Original investigation

Fluid handling dynamics and durability of silver-containing gelling fibre dressings tested in a robotic wound system

ABSTRACT

Objective To develop a robotic phantom system containing multiple simulated wound replicates to determine the synergy in fluid absorbency and retention (sorptivity) performances and the post-simulated-use mechanical durability of silver-containing gelling fibre primary dressings when used with a secondary dressing, as per clinical practice.

Methods Using a robotic system containing six identical wound simulators, the authors tested the sorptivity performances of the Exufiber Ag+ (Mölnlycke Health Care, Gothenburg, Sweden) primary dressing (ExAg-polyvinyl alcohol [PVA]) against a market-leading comparator product, when used with a secondary foam dressing. The durability of the primary dressings after simulated use was further investigated through tensile mechanical testing.

Results The ExAg-PVA primary dressing delivered greater fluid amounts for absorbency and retention by the secondary foam dressing, approximately 2- and 1.5-fold more than the comparator dressing pair after 10 and 15 hours, respectively. The ExAg-PVA dressing was also substantially less sensitive to the direction of pulling forces and, accordingly, exhibited post-use mechanical strength that was approximately four- and six-times greater than that of the other primary dressing (when the latter dressing was tested out-of-alignment with its visible seams) after 10 and 15 hours, respectively.

Conclusions The dynamics of the sorptivity and fluid sharing between primary and secondary dressings and the effect of directional preference of strength of the primary dressings for adequate durability, resulting in safe post-use removals, have been described. The comparative quantification of these capabilities should help clinical and nonclinical decision-makers select dressings that best meet their patient needs.

Keywords biomechanical model, exudate management, laboratory testing, sorptivity, tissue phantom, wound care

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INTRODUCTION

Wounds of all types, including chronic cavity wounds such as pressure injuries, are one of the most impactful, expensive, and common medical problems. Nearly 2.5% of the US population experiences wounds, which is similar, for example, to the prevalence of stroke in the US.[1–4] As the population ages and the prevalences of diabetes and obesity increase, there is a sharp growth in demand for advanced and cost-effective wound care to deliver improved patient outcomes. Treatment

dressings play a pivotal role in all aspects of wound healing. Designed, in essence, as a temporary artificial substitute for intact skin, treatment dressings protect the wound and manage the exudates that result from periwound inflammatory processes. The presence and composition of exudates typically support the function of tissue-repairing cells and newly generated tissues; thus, in a normal tissue-repair process, the rate of exudate and its constituents will match the healing phase.[5–7] However, abnormal prolongation of the inflammatory stage, such as in chronic wounds, may disrupt the physiologic control of exudate production, leading to excessive exudate amounts or altered ratios of protein content which causes the fluid to be thick, highly viscous, or even sticky.[5]

Effective wound dressings are required to manage exudate fluids secreted at varying rates and viscosities, in the same wound at different times, or for wounds of the same etiology but different patients. A common clinical practice is to insert a primary wound dressing through the wound opening to form the first-line reservoir for fluid absorption and retention on the wound bed. A secondary dressing is then placed above the cavity (and the primary dressing) for mechanical and biological protection, as well as to make a second vessel for the accumulating fluids. Gelling fibre dressings composed of polyvinyl alcohol (PVA) fibres or sodium carboxymethyl cellulose (CMC) are widely used as primary dressings because of their ability to trap fluids by transformation into a gel phase[8] (examples of these commercial primary wound dressing products are listed in the woundsource.com resource database[9] under the "Gelling Fiber Dressings" wound dressing product category). A variant of these primary gelling fibre dressings are those that contain silver ions to further induce an antimicrobial effect. To deliver effective treatments, a primary dressing and a secondary dressing must work in synergy; that is, neither dressing should approach its maximum fluid absorption capacity within the timeframe indicated for use.[3,10–12]

The performance of a wound dressing depends primarily on the specific material composition, structure, and manufacturing technology of the dressing. These characteristics, in combination with the relevant clinical protocol, specific wound environment, and the type of paired secondary dressing, impact the safety and efficacy of the primary dressing product. Two fluid-structure interaction properties that are relevant to the function of primary dressings are "sorptivity," the capacity of a dressing structure to transfer excessive exudate away from the wound bed and onward to the secondary dressing through capillary action,[10,13] and "durability," the ability of a dressing to withstand patient body weight and other mechanical forces applied during changes and remain intact within the wound over the period of use or upon removal.[10,13]

In the 1970s, it was reported that the presence of gauze dressing particles in wounds "act as foreign bodies and may delay healing. Their removal has been associated with accelerated healing."[14] More recently, Chakravarthy and colleagues[15] documented grossly visible disintegration of modern (hydrocolloid) dressings in wounds. Dressing disintegration was associated with inflammatory giant cells—pathologic evidence for a foreign-body reaction—which highlights the importance of durability at both the macroscale and microscale. Specifically, Chakravarthy et al[15] evaluated the density of giant cells in histologic tissue sections that were extracted from wounds in a pig model of wound healing and subsequently stained by hematoxylin and eosin. They documented the presence of foreign material (ie, dressing debris) in the vicinity of the giant cells in the histologic slides, which correlated with their observed fragmentation of some of the tested hydrocolloid dressings upon removal during dressing changes.[15]

