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The sorptivity and durability of gelling fibre dressings tested in a simulated sacral pressure ulcer system

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Abstract

Wound-dressing performances are affected by exudate viscosity, resistance to flow because of gravity, and bodyweight loads, the level of which is related to the body position. Here, we focussed on two dressing properties: (a) *Sorptivity*—the ability of dressings to transfer exudate away from the wound bed by capillary action—and (b) *Durability*—the capacity of dressings to maintain their integrity over time and during their removal. Both properties are critically important for avoiding further tissue damage but require the development of new laboratory tests for their measurement. A computer-controlled phantom of an exuding sacral pressure ulcer has therefore been developed and used to compare the performances of Exufiber (Mölnlycke Health Care) vs an alternative market-leading dressing. Sorptivity was determined using weight tests, and durability was measured through tensile tests of the used dressings. For a supine configuration, the Exufiber dressing demonstrated ~three times higher sorptivity and better durability, withstanding ~five times greater strain energy than the other product before failure occurred. This work paves the way for quantitative, standardised testing of dressings in all aspects of exudate management. The reported tests are further suitable for testing dressing combinations or how dressings interact with negative pressure wound therapy.

KEYWORDS

chronic wound, pressure injury, primary and secondary dressings, tissue phantom

1 | INTRODUCTION

Pressure ulcers (PUs), also known as pressure injuries in the United States, Canada, and Australia, are a common complication of prolonged bed rest or sitting.[1-3] It has been established in numerous studies that PUs are a cause of morbidity, mortality, pain, and reduced health-related quality of life. Substantial direct (eg, treatment and rehabilitation) and indirect (eg, potential litigation and insurance) expenditure can also be incurred through the development of a PU. In their early stages of development, PUs stimulate the innate inflammatory response of the immune system to increase the vascular permeability around the site of tissue damage. This enables extravasation and infiltration of immune system cells (leukocytes) to the damaged tissue and, consequently, results in exudate leakage from the vasculature surrounding the wound.[4-7] Exudate is a serum-based fluid with a dynamic

composition of neutrophils and proteins, which typically correlate to the healing phase, presence of pathogens, and the overall severity of the specific wound. A mildly moist wound environment is needed for adequate healing[8] as the exudate facilitates transport of essential nutrients, as well as immunological factors, to the wound bed[8,9]; stimulates fibroblast and endothelial cell proliferation[10]; and improves epithelisation.[11,12] Exudate also acts as a buffer to maintain an adequate pH environment, for example, after exposure to bacterial infections.[13] Exudate secretion in a wound is, therefore, not only normal but also has a crucial role in the healing process. However, excessive exudate amounts may interrupt the healing cycle or cause cytotoxicity. The exudate may also become the transport medium for bacteria growing in the wound bed, carrying pathogens to newly regenerated tissues in the wound bed or to adjacent, non-wounded tissues.[14] Accordingly, it is commonly accepted that wound exudate should be absorbed or retained to an adequate extent by dressings to support the healing process and protect skin and non-injured tissues surrounding an existing PU. Gelling fibre dressings, also referred to here as primary dressings, are designed for these purposes.

Historically, gelling fibre dressings have been composed of sodium carboxymethyl cellulose (CMC), strengthening cellulose fibres, and other blended superabsorbent materials.[9,15-17] More recently, dressings consisting of a non-woven pad or ribbon made from very tightly entangled polyvinyl alcohol (PVA) fibres have become available.[18] This type of dressing locks fluids that are absorbed into the dressing structure; the dressing then swells and takes the form of a gel, which ideally conforms to the wound cavity shape. The transformation of the dressing from dry state to an absorptive state assists in maintaining a moist environment in the wound bed. This moist condition is required for the formation of healthy granulation tissue, as explained above. In a good treatment dressing, the retention of exudate in the dressing structure occurs so that the exudate levels are controlled, which in turn also helps to reduce the risk of peri-wound maceration. After application of the gelling fibre primary dressing to the wound cavity, a secondary larger dressing is applied over the primary dressing to absorb excess exudate, protect the wound from becoming overly dry, maintain a physiological temperature, and protect the wound from further mechanical trauma and exposure to environmental pathogens.

As with any wound dressing, the performances of gelling fibre dressings are primarily a function of the dressing technology, that is, the specific material composition and micro-architectural arrangement of the fibres and superabsorbent elements, which determine the modes of action of the dressings and their effectiveness. Nonetheless, in any real-world clinical scenario, the dressing structure always interacts with the patient and the individual wound characteristics, as well as the specific environment acting on the wound (eg, the support surface for a non-off-loaded wound and the forces and microclimate conditions that develop there). The clinical protocol and the practice of care further impact dressing performance.

For example, a certain viscosity level of the exudate, which is correlated with protein content and often associated with wound infections, can affect the exudate uptake rate of the dressing. A slow absorbance process in the dressing, because of a high exudate viscosity level, will increase the risk of exudate backflow into the wound bed and, thereby, pooling of the exudate in the wound cavity, resulting in excessive wound bed hydration and potential skin maceration. Likewise, the body position of the patient dictates the resistance to the exudate flow by gravity. Furthermore, any bodyweight forces exerted on the wound (in a non-off-loaded wound) can decrease the effective volume of the dressing reservoir or perhaps even cause a pressure-induced release of fluids locked in the dressing. The phenomena of patient bodyweight forces mechanically distorting the wound bed and squeezing the dressing may amplify if a patient is repositioned; repetitively moves spontaneously, for example, because of spasms, seizures, or agitation[19]; migrates (slides) in their bed as the head of the bed is elevated[20]; or is transferred between support surfaces, as well as in numerous others clinical scenarios. Furthermore, throughout the treatment period, dressings will be mechanically loaded by clinicians during dressing changes.

With respect to the modes of action of wound dressings, the classic "fluid retention" and "fluid management" attributes are often mentioned by manufacturers and are typically gauged in simple, non-realistic laboratory setups, rather than by means of clinically relevant test configurations.[21] Currently, the most commonly accepted testing standard in this regard, used by many companies in the dressing industry and also as the basis for their commercial demos, is the British Standard no. EN 13726 for the testing of primary wound dressings (2002).[22] In the above British Standard, retention tests of dressings are conducted using distilled water rather than more viscous fluids, which disregards the strong effect of the exudate viscosity level on the flow through the dressing micro-architecture and, thereby, on the fluid absorption rate and the effectiveness of fluid retention. Not only do many clinicians recognise the viscosity of the wound exudate as a major factor affecting their dressing selection decisions, the theory of fluid flow in porous media identifies the viscosity of the flowing fluid as a fundamental parameter that characterises the flow.

