


ORIGINAL ARTICLE

Three-dimensional shape-conformation performances of wound dressings tested in a robotic sacral pressure ulcer phantom

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Abstract

Effective exudate retention by dressings requires close and intimate dressing-wound contact, immediately and continuously after the dressing application. Any dressing-wound spaces may allow for build-up of non-retained fluids, causing exudate pooling which forms a favourable environment for pathogen growth. Maceration may follow if the pooled exudates spread to peri-wound skin. Dressings with a claimed 3D-shape-conformation technology are commercially available; however, their effectiveness in minimising dressing-wound gaps has never been scientifically investigated. We present a novel bioengineering methodology for testing the effectiveness of such 3D-shape-conformation dressings, using our recently reported robotic phantom system of a sacral pressure ulcer. By means of 3D laser scanning and bespoke software, we reconstructed dressing shapes after simulated use and calculated the goodness-of-fit between each dressing (swelled to near-saturation) and the corresponding wound geometry. Two dressing sizes (10×10 cm and 12.5×12.5 cm) and two wound depths (2.5 or 2 cm) were considered. All the tested dressings were far from reaching good contact with the (simulated) wounds: Approximately one-third of the wound volume and nearly half of the wound surface were not in contact with the swelled dressings. Our present findings question whether 3D-shape-conformation dressings are effective, by revealing their swelling behaviour which was previously unknown.

KEYWORDS

exudate pooling, fluid retention, laboratory model, swell testing, wound dressing

1 | INTRODUCTION

Pressure ulcers (PUs) or pressure injuries (as they are increasingly being termed in the United States, Canada,

and the Asia-Pacific region) are one of the classic chronic wound types and a common complication in patients who are immobile, insensate or both.¹ These wounds have always had a major clinical and economic burden

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on health care systems, which looks set to increase, primarily due to ageing of the population and the spread of diabetes. Moreover, the current prevalence of PUs has been reported to be exponentially higher because the breakout of the coronavirus 2019 pandemic.²⁻⁵ Serious PU cases are typically associated with considerable suffering, loss of quality of life, and sometimes severe pain, risk of infection, osteomyelitis, sepsis, and development of multiple organ failure leading to death.^{1,6} Furthermore, the treatment of PUs is typically lengthy and costly, may involve expensive litigation and can negatively impact institutional quality measures⁷. The most common anatomical site for hospital-acquired PUs is the sacrum, a region at which deep injuries (nearing or reaching bone tissue) account for at least one of four wounds.^{8,9} Exuding sacral PUs are, therefore, a major and frequent clinical challenge encountered by health care professionals who treat chronic wounds.

Excessive presence of exudate and associated elevated inflammatory cytokine levels in the wound bed act to delay healing.^{10,11} Exudate production begins very early in the development of a PU and is triggered by the inflammatory response of the immune system, which increases the vascular permeability around the wound site to enable infiltration of immune system (leukocyte) cells. The dilation and relaxation of blood vessel walls, and specifically, the loosening of endothelial tight junctions to facilitate the inflammatory extravasation from the vasculature, results in leakage of plasma which is the primary fluid component of exudates.^{12,13} A mildly moist wound bed is required for optimal healing^{10,14} as exudates are the medium of transport of cells, essential nutrients, and immunological factors adjacent to and within the wound.¹¹ The moist environment is also essential for proliferation and migration of keratinocytes, fibroblasts, endothelial, and other cells which play a role in the re-epithelialization process.^{12,15,16} However, excessive exudate amounts may interrupt the healing cycle or cause cytotoxicity, as exudates may be infected by pathogens, and/or contain metabolic waste products.¹⁷ Accordingly, exudates should be absorbed and retained in dressings while keeping the wound bed moist. Importantly, the most fundamental role of a dressing is to prevent exposure of the wound to conditions or episodes where excess exudates accumulate over the wound bed surface. Pooling of wound exudates in the wound bed at dressing-wound gaps not only delays closure and healing but also creates an ideal environment for bacterial and fungal growth.¹⁸⁻²⁰

The main concern regarding excess amounts of exudate in a wound with bacterial colonisation is the likelihood of these pooled fluids to spillover onto newly regenerated tissues or peri-wound skin, which may result in tissue cross-contamination, widening of the inflammatory-irritation areas or maceration, all of which

Key messages

- effective exudate retention by dressings requires close dressing-wound contact
- dressings with a claimed 3D-shape-conformation technology are available
- to determine their performances, we utilised a robotic pressure ulcer phantom
- using 3D laser scans, we reconstructed the dressing shapes after simulated use
- our findings question whether 3D-shape-conformation dressings are effective

can lead to delayed wound healing.^{18,21} Furthermore, exudate fluids in chronic wounds typically contain degrading enzymes including serine, cysteine, aspartic proteases, and matrix metalloproteinases (MMPs) which, under normal healing conditions, have an important role in tissue repair processes as they degrade the proteins of damaged tissue, catalyse tissue regeneration, and overall prepare the wound for healing.¹² Nevertheless, this proteolytic activity transported in excess in a hyper-hydrated wound has an abnormal ratio of degradative versus protective effects, which eventually favours wound degradation and therefore, contributes to wound chronicity.²² Prevention of exudate pooling clearly requires a close contact between the absorptive dressing surface and the wound bed, immediately and continuously after application of the dressing. Such close contact involves conformation and adaptation of the applied dressing structure to the specific wound cavity shape, as early as possible after application of the dressing. Mechanical forces, such as the static or dynamic bodyweight forces or those applied by medical devices near or above the wound (eg, compression stockings), may further distort and deform both the dressing and the wound, which makes the design requirement of full and continuous dressing-wound contact challenging.