Accordingly, poorly performing wound dressings or dressing pairs may cause suboptimal moisture balance, mechanical damage to tissues, foreign-body reactions, or a combination of these adverse events. Such dressing failure modes should be identified through methodological bioengineering laboratory testing so that medical claims can be controlled by regulatory bodies and dressing failure in clinical settings can be avoided. In this context, the authors continue to invest research efforts into the development and improvement of preclinical and laboratory testing methods for objective, quantitative, and standardised evaluation of wound dressing performance.[3,10,11,13] Here, the authors present a novel robotic phantom system that contains multiple simulated wound replicates for the simultaneous testing of dressings. The system was developed and used to determine the synergy in fluid absorbency and retention performances of two silver-containing gelling fibre primary dressing products. The methods, equipment, and protocols reported herein form the basis for the next level of clinically relevant performance testing for wound dressings, focused on both safety and efficacy.

METHODS

Robotic Exuding Wounds

The researchers developed and used a robotic phantom system comprising six wound replicates. Each wound unit in this system simulated an exuding, 2.5 cm-deep cavity wound (Figure 1). All six wound units included three layers of synthetic soft-tissues simulants (Figure 1). The top layer, representing the peri-wound skin, consisted of 5 mm-thick transparent silicone rubber (RTV615, Momentive Performance Materials Inc, Waterford, New York). An 8-mm-thick layer of paraffin gel ("candle-gel"; Ziv Chemicals Ltd., Holon, Israel) was placed below this "skin" layer, to represent adipose tissue. The inferior layer (with thickness of 12 mm) representing skeletal muscle was again made of silicone rubber (identical to that used as the skin simulant). The elastic modulus of the aforementioned silicone rubber material, measured through uniaxial tensile testing using an electromechanical material-testing machine (Instron model 5944; Instron Co, Norwood, Massachusetts) following ASTM D412-06,[16] is 1.5 MPa, which is characteristic of both skin and muscle tissues under large deformations.[17–19] The elastic modulus of the paraffin gel used to represent adipose

tissue was measured through previously reported indentation tests[20] and found to be 5 kPa, which is similar to the reported stiffness of native adipose tissues.[21] To simulate continuous secretion of exudate from the above wound constructs, a spiral perforated irrigation tube was laid in each simulated wound bed and tunneled through the phantom structure to connect to a multichannel, programmable syringe pump (NE-1600; New Era Pump Systems Inc, Farmingdale, New York; Figure 1). The effective wet surface formed in the simulated wound beds through this irrigation element was approximately 24 cm^2, corresponding to an effective irrigation depth of approximately 2.5 cm. The multichannel syringe pump provided precise control over the flow volume and release rate of an exudate-substitute fluid delivered into the simulated wound beds. The safe and reproducible exudate substitute fluid formula is based on Xanthan gum (C35H49O29); it was previously developed by the authors' research group for use with the robotic wound phantom systems. This formula facilitates control of the fluid viscosity and pH level to adequately represent the physical characteristics of native exudates.[10-13,22] Two exudate solutions were prepared, with high and low viscosities of 0.23 Pa×s and 0.06 Pa×s, respectively; the fluid density was 1.03 g/mL for both. An infrared heating lamp was positioned above the six wound replicas to maintain them at a temperature of 33 ± 2° C;[23] the temperatures were monitored via a digital thermometer (Newtron TM-5005-SINGLE I/P; MRC Laboratory Equipment Ltd, Holon, Israel).