Furthermore, the aforementioned British Standard does not consider other critical clinical factors such as the anatomical, physical, and pathophysiological environment of the wound (eg, if there is undermining and, if so, what are the effects of the associated geometrical confinements on the conformation of the dressing structure; potential spatial and temporal variations in wound temperatures and pH levels; roughness and adhesiveness of the wound surfaces etc.). In some of the test protocols specified in the above British Standard,[22] for example, in its section 1 "Aspects of Absorbency," there is no consideration of the directionality of the exudate flow (from the wound bed into the dressing and from the wet front to the dry aspect of the dressing, as occurs in real-world conditions) as, in these tests, dressing specimens are submersed instantaneously in fluid. Likewise, the regime of mechanical loads applied on the dressing while it is being used (eg, because of patient bodyweight forces that apply statically or dynamically and the loads applied by clinicians in pulling the dressing out of the wound cavity during dressing changes) are not considered. The wear-and-tear effects on the dressing because of prolonged duration of use in the often-hostile wound bed environment are also not accounted for. Consequently, the dressing tests commonly used by manufacturers and regulators (based primarily on the above British Standard), such as tests where dressing specimens are submersed in vessels containing watery dyes, do not adequately represent the body and wound environments. The complex physical fluid-structure interactions that occur in wound dressings applied to real wounds, which discharge viscous exudates, cannot be considered in such simplified set-ups. Specifically, a key fluid-structure interaction concept, "sorptivity," which is the capacity of a dressing structure to transfer excessive exudate away from the wound bed by capillary action, has not been addressed in the wound care literature to date. In addition, the durability of a dressing, defined as the dressing capacity to withstand the aforementioned patient bodyweight forces and the forces applied on the dressing during changes, so that the dressing does not disintegrate within the wound over a period of use and the gel does not fracture into particles upon removal, is critical. These two important dressing characteristics, sorptivity and durability, directly relate to the potential for peri-wound maceration and possible inflammatory foreign-body reaction to any retained dressing debris and gel particles, respectively.

Importantly, despite the fact that gelling fibre dressings made by different manufacturers are already in extensive clinical use, there are no standardised and clinically realistic laboratory tests, protocols, or studies to assess the performances of these dressings in their clinical wound environment, taking into account relevant fluid-structure interaction phenomena. In particular, the above-described sorptivity and durability of these dressings have never been addressed, and appropriate tests for these properties have not been proposed. We therefore developed, for the first time in the literature, a simulated experimental environment that is anatomically and pathophysiologically representative of sacral PU wound bed conditions to assess the function of primary dressings and the synergy in action between a primary and secondary dressing. Use of this new robotic phantom of an exuding sacral PU is exemplified here through a comparison of the performances of two primary dressing types, with a focus on the sorptivity and durability properties of the two primary dressing products. The present method and system are a significant innovation for evaluating all the known aspects of exudate management, spanning from efficacy research to design and product evaluation. In particular, the bioengineering laboratory tests reported here are versatile and, we believe, would be suitable for testing any combination of wound filler materials and secondary dressings, or the interaction of primary and secondary dressings with various exudates, in consideration of relevant clinical factors and practice.

2 | METHODS

2.1 | Phantom of an exuding sacral PU

We have designed, developed, and built a robotic phantom of an exuding sacral PU, simulating an active wound environment in an anatomically and pathophysiologically realistic form (Figure 1A). This robotic phantom includes a rigid plastic replica of the pelvic bones and soft-tissue substitutes made of a two-component silicone rubber (RTV615, Momentive Performance Materials Inc., Waterford, New York), which is cast in the shape of the buttocks of an adult male (with normal body mass index, BMI). The stiffness of the aforementioned silicone rubber material, that is, elastic modulus of 2.5 MPa, was measured through uniaxial unconfined compressive testing (Instron electromechanical testing apparatus model 5944, Instron Co., Massachusetts). A cylindrical geometry has been carved into the sacral region of the phantom, to a depth of 2.5 cm, which exposed the (plastic) sacrum, thereby simulating a category 4 PU. Within the above-mentioned cavity, we placed a three-dimensional-printed custom-made component, which simulates the exuding wound bed. This wound bed simulator has a truncated conical shape (ie, a "crater wound") with a diameter of 4.5 cm superficially and a maximum depth of 2 cm with respect to the adjacent phantom surface (Figure 1B).

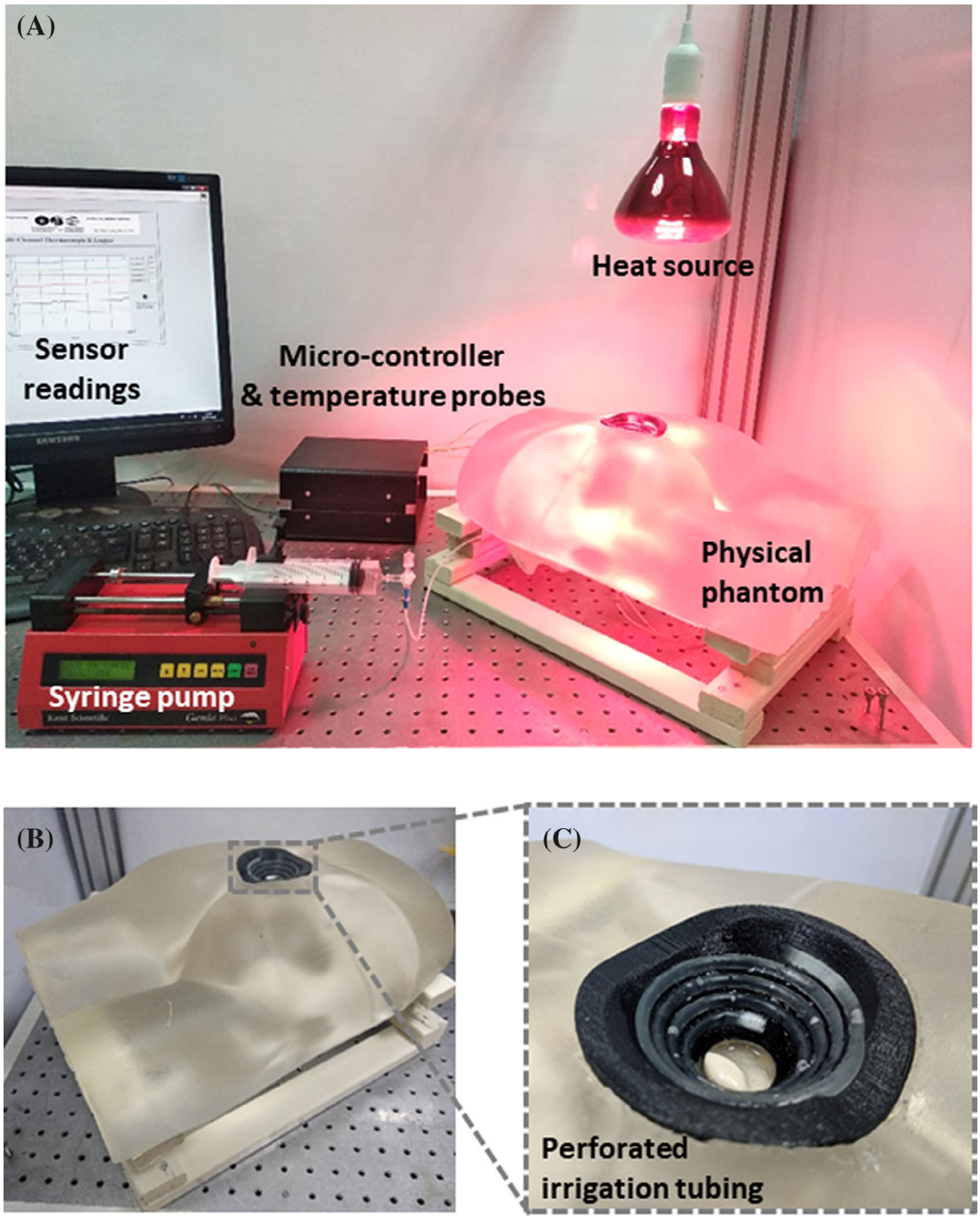

FIGURE 1 The robotic phantom of a sacral pressure ulcer and its control set-up, A, which forms an anatomically realistic automated testing system for wound dressings, B, including an exuding "wound bed," C, that can be treated by means of any (combination of) dressing products and clinical protocols for laboratory testing purposes [Color figure can be viewed at wileyonlinelibrary.com]

To simulate the continuous secretion of exudate, a spiral perforated irrigation tube was incorporated in this "wound bed" and tunnelled through the phantom structure to connect to an electromechanical syringe pump (Genie Plus model, Kent Scientific, Torrington, Connecticut). This automated system allowed the release of exudate-substitute fluids into the "wound bed" at controlled, preset flow volumes and rates. The effective wet surface of the simulated wound bed was ~25 cm^2. The margins of the wound were not irrigated (the irrigation depth was ~2 cm). This simulated wound design, including its effective wet area and irrigation depth, is clinically consistent with highly exuding wounds and replicates some deep sacral wounds observed by our clinician co-authors (PA, NS). To achieve thermodynamic similarity across experiments, we further positioned an

adjustable-distance infrared heating lamp directly above the "wound bed" (Figure 1A), which facilitated adjustment of the wound cavity temperature within a range of 31°C to 35°C, which has been reported for sacral PUs.[23] Five thermocouples embedded along the "wound bed" perimeter were used to verify a limited range of "wound" temperatures of 33°C ± 2°C (mean ± SD) circumferentially.