One approach to maximise the contact between the dressing and wound bed (regardless of the depth and shape of the wound) is to use filler dressing materials, such as gelling fibre dressings, which can be pushed into open wounds to the extent needed to eliminate any dead space. We have reviewed this dressing technology and its performances, analysed through bioengineering laboratory testing, in our recently published work.²³ A different design approach is the so-called three-dimensional (3D) shape-conformation dressing technology. It is claimed that dressings based on this 3D shape-conforming design absorb and retain exudate

fluids and by doing so, swell to the mirror (complementary) shape of a wound up to 2 cm-deep, thereby preventing dressing-wound gaps from forming.²¹ However, no standardised and clinically realistic laboratory test methods have been developed to assess the ability of such dressings to effectively minimise dressing-wound gaps through shape-conformation as they swell into a wound. In fact, clinicians applying these dressings have no way of knowing that the applied dressing actually conforms to the shape of the wound and that no exudate pooling is present.

In their recent review work on wound dressing technologies, Ghomi and colleagues²⁴ have named the ideal wound dressing features, such as removal of exudates, moisture control, and gas transmission—which are all mass transport features, and continued to list infection prevention, mechanical stability, reduction of wound necrosis, pain alleviation, and cost-effectiveness, to mention a few. It is remarkable that nearly all the non-mass-transport features listed in their work derive from the primary exudate management performances, for example, the risk of infection can be reduced if the dressing does not allow or does not cause spillover of pooled exudates. Likewise, if there is no pooling of excess exudates, the dressing is more likely to remain mechanically stable (as it is not degraded by the often aggressive, acidic or alkaline wound fluids with the enzymatic agents that they contain). An adequately performing dressing which effectively absorbs and retains exudates is also likely to prevent maceration of periwound skin and wound necrosis and thereby, alleviate the pain associated with the non-healing and with such additional tissue damage. Finally, such dressing is clearly cost-effective as it only needs to be changed when it has utilised its absorbance capacity to its full extent. These are just a few of many examples where features that are regarded as ‘ideal’ in dressings are essentially a derivative or a result of their exudate management performances.

Here we developed, for the first time in the literature, a bioengineering methodology for testing the shape adaptation and conformation performances of dressings and the effectiveness by which such ‘3D-shape-conformation dressings’ actually fill wound cavities. For the above testing, we have utilised a novel robotic phantom developed by our group which replicates a sacral PU.²³ The presently reported method is a significant innovation for evaluating the shape-conformation aspects of dressing products, spanning from efficacy research to design and product evaluation. Our specific findings reported below question the efficacy of 3D-shape-conformation dressings, by revealing information which has not been available to clinicians previously, on the swelling behaviour of the absorptive aspect of these dressings once they are applied to the wound.

2 | METHODS

2.1 | A computer-controlled phantom of an exuding sacral pressure ulcer

In order to simulate clinical use of the studied dressing, we utilised a computer-controlled, robotic phantom of an exuding sacral wound which has recently been developed in our laboratory and described in detail elsewhere.²³ For completeness, the main components and functions of this robotic phantom are also described here. The system facilitates standardised experiments where dressings are exposed to exudate-like fluids under mechanical, thermodynamic, and use conditions which replicate the real-world clinical setting (Figure 1A). The phantom includes a plastic replica of the pelvic bones and soft tissue substitutes, made of silicone and casted in the shape of an adult male buttocks. Specifically, the weight of the buttocks phantom is ~10 kg which is consistent with anthropometric

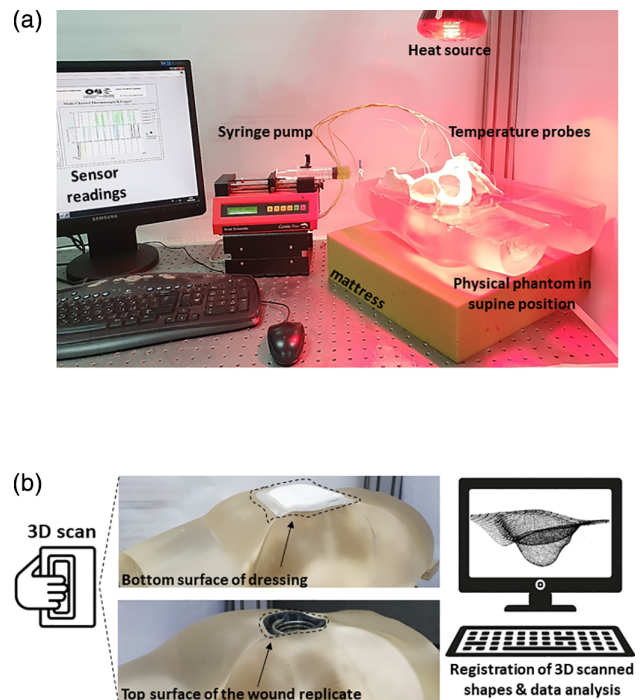


FIGURE 1 The robotic phantom of a sacral pressure ulcer for evaluating the use of wound dressings. For the present study, the phantom has been placed in a supine position on a standard foam mattress. The controlled setup of the system, including monitoring of the wound replicate surface temperatures and the controlled release of exudate substitute are also shown (A). Following the application of a dressing, the (simulated) wound surface and dressing are laser-scanned (separately) to acquire the three-dimensional (3D) shapes of their interfacing surfaces. The acquired 3D geometrical data are then imported to a dedicated computer software for further data analysis (B)