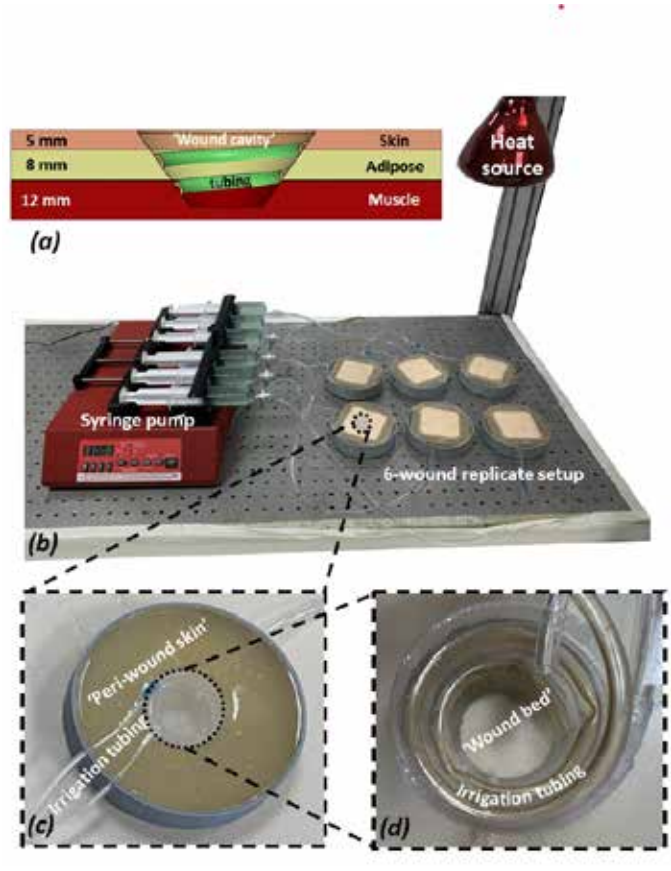

Figure 1. The experimental setup and its components
a) A scheme of a cross-section through a single "wound" simulator unit showing the different tissue simulant layers and their respective thicknesses, the shape and depth of the 'wound cavity' and the configuration of the spiral irrigation tubing. (b) A photograph of the robotic phantom system including the six wound replicates and the control unit. (c) A close-up view of a single simulated wound. (d) Zoom on the simulated exuding "wound bed."

Simulated Treatments

Two types of 10×10 cm primary gelling fibre dressings were investigated: Exufiber Ag+ (Mölnlycke Health Care AB, Gothenburg, Sweden) with PVA fibres (ExAg-PVA) and an equivalent, commercially available, and market-leading silver ion dressing product containing sodium CMC as the gelling material (Ag-CMC). The Ag-CMC dressing is a soft, sterile, nonwoven pad composed of sodium CMC hydrocolloid fibre material that is impregnated with 1.2% ionic silver.[24-26] It is indicated for clinical use in various wound types, both acute and chronic, and its physical and antibacterial properties have been described in detail elsewhere.[24-26] Of note, although the two types of primary dressings selected for this study—PVA-based and CMC-based—are made of distinct materials and produced through different manufacturing technologies, both are clinically indicated for use as cavity wound fillers, which was the rationale for the current comparison. Mepilex Border Flex (MBF-Foam; Mölnlycke Health Care), a multilayer bordered silicone-foam dressing, was used as the secondary dressing to cover the simulated wounds in all the tests. The MBF-Foam is a five-layer dressing that includes (from the outer dressing surface to its wound-facing aspect): backing film, a retention layer, a spreading layer, an absorptive foam layer (which transports exudate to the spreading layer), and a wound contact layer.

Prior to applying the dressing products onto the simulated wounds, each dressing (primary or secondary) was weighed. The dressings were then applied according to manufacturer instructions. The simulated wounds were positioned facing upward, so that the tested dressings were required to absorb and retain the exudate substitute through capillary action (ie, against gravity). The robotic system was activated with a flow rate of 2 mL/h. To determine the time course of the absorbency performances of the tested dressings and, importantly, the dynamics of the fluid distribution between the primary and secondary dressings, the products were tested for multiple durations of simulated use: 5, 10, and 15 hours.

DRESSING STUDIES

Fluid Retention and Distribution Between the Primary and Secondary Dressings. Following simulated use in the robotic phantom system, the dressings were reweighed to calculate the net mass gain in each dressing due to fluid absorption; any nonretained, residual fluids were carefully collected from the wound cavities and also weighed. After converting the measured fluid masses to volumes (by dividing the absorbed and residual fluid masses by the fluid density), the total exudate volume was calculated separately for each test as the sum of the fluid volumes in the primary and secondary dressings plus the volume of the residual fluid. Next, the distribution of fluid volumes between the

primary and secondary dressings was calculated for each test as the percentage of fluid retained in the primary versus the secondary dressing, with respect to the corresponding total exudate volume (the theoretical value of which is also calculable, as the product of the predetermined flow rate and the time of operation of the robotic wound system).[10]

Fiber Directionality. For gelling fibre dressings, the directionality of the fibres, which typically is related to the manufacturing technology of these primary dressings (ie, PVA vs CMC), likely affects the performances of the dressing product, such as the sorptivity (the fibres become the structural conductors for the capillary action) and the durability (the fibres provide structural support and mechanical tolerance against forces that are aligned with their primary direction). Accordingly, the researchers assessed the directionality of the fibres in the two primary dressing types by digital image processing of microscopy images of the dressing surfaces, which were acquired using a light optical stereo microscope (Axiolab A450909; Carl Zeiss AG, Oberkochen, Germany). The micrographs of the dressing surfaces were acquired in transmitted light mode using a 1.25× magnification objective, a C-mounted digital camera (Swift Cam SC1803; Swift Optical Instruments Inc, Schertz Texas) and the Swift Imaging software (version 3.0, Swift Optical Instruments Inc.). Five fields of view (FOVs) were captured at consistent surface locations from two primary dressing specimens of each type: One FOV was located at the center of the dressing, and the other four FOVs formed a cross around the dressing center, with each such peripheral FOV located at a distance of 2.5 cm from the dressing edges. This resulted in a total of 15 digital micrographs of the FOVs per dressing type, each with dimensions of 4,912 × 3,684 pixels (1 square pixel = 0.919 μm^2). For the purpose of the fibre directionality analyses, the acquired FOVs were further divided into three rectangular sub-FOVs, each with dimensions of 1445×3288 pixels. The fibre directionality analyses were conducted using the postacquisition plugin "OrientationJ" of the ImageJ software suite (version 1.X),[27,28] which segments the fibres in the digital micrographs and calculates the probability function for their planar orientation in each analyzed sub-FOV. After calibrating this code and visually verifying its performances, the normalised histograms of the fibre orientations in the studied primary dressings were extracted.