2.1.1 | Exudate substitute fluids

We developed a safe and reproducible exudate substitute fluid formula (for use with our robotic phantom system), which facilitates control of fluid viscosity and pH levels so that they adequately represent the physical characteristics of native exudate fluids. Specifically, food-standard Xanthan gum powder at a concentration of 0.01%, 0.05%, 0.1%, 0.15%, or 0.2% is mixed with distilled water, which results in a range of fluid viscosities, from watery to thick exudate substitutes (the more viscous slough exudate types, which contain proteinaceous tissues, fibrin, neutrophils and bacteria, are clinically associated with inflamed and likely heavily infected wounds).[8] It should be noted that rheological properties of human wound exudates, and quantitative (numerical) data of exudate viscosities in particular, have not been reported in the literature so far. Specifically, while qualitative and descriptive clinical terminology, using wording such as "thin," "watery," "thick," "sticky," "creamy" etc.,[8,24] is routinely being used by health care professionals to categorise exudate viscosities in their wound assessments,[25] quantitative physical and engineering measurements of exudate viscosity data are currently absent from the literature. Accordingly, we have developed our artificial exudate fluids to have viscosity properties in the same range of other human biological fluids (including protein-rich fluids) for which quantitative (numerical) viscosity data are available in the literature. The list of these viscosity values that have been reported, for example, for human blood plasma, whole blood, breastmilk, tears, saliva, and gastrointestinal and respiratory mucus, are summarised in Table 1. For example, Xanthan gum concentrations of 0.01%, 0.05%, and 0.10% in our exudate fluid replica result in artificial exudate viscosities of ~0.006, ~0.06, and ~0.24 Pa·s, respectively. The first value corresponds to the viscosity of whole blood, whereas the second and third values define much of the range of gastrointestinal mucus viscosities. Overall, our artificial exudate viscosity property is adjustable throughout ~2/3 of the viscosity range that is characteristic of human biological fluids (Table 1).

TABLE 1 Values and ranges of viscosity of human biological fluids

Fluid type	Viscosity (Pa·s)	References to literature
Water	0.71×10^{-3}	26
Blood plasma	1.24×10^{-3}	27,28
Whole blood	5.99×10^{-3}	28
Brest milk	$2\text{-}9 \times 10^{-3}$	29
Tears	$1.5\text{-}9 \times 10^{-3}$	30
Saliva	$5\text{-}25 \times 10^{-3}$	31
Gastrointestinal mucus	$6\text{-}84 \times 10^{-3}$	32,33
Gastrointestinal mucus of patients with a duodenal ulcer	$2.5\text{-}30\times 10^{-2}$	33
Respiratory mucus	12-15	32
Nasal mucus	1.3-46	32
Cervicovaginal mucus	20-80	32
Respiratory mucus in cystic fibrosis patients	Up to 110	32

After preparing the fluids using the above-listed Xanthan gum concentrations, their consistency was first evaluated and confirmed by our nursing expert co-authors (PA, NS) based on their clinical experience and were approved to be qualitatively representative of real-world exudates.[8] Next, quantitative laboratory evaluations of the exudate replica fluids were conducted, by means of rheology tests, to verify that the resulting fluid viscosities were representative of the human biological fluid viscosity range and to further characterise this substitute-exudate formula (rheometer model AR-G2, TA instruments, New Castle, Delaware). The above rheological testing demonstrated a shear thinning behaviour of the exudate substitutes with an increase in the shear rate (Figure 2A), which is consistent with the testing of biological mucus fluids.[32,33] Of note is that the present artificial exudate formula, reported here for the first time in the literature, avoids the use of potentially infectious natural biological materials such as animal blood plasma or serum, which can potentially be used to simulate exudates in laboratory experiments or product demonstrations. The resulting fluids had densities of ~1.01 to 1.05 g/cc (ie, mildly denser than water, which overlaps the range of blood plasma to whole blood densities) and viscosities in the range of 0.006 to 0.71 Pa·s (Figure 2B), depending on the specific Xanthan gum concentration.

The pH of the exudate substitute was determined as acidic and equalled 5 for all the presently reported experiments, which is typical for non-infected wounds[13,34];

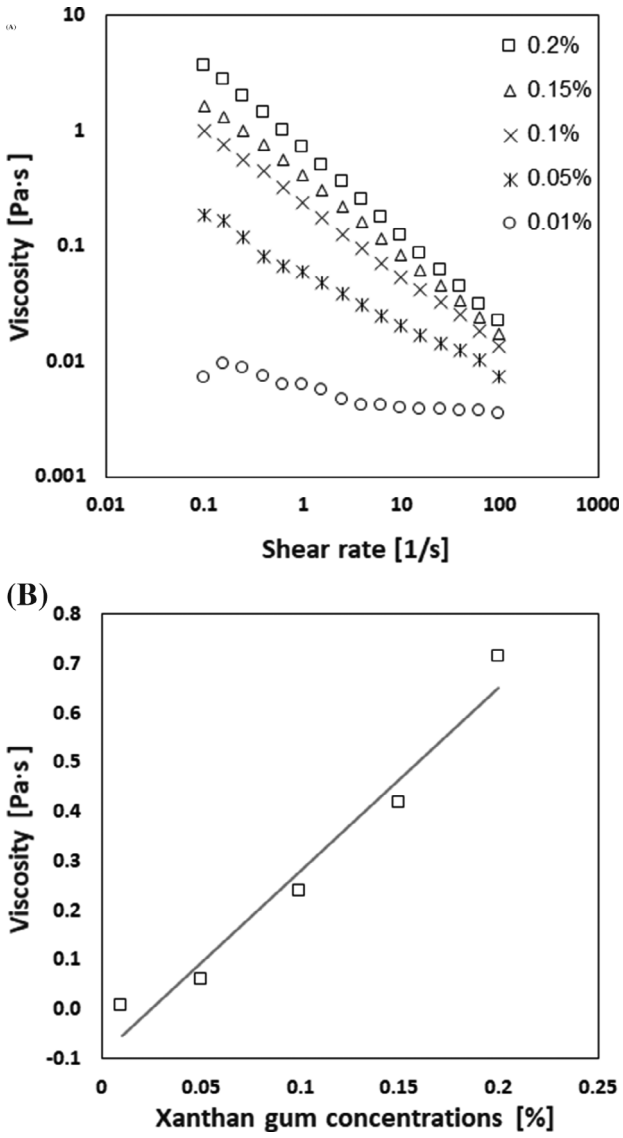

FIGURE 2 Rheology test data for the exudate substitute fluids: A, Viscosity vs the shear rate and B, viscosity at a preset unity (1/s) shear rate for different Xanthan gum concentrations in distilled water

however, this "exudate" property can be adjusted as needed, for example, be made more acidic through the gradual addition of 5% standard-food vinegar. Finally, three drops of green food dye were added to each 50 mL of the exudate substitute for visualisation of the spread of the fluid in the "wound bed" and the tested dressing products.

