

**REVIEW ARTICLE**

# The performance of gelling fibre wound dressings under clinically relevant robotic laboratory tests

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**Abstract**

The effectiveness of wound dressing performance in exudate management is commonly gauged in simple, non-realistic laboratory setups, typically, where dressing specimens are submersed in vessels containing aqueous solutions, rather than by means of clinically relevant test configurations. Specifically, two key fluid–structure interaction concepts: *sorptivity*—the ability of wound dressings to transfer exudate, including viscous fluids, away from the wound bed by capillary action and *durability*—the capacity of dressings to maintain their structural integrity over time and particularly, at removal events, have not been properly addressed in existing test protocols. The present article reviews our recent published research concerning the development of clinically relevant testing methods for wound dressings, focussing on the clinical relevance of the tests as well as on the standardisation and automation of laboratory measurements of dressing performance. A second objective of this work was to compile the experimental results characterising the performance of gelling fibre dressings, which were acquired using advanced testing methods, to demonstrate differences across products that apparently belong to the same “gelling fibre” family but differ remarkably in materials, structure and composition and, thereby, in performance.

**KEYWORDS**

exudate absorption and retention, material sorptivity, primary and secondary dressing pairs, structural strength and durability, testing standards

**Key messages**

- sorptivity and durability are key performance metrics of gelling fibre dressings
- to determine these metrics we developed multiple robotic wound phantom systems
- we then measured and compared sorptivity and durability of gelling fibre dressings
- we observed significant differences in sorptivity and durability of tested products
- gelling fibre dressings differ in material composition and, thereby, in performance

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## 1 | INTRODUCTION

### 1.1 | Exudate management in the treatment of hard-to-heal cavity wounds

Hard-to-heal wounds such as pressure ulcers (PUs, also known as pressure injuries), diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) are one of the most prevalent and serious health problems and correspondingly, are a continuous cause of major financial burdens to health organisations.<sup>1-5</sup> With the social distancing brought by the coronavirus disease 2019 (COVID-19) pandemic still in force, access to preventive wound care became more difficult and less frequent (particularly in the community), which is expected to worsen the problem going forward. Enduring factors, including the ageing of the population and the spread of chronic diseases, particularly diabetes and obesity, have contributed to the global escalation in the occurrence rates of chronic wounds; it also appears that the breakout of the coronavirus 2019 disease has increased the prevalence of chronic wounds (likely as a result of less effective preventative care and shift of health resources to fight the pandemic, as well as because prone patient positioning, causing anterior PUs, became more common).<sup>6-12</sup> Overall, hard-to-heal wounds are typically associated with considerable suffering, loss of quality of life for patients and family members and, sometimes, with severe and chronic pain, risk of infections, osteomyelitis, sepsis and the development of multiple organ failure leading to death.<sup>1,13</sup> For example, the 5 year mortality rate for people with DFUs and associated (minor/major amputation) complications is comparable to those of common cancers (e.g., breast or lung).<sup>14</sup> Furthermore, the treatment of chronic wounds is typically lengthy, may involve expensive litigation and can negatively impact institutional quality measures.<sup>4,15,16</sup>

All wounds activate a local, innate inflammatory response of the immune system to increase the vascular permeability around the site of the tissue damage. This enables extravasation of immune cells to the tissue damage site and, consequently, results in leakage of a serum-based fluid, i.e., the exudate, from the vasculature surrounding the wound.<sup>17-20</sup> Exudates have a wound-specific and dynamic composition of neutrophils and proteins, which typically correlates to the aetiology and severity of the wound, the healing phase, potential presence of pathogens and the general condition of the patient. A mildly moist wound environment is needed for adequate healing<sup>21</sup> to facilitate transport of the essential nutrients as well as the immunological factors in the interstitial serum to the wound bed,<sup>21,22</sup> stimulate fibroblast and endothelial cell proliferation<sup>23</sup> and improve epithelialisation.<sup>24-26</sup> However, if the wound moisture level is not properly maintained,

excess exudate may interrupt the healing process, cause cytotoxicity, dissolve the deposited collagen in the repairing wound or macerate the peri-wound skin. Excess exudate may also become the growth and transport medium for bacteria in the wound bed, irritate healthy tissues, induce inflammatory pain and carry pathogens and metabolic waste products to newly regenerated tissues or to other body regions.<sup>23,27-31</sup> Of note, the commonly accepted clinical principle of moist wound healing requires the presence of a minimal amount of exudate in the wound at all times to moisturise the wound bed (so that it does not dry out); hence, the other end of the spectrum, i.e., dry wounds, should be avoided as well.<sup>32,33</sup>