Strength of the Primary Dressings After Simulated Use. Immediately after the simulated use sessions, the tensile strength of each primary dressing specimen was tested using an electromechanical testing machine (Instron model 5944; Instron Co) equipped with a 2kN load cell, following a protocol that is based on ASTM D882-02.[29] Primary dressing specimens prepared according to the above testing standard were stretched at a deformation rate of 50 mm/min until ultimate failure occurred. Based on the resulting force-deformation data, stress-strain curves of the dressings after simulated use were plotted and the area under the stress-strain curve, which is the strain energy density (SED) to failure, was calculated for each test using a dedicated MATLAB computer code (ver. R2019a; MathWorks, Inc, Natick, Massachusetts). Based on these microscopy analyses of the fibre orientations, the ExAg-PVA dressing was treated as a structure without a specific directional preference (ie, test specimens from this dressing type were prepared and mechanically tested at random directions). However, the Ag-CMC silver-containing primary dressing, which has a specific directional preference of its fibres (as further detailed in the Results), was tested in two different configurations: where its principal fibre direction was fully aligned with the loading axis of the material testing machine, and where the fibres were out of such alignment.

Statistical Analyses

All the experiments reported above were conducted in replicates of six and descriptive statistics of means and SDs were calculated for the retained fluid volumes, the distribution of fluid contents between the primary and secondary dressings per each simulated use duration (5, 10, and 15 hours), and the SED to failure of the primary dressings (depending on the directionality of the fibres with respect to the loading axis, as noted previously). Next, analyses of variance (ANOVA), followed by post-hoc Tukey-Kramer multiple pairwise comparisons, were run to identify potential differences between the dressing performances in the previously described fluid management (sorptivity) and material strength tests. Specifically, two-way ANOVAs for the factors of the usage time and the primary dressing type were conducted for the fluid retention and fluid distribution data. In addition, a three-way ANOVA for the factors of the usage time, the primary dressing type, and the directionality of the tensile test with respect to the fibre orientation (in the primary dressing that exhibited directional preference of fibre orientation) was performed for the material strength data. Only the longer exposure times of 10 and 15 hours, for which substantial fluid mass had accrued in the tested primary dressings, were considered for the latter three-way ANOVA. With respect to the directionality factor, based on the microscopy analyses, the last ANOVA considered the ExAg-PVA dressing, which did not show any specific and consistent directional preference of its fibres, as having a single strength (SED-to-failure) property. However, the Ag-CMC had two strength properties, namely, the strength measured (1) when the fibres were fully aligned with the loading axis of the material testing machine and, (2) when they were out of such alignment. $P < .05$ was considered statistically significant.

RESULTS

When examined in isolation, the absorbency of the ExAg-PVA primary dressing was lower (approximately 11-22%) than that of the Ag-CMC primary silver dressing (Figure 2a). However, this difference was due to a more effective transfer of the exudate-like fluid from the ExAg-PVA dressing to the secondary dressing, as evident when examining the data for the fluid distribution between the primary and secondary dressings (Figure 2b). Specifically, when functioning in a pair with the ExAg-PVA dressing, the secondary dressing contained

approximately twice the amount of fluid at the 10-hour time point and 1.5-times the amount of fluid after 15 hours with respect to the comparator pair (Figure 2b). The dynamics of the fluid distribution between the primary and secondary dressings over time (Figure 2b) further revealed that the reservoir of the secondary dressing began to receive fluid no earlier than 5 hours from the time of the dressing application (Figure 2b). After 15 hours, the secondary dressing shared approximately 54.2% of the retained fluid when the primary dressing was ExAg-PVA but only 36.7% when the Ag-CMC primary dressing was used ($P < .05$; Figure 2b). Importantly, these results represent the performances of the dressing pairs and therefore, better reflect real-world clinical practice, as opposed to assessments of the function of wound dressings in isolation (Figure 2b).