measurements of adult males in which the pelvis area is $\sim 11\%$ to 13% of the total bodyweight²⁵ (eg, representing a male whose bodyweight is in the range of 70–80 kg). A cylindrical wound geometry is carved into the sacral region, into which a three-dimensionally (3D) printed, custom-made component is inserted to simulate an exuding wound. We manufactured two distinct wound simulators that have a truncated conical shape (ie, a ‘crater wound’) and which differ in their depths and surface areas, as follows. The first one represents a 2.5 cm-deep ‘wound’ in which the (plastic) sacral bone is exposed, which hence simulates a category-4 PU. The second one represents a 2 cm-deep ‘wound’, in which the sacrum replica is not exposed, which is representative of a category-3 PU. Both wound replicates have a diameter of 4.5 cm superficially, and 2.5 and 3.5 cm diameters at the deepest level for the 2.5- and 2 cm-deep wounds, respectively. The effective wet surface was approximately 25cm^2 for the 2.5 cm-deep and 17cm^2 for the 2 cm-deep simulated wounds, respectively. To simulate secretion of exudate-like fluids from these insertions, we embedded tubing systems within each of them, which were tunnelled through the silicone-made ‘soft tissues’ and connected to a syringe pump, allowing the release of exudate substitutes at predetermined flow volumes and rates. We further developed a safe and reproducible exudate substitute fluid formula (for use in our phantom system), which facilitates control of the fluid viscosity, so that the flowing exudate-like fluid adequately represents the physical and some chemical characteristics of native exudate fluids (eg, the pH is also controlled).²³ The above fluid specifically contains food-standard Xanthan gum powder at a concentration of 0.1%, mixed with distilled water and a green food dye (for visualisation), which results in fluid viscosity of 0.23 Pa·s and density of 1.01 g/cm^3 that are representative of protein-containing biological fluid viscosities/consistencies and densities reported in the literature.²³ The temperature is also controlled, an important consideration in simulations of real-world use of dressings, given the effects of temperature on fluid viscosity (and thereby, on the flow regime) as well as the potential influence of temperature on the behaviour of the dressing materials. An infrared lamp is therefore stationed above the phantom as a heat source, using an adjustable setup that allows tuning of the simulated wound cavity temperatures within the range of 31°C to 35°C , as reported for sacral PUs.²⁶ Five thermocouples were embedded around the simulated wound to monitor the spatial temperatures and record these to the controlling computer once per second.

2.2 | Simulated treatments of the sacral pressure ulcer

In the experiments reported below, we used a commercially available wound dressing for which a claim is made by its manufacturer that it employs a 3D-shape-conformation technology, that is, it conforms to the shape of the wound bed for wounds that are up to 2 cm in depth.²¹ Conformance of a dressing is generally defined as close contact of the dressing surface with the wound bed, to reduce potential exudate pooling in dressing-wound gaps and thereby, avoiding tissue damage and improving the wound healing conditions. To test the intimacy of physical contact of the selected dressing with the wound replicates in our phantom system, we developed an original experimental methodology as follows.

2.2.1 | Dressing specimens

We tested two different dressing sizes (of the same 3D-shape-conformation dressing technology described above), 10×10 cm and 12.5×12.5 cm, using both wound insertions in our phantom. Tests were repeated five times for each possible combination of dressing size and wound depth (ie, shallow wound and small dressing; shallow wound and large dressing; deep wound and small dressing; deep wound and large dressing). Accordingly, we conducted 20 trials in total. Both of the aforementioned dressing sizes completely covered the top surfaces of the two wound replicates.

2.2.2 | Application of dressings to the phantom and settings of the test parameters

Prior to applying a dressing to the simulated sacral wound, we weighed the new out-of-package dressing and documented its initial (dry) weight. The robotic phantom system was then positioned in a supine posture on a standard medical foam mattress, simulating a ‘non-off-loaded’ wound associated with treatment conditions that enforce supine positioning of the patient, for example, mechanical ventilation, extracorporeal life support or a specific surgical intervention (Figure 1A). Of important note, in a supine position, the direction of flow of exudates from the wound bed aligns with the gravity vector. That is, there is no need for capillary action or any other physical principle other than simple gravitational flow for the dressing to absorb the exude-like fluid. The tested dressings should therefore theoretically present their best

performances under our selected testing conditions. Finally, the phantom system was activated with the following set of parameters: 0.23 Pa·s exudate substitute viscosity, 3 mL/hour flow rate (which translates to a 0.12 mL/cm²/hour for the 2.5 cm-deep wound insertion and to 0.17 mL/cm²/hour for the 2 cm-deep wound insertion, both corresponding to highly-exuding wounds²⁷). The duration of the simulated use was 5 hours across all trials.