### 1.2 | Gelling fibre dressing technologies in exudate management

As explained above, exudate should be absorbed and retained in dressings to the extent that keeps the wound bed moist but not wet at all times<sup>32,33</sup> and while protecting the wound from any mechanical insult or invasion of pathogens. In clinical practice, more than one type of dressing is often applied concurrently to fulfil these critical roles. Specifically, to treat cavity wounds, a primary gelling fibre dressing can be inserted through the wound opening and be folded in the cavity to occupy as much of its space as possible, to form the first-line “exudate management reservoir” for direct fluid absorption and retention from the wound bed. A secondary dressing is then placed above the cavity (and the primary dressing within) to protect the wound from external forces, from bacteria and fungi or from becoming overly dry. The secondary dressing is also useful for preventing leakage of drainage onto clothing or the bedsheets. Importantly, if properly chosen, the secondary dressing can also serve as a second vessel for the accumulating exudates, or better, for sharing the fluid retention with the primary dressing to free space for new exudate in the primary dressing. Historically, the first type of gelling fibre dressings was alginate-based.<sup>34-36</sup> Later technological developments in the field of gelling fibre dressings included manufacturing of dressings from chitosan [<sup>37,38</sup>] or sodium carboxymethyl cellulose (CMC).<sup>22,39-41</sup> Of note, alginate and chitosan are naturally occurring gelling agents in marine organisms (alginate is produced from algae and chitosan is extracted from the shells of crustaceans), whereas CMC is a synthetic substance.<sup>39</sup> More recently, dressings consisting of nonwoven ribbon produced from tightly entangled polyvinyl alcohol (PVA) fibres have become available.<sup>42,43</sup> This latter type of PVA-based dressings locks absorbed fluids into their structure, then swells and takes the form of a solid gel which gradually conforms to

the wound shape. An important design variant of these gelling fibre dressings are ones that also contain silver ions for an antimicrobial effect. To deliver effective treatments, a primary dressing and a secondary dressing must work in synergy, that is, both dressings should not approach their maximum fluid absorption capacity and they should ideally share the retained fluid volume as equally as possible at the time when a dressing change is planned.<sup>44-47</sup>

### 1.3 | The influence of clinical factors and requirements on wound dressings

Whilst the exudate absorption and retention performance of wound dressings are a function of the dressing technology (i.e., the material composition and structure), the performance is also strongly influenced by clinical factors and requirements that are specific to the wound and the patient. For example, a certain viscosity level of the exudate, which stems from, and is correlated with the protein content in the exudate, affects the exudate uptake rate into the dressing and, thereby, the exudate fluid volume that can be retained in the dressing after a certain time period. Likewise, the body position of the patient dictates whether the wound is completely off-loaded, partially off-loaded or non-off-loaded. Bodyweight forces exerted on a non-off-loaded wound, which can occur, for example, because of a need to ventilate a patient at a specific posture, can decrease the effective volume of the dressing reservoir or perhaps even cause a pressure-induced release of fluids that have already been absorbed in the primary or secondary dressings. Furthermore, the direction of the flow from the wound bed into the dressing with respect to the gravity vector, which is also a function of the body position, determines the primary physical mechanisms by which exudate enters the dressing. This could be, for example, gravity itself pushing the exudate into the dressing if the dressing is placed directly below the wound (as in a non-off-loaded sacral PU of a supine, ventilated patient), or capillary action if the dressing is placed above the wound (e.g., if considering the same patient ventilated prone, so that the sacral wound is fully off-loaded).

The average time of use of a set of primary and secondary dressings depends, among other factors such as the institutional guidelines and practices, on whether the wound is infected or not; wound infections are typically associated with more frequent dressing changes in clinical practice.<sup>48</sup> Generally, the longer a primary dressing remains in the wound cavity, the more it is exposed to the aggressive exudate fluids (and the enzymes and pH of the fluid), as well as to the body temperature and to any sustained forces that apply in the wound environment, such as the inherent swelling forces of the dressing and

the reaction forces from the wound walls. The time of stay of a primary dressing under these chemical, thermal and mechanical conditions therefore affects its likelihood to remain intact and to not disintegrate when being exposed to the instantaneous, intense forces of pulling (by forceps or the gloved fingers of the healthcare professional) when it is time to change and discard it. Any dressing debris, macroscopic or microscopic, that remains in the wound as a result of a mechanical failure of the primary dressing becomes a foreign body in the wound which promotes chronic inflammation and the chronicity of the wound and compromises the capacity of the body systems to heal the wound as a result of the biological resources (i.e., the numerous giant cells, macrophages and fibroblasts), which are required for isolating foreign dressing objects within or upon the wound bed.<sup>44,49,50</sup>

### 1.4 | Current gaps in testing standards for wound dressing performance evaluations and the objectives of this work

The effectiveness of wound dressing performance in exudate management is commonly gauged in simple, non-realistic laboratory setups, typically where dressing specimens are submersed in vessels containing aqueous solutions with dissolved salts, rather than by means of clinically relevant test configurations.<sup>46,51,52</sup> Specifically, two key fluid-structure interaction concepts: *sorptivity*—the ability of wound dressings to transfer exudate, including viscous fluids, away from the wound bed by capillary action (against the gravitational direction); and *durability*—the capacity of dressings to maintain their structural integrity over time and particularly at removal (change) events, have not been properly addressed in existing test protocols.<sup>46,52</sup>