2.2 | Simulated treatments

Prior to applying dressing products to the simulated sacral wound, we weighed both the primary dressings (we used Exufiber [Mölnlycke Health Care AB, Gothenburg, Sweden] with PVA fibres) and an alternative existing market-leading product with CMC fibres, referred to here as the "other product" and secondary multi-layer absorbent foam dressings (Mepilex Border Sacrum = MBS, Mölnlycke Health Care AB, which has been used in all the present trials). Expert clinicians (co-authors PA, NS) guided the cutting and fitting of the two primary dressing products into the "wound bed" to carefully fill the wound cavity, following which the wound was covered with a secondary dressing as per the instructions for use provided by the manufacturers. The robotic phantom was then positioned prone, supine, or in a side-lying (lateral) position (as the specific test required; details follow), and the system was activated with the following set of parameters: exudate density = 1.03 g/cc; exudate viscosity = 0.23 Pa·s (associated with a Xanthan gum concentration of 0.1%); flow rate = 0.08 or 0.12 mL/cm^2/hour, corresponding to medium-exuding or highly exuding wounds, respectively[35]; and simulated use time = 5 hours ("short use") or 15 hours ("long use"). While the aforementioned use times are shorter than some reported real-world use times for wound dressings (ie, once a day or even less often for home care), the selected use times were specifically chosen so that dressing products could be tested before they were completely saturated (soaked) with the simulated exudate and before material ageing had progressed to extreme (which is conservative bioengineering testing). In addition, for completeness of the experimental work and to verify the generalisability of our present results to silver ion (Ag +)-containing antimicrobial dressings,[36] we repeated one experimental set where the phantom was in the supine position, using the equivalent Ag +-type dressing for each of the tested products, that is, we tested the Exufiber Ag + vs the Ag + version of the same market-leading competitive primary dressing. Each trial (with a given combination of the above experimental parameters) was repeated at least four times (the specific number of repetitions differed across the test types, as reported hereunder, and is provided in the captions of the graphical data where appropriate, for each test type).

2.3 | Testing of the dressings post-simulated use

2.3.1 | Retention and fluid distribution tests

Following simulated use, both the primary and secondary dressings were removed in a manner in which an experienced clinician would remove them from a real-world wound, based on guidance and rigorous hands-

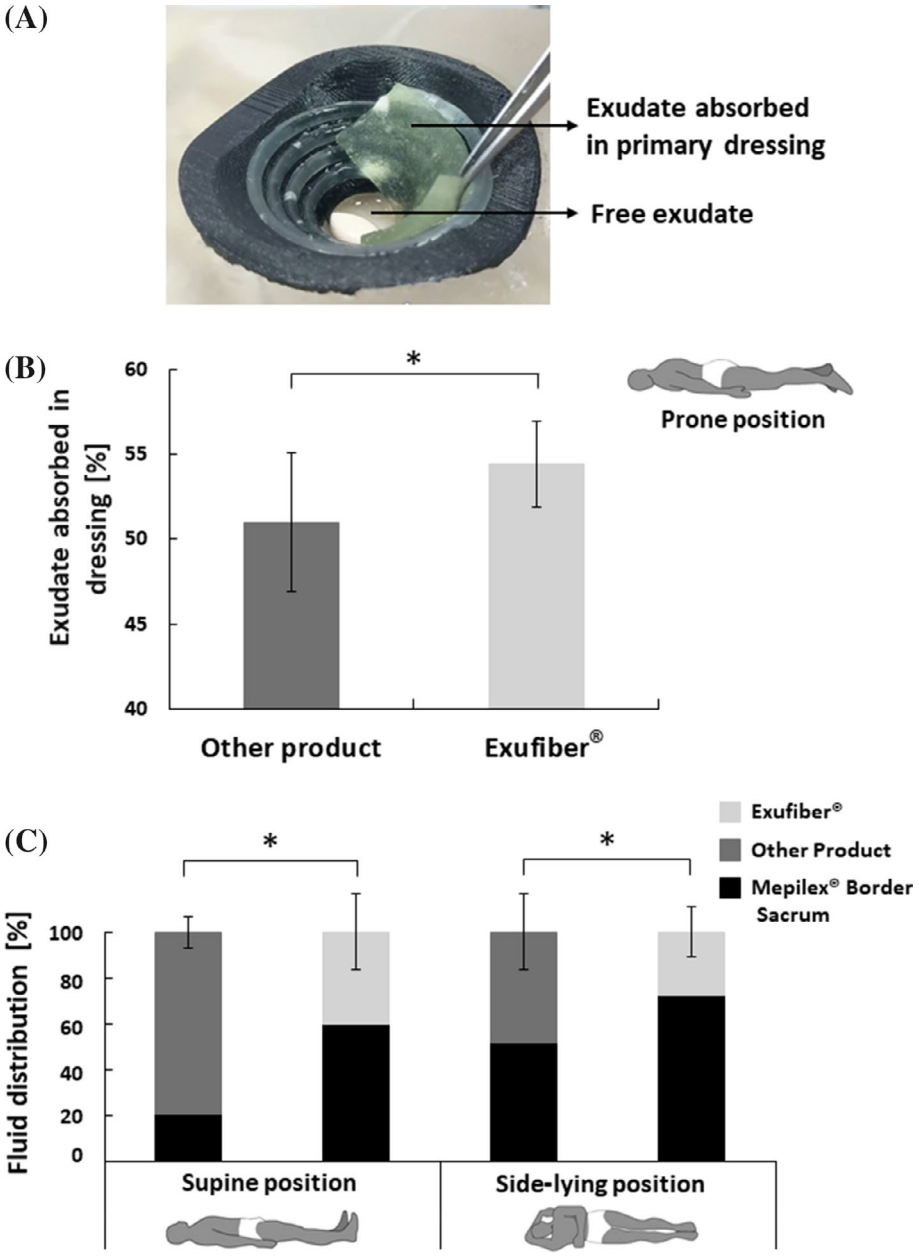

FIGURE 3 Fluid retention and distribution testing of dressing products: A, post-simulated use, exudate substitute is absorbed in the primary dressing (shown) and a secondary dressing (not shown); some free exudate typically resides in the simulated wound bed. B, Fluid retention (reported as percentage of total exudate volume) after 15 hours of simulated (long) use in a prone position (N = 10 test repetitions per dressing configuration). C, Fluid distribution between the primary and secondary dressings after 5 hours of simulated (short) use in supine and side-lying positions (N = 4 test repetitions per dressing configuration). The error bars are the SDs, and an asterisk indicates a statistically significant difference in outcome measures ($P < .05$) [Color figure can be viewed at wileyonlinelibrary.com]

on training provided by our clinician co-authors (PA, NS) (Figure 3A). The used dressings were then weighed again. The free exudate substitute in the wound bed was collected (Figure 3A). The total exudate volume (TEV) was then calculated by summing the volume of fluid in the primary dressing (wet minus dry weight, divided by respective "exudate" density $\rho = 1.03$ g/cc), the secondary dressing, and the free exudate substitute in the wound bed. The latter, calculated TEV was always mildly lower (by 15% on average) than the theoretical TEV, which is the product of the flow rate and simulated use time, because of evaporation and residual fluid in the tubing. We determined the fluid retention in each (primary or secondary) dressing as the wet-dry weight difference divided by the aforementioned exudate fluid density. We further evaluated the fluid distribution between the primary and secondary dressings per each trial as the ratio of the fluid volume retained in each dressing over the calculated TEV in the respective trial.