It should be noted that quantitative (numerical) data of wound exudate volumes, either normal or in excess state, have not been reported in the literature so far. Specifically, while qualitative and descriptive clinical terminology, using wording such as 'dry', 'moist', 'wet', 'saturated', 'leaking'¹³ or quantity evaluation terminology like 'none', 'scant', 'small', 'moderated', 'large'^{12,28} etc. is routinely being used by health care professionals to categorise exudate volumes in their wound assessments,²⁹ quantitative physical and engineering measurements of exudate volume data are currently absent from the literature. As stated in the Introduction section above, exudates are the transport medium for cells, cell-cell signalling molecules, extracellular regulators, and pro-inflammatory mediators and are also the vehicle for supply of essential nutrients.¹¹ This infers that a moist environment is essential for proliferation and migration of keratinocytes, fibroblasts, endothelial, and additional cell types which play a role in the re-epithelialization process, as well as to other biological functions of these cells (eg, collagen synthesis by fibroblasts). Accordingly, here we define the normal moisture conditions in a wound-bed based on laboratory science work, where the amounts of medium required for viability and growth of cultured cells are known in the art. Specifically, the commonly accepted ratio of culture volume to surface area used in basic cell culture protocols is 0.2 to 0.5 mL/cm²³⁰; this is defined as the minimal substrate volume which facilitates metabolism in cell cultures. According to the dimensions of the wet surface area of our wound inserts (ie, ~25 cm² for the 2.5 cm-deep and 17 cm² for the 2 cm-deep simulated wounds) and using the aforementioned ratio from the cell culturing literature, a normative level of fluid volume in our wound models should be 3.4 and 5 mL for the 2 and 2.5 cm-deep wounds, respectively. Our chosen flow rates (0.12 and 0.17 mL/cm²/hour for the 2 cm-deep and 2.5 cm-deep wound insertions, respectively), which correspond to highly exuding wounds,²⁷ result in a final volume of 15 mL of exudate replica which are released by the robotic phantom after the 5 hours of the simulated-treatment protocol. Hence, we have deliberately designed our wound phantom system to build-up excess exudate levels which are ~3 to 5 times larger than the normative

ones, to test the absorbency of the studied dressings where excessive exudates are expected (which is where the clinical challenge exists).

2.3 | Testing of the dressings post simulated use

2.3.1 | Retention tests

Following each 5-hours simulated use session, the used dressing was weighed again and the free exudate substitute which remained in the simulated wound was collected in full.²³ We determined the fluid retention in each dressing specimen as the wet minus the dry dressing weight, divided by the exudate fluid density (1.01 g/cm³). The total exudate volume (TEV) was then calculated, by summing the fluid volume retained in the dressing with the free exudate substitute volume collected from the simulated wound. The latter, calculated-TEV was always mildly lower (by 15% on average) with respect to the theoretical-TEV which is the product of the flow rate and simulated use time, due to evaporation through the dressing and residual fluid in the tubing. Here we report the fraction of volume of exudate substitute fluid retrained in the dressings, normalised with respect to the corresponding calculated-TEV per each 5-hours trial (in percentages).

2.3.2 | Laser scanning of the used dressings for 3D shape acquisition

We gently placed each used dressing on a rigid square frame with a surface shape that was the exact mirror shape of the (sacral) region of dressing application in the robotic phantom. This preserved the original orientation of the applied dressing while its surface, which was previously facing the simulated wound (ie, its absorptive surface), was exposed. We then scanned the absorptive surface of the used dressings using the Sense™ 3D Laser Scanner (3D Systems Inc., Rock Hill, South Carolina), which captured the (absorptive) surface topography of each used dressing, to determine how specifically it has swelled within the wound replicate during the use trial (Figure 1B). The above Laser Scanner has a 0.9 mm x/y spatial resolution and a 1 mm-depth resolution as specified by the manufacturer. In addition to scanning the used dressings, each 3D-printed simulated wound insertion (ie, the 2.5 cm-deep and the 2 cm-deep) of the phantom was similarly laser-scanned and their surface topographies were digitised as well, for the data processing and analyses described below.

2.4 | Data processing and analyses

The above laser scans of the used dressings and wound replicate shapes were uploaded as stereolithography (STL) files to the MATLAB software (ver. R2019b, MathWorks, Inc., Natick, Massachusetts) for data processing and analyses. We developed a dedicated MATLAB code for processing the scanned dressing/wound shapes, including surface registration and extraction of geometric parameters from the superimposed dressing-on-wound shapes. First, we defined an 8 mm-thick ring-shaped surface at the back side of the dressing scan (depth ≤ 9.1 mm; Figure 2), across which the wound bed replicate and dressing are known to be in tight contact. This region was termed the registration region (RR). Using the 'pregisteric' MATLAB function,³¹ we transformed the RR coordinates of the dressing to best-fit the location of the wound coordinates in this region and calculated the transformation matrix. Next, we used the aforementioned matrix to superimpose the entire dressing scan with that of the corresponding wound bed scan (Figure 2). The root-mean-square error (RMSE) of this registration process was 1.10 ± 0.13 mm (mean \pm SD of $N = 20$ scans), with a maximal error value of 1.4 mm. After achieving the superimposed dressing-wound geometry reconstructions, we extracted the maximal depth of the absorptive surface of each dressing in the simulated wound, with respect to the depth of the wound in which the corresponding dressing was contained (Figure 2). We further calculated the cavity volumes of each dressing and simulated wound shapes.

Next, in order to calculate the areas of the absorptive surfaces of the used dressings as well as those of the two wound replicate types, we reconstructed the 3D laser scans using the 'MyCrustOpen' MATLAB function³² that enables triangulation of 3D point sets. The outcome of the above action was fully triangulated meshed surfaces (Figure 4), from which we extracted the dressing and simulated wound surface areas. Next, we used the 'distanceVertex2Mesh' MATLAB function³³ to calculate the nearest distance from each node of a dressing mesh to the surface of the respective simulated wound. This generated a spatial map of distances between the superimposed dressing/wound shapes. Existence of physical 'contact' of a dressing element with the simulated wound surface was considered to occur when the said element was less than 2 mm apart from the wound surface. This specific threshold was chosen so that it is sufficiently greater than the ~ 1 mm scanning resolution of the Laser Scanner. We further considered that the above contact threshold should be greater than any possible numerical errors that might have occurred in the process of surface registration (based on the above RMSE criterion), or