The present article reviews our recent published research concerning the development of clinically relevant testing methods for wound dressings, focussing on the clinical relevance of the tests as well as on the standardisation and automation of laboratory measurements of dressing performance.<sup>45,47</sup> A second objective was to compile the experimental results characterising the performance of gelling fibre dressings, which were acquired using advanced testing methods, in order to demonstrate differences across products that apparently belong to the same “gelling fibre” dressing family, but differ remarkably in materials, structure and composition (e.g., PVA-based versus CMC-based gelling fibre dressings) and, thereby, exhibit distinguished performance. Specifically, we demonstrate here how robotic wound phantom test systems are able to measure fluid absorbency and retention for different exudate substitutes having a range of biophysical properties, while considering the multiple

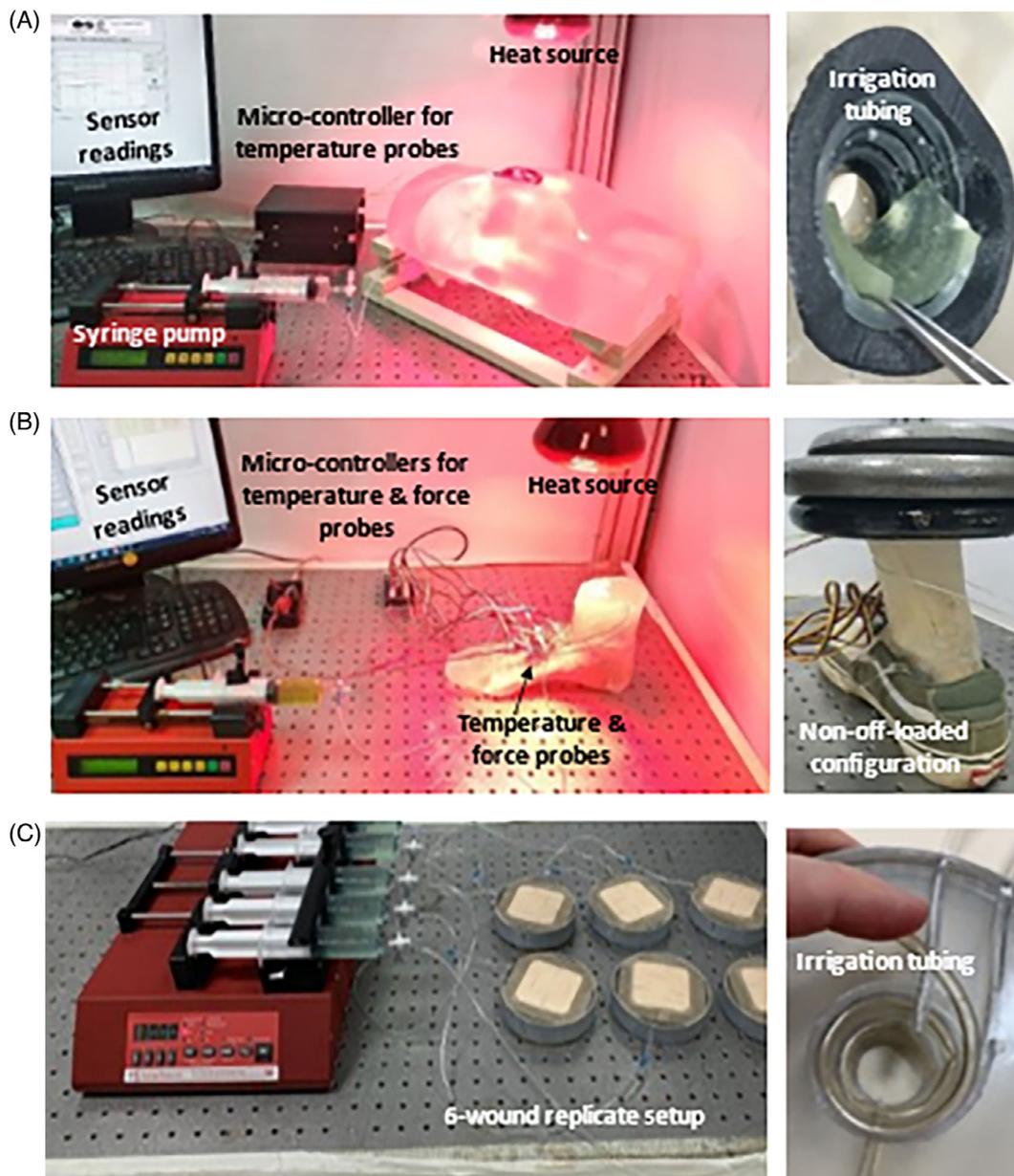
clinical factors that were described above. The methods and test systems that are described here are versatile and enable the simulation of various active wound environments in anatomically and pathophysiologically realistic forms, but under controlled laboratory conditions, facilitating complex bioengineering testing of the individual and combined performances of primary and secondary dressings used for treating cavity wounds. The specific cases of pairing different gelling fibre dressings as primary dressings with foam dressings as secondary dressings is analysed in detail in this work.