2.3.2 | Material strength tests

Each primary dressing specimen was tested for tensile strength immediately post-simulated use (Instron electromechanical testing apparatus, model 5944 Instron Co.), following the ASTM D-882-02 standard. A load cell with a 2 kN capacity was used for these tests. Dressing specimens prepared according to the above testing standard

were stretched at a 50-mm/min deformation rate until ultimate failure (rupture) occurred. Stress-strain curves were then plotted based on the resulting force-deformation data, and the strain energy density (SED), that is, the area under the stress-strain curve required to reach the first major failure point (defined as a minimum of 10% decrease in the stress level), was calculated using a dedicated computer code (MATLAB software suite ver. R2019b, MathWorks, Inc., Natick, Massachusetts). Selection of the SED as a scalar measure of the failure strength of each primary (used) dressing was motivated by the usage of the SED as a well-established failure criterion in numerous material studies and in multiple engineering fields.[37]

2.4 | Statistical analysis

We report here the descriptive statistics (mean ± SD) for all outcome measures. Unpaired, two-tailed *t* tests were conducted (Microsoft Office Professional, Excel 2016) to detect potential statistically significant differences in fluid retention capacities and distributions, as well as SED-to-failure, between the two dressing configurations (Exufiber + MBS vs other product + MBS). The statistical significance level was set as $P < .05$.

3 | RESULTS

The retained fraction of total exudate fluid volume and the distribution of fluids between the primary and secondary dressings post-simulated use, for the two primary dressing products that have been tested here, are shown in Figure 3. A comparison of the retention performances between these tested products after 15 hours of simulated use in a prone position (Figure 3B) demonstrated superior performances of the Exufiber dressing over those of the other market-leading product. Specifically, when the phantom was used in its prone configuration, gravity pulled the irrigated exudate (which was delivered in these experiments at a rate of 0.08 mL/cm^2/hour) downwards to the bottom of the wound bed. From a clinical perspective, this would imply a risk of pooling of exudate fluids at the depth of the wound bed and, thereby, potential over-hydration of the wound. In this testing scenario, the Exufiber dressing retained 54.4% ± 2.5% (mean ± SD) of the simulated exudate compared with the retention of 51% ± 4% of the fluid in the other product, which was a statistically significant difference ($P < .05$, Figure 3B). Worth noting is that, in this prone position, the percentage of non-retained exudate, about 50%, is relatively high as the fluid would naturally stay at the bottom of the wound bed, and so, a primary dressing would require effective "capillary action," that is, that the exudate would flow in the narrow spaces of the dressing micro-architecture in opposition to gravity. In that aspect, Exufiber demonstrated better capillary action, which is likely propagated by its tightly entwined PVA fibres. This is in stark contrast to the CMC-composed gelling fibre dressing, which appears to be occlusive. In other words, given that both dressing products were tested in exactly the same geometrical, fluid flow, and temporal configurations, the *sorptivity* (ie, the capacity of the dressing structure to absorb liquid by capillarity[38]) is significantly greater for the Exufiber dressing.

Given the present data and explanations, it is not surprising that, in our prone configuration experiments described above, we could not identify a sufficiently measurable amount of exudate fluids in the secondary MBS dressings (for either primary dressing type). The reason for this is that capillarity per se is insufficient for overcoming gravity and pushing the large exudate fluid mass all the way from the irrigation site (near the bottom of the wound bed) up to the level of the surface of the "prone" body. To determine if increasing the rate of the exudate irrigation—still in a prone position—would lead to some fluid retention in the secondary MBS dressing, we repeated the above set of experiments after adjusting the exudate flow rate to 0.12 mL/cm^2/hour (for experimental sessions of 15 hours), representing a highly exuding wound. Increasing the exudate flow rate as above did cause a mean of 2.7% of the total exudate mass to accumulate in the secondary MBS dressing in the trials where Exufiber was the primary dressing (for N = 3 trial repetitions), with an indistinguishable difference in total retained vs non-absorbed fluid between the product types. However, the MBS consistently remained dry where the other primary dressing product was used. This additional set of experiments therefore further confirmed the good sorptivity of Exufiber.

In contrast to the prone experimental configuration studies, positioning the phantom system supine, as in a non-offloaded sacral wound, would cause gravity to clear exudate away from the bottom of the wound bed and thereby, theoretically, lower the risk of maceration in this aspect. Nevertheless, in a real-world clinical scenario, loading the wound with bodyweight forces would also subject the wound bed and peri-wound tissues to sustained large tissue deformations, which are likely to cause additional deformation-inflicted tissue damage and, furthermore, secondary and tertiary inflammatory and ischaemic damage, respectively.[4,5,39] The decision of whether to position a patient prone or supine (or in another posture) would eventually be based on clinical judgement, depending on many other vital medical

parameters. For example, such decisions would be dictated by the need to achieve better tissue oxygenation by ventilating acute respiratory distress syndrome patients prone or by placing patients on extracorporeal membrane oxygenation treatment where they must be positioned supine. In this context, it is important to test the performances of wound dressings in a simulated supine posture, as well as in other potential and common body positions, for example, the lateral posture. Given that the drainage of excess exudate from a sacral wound occurs more naturally in a supine posture, because of the action of gravity, we conducted shorter, 5-hour experiments for supine and lateral phantom configurations.

Accordingly, the fluid distribution between the primary and secondary dressings was measured after 5 hours of simulated use in supine and lateral positions, where an exudate flow rate of 0.12 mL/cm^2/hour was set. The results from these experiments, shown in Figure 3C, demonstrate that, as expected, a substantial portion of the TEV, 21% to 73%, reaches the secondary MBS dressing at the surface of the "body" (which is at least 10 times the amount of fluids that were absorbed in the secondary dressing in the prone experiments). Moreover, when the capillarity of the dressing structures was fully aligned with the direction of gravity forces (as in the supine phantom configuration) or was partially aligned with gravity (for the lateral experiments), the differences in performances of the primary dressings became even more apparent. For the supine position, the Exufiber dressing was able to retain 40% of the exudate but, importantly, deliver the other 60% of the fluid away from the wound bed, into the secondary MBS dressing. In comparison, the other product was only able to transport 21% of the fluid to the MBS dressing, which clinically implies that more exudate remains within the wound bed ($P < .05$, Figure 3C, left panel). In agreement with the above observations, the total retained fluid for this experimental set was 99% ± 0.04% for the Exufiber dressing, compared with 96% ± 0.2% for the other product ($P < .05$). Consistently, for the lateral position, the Exufiber dressing retained 27% exudate but, again, transferred the other 73% of the fluid into the secondary MBS dressing; the other product only transported 52% of the fluid to the secondary MBS dressing ($P < .05$, Figure 3C, right panel). In related observations, in three of five trials performed with that other product in the lateral position, some fluid leakage was observed, likely because of excessive build-up of fluids in the wound bed; this never occurred in the trials conducted using the Exufiber + MBS dressing combination. The total retained fluid data for this experimental set underpins the superior absorbency of the Exufiber dressing, which achieved 93.8% ± 1.3% retained fluid, compared with only 78% ± 18% retained fluid in the other product (leakage around the primary dressing caused the relatively high variability in the latter result).

Consistent with the non-silver dressing data, the Exufiber Ag + dressing retained 51% of the exudate fluid and transferred the other 49% into the secondary MBS dressing, whereas the comparator silver-containing primary dressing transported only 31% of the fluid to the secondary dressing ($N = 5$, $P < .05$).