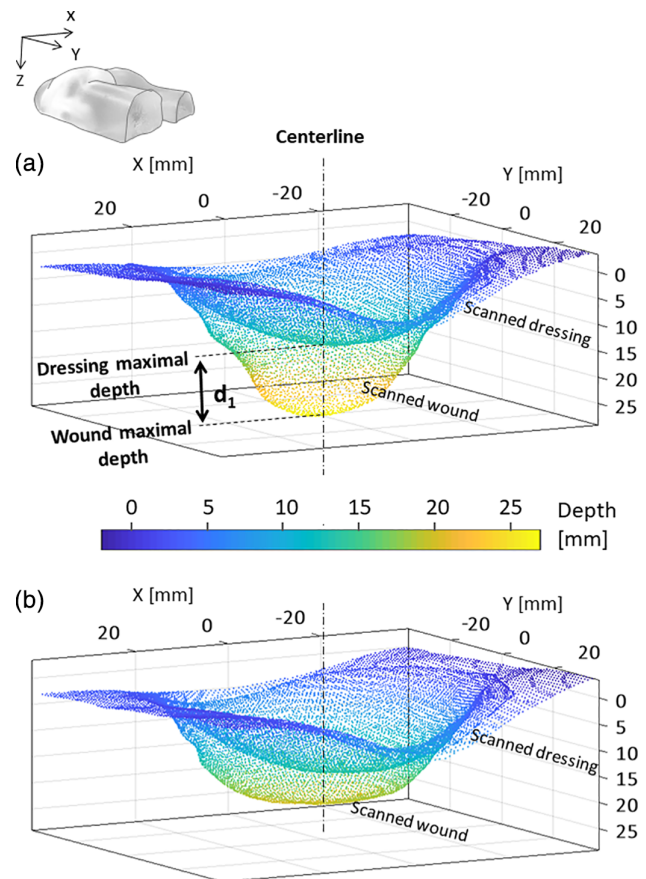


FIGURE 2 Scans of the wound replicate surface and (used) dressing shapes are superimposed by means of our dedicated analysis software. The example experimental data were obtained using (A) 2.5 cm-deep and (B) 2 cm-deep (simulated) wound components of the phantom system. The peak of the dressing does not meet the maximal depth of the wound for either depth, for example, for the 2.5 cm-deep wound, a gap (d_1) of ~ 13 mm (mean of $N = 5$ test repetitions) exists, which allows for potential pooling of fluids in the void under simulated real-world conditions

other reasonable random measurement inaccuracies, for example, those caused by the experimental preparation of the dressing specimens for laser scanning.

The total runtime of each such dressing analysis was ~ 51 minutes, using a 64-bit Windows 10-based workstation with a central processing unit (CPU) comprising 4 Intel[®] core™ i7-6700 processors at a clock speed of 3.40 GHz and 16 GB RAM.

2.5 | Outcome measures and statistical analyses

The following ratios were determined (all in percentages) and compared between the two dressing sizes and two wound replicate depth conditions: (a) The maximal depth of the absorptive surface of the used dressing in the

wound, with respect to the maximal wound depth. (b) The volume of the used dressing over the volume of the corresponding wound cavity. (c) The area of contact (ie, where there is less than 2 mm distance) between the absorptive surface of the used dressing and the wound bed. Two-way analysis of variance (ANOVA) statistical tests were used to compare the above outcome measures between each possible pair of the four specimen groups (small/large dressings and shallow/deep wounds). These ANOVA tests were followed by post hoc Tukey-Kramer pairwise comparisons, to identify any specific significant differences between the test groups. The statistical significance level was set as $P < .05$.

3 | RESULTS

For the 2.5 cm-deep wound insertion, the percentage substitute fluid volume retained in the dressings (normalised by the calculated-TEV) was $95 \pm 3.3\%$ (mean \pm SD) and $95.6 \pm 6.1\%$ for the smaller (10×10 cm) and larger (12.5×12.5 cm) dressings, respectively. For the 2 cm-deep wound cavity, the percentage-retained-fluid volumes were $95 \pm 9.1\%$ and $89 \pm 5.1\%$ for the smaller and larger dressings, respectively. None of these fluid volume fraction values were statistically significantly different from the others, which indicated the following: (a) the dressing specimens were similarly loaded with exudate substitute across all the experimental sessions; (b) the dressings were loaded to near-saturation across all four experimental conditions (small and large dressings, shallow and deep wounds); (c) shape-conformation performances of the tested dressings, as reported below, represent the nearly saturated dressing condition (ie, percentage-retained-fluid volumes of $\sim 90+$ %), so if we would have waited longer than 5 hours, any additional potential shape changes would have been small or negligible, considering that there is continuous evaporation from the dressing so that dressings in use are never 100% saturated.

Examples of the superimposed dressing-on-wound surface shapes (for the 2.5 and 2 cm-deep wounds with 10×10 cm dressings), obtained by means of the surface registration process utilising our dedicated code, are shown in Figure 2. The maximal depth of the dressings did not meet the maximal depth of the simulated wounds, in neither of the shown examples nor the other experiments. That is, gaps (marked d_1 in Figure 2) of 13.8 ± 0.4 mm for the 2.5 cm-deep and 6.9 ± 0.6 mm for the 2 cm-deep simulated wounds consistently existed (mean \pm SD for $N = 5$ test repetitions per each wound depth). For the larger (12.5×12.5 cm) dressing size, these gaps were mildly lower, being 12.6 ± 0.3 and

4.9 ± 0.3 mm for the 2.5 and 2 cm-deep simulated wounds, respectively, but still, the peak of the dressing surface never touched the bottom of the simulated wound. Clearly, the above gaps allow for potential pooling of exudate fluids in the dressing-wound bed voids and indeed, such pooling was observed in our phantom trials.