## 2 | METHODS

### 2.1 | Robotic cavity wound simulators

#### 2.1.1 | Robotic phantom of an exuding sacral pressure ulcer

A robotic phantom of an exuding sacral PU was developed for conducting wound dressing tests and is described in detail in our published work.<sup>45,53</sup> This robotic phantom includes a rigid plastic replica of the



**FIGURE 1** Versatile robotic phantom systems simulating active, exuding wounds in different anatomical sites and body postures with their control setups which form effective, robust, automated testing systems for wound dressings: (A) A sacral pressure ulcer test environment, including an exuding “wound bed,” which can be “treated” by means of any (combination of primary and secondary) dressing products and by following various clinical protocols. (B) A simulated diabetic foot (heel) ulcer, which can be used for testing dressings, including in shoed standing configurations as shown here. (C) A multiple wound system comprising of six wound replicates

pelvic bones and soft tissue substitutes made of a two-component silicone rubber, which is cast in the shape of the buttocks of an adult male (Figure 1A). A cylindrical wound geometry is carved into the sacral region of the phantom, to a depth of 2.5 cm, which exposes the (plastic) sacrum, thereby simulating a category-4 PU. Within the abovementioned cavity, we placed a 3D-printed custom-made component, which simulates the exuding wound bed (Figure 1A). This wound bed simulator has a truncated conical shape (i.e., of a “crater wound”) with a diameter of 4.5 cm superficially and adjustable maximum depths up to 2.5 cm with respect to the adjacent phantom (“buttocks”) surface.

### 2.1.2 | Robotic phantom of an exuding diabetic foot ulcer

We further developed a robotic DFU phantom containing a diabetic heel ulcer (DHU), i.e., a plantar heel ulcer.<sup>47</sup> This DFU phantom consists of rigid plastic replicates of the foot and ankle bones, including the entire foot skeleton and the distal tibia and fibula (Figure 1B). The soft-tissue substitute is similarly made of a two-component silicone rubber cast in the shape of the foot of an adult male. A cylindrical cavity is carved into the plantar heel region of the foot phantom, directly under the calcaneus bone replica, to a depth of 2 cm which exposes the (plastic) calcaneus, thereby simulating a grade-3 DHU according to the Wagner ulcer classification system. Within the abovementioned cavity, we placed a 3D-printed custom-made component to simulate the exuding wound bed. This wound bed simulator is a truncated conical shape, forming a crater-shaped DHU with a diameter of 3.1 cm superficially and maximum depth of 1.3 cm with respect to the adjacent plantar surface of the foot phantom (Figure 1B).

### 2.1.3 | A robotic phantom system of multiple simulated wound replicates

A robotic phantom system comprising six identical wound replicates has been developed,<sup>54</sup> with each wound unit in this system simulating an exuding, 2.5 cm-deep cavity wound (Figure 1C). All the six wound units include three layers of synthetic soft-tissues simulants. The top layer, representing the peri-wound skin, consists of 5 mm-thick transparent silicone rubber (Figure 1C). A layer of paraffin gel (“candle-gel”) with thickness of 8 mm is placed below this “skin” layer, to represent adipose tissue.<sup>55</sup> The inferior layer, with thickness of 12 mm, representing skeletal muscle, is again made of

silicone rubber (identical to the one used as the skin simulant).

## 2.2 | Automated control systems

To simulate the continuous secretion of exudate from the wound bed, spiral perforated irrigation tubes were incorporated in all the different “wound bed” types described above (Figure 1A to C). Each such irrigation tube was tunnelled through the “wound” structure to eventually connect to an electromechanical syringe pump. This configuration allowed the release of exudate-substitute fluids into the “wound beds” at controlled, pre-set flow volumes and rates. To achieve thermodynamic similarity across the experiments, we positioned an adjustable-distance infrared heating lamp in proximity to the “wound beds” (Figure 1A,B), which facilitated adjustment of the wound cavity temperature. Furthermore, in the sacral PU and DHU phantoms, we incorporated thermocouple probes along the “wound bed” perimeters to verify a limited range of “wound” temperatures circumferentially (Figure 1A,B). The six-wound system was likewise thermodynamically monitored, using digital thermometry.

To further simulate the physiological bodyweight loads associated with a standing posture that are transferred to the DHU in the DFU phantom, we placed weights on top of the DFU phantom corresponding to a body mass of 60 kg (Figure 1B). A force measurement system consisting of seven flexible, 203  $\mu\text{m}$ -thin force sensors connected to a microcontroller board, was developed and used to monitor the forces in and around the DHU during these simulated standing tests (Figure 1B). Five of the sensors were embedded within the “soft tissue” silicone beneath the calcaneus bone, and the two remaining sensors were attached to the plantar foot surface. The sensors were calibrated by means of precision calibration weights (5–45 kg) to obtain the resistance-weight ( $\Omega/\text{Kg}$ ) curve for each sensor, as previously reported.<sup>47</sup>