The tensile tests of the used primary dressing products demonstrated a considerably distinct failure pattern. The used Exufiber dressing was shown to be substantially more extensible and structurally stable post-use compared with the other product, which demonstrated tears in its fibres early during the course of stretching (Figure 4). The stress-strain data of the two products (Figure 5A) further showed that the Exufiber dressing can withstand strains of up to ~200% without any apparent loss of fibre integrity, whereas in the other primary dressing product, the first fibres failed at strains as low as 37%, with more substantial early failures occurring at 45% strain (a "peak & drop" behaviour, where additional

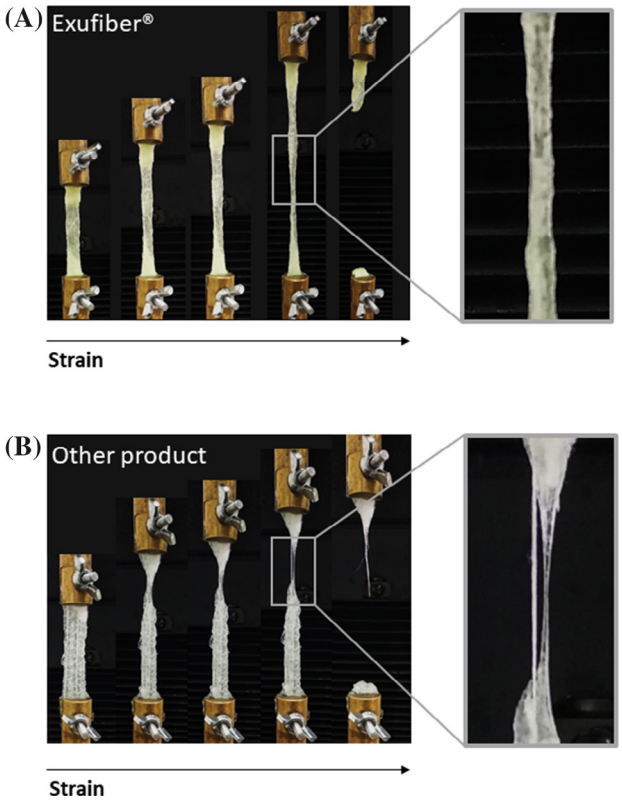

FIGURE 4 Material strength tests comparing the failure behaviours of the two primary dressing types evaluated here (each photographed during a representative trial). The failure region at the time point preceding the ultimate failure has been magnified for each dressing type to show the structural integrity and fibre rupture state [Color figure can be viewed at wileyonlinelibrary.com]

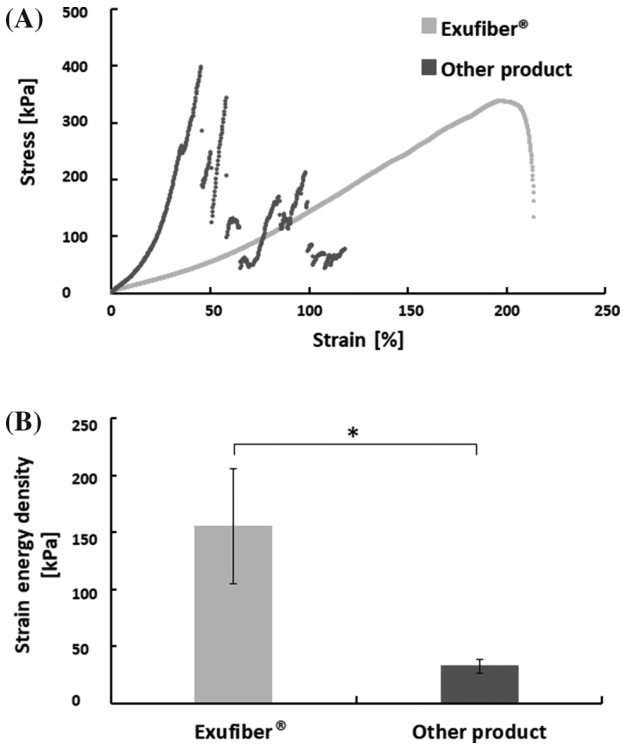

FIGURE 5 Determination of the strain energy density (SED) to failure of the used primary dressings after 15 hours of simulated (long) use: A, representative stress-strain curves for the two dressing types, showing continuity associated with robustness of the Exufiber dressing, vs discontinuity because of multiple fibre rupture events for the "other product." B, The corresponding SED to failure of the two dressing types (N = six test repetitions per dressing configuration). The error bars are the SDs, and an asterisk indicates a statistically significant difference in outcome measures ($P < .05$)

fibre failure continued thereafter and repeated until ultimate failure occurred; Figure 5A). The latter failure pattern continuously fractures the gel, and hence, any individual fibre failure events may release dressing micro-particles into the environment. Calculations of SED data from the acquired experimental stress-strain curves indicated that the Exufiber dressing is ~five times more endurable than the other primary dressing product and would therefore be able to withstand (statistically) significantly greater mechanical energy before its fibres would fail ($P < .05$, Figure 5B).

4 | DISCUSSION

Exudate fluids play a key role in wound healing and tissue repair. The wound bed needs to be mildly moist for adequate healing to occur. The moisture in the wound bed facilitates cell proliferation, migration, and growth, as well as the synthesis of collagen towards tissue repair. However, excessive exudate volumes may disrupt the healing cycle and be an irritant, toxic, or infectious to adjacent tissues. Excessive exudate should therefore be retained in therapeutic dressings to support healing. Gelling fibre dressings are designed for the above purpose. Historically, gelling fibre dressings have typically been made of CMC fibres, but now, primary gelling fibre dressings based on PVA fibres are available. The PVA fibre-based dressings are intended to continuously absorb and lock in secreted exudates so that the fluid level in the wound bed is controlled. It is surprising, given the extensive use of wound dressings, that bioengineering work in this field is poor and sparse with respect to other fields of medical applications. In particular, while a small number of laboratory tests is used to gauge fluid management properties of treatment dressings,[40*] current testing methods may not necessarily reflect the impact of real-world factors on dressing performances, including, for example, the effects of treatment protocols, positioning of patients, time and clinical technique of dressing changes, exudate properties, etc. Our novel laboratory method and system facilitates experiments that expose dressings to exudate-like fluids at the chemical, mechanical, thermodynamic, and use conditions, which replicate real-world settings. This then facilitates objective, quantitative, and standardised evaluations of dressing products, and thereby systematic comparisons of dressing performances, while effectively accounting for the clinical considerations that apply in practice.

