時間静置した後、創周囲への色素の広がりを 2 元化して計測した。結果として被覆材の粘着層のタイプと創周囲への粘着の程度に明らかな差はなく、被覆材による素早く十分な浸出液の吸収により、創周囲への浸出液の漏れと浸軟は防ぐことができた。

臨床現場においても、創周囲への浸出液の漏れを防ぎ、浸軟を避けるために、創面を湿潤に保ちつつ浸出液を素早く十分に吸収する被覆材を選ぶべきである。

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〈キーワード〉 創傷被覆材、創周囲皮膚、漏出、浸軟

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