The ratios of maximal dressing depth to the corresponding maximal wound depth are shown in Figure 3A for both wound insertions and dressing sizes; all the pairwise comparisons were statistically significantly different ($P < .05$). Consistent with the above data, the results in Figure 3A revealed that the dressing-wound gap size was at a minimum $\sim 23\%$ for the 2 cm-deep wound and up to $\sim 48\%$ for the 2.5 cm-deep wound. Likewise, the data of volumetric occupancy of the dressings in the wound beds, presented in Figure 3B, show a similar trend of results and again, all pairwise comparisons were statistically significant ($P < .05$). In terms of

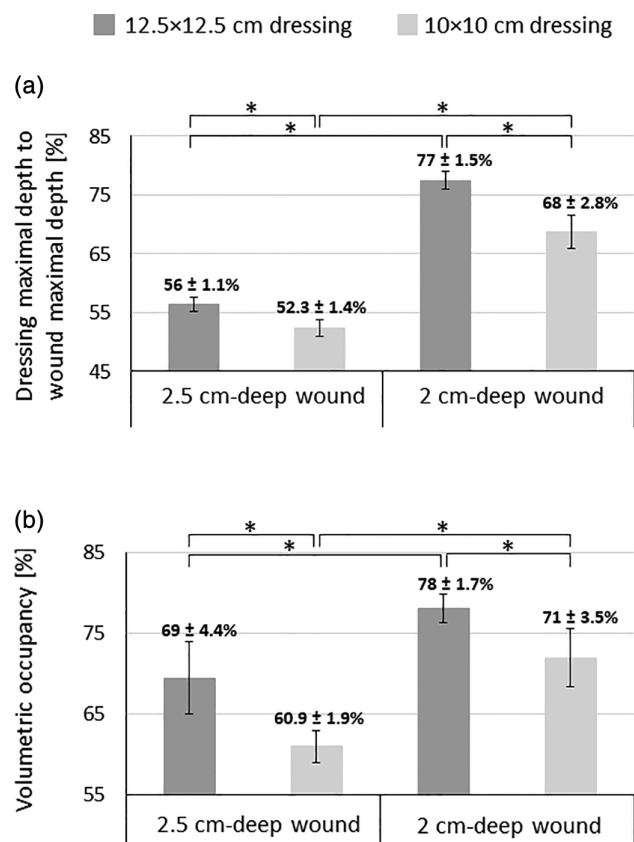


FIGURE 3 Dressing maximal depth to (simulated) wound maximal depth ratio (%) (A) and the volumetric occupancy of the dressing in the wound cavity [%] (B) for the two studied wound depths and two dressing sizes ($N = 5$ test repetition for each outcome measure). The error bars are the SD from the mean. Asterisks indicate a statistically significant difference between a pair of means ($P < .05$)

volumetric occupancy, the voids between the dressing and wound shapes were 22% at a minimum for the 2 cm-deep wound and grew to ~39% for the deeper (2.5 cm-deep) wound cavity (Figure 3B).

We further quantified the effective contact area between the dressing and the wound surface at the end of each simulated use session, as shown in Figure 4A,B (any dressing-wound region at a proximity of ≤ 2 mm was considered as a 'contact' region for the purpose of these analyses). Our analyses of the dressing-wound contact area data (Figure 4C) agreed with the above reported outcome measures. In fact, despite that a conservative ≤ 2 mm contact threshold has been applied (ie, we did not require zero or near-zero distance between the applied dressing and wound), at least ~45% of the wound surface area was not in 'contact' with the dressing, as per the aforementioned definition of contact (for $N = 20$ trials). Moreover, for the smaller size (10 \times 10 cm) dressings, ~50% of the wound area was not in contact with the dressing (Figure 4C). Of note is that for the 2 cm-deep wound, the larger (12.5 \times 12.5 cm) dressing performed slightly better than the smaller one, by providing ~7% more contact with the wound surface ($P < .05$), however, for this wound depth, even the larger dressing did not reach more than ~54% contact with the wound, which indicates poor shape-conformation of the dressing to the wound cavity.

Another interesting observation is that the overall dressing-wound contact values, in percentages (Figure 4C), are lower than both the dressing-wound depth (Figure 3A) and dressing-wound volumetric occupancy (Figure 3B) ratios. Visual inspection of the swollen dressing surface shapes within the wound cavities (Figure 2) allowed us to explain the above phenomenon: The tested dressings consistently swelled at an approximately hemispherical pattern (as evident in Figure 2), whereas the wound cavity shape was more conical. Consequently, the circumferences of the wound surface, particularly at its deeper third, was unreached by the swollen dressing. We conclude that the dressing swelling pattern better fits hemispherical wound surfaces, however, most of the chronic wounds, including open PUs and diabetic foot ulcers are typically conical (crater-like) in shape. Hence, the poor contact between the dressing design (when swelled) and wound cavity geometry is at least in part inherent to the sphere (swollen dressing) versus cone (wound) shape mismatch. From a clinical perspective, the above shape mismatch would imply a high likelihood of pooling of exudate fluids in the dressing-wound gaps, a likelihood which would rise further with the wound depth or exudate release rate of the treated wound.