The digital microscopy image analyses of the primary dressings indicated that the ExAg-PVA dressing had no distinguishable directional fibre preference. Specifically, to verify the relative lack of directional preference of the ExAg-PVA dressing with respect to that of the Ag-CMC primary silver-containing

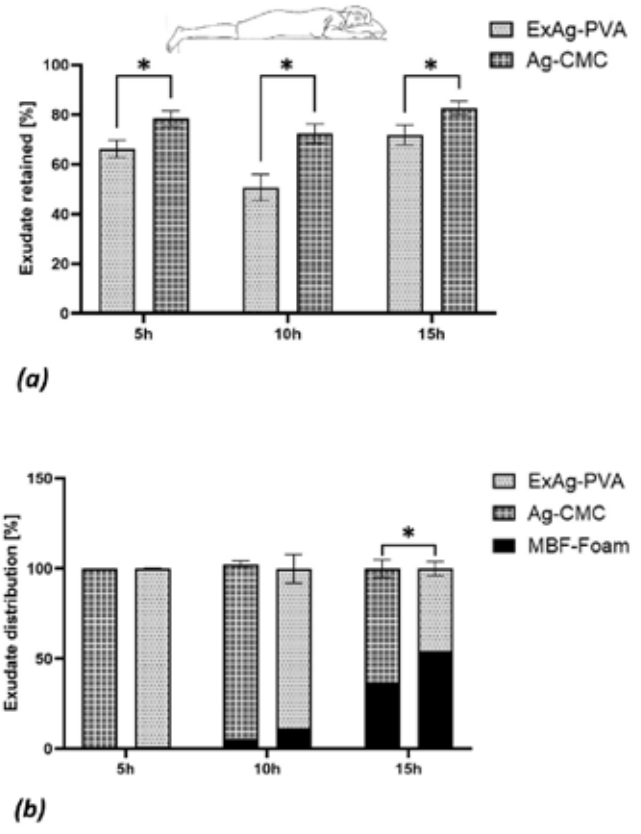

Figure 2. Fluid absorption and retention performances of the tested dressings (a) The fluid retained in the primary dressings, reflecting the sorptivity of these dressings (reported as percentage of the total fluid volume retained in the primary and secondary dressings plus the residual fluid in the simulated wound bed). (b) The fluid distribution between the primary and secondary dressings after 5, 10, and 15 hours of simulated use in offloaded wounds (as in a prone position). The error bars are the SDs from the mean values of six test repetitions per test configuration and an asterisk indicates a statistically significant difference in the relevant outcome measure (P < .01).

dressing, the researchers calculated the integral bounded between the fibre orientation histogram curve and the 0.5 (midpoint) level for the two primary dressings. This integral is defined here as the fibre orientation index (FOI). When a dressing does not exhibit a directional preference of its fibres, the positive and negative areas between the aforementioned histogram curve and the 0.5 level approximately cancel each other out, which results in a relatively low FOI value. The analyses of the FOI data indicated that the ExAg-PVA dressing had a statistically significant, approximately 3.9-fold lower FOI (15.6 ± 11.8) with respect to that of the Ag-CMC primary silver-containing dressing (60.8 ± 48.8; $P < .05$ for five different microscope FOVs on each dressing type). This FOI property ratio quantitatively demonstrates the strong preference of the fibre alignment in the Ag-CMC primary dressing toward the direction of the visible reinforcing seams in that dressing (the 90° direction marked in Figure 3a). Of note, the fibre orientation histogram of the latter (Ag-CMC) dressing was always above the midpoint level, which again indicates a strong directional preference (Figure 3a). Visual inspection of the microscopy data confirmed that the majority of the fibres in the Ag-CMC primary dressing were aligned and grouped together to connect to the vertical (90°-oriented) visible seams. The micrographs further demonstrated numerous elliptically shaped voids with characteristic maximum length dimensions of approximately 400 to 600 µm in the Ag-CMC primary dressing (Figure 3a). These findings, of a preferred fibre orientation and abundant presence of noncircular voids, justified the selection of the Ag-CMC primary silver-containing dressing as having a specific directional preference (ie, along its visible seams) for the purpose of further mechanical testing, as follows.

For the mechanical testing of the primary dressings post simulated use, the later time points of 10 and 15 hours of fluid exposure were selected because the previous results indicated that at 10 hours and afterward, both primary dressing types had transferred fluid to their paired secondary dressings (Figure 2b). Thus, at the 10- and 15-hour timepoints, both primary dressing types used their fluid reservoirs in a manner indicating that they were indeed tested at their "wet" state. Further, based on the results of the microscopy analyses, the ExAg-PVA dressing was tested as a structure without a specific directional preference (ie, irrespective of the direction by which test specimens were cut from this dressing type), whereas the Ag-CMC dressing was tested in two different configurations: fully aligned with the primary fibre orientation (90° direction), which is the direction of the visible seams, and out of such alignment (ie, randomly selected but different from the 90° direction).