## 2.3 | The exudate substitute fluids and their rheological properties

For use with the robotic phantom systems described above, we developed a safe and reproducible exudate substitute fluid formula, which facilitates control of the fluid viscosity and pH levels, so that they adequately represent the physical characteristics of native exudate fluids. The exudate substitutes can be further coloured using food dyes, to provide a clinically realistic appearance of the exudate. Specifically, to prepare the exudate substitute,

food-standard Xanthan gum powder was added to distilled water at concentrations of 0.01% to 0.2%, which results in a range of fluid viscosities, from aqueous to thick exudate substitutes. It should be noted in this regard that quantitative rheological behaviour and properties, and fluid viscosities in particular, have not yet been reported in the literature for human wound exudates. Rather, exudates are often described qualitatively and using descriptive clinical terminology, by words such as “thin,” “watery,” “thick,” “sticky,” “creamy” etc.<sup>21,56</sup> The most common assessment of wound drainage is the amount; then, it may be described as a serous, serosanguinous, sanguineous, fibrinous or purulent exudate.<sup>21,56</sup> This language is also routinely used by healthcare professionals to categorise observed exudate viscosities in wound assessments.<sup>57</sup> For these reasons, we had to develop our artificial exudate fluids so that their viscosity can be adjusted within a range of human biological fluids (including protein-rich fluids) for which quantitative viscosity data are available in the literature, such as blood plasma, whole blood, saliva, breast milk and mucous. The consistency of the resulted exudate substitute fluids was validated both qualitatively, by nursing experts from their clinical experience perspective, and quantitatively, by means of rigorous rheology tests, to verify that the exudate-like fluid viscosities were representative of the human biological fluid viscosity range. These rheology tests resulted that:

$$\begin{aligned} & \text{Xanthan gum concentration [\%]} \\ & = 0.26 \cdot \text{Viscosity} \left[ \frac{\%}{\text{Pa} \cdot \text{s}} \right] + 0.02 [\%], \end{aligned} \quad (1)$$

where the Xanthan gum concentration is given in percentage weight of the distilled water into which it is mixed, and the viscosity is in units of Pa·s.

The pH of the exudate substitute was determined as acidic for the purpose of the experiments reported here, and equalled five consistently throughout our reported work, which is typical for non-infected wounds.<sup>58,59</sup> With that said, this property can be adjusted by controlled addition of weak acid or alkaline agents to the fluid. Lastly, 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 within the tested dressing products.

## 2.4 | Simulated treatments of the cavity wounds

Prior to applying dressings to the simulated wounds, we weighed both the primary and secondary dressings, per

each experiment. The primary dressings were then cut and fitted into 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 phantoms were then positioned in the relevant configuration, such as in a prone, supine or side-lying (lateral) position for the sacral PU phantom, or in a standing or supine position for the DFU phantom. The robotic wound systems were activated with the following set of parameters: exudate substitute density = 1.03 g/cm<sup>3</sup>, exudate viscosity = 0.23 Pa·s and exudate flow rate = 0.08 mL/cm<sup>2</sup>/h (corresponding to medium-exuding wounds,<sup>60</sup>). We defined “short,” “medium” and “long” simulated use times as 5, 10 and 15 hours, respectively. Of note, in real-world clinical scenarios, wound dressings remain in place for a typical period of 1 up to 7 days (depending primarily on whether the wound is infected or not), with the majority of dressing changes in hospital settings occurring every 2 to 3 days.<sup>48,61,62</sup>

Accordingly, the above timeframes reflect conservative assumptions regarding the resulted performance metrics of the dressings under investigation, whilst also considering that it is not feasible to run the experimental laboratory tests continuously for a period of days, for reasons related to safety, the need to continuously monitor the experiments and equipment wear-out. The tested dressing products and the selected parameters for each experimental set reported here are specified in Table 1.

## 2.5 | Testing the primary dressings post-simulated use

### 2.5.1 | Retention and fluid distribution tests

Following each simulated use session, the used dressings were weighed again, and the free exudate substitute which remained in the wound cavity was fully collected and weighed as well.<sup>45</sup> Next, we determined the fluid volume retained in each dressing specimen as the wet minus the dry dressing weight, divided by the exudate fluid density (1.03 g/cm<sup>3</sup>). The total exudate volume (TEV) was then calculated by summing the fluid volume retained in the dressing and the free exudate substitute volume collected from the wound cavity. To facilitate comparisons across experimental conditions and dressing product types, the volumetric fraction of the exudate substitute fluid retained in the dressings was calculated, through normalising the fluid volume retained in the dressing by the corresponding TEV, per each trial (so that retention data could be reported in percentages). We further evaluated the fluid distribution between the pair of primary and secondary dressings, per each trial, as the ratio of the fluid volume retained in each dressing (primary or secondary) over the calculated TEV in the respective trial.

TABLE 1 Detailed description of the testing configurations and tested products

	Testing configuration			Tested products			
	Position	Duration (h)	Mechanical loading	Primary dressings		Secondary dressings	
Sacral pressure ulcer	Prone	15	Off-loaded	Exufiber (PVA-based)	Other gelling fibre, CMC-based primary dressing	Mepilex Border Sacrum	
	Supine	5	Non-off-loaded				
	Side-lying		Off-loaded				
Diabetic foot (heel) ulcer	Standing	5	Non-off-loaded	Exufiber (PVA-based)	Other gelling fibre, CMC-based primary dressing	Mepilex Border Flex	Other secondary foam dressing
	Supine		Off-loaded				
Multiple wound system	Prone	5	Off-loaded	Exufiber Ag + (PVA-based)	Other gelling fibre, CMC-based Ag + primary dressing	Mepilex Border Flex	
		10					
		15					

Abbreviations: CMC, sodium carboxymethyl cellulose; PVA, polyvinyl alcohol.