The size of the tested dressings had little effect on the trends observed here. Specifically, the larger

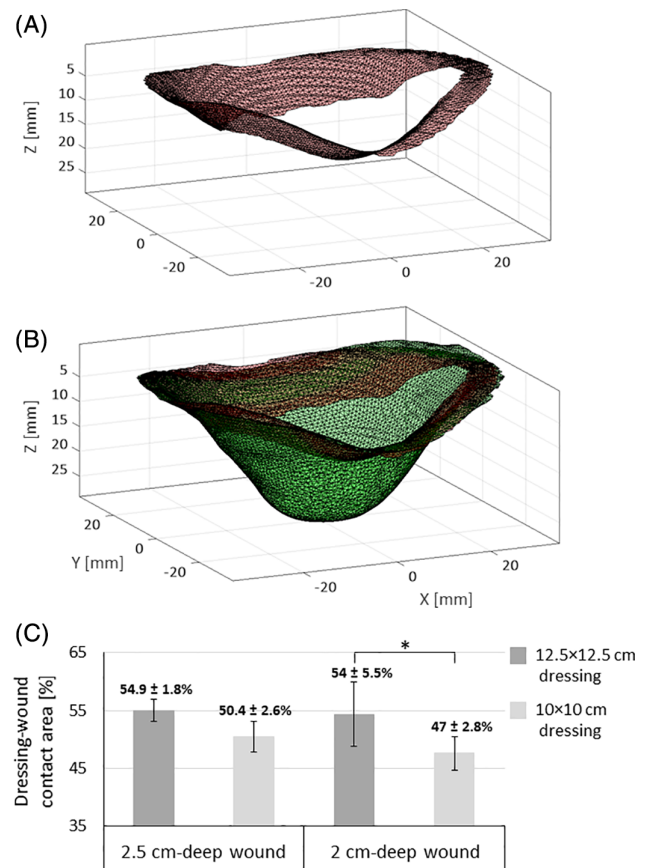


Figure 4

FIGURE 4 The wound-dressing contact analyses: (A) An example (triangulated mesh) contact surface between the 'wound' in the phantom and a tested dressing ('contact' of a dressing element with the wound surface is considered to occur when the said element is less than 2 mm apart from the wound surface). The simulated wound in this example is 2.5 cm-deep and the dressing size is 10 \times 10 cm. (B) The above surface of wound-dressing contact (in red) superimposed on the entire wound surface (in green). (C) Quantitative comparisons of wound-dressing contact areas (in percentage from the total wound surface area) for the two studied wound depths and two dressing sizes ($N = 5$ test repetition for each outcome measure). The error bars are the SD from the mean. Asterisks indicate a statistically significant difference between a pair of means ($P < .05$)

(12.5 \times 12.5 cm) dressing had 4% to 9% better dressing-wound depth ratio outcome (Figure 3A), 8% to 9% greater volumetric occupancy within the wound (Figure 3B) and 5% to 7% higher wound area coverage (which was statistically indistinguishable for the deeper 2.5 cm wound; Figure 4C). Theoretically, the larger dressings have a greater absorption reservoir and therefore, better potential for shape-conformation. In practice, however, while the size feature mildly improved the present outcome measures (Figures 3A,B and 4C), the extents of these improvements appeared to be insufficient for obtaining a

substantially better conformation of the dressing to the wound cavity shapes (that is, for avoiding dressing-wound gaps in which exudate pooling may occur), as evident from the above results.

4 | DISCUSSION

Wound dressings are primarily designed to absorb and retain exudate fluids. Although exudate fluids hold an important role in wound healing and tissue repair, the wound bed needs to be (only) mildly moist for adequate healing to occur. Excessive exudate volumes may disrupt the healing cycle and be irritant, toxic, or infectious to adjacent tissues and should therefore be retained in therapeutic dressings to support healing. According to the theory of fluid flow in porous media, there are three key parameters that altogether determine the flow of exudates from the wound bed to the dressing. These are the exudate viscosity, the specific dressing technology (ie, its material composition and inner architecture), and the intimacy of the physical interface between the wound bed (from which exudates are released) and the applied dressing.²³ With respect to the latter, ideally, the dressing should exactly conform to the wound shape, so that the entire exudate-releasing surface of the wound would make contact with the absorptive surface of the dressing, resulting in maximisation of fluid transfer into the dressing. In the real-world, however, dressing-wound contacts are never perfect, that is, physical contact with the dressing does not occur over the entire wound bed, but such contact should exist at least over the vast majority of the potential dressing-wound contact area. Any spaces between the dressing and wound may allow for build-up of non-retained fluids and lead to exudate pooling.¹⁸ The larger the dressing-wound gaps, the more risk of pooling, which forms an environment for bacterial growth and thereby, increases the likelihood of infection.²⁰ Pooling of exudates may further cause maceration if the pooled exudates spread to peri-wound skin.^{18-20,34}

Dressings with a 3D-shape-conformation technology, for which the manufacturer claims that they conform to the shape of the wound bed are currently in clinical use. However, the ability of such dressings to effectively minimise dressing-wound gaps have never been studied objectively and quantitatively and no relevant tests have been reported in the wound care literature thus far. Moreover, prior to the present work, there were no standardised laboratory methods to assess the conformability of dressings using a test bench that simulates the clinical reality of treating wounds. Of particular note is that the above dressings are non-transparent and therefore, once applied, it is practically impossible for a clinician to know

for certain that the dressing makes good contact with the wound and that pooling of exudates does not occur under the applied dressing.

In the present work, we introduce, for the first time, a novel bioengineering methodology for testing the fit performances of wound dressings and the effectiveness by which '3D-shape-conformation' dressings actually fill wound cavities to mitigate exudate pooling. Specifically, we have built upon our recently reported robotic phantom system of a sacral wound,²³ by adding 3D laser scanning of the dressings post simulated use sessions. A dedicated computer code has further been developed to analyse the computerised 3D reconstructions of the used dressings and to extract multiple test parameters that altogether describe the goodness-of-fit between the dressing and wound.