The primary mechanism of action for gelling fibre treatment dressings is capillary motion, where exudates (also carrying the biological debris) are being lifted and moved away from the wound surface through a capillary effect.[41] The ability of an absorbent material to transfer a certain viscous fluid by capillary motion through the intrinsic narrow spaces in its porous microstructure is generally described as[38]

$$V = AS\sqrt{t} \tag{1}$$

where V is the cumulative volume of the liquid absorbed through a cross-sectional area A of the absorbent material at time t (as long as the material is not fully saturated), and S is the sorptivity of the absorbent material. The sorptivity S (defined in[42]) is formulated as[43]:

$$S = \left(d\sqrt{\frac{\gamma}{\mu}}\right)\left(\frac{\varepsilon}{\lambda}\sqrt{r}\right)\left(\frac{\cos\theta}{2}\right) \tag{2}$$

where d, γ, and μ are the density, surface tension, and viscosity of the fluid undergoing the capillary uptake, respectively; ε is the effective porosity of the dry

absorbent material; λ is the average tortuosity factor of the capillaries (tortuosity is the ratio of the length of a flow path between two points in the absorbent material to the corresponding straight-line distance and, hence, for all practical materials, $\lambda > 1$); r is the average pore radius; and θ is the contact angle of the interface between the liquid and pore walls. Thus, referring to the right-hand side of Equation (2), the first term (from left to right) only contains parameters that characterise the liquid, whereas the second term consists of variables of the absorbent material microstructure, and the third term represents the interface between the absorbent material and liquid. Worth noting is that, from a medical-clinical perspective, some of the parameters in Equation (2) depend on the environment and microclimate of the wound, for example, the surface tension (γ) and viscosity (μ) of the exudate fluid depend on the temperature of the wound bed. The tortuosity (λ) depends on the fluid pressure gradient, which is a function of the sustained mechanical loads applied onto the wound (associated with the body position). Taken together, Equations (1) and (2) indicate that an exudate fluid with a lower viscosity would cause greater sorptivity and, hence, more exudate transfer into the dressing through capillary action; however, that can be counteracted by a low porosity (ε) or small pores (r) in the dressing material. This is an important and illustrative analytical example that highlights the reasoning for the present experimental model for testing dressings, which accounts for these complex physical interactions.

With respect to the clinical use of treatment dressings, good sorptivity of a primary dressing is critical in clearing excess exudate fluids away from the wound bed, especially if a secondary dressing is used. This dressing property is even more crucial when the sorptive material (with capillary action) should perform against gravity forces as some patient positions may dictate. Dressings with poor sorptivity, even ones with a high theoretical retention capacity, that is, having a high saturation threshold tested in sterile conditions, will have a limited effective retention capacity when used in practice, where opposing gravity forces will prohibit such dressings from reaching their full saturation potential. Good total fluid handling of a dressing should therefore include sorptivity through capillarity, that is, adequate fluid transfer from the primary treatment dressing to a secondary dressing, as well as sufficient retention reservoirs, using the capacities of both dressings. Not allowing effective transfer of wound fluids between the primary and secondary dressings will cause a "plugging effect." The plugging, if occurs, will limit the maximal fluid volume absorbed in the system of dressings (ie, the primary plus the secondary dressings), which should work synergistically to the capacity of the primary dressing alone, and thus increase the risk of the return of exudate to the tissues or leaks that could cause maceration or secondary irritation and provide a pathway into the wound for pathogens.

The exudate composition changes in correlation to the wound-healing stage and severity, as well as because of underlying conditions and chronic diseases, with a physiological mechanism regulating immunological factors, that is, neutrophils and proteins in the wound bed. Values of exudate viscosity and pH, as well as the TEV, ultimately reflect these complex biological and pathophysiological interactions at the wound level and the whole-body system level. Viscosity ranges from that of thin and watery fluid to that of a thick sticky mass, and pH may be acidic or sometimes alkaline, being highly influenced by the nature of the microbiome, that is, the populations of the bacterial or fungal (eg, yeast, mould) contaminations that typically exist in chronic wounds.[44] This tight correlation makes wound exudate a key wound parameter, defined as one of the "three continuums," namely, the wound-healing continuum, the wound infection continuum, and the wound exudate continuum, used in the "wound management framework"[25] for the assessment of wound and patient's health status in a logical and systematic way. In clinical practice, exudate volume and consistency levels are being collected and categorised periodically to determine improvement or deterioration in wound status and to identify alteration in the wound bioburden and development of infections, which require careful consideration. The dynamic nature of wound exudates translated into their viscosity, and the known effects that viscosity (μ) has on capillary motion in dressings, as formulated in Equation (2), make the viscosity parameter (which is specific to the patient and the wound-healing stage as explained above) an important consideration when testing any treatment product performances.

Patient positioning will also have a fundamental effect on wound-dressing performances, as demonstrated by our present data (Figure 3C). Patients with sacral PUs will preferably have their wounds off-loaded, that is, in prone or lateral positions, to alleviate the tissue stresses formed because of the bodyweight loads and, thereby, lower the risk for continued tissue deformation-inflicted damage to the wound and its surroundings. Nevertheless, in a real-world clinical scenario, other vital medical considerations may exist that overweigh the need to off-load the wound, making all possible lying positions (including the supine position) relevant to the testing of sacral dressings performances. Using our system to test dressing performances while the phantom was used in a prone configuration allowed us to evaluate the sorptivity of primary wound dressings, where the primary dressing is

required to act against gravity forces in maintaining the exudate balance in the wound and wicking excess fluids away from the wound bed. An important observation is that the percentage of exudate absorbed in the Exufiber dressing for the above "prone" experiments is greater with respect to the other product (Figure 3B). This could only be achieved through better capillarity of the Exufiber dressing, consequently clearing more excess exudate from the simulated wound. Furthermore, the Exufiber dressing facilitated superior fluid transfer to the secondary MBS dressing compared with the other primary dressing, regardless of the body position (Figure 3C). The "plugging effect" of the other dressing, because of its limited capillarity and low sorptivity, is clearly demonstrated in our results (Figure 3C) and was consistent for even relatively high exudate flow rates set in the robotic phantom system.

In supine and lateral positions (Figure 3C), gravity forces "help" to clear exudate away from the wound bed as fluids are naturally drained in the general direction of the dressing. With that said, this downward exudate motion also creates a large volume of exudate fluid for the dressing to absorb and handle momentarily. Fluid accumulated at the interface with the primary dressing is being gradually absorbed, first by maximising the primary dressing capacity and, ultimately, by capillary motion to reach the secondary dressing. Accordingly, the fluid distribution between the primary and secondary dressings strongly depends on the sorptivity level of the primary dressing (Equation 2). The Exufiber dressing has been shown to deliver higher fluid amounts to be ultimately absorbed in the secondary dressing, which has been consistent for the supine and side-lying body postures, as well as between the non-silver and silver versions of this dressing. The more fluid that is being transferred to the secondary dressing, the better the primary dressing can absorb newly secreted exudate without maxing out its capacity. In other words, good sorptivity of the primary dressing enables the retention reservoirs of both the primary and secondary dressings to be used. For the other product that has been tested here, we observed lower amounts of fluid delivered to the secondary dressing (Figure 3C) and, as a result, unsurprisingly, some leaking of the simulated exudate caused by the excessive build-up of fluids. Of note is that, in a real-world scenario, such leaking of excess exudate may cause periwound maceration of the skin, secondary infections, or at least skin irritation, which are all unwarranted. Another noteworthy point is that posture had little effect on the performances of the Exufiber dressing, which delivered similar amounts of fluid to the secondary dressing in the supine and side-lying experimental configurations (Figure 3C). In contrast, the other primary dressing had inferior sorptivity in the supine posture than in the lateral lying position, which is not favourable as a dressing should ideally maintain its performances independent of the body posture.