### 2.5.2 | Fibre directionality analyses

For gelling fibre dressings, the directionality of the fibres, which typically relates to the manufacturing technology of these primary dressings (i.e., PVA versus CMC), likely affects the performance of the dressings, such as the sorptivity as the fibres become the structural conductors for the capillary action, and the durability because the dominant fibres also provide the greatest structural support and highest mechanical tolerance against forces that are aligned with their primary direction.<sup>54</sup> Accordingly, the fibre directionality in the primary dressings was assessed by means of digital image processing of microscopy images of the dressing surfaces. Specifically, five fields of view (FOVs) were captured from the surfaces of selected primary dressing products, at consistent locations which were the centre of the dressing specimen and additional four FOVs that formed a cross shape around the dressing centre; each such peripheral FOV was at a distance of 2.5 cm from the dressing edges. The fibre directionality analyses were conducted using the post-acquisition plugin “OrientationJ” of the ImageJ software suite (Version 1.X),<sup>63,64</sup> which segmented the fibres in the digital micrographs and calculated the probability function for their planar orientation in each analysed FOV. After calibrating the image processing code and visually verifying its performances, we employed it for extracting the normalised histograms of the fibre orientations in the studied primary dressings, to determine the directional preference of the dominant, visible fibres in each dressing type, if such exists.<sup>54</sup>

### 2.5.3 | Primary dressing strength tests

Each primary dressing specimen was tested for its tensile strength immediately post-simulated use, by means of an electromechanical material testing machine (Instron model

5944 Instron Co., Norwood, Massachusetts). A load cell with capacity of 2 kN was used throughout the tests. All the primary dressing specimens were stretched at a deformation rate of 50 mm/min until ultimate failure (i.e., total rupture) occurred. Stress–strain curves were then plotted, based on the acquired force-deformation data, and the strain energy density (SED), i.e., the area under the stress–strain curve until 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).<sup>65</sup>

In a sub-set of trials performed after the simulated dressing usage sessions in the multiple wound system (Figure 1C), the tensile forces of the strength tests were applied in consideration of the directionality of the visible fibres in the primary dressing, based on the above-described microscopy-aided fibre directionality analyses, as follows. Primary dressing products identified as lacking a specific directional preference of the visible fibres were mechanically tested at a randomly chosen direction of the stretching. However, dressings which had been recognised as having a specific directional preference of their visible fibres were tested in two different configurations: (a) where the principal visible fibre direction was fully aligned with the loading axis of the material testing machine and (b) where the fibres were out of such alignment.

## 3 | RESULTS

### 3.1 | Retention and fluid distribution tests

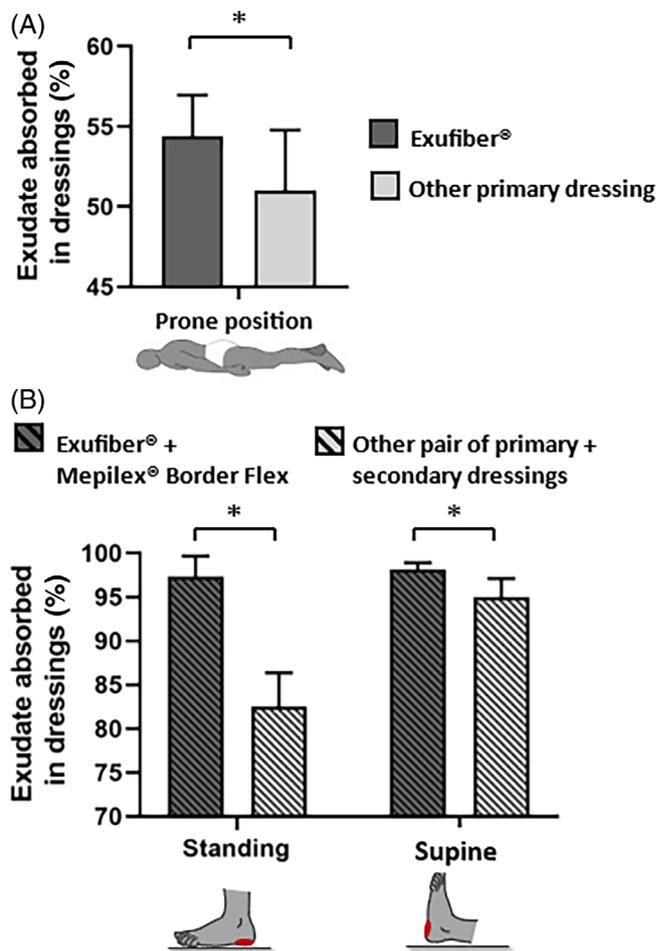
#### 3.1.1 | Sacral pressure ulcer studies