The SED-to-failure data for the two primary dressing types are shown in Figure 3b and demonstrate considerable differences in mechanical behaviors of the post-use dressing types, particularly concerning the ductility of the ExAg-PVA dressing versus the Ag-CMC product. Ductility is the degree to which a material or structure can sustain plastic/irreversible

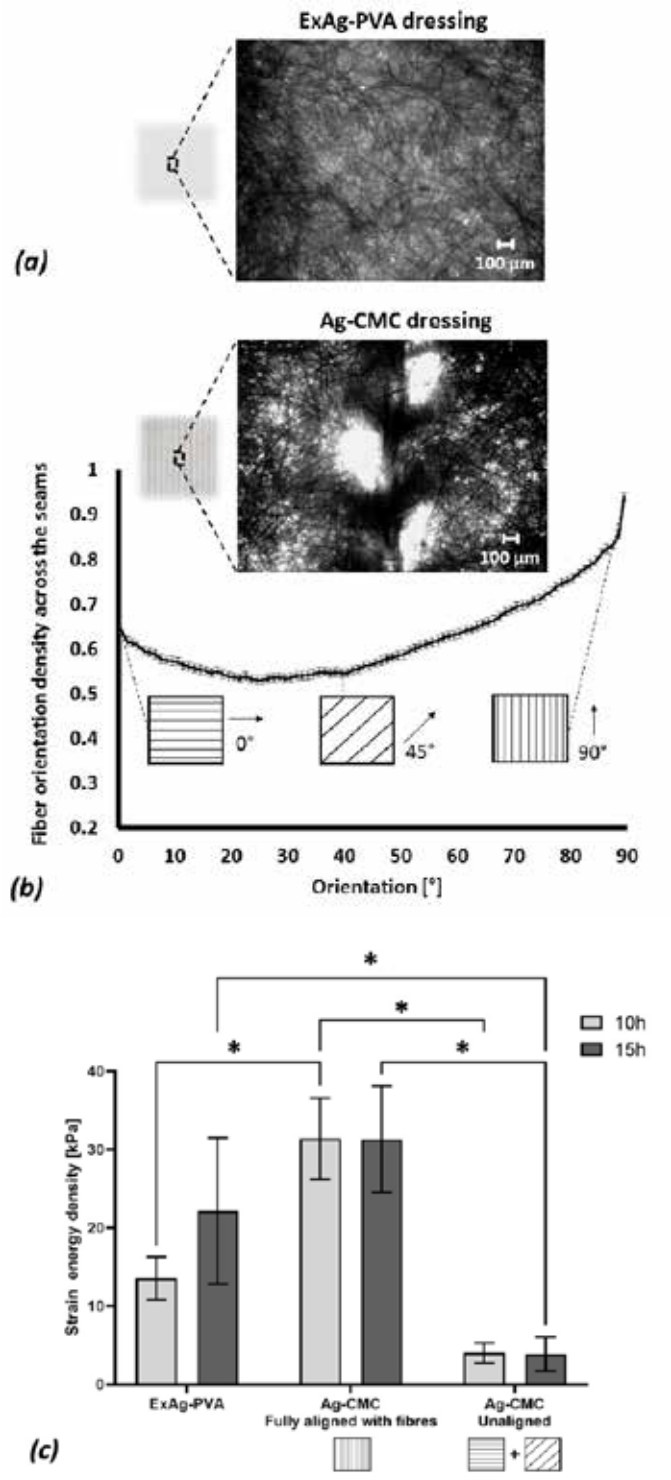

Figure 3. Structure-function analyses of the tested primary wound dressings (a) An example of a microscopic image of the Exufiber Ag+ (ExAg-PVA) dressing. (b) Representative microscopy image analysis of the fiber orientation in the Ag-sodium carboxymethyl cellulose (CMC) dressing, showing the normalised planar distribution of fiber orientations in this primary dressing type. (c) The strain energy density to failure of the two tested primary dressing types post simulated use of 10 and 15 hours, where the Ag-CMC product has been tested in two configurations, either in full alignment of the principal direction of the fibers of the dressing with the loading axis of the testing machine, or out of such alignment. The error bars are the SDs from the mean values of six test repetitions per test configuration and an asterisk indicates a statistically significant difference in the relevant outcome measure (P < .01).

deformations and continue to absorb strain energy under tensile loading before catastrophic failure occurs. Interestingly, the ExAg-PVA dressing appeared to gain ductility as it absorbed more fluid and gelled and accordingly, at 15 hours, it had 1.7-times greater SED-to-failure than it did at 10 hours. In contrast, gelling transformation did not translate into greater ductility for the Ag-CMC primary dressing; its SED-to-failure data were indistinguishable for the 10- and 15-hour time points (Figure 3b). Moreover, the aforementioned strength tests clearly indicated that the main loadbearing structure in the Ag-CMC primary dressing was, indeed, the reinforcing (visible) seams and the (near) 90°-oriented fibres. When tested out of alignment, the strength of the Ag-CMC primary dressing dropped significantly, by more than 8-fold ($P < .05$). With respect to the mechanical strength of the ExAg-PVA dressing, the Ag-CMC primary dressing had an out-of-alignment strength that was approximately four and six times lower for the 10- and 15-hour time points, respectively ($P < .05$).