Wound dressings are designed primarily to absorb and retain fluids; nevertheless, it is crucial that the used dressings maintain their mechanical strength and structural integrity to endure extraction forces that occur as they are removed from a wound (eg, during dressing changes) without leaving debris from the dressing materials in the wound bed. Any dressing debris left in the wound bed may result in a "foreign body response,"[45] which prolongs the inflammatory phase and, therefore, delays the wound healing. The Exufiber dressing has a robust and consistent micro-architecture, allowing it to endure higher tensile and frictional forces (with SED that is up to five times greater than the comparison; Figure 5B), which a clinician may generate using forceps during a dressing change manoeuvre (replicated in our laboratory by means of an electromechanical testing system; Figure 4). From the stress-strain curves produced through these mechanical tests (Figure 5), we identified a "rubber-like" material behaviour under tensile loading for Exufiber, as opposed to a classic mechanical failure pattern ("peak-and-drop") for the other product, which demonstrated poor mechanical strength. The mechanical behaviour of the latter dressing, which contains oriented woven fibres to reinforce it, has a directional stiffness preference that results from its weave pattern. Our present test data were obtained where the dressing was stretched in a direction that aligns exactly with the orientation of the structural fibres in the dressing. That is, we performed our tests to represent the best-case scenario for this dressing, where the reinforcing fibres take full part in the mechanical loading, which is not necessarily how a clinician would pull that dressing from a wound. The images in Figure 4B document a clear-cut separation of the dressing material component designed to provide mechanical strength and structural support (ie, the reinforcing fibres) from the material component designated to absorb fluids. As the absorbent material ingredient has nearly no structural strength of its own, the risk of disintegration of the dressing with pull-out or frictional forces or a combination of both clearly increases during dressings changes. While we did not see such breakdown of the dressing material in the simulated wound bed (but only afterwards, during the mechanical testing post-simulated use; Figure 4B), we suspect that the reason for this relates to a limitation of our experimental wound system. Specifically, we surmise that the reason for the dressing showing a "peak-and-drop" failure behaviour to not fail already in the simulated wound bed is that our wound surfaces were relatively smooth and non-sticky

(3D-printed plastic), which is a simplification of the real-world wound bed conditions. A native wound would have relatively rough sticky surfaces and potential adhesion sites with the primary dressing. Our mechanical testing data (Figures 4 and 5) should therefore be interpreted as demonstrating a much more likely breakdown of the other dressing compared with Exufiber, where there is an attempt to pull the dressing out of a rough or sticky wound or when a part of the primary dressing is trapped in or is rubbing against undermining or some other odd-shaped deep cavity of a wound. Another limitation of the present robotic phantom version may therefore be the absence of undermining, which can be included in future versions of the 3D-printed wound bed.

An additional potential future use of our novel robotic phantom system is for moisture-vapour transpiration (MVT) studies, particularly studies of the interaction of MVT with the sorptivity of the tested dressings. Theoretically, a high MVT rate of a dressing would promote the capillary action in that dressing against the wound bed surface as a larger portion of the dressing volume becomes unsaturated and, therefore, available for new absorption of exudate fluids. Future work with our present phantom system should explore these very complex and coupled transport phenomena. It is also possible to study how the MVT and sorptivity performances may depend on the body core temperature of the patient (which can be altered in our robotic phantom system), as well as on the exudate flow rate and the ambient conditions. The simulated ambient conditions may be selected to represent different geographical climate variations or characteristics of a clinical setting (eg, use of air conditioning and the specific temperature adjustments in the air-conditioning system) in order to predict how dressings may behave in specific countries and medical settings.

To summarise, a novel, active exuding sacral wound simulator, which makes a "robotic phantom" for dressing tests, has been developed and built to facilitate, for the first time, complex experiments that expose dressings to exudate-like fluids at the mechanical, thermodynamic, and use conditions, which duplicate real-world care settings. Using the above system, we compared the performances of the Exufiber dressing against an existing market-leading product, which is a mainstream clinical choice. Both types of primary dressings interacted with the MBS dressing, which served here as the secondary dressing applied to the robotic phantom. The Exufiber dressing demonstrated good sorptivity and capillary action, that is, adequate transfer of fluids to the secondary MBS dressing (for different body postures), so that fluids are being wicked away from the wound and into the secondary dressing. In contrast, the other market-leading dressing acted more as a "plug," which, in real-world conditions, may cause hyper-hydration of the wound or peri-wound skin maceration, irritation, and infection (some or all of the above) because of accumulation of exudate fluids under or around the dressing when it is saturated (ie, a "pooling" effect). We further found that, for a supine posture, that is, when the wound bed was fully loaded by simulated bodyweight forces and where gravity forces aligned with the direction of the exudate flow, there was an even stronger effect of fluid transfer from the Exufiber dressing to the secondary MBS dressing (Figure 3C). Finally, we found that the Exufiber dressing was more able to resist pulling forces, and its mechanical strength was ~five times better than that of the comparison (Figures 4 and 5), which is critically important for the dressing to not leave debris when being pulled out of the wound bed upon removal. Any dressing debris that is left behind in the wound bed can trigger a local inflammatory reaction (known as a "foreign-body-reaction") and, thereby, consume inflammatory system resources that are needed for healing the wound at that time.

In closure, there are currently thousands of dressing products and brands available for clinicians to choose from in their wound care practice; these products belong in diverse classes, have distinguished design concepts and mechanisms of action, and also vary in their cost per item and recommended replacement time (which also affects the cost of use). It is up to the clinician to select the suitable dressing for the specific patient, clinical case, and healing phase, which is not an easy task.[41] Our present work underpins some of the fundamental considerations for adequately choosing a dressing, with a focus on the function of a primary-secondary dressing system as a synergistic one. Here, we report a quantitative and rigorous bioengineering evaluation of two dressing products, which has been performed in a clinically relevant simulated wound environment. The two tested dressing products differ in their micro-architectural design and, consequently, in the fluid-structure interactions that occur in their construction, which result in fundamentally different performances. Specifically, the Exufiber dressing, made of tightly entangled PVA fibres, demonstrated greater sorptivity and, therefore, superior retention performances in all the simulated lying positions compared with the CMC-containing product. In the mechanical tests of dressings post-simulated use, the Exufiber dressing exhibited significantly better durability, which is again a consequence of its densely packed anisotropic PVA fibre arrangement.

Our novel laboratory approach paves the way for an objective, quantitative, and standardised testing of wound dressings in all aspects of exudate management, for

example, efficacy research and product evaluation including systematic comparisons for both classic dressing designs and other advanced wound filler materials. Our robotic phantom and standardised experimental protocols incorporate clinically relevant scenarios and consider interactions of different dressing technologies with relevant clinical practice. Our approach and technology can therefore support a more informed decision-making process, for example, regarding the purchase of dressing products by clinicians and administrators, or where it concerns the prescription of dressings to individuals based on their health and wound conditions. Importantly, the present work is also a cornerstone for the development of testing standards for wound dressings. Such testing standards should incorporate the clinical practice aspects and a high degree of realism of the testing (in order to mimic the real-life use of dressings) while also facilitating the reproducibility and precision of laboratory tests. Finally, as we continue to improve our robotic phantom technology for testing dressings and perhaps, in the future, negative pressure wound therapy systems as well, we already envision a second generation of our robotic phantom system. Such a second-generation robotic phantom should better replicate rough wound surfaces, undermining conditions, sticky or sloughy wound beds, and perhaps even incorporate bacterial growth features, including a module to monitor the growth of a bacteria model (eg, *Escherichia coli* or Bifidobacterium) or its elimination in the simulated wound. Through present and future innovative robotic phantom studies, we expect to change the behaviour of clinicians and administrators with regard to purchase and prescription of wound dressings, particularly by facilitating informed decisions and development of testing standards, which will certainly contribute to basing dressing selection on quantitative research evidence rather than marketing assertions, thus ultimately improving patient care globally.

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ENDNOTE

[*] Currently used testing methods relevant to the present study (reviewed comprehensively by Thomas & Uzun, 2019) are designed to measure simple aspects of absorbency as defined, for example, in the British (2002) Standard.[22] Typically, such a test would compare the mass of a dressing after water absorption (M_2) to its dry mass (M_1) and calculate the dimensionless mass change $(M_2 - M_1)/M_1$, an oversimplification that neglects the effects of multiple relevant clinical factors.

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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