A comparison of the retention performance between the tested dressing products after 15 hours of simulated use

to “treat” the sacral PU in the robotic phantom in a prone (off-loaded) position (Figure 2A) demonstrated superior outcomes for the Exufiber (Mölnlycke Health Care, Gothenburg, Sweden) PVA-based primary dressing over those of the comparator CMC-based market-leading primary dressing product (marked as the “other primary dressing” in the figures). The comparator CMC dressing is a soft, sterile, non-woven pad composed of sodium CMC (NaCMC) hydrocolloid fibre material, which is indicated for clinical use in both acute and chronic wounds, and its properties have been described in detail in the literature.<sup>66-68</sup> Importantly, the two types of the studied primary dressings, i.e., the PVA-based and CMC-based, are made of distinct materials and are manufactured through different technologies; however, both dressing types are clinically indicated for use as cavity wound fillers, which have been the rationale for comparing their performances.

When the sacral PU phantom was positioned prone, gravity pulled the exudate substitute downwards, towards the bottom of the wound cavity. In this testing scenario, the aforementioned PVA-based dressing type retained  $54.4 \pm 2.5\%$  (mean  $\pm$  standard deviation) of the exudate simulant, compared to  $51 \pm 4\%$  of the fluid retained by the CMC-based dressing product ( $P < 0.05$ , Figure 2A). Of note, in this prone position, the percentage of the non-retained exudate simulant, approximately 50%, is relatively high, as the fluid tends to accumulate at the bottom of the wound cavity, and the sorptivity, or the capillary action, is the only mechanism by which it may be lifted upwards into the primary dressing. Hence, the aforementioned results demonstrate significantly greater sorptivity for the PVA-based primary dressing than for the CMC-based dressing.

The associated fluid distribution between the primary and secondary dressing combinations is shown in Figure 3A, for the supine and side-lying phantom positions (at the right part of the bar graph). These data demonstrate that the exudate substitute reached and entered the secondary multi-layered foam dressing (Mepilex Border Sacrum, manufactured by Mölnlycke Health Care) in all the test configurations but at considerably different amounts. The uptake of the secondary dressing was substantially and statistically significantly greater where the primary dressing was PVA-based (60%-73%), than when it was CMC-based (21%-52%). When the capillarity of the dressing structures was partially aligned with gravity, which was the case for the side-lying position (Figure 3A; most right-hand sided bar), both primary dressing types were able to transfer a greater volume of the exudate substitute to the secondary dressing, but the PVA-based dressing transferred a larger portion of the fluid to the secondary dressing ( $73\% \pm 11\%$ ) with respect to the CMC-based dressing ( $52\% \pm 16\%$ ;  $P < .05$ ). For the



**FIGURE 2** Fluid management data for tested wound dressings: (A) Fluid retention in primary gelling fibre dressings after 15 hours of simulated use in a prone-positioned robotic sacral pressure ulcer system ( $N = 10$  test repetitions per dressing type). (B) Fluid absorbed and retained in primary gelling fibre and secondary foam dressings—considered together as a pair, after simulated 5-hour shoed standing or barefoot lying sessions in the robotic diabetic heel ulcer system. Values are the percentages of the total fluid mass delivered by the robotic systems to the simulated “wound beds.” The error bars are the standard deviations, and an asterisk indicates a statistically significant difference in outcome measures ( $P < .05$ )