Irrespective of the specific test scenario (ie, shallow wound and small dressing; shallow wound and large dressing; deep wound and small dressing; deep wound and large dressing), the tested dressings were overall far from reaching good contact with the (simulated) wounds (Figures 2-4). The volumetric occupancy and contact area analyses indicated that approximately a third of the wound volume and around half of the wound surface (at the deeper wound parts) had not been in contact with the dressings throughout the simulated use periods, despite that the dressings were nearly saturated at the end of the simulated use sessions (Figures 3,4). The '3D-shape-conformation' dressings swelled hemispherically, which would never fit a conical (crater) wound shape (Figure 2) or any wounds with undermining. In such cases of real-world wounds, based on the present data and findings, a '3D-shape-conformation' technology would not prevent gaps and, thereby, exudate pooling (potentially leading to infections and maceration) would become very likely. An important note is that although this research was focused around a sacral wound model, the findings are arguably just as relevant to all cavity wounds, irrespective of their anatomical location.

Several of the technical aspects and chosen test parameters in our present laboratory experiments should be discussed in view of the clinical practice and real-world conditions. First, all the tests were conducted with the robotic phantom in its supine configuration so that the exudate flow direction was fully aligned with the gravity vector. We have selected this phantom position to allow the tested dressings to showcase their best performances, as fluid transfer to the dressings and the associated fluid retention were maximal for this position. In preliminary work, we have also attempted to test the dressings using a prone phantom position (so that the fluid absorption will need to occur in opposition to gravity, through capillary action, as the dressing will be

positioned above the fluid source), however, the dressings showed nearly no absorption or shape adaptation to the simulated wound cavities for the prone phantom position. This is not surprising, as fluid flow opposing to the direction of gravity through capillary flow (sorptivity) requires adequate contact between the dressing and fluid and cannot occur if there are major dressing-wound gaps. We therefore suspect that when '3D-shape-conformation' dressings are applied to a wound and the body position of the patient is such that the dressing is constantly above the wound bed, the shape adaptation performances of these dressings would be even poorer (Figures 2-4). The latter point highlights the fact that a dressing must have a sufficient initial contact area with the wound bed for capillary action to commence once the dressing has been applied; this should be an important clinical consideration when choosing a wound dressing.

Another technical aspect which is relevant to clinical practice is our choice of the studied (simulated) wound depths. We have focused on 2 and 2.5 cm-deep wound replicates and have deliberately tested the aforementioned two close, but still different, depths, as in practice, many clinicians would either estimate the wound depth visually or use a cotton swab (Q-tip) to roughly assess the wound depth. Clearly there is an inherent error in such quick clinical assessments of wound depths (which are not meant to be accurate) and so, the different performances of the tested dressings observed over the two studied simulated wound depths (Figures 2-4) may represent the uncertainty of the goodness-of-fit performances when the depth is an estimate, not an accurate datum. In this regard, manufacturers may recommend using a '3D-shape-conformation' dressing for wounds up to a certain depth but in clinical practice, wound depths are assessed, not precisely measured.

As in all studies, limitations must be acknowledged. Firstly, the wound-bed simulator inserts are 3D-printed custom-made pieces, constructed from a 3D-printed hard plastic material which adds stiffness to the simulated wound environment. Of note, although the wound shape itself does not deform in our current phantom system, the mattress underneath the phantom is deformable, which allowed the dressings to swell externally, as well as internally into the wound cavity (until contact has been reached with the wound cavity walls). A second limitation which is noteworthy is the simulated clinical practice. Specifically, the clinical practice simulated in our present experiments did not consider patient repositioning (either manual or by means of a dynamic mattress), however, in a real-world scenario, the 5-hours duration of the simulated dressing usage would at best include two manual repositioning manoeuvres. Introduction of the effect of repositioning is of interest but would have added an

additional (potentially influential) parameter to the study design, as the studied dressings would have been required to function where placed at different orientations with respect to the gravity vector. This is a feature that can be added to future work, but it is likely to add variability to the study results, as the direction of the exudate flow in space and through the wound and dressing structures would vary during the dressing test period, depending on the position and frequency of repositioning of the phantom. Such study design is clearly different from the 'best-case-scenario' chosen here, where the dressings only needed to function while the direction of the exudate flow constantly aligned with the direction of the gravity vector, so each studied dressing could swell to its full extent and thereby, maximise its 3D shape-conformation potential. Additional variables can further be introduced in future research, to simulate for example spontaneous patient movements, or use of specific positioners in the process of care, but such additional orientation changes of the wound-bed are expected to reduce the time where the flow direction fully aligns with the gravity vector, which would compromise the 'best' performances of the studied dressings as reported here.

In conclusion, we have presented here a state-of-the-art, standardised method for testing the shape-conformation performances of wound dressings, utilising our new robotic phantom of an exuding sacral wound.²³ Building upon our recently published phantom work, we have developed novel tests of the goodness-of-fit of dressings in the wound cavity, which clinicians cannot assess in their practice, using the unaided eye. Our findings importantly revealed unsatisfactory shape adaptation of the so-called '3D-shape-conformation' dressings to clinically typical, conical (crater-like) wound cases. The evident and considerable gaps shown to occur between the applied dressing and wound bed are conducive of exudate pooling and the associated wound complications of infection and maceration. Clinicians should consider the present findings and make informed decisions with regard to their dressing selection for each individual wound, accounting for the wound depth and shape, patient position (or their dominant position), the level of exudation and the healing stage.

DISCLOSURE OF INTERESTS

This work was supported by an unrestricted educational grant from Mölnlycke Health Care (Gothenburg, Sweden).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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