DISCUSSION

Wound exudates are critical for tissue repair—they facilitate cell mobility and transport of signaling molecules and growth factors across the wound bed. However, excess exudate production may lead to maceration, become a medium for infections, or prolong the inflammation period.[30,31] Thus, excess exudate amounts should be absorbed and retained in therapeutic dressings to support the natural wound-healing process. Clinical practice in treating cavity wounds as well as other highly exuding wounds (such as venous leg ulcers and burns) is to use a nonadherent wound filler as the primary dressing to induce a moist wound-healing environment while maximising dressing contact with the wound bed for effective absorbency. A secondary dressing is then applied to close the wound and protect it from potential mechanical traumas and pathogen invasion while also allowing evaporation of the exudate and release of byproduct gases. The secondary dressing also potentially provides an additional reservoir for absorbency and retention of the wound fluids, but it strongly depends on the sorptivity of the primary dressing for effective exudate management. Hence, for effective treatments, the primary and secondary dressings must work in synergy; both dressings should share the retained fluid mass as equally as possible and not approach their maximum fluid absorption capacity until a dressing change is indicated.[3,10,11] Of note, for clinical realism, sorptivity should be assessed by testing a wound dressing pair using a relatively viscous, not watery, test fluid, which was the approach of the current study.[10,11] New exudate cannot enter a primary dressing if there is no space for it at the wound-contacting aspect of the dressing; however, the existence of such available space depends on adequate transport of existing exudate from the primary to the secondary dressing.[10,11] The capillary action that enables this fluid movement is inversely proportional to the square root of the viscosity of the transferred fluid (see Equation 2 in Lustig et al[10]); that is, the more viscous the fluid, the more difficult it is for it to be transported against gravity upward to the secondary

dressing in any offloaded wound.[10] Of note, nonoffloaded wounds may occur in real-world clinical practice and include, for example, wounds that are subjected to body weight forces such as plantar diabetic foot ulcers or sacral pressure injuries in patients who are ventilated supine, or wounds that are compressed by a medical device such as compression stockings applied on venous leg ulcers. The current study and configuration of the robotic exuding wounds apply to off-loaded wounds only; the additional biophysical complexity that arises from the action of bodyweight or external (eg, medical device-related) forces on a wound or its vicinity was not taken into account.

Gelling fibre dressings based on PVA or CMC fibres are used as primary dressings on a variety of highly exuding wound types. These dressings are meant to form a soft, cohesive gel when in contact with exudate, which induces the necessary moisture in the wound. However, such dressings must exhibit sufficient capillary action (sorptivity) to effectively transfer any excess exudate fluids away from the wound bed and prevent their pooling at the wound-dressing interfaces or within any undermining or tunneling spaces.[3,10,11] In this work, a robotic phantom system of multiple simulated wound replicates was developed and used to evaluate the synergy in fluid absorbency and retention performances (facilitated through sorptivity) of two market-leading silver-containing gelling fibre primary dressing products when used with a secondary foam dressing, as per clinical practice. The ability of these primary dressings to stay intact while being subjected to pulling forces post simulated use sessions (ie, to exhibit clinically relevant durability) was further tested. These pulling forces mimic the mechanical effect of the forces that a clinician would apply with his/her gloved fingers or forceps when removing a used dressing and replacing it with a new one.

The ExAg-PVA was substantially more effective in transferring exudate simulants to the secondary foam dressing compared with the Ag-CMC. The ExAg-PVA dressing contained less fluid at each time point, and its paired secondary dressing accepted that fluid and retained it at increasing amounts over time. The latter results are particularly innovative because they reveal, for the first time in the literature, that the sharing process initiates between 5 and 10 hours after application of the dressings and amplifies thereafter. Specifically, the ExAg-PVA primary dressing delivers greater fluid amounts for absorbency and retention by the secondary dressing, approximately 2- and 1.5-fold the amounts of fluid at the 10- and 15-hour time points, respectively, with reference to the comparator dressing pair. The more fluid that is transferred to the secondary dressing, the greater the available capacity of the primary dressing to manage new inflowing exudates. Thus, laboratory evaluations must assess the function of wound dressings in the relevant clinical context (ie, measuring the function of the primary-secondary dressing pair as opposed to testing dressing products in isolation). Importantly, these experimental results demonstrate that the extent and rate of fluid sharing depend on the dressing materials and composition, indicating that there are more and less optimal choices of primary-secondary dressing combinations.

Nevertheless, sorptivity and the associated absorbency and retention performances are only one aspect to consider when assessing the safety and effectiveness of wound dressings through bioengineering laboratory testing. The mechanical strength of a primary dressing must be sufficient to endure the forces that occur throughout the life cycle of the dressing, including under the extraction forces that a clinician applies when the dressing is removed. Despite being exposed to the aggressive chemical and thermodynamic environment of the wound, a dressing must not disintegrate or leave debris or particles in the wound. Any debris (even microparticles) that originate from the primary dressing and spread onto the wound surface may initiate a foreign-body reaction whereby the immune system attempts to form granuloma (aggregation of macrophages and fibroblasts around each particle to isolate it from the body tissues). Such events consume valuable inflammatory and tissue repair efforts, which detract from the local biologic healing resources (eg, the potential numbers of the immune and fibroblast cells that are available for the tissue repair task).[3,10,15,32]

The microscopy image analyses did not show a consistent, strong directional preference of the fibres in the ExAg-PVA dressing, indicating low directional strength preference compared with the Ag-CMC, which did demonstrate a strong directional preference associated with its weave structure, specifically toward the visible reinforcing seams of the dressing. The durability testing results were consistent with the aforementioned microscopy findings for the Ag-CMC. Specifically, the Ag-CMC demonstrated poor mechanical strength when the direction of the pulling forces did not fully align with that of the reinforcing seams. Moreover, the current mechanical testing indicated that the strength of the Ag-CMC dressing is dominantly provided by the visible reinforcing seams and the closely aligned fibres; this imposes a real-world requirement (not presented by the manufacturer) that a clinician removing the dressing should be aware of the orientation of the seams and attempt to pull in that specific direction so as to avoid accidental (partial or complete) tearing. Yet, when removing a primary dressing from the wound cavity, the likelihood that a nurse would (blindly) pull the dressing at a specific orientation that exactly matches the primary fibre orientation of the dressing approaches zero. Moreover, removing a dressing in line with its primary fibre orientation is made even harder if the dressing takes on the same color as the exudate while in the wound. Because dressings are typically folded in the wound cavity and most of their structure is invisible, even if a nurse would hypothetically attempt to pull the dressing in a specific direction (to conform with the dressing's optimal mechanical energy absorption to failure properties), then still, from a cost-effectiveness perspective, a dressing requiring removals at specific orientation and extra attention to that aspect adds to the clinical workload. The above implies that in real-world, clinically relevant scenarios,

the Ag-CMC would have a four to six times lower strength (ie, mechanical energy absorption to failure) than that of the ExAg-PVA dressing, and the Ag-CMC dressing is therefore much more likely to leave debris or particles in a wound. The likelihood of such dressing failure events increases further when a wound has undermining, is tunneled, or has sticky or rough surfaces, all of which may be associated with greater pullout forces required to release the used dressing to be changed.

As with any experimental study, there are limitations in the ability to mimic in vivo processes and the large variety of clinical scenarios. Accordingly, in future work, additional experiments focusing on typically nonoffloaded wounds such as venous leg ulcers, are warranted. There is also a need to test additional wound dressing types and technologies from various manufacturers and include the aspect of cost-effectiveness versus the measured performance parameters. Other sensors and post analyses can potentially be added to the apparatus (and to each wound simulant unit) or be integrated in the testing methodology, such as intrawound continuous pH monitoring or mass spectrometry of the residual fluids following dressing usage periods. Further progress can be achieved by introducing exudate substitutes that contain specific microbiomes that may represent different wound etiologies, such as infected pressure injuries or diabetic foot ulcers. All of these future improvements would require additional validation and reliability studies before informing clinical practice.

CONCLUSIONS

Using an automated robotic phantom system of multiple open cavity wounds, the authors evaluated the absorbency and retention and therefore the sorptivity performances of silver-containing gelling fibre dressings paired with a secondary foam dressing. The mechanical durability of the primary silver-containing dressings was tested after simulated use. The current experimental system and protocol were designed with emphasis on the clinical relevance of the bioengineering laboratory testing, to reproduce how wound dressings are used in practice and consider the real-world scenarios that may be associated with their failure. Consistent with the previous published work of the authors, sorptivity and durability were again identified as critical factors that should be assessed when evaluating wound dressings in laboratory testing.[3,10,11] The present findings further underpin that wound dressings belonging to a certain product category, such as silver-containing gelling fibre dressings, are not all the same, and the specific absorption, retention, and, importantly, the ability to synergistically work with a secondary dressing (which good sorptivity enables) differ across products, depending on the specific materials and composition of the dressing.[3,10,32,33] The present experimental data revealed that the ExAg-PVA dressing has better sorptivity and durability than the comparator Ag-CMC product. Moreover, the authors described the dynamics of the fluid sharing between primary and secondary dressings and identified the importance of not having a specific fibre directionality in a primary dressing for durability and safe post-use removals. The comparative quantification of these capabilities should help both clinical and nonclinical decision-makers to assess and select the wound dressings that best meet the needs of their patients. As with any preclinical work, the current laboratory findings need to be validated against randomised controlled trials with appropriate sample sizes of different wound etiologies. The role of the laboratory work reported here is primarily to guide such potential clinical research to focus on the novel aspects of fluid sharing between the primary and secondary wound dressings, and the ability of the primary dressings to remain intact during removals, topics that have been poorly addressed in the literature thus far.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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