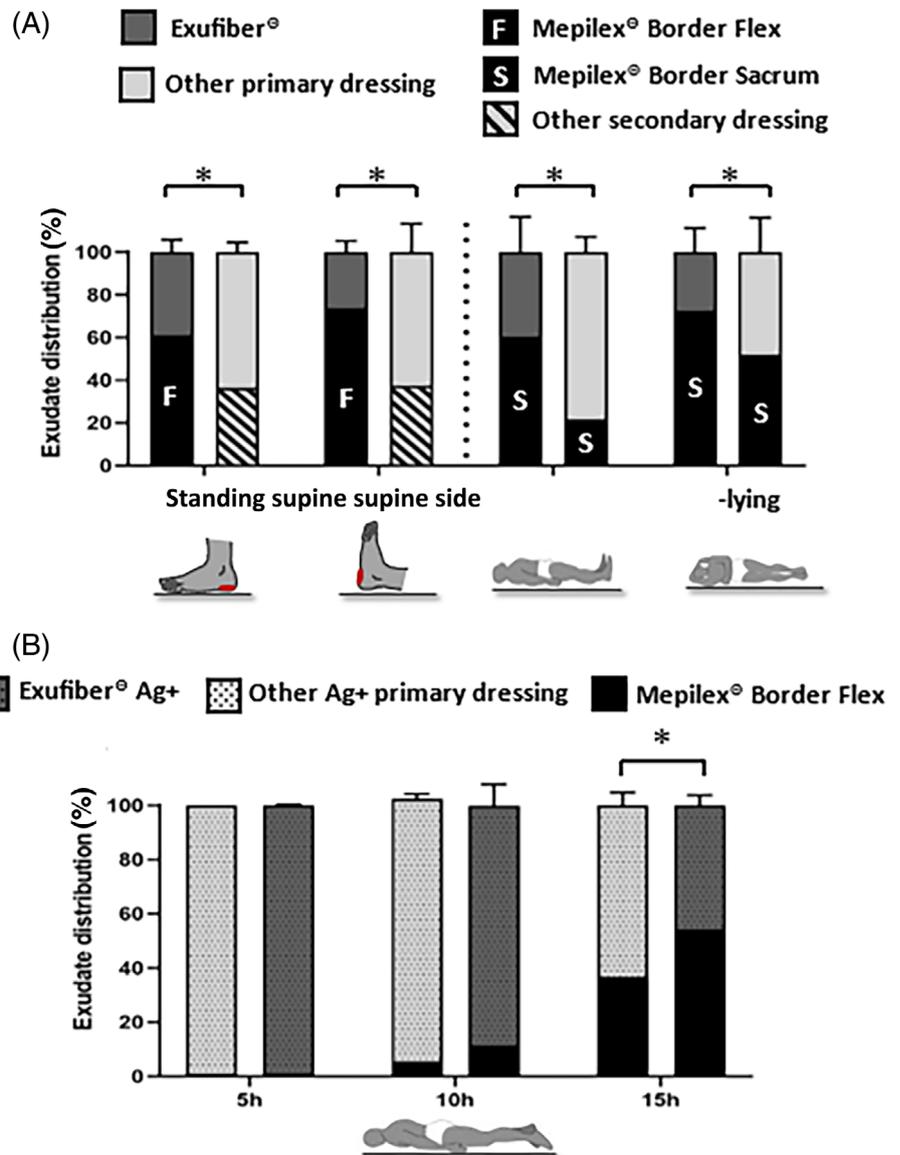
supine position, where the direction of flow from the wound bed to the primary dressing fully aligned with the gravity vector, the PVA-based dressing was able to deliver 60% of the fluid away from the wound bed and carry it forward into the secondary dressing, whereas the CMC-based dressing was only able to deliver 21% of the fluid into the secondary dressing ( $P < .05$ , Figure 3A, right two panels). This finding is likely associated with the higher entrance pressure of the fluid into the primary dressing in the supine configuration, and the different capacities of the two primary dressing types to handle and transfer viscous fluid. The primary dressing technology and

material composition are therefore dominant factors in the capacity of the primary dressing to share fluid with a secondary dressing (given that all the other experimental conditions were the same for these PVA-based versus CMC-based primary dressing comparisons).<sup>45</sup>

### 3.1.2 | Diabetic foot ulcer studies

A comparison of the retention performance between the investigated dressing combinations in the DFU phantom (Figure 2B) consistently revealed superior fluid absorbency and retention by the PVA-based dressing, this time paired with a different secondary foam dressing (Mepilex Border Flex, by Mölnlycke Health Care), over those of a pair of a CMC-based primary dressing and a secondary foam dressing made by the same manufacturer of the

CMC-based dressing.<sup>66-68</sup> The superior performance of the PVA-based dressing was consistent for both the non-off-loaded and off-loaded DHU test configurations. Specifically, when the DFU phantom was used in a standing configuration (i.e., the simulated DHU was in a non-off-loaded position), the direction of the fluid flow aligned with the gravity vector, effectively causing the exudate simulant to drip directly onto the primary dressing. In this testing configuration, the PVA-based primary dressing with its paired foam dressing retained  $97.3 \pm 2.3\%$  of the exudate substitute fluid, whereas the fluid retention in the CMC-based primary dressing and its paired secondary foam dressing was  $82 \pm 3.8\%$  ( $P < .05$ , Figure 2B). Positioning the foot phantom to represent supine lying so that the DHU was off-loaded demonstrated a similar trend with greater ( $98.2 \pm 0.7\%$ ) retention for the pair with the PVA-based dressing than for the comparator



**FIGURE 3** Fluid distributions between primary gelling fibre and secondary foam dressings in dressing pairs used for treating diabetic foot ulcers or pressure ulcers: (A) Fluid sharing between primary, non-silver gelling fibre dressings and secondary foam dressings following 5 hours of simulated use (minimum 4 test repetitions per dressing configuration). (B) The time evolution of the fluid sharing between primary, silver-containing gelling fibre dressings and secondary foam dressings during 15 hours of simulated use in the robotic, prone-positioned sacral pressure ulcer system, i.e., where dressings are off-loaded ( $N = 6$  test repetitions). The error bars are the standard deviations, and an asterisk indicates a statistically significant difference in outcome measures ( $P < .05$ )

pair ( $95 \pm 2.1\%$ ;  $P < .05$ , Figure 2B). Of note, in the “standing” test configuration, the applied weights representing the body mass (Figure 1B) caused the investigated dressing pairs to perform under compressive deformations, which potentially influence the total retention reservoir of the pair, but despite that, the pair with the PVA-based dressing performed similarly in the two simulated DFU phantom postures (Figure 2B). The comparator pair with the CMC-based dressing, however, exhibited a 13% decrease in retention for a supine to standing transition (which in the real-world would represent, for example, getting out of bed), indicating that the retention reservoir for that pair (with the CMC-based primary dressing) reduced because of the simulated bodyweight (Figure 2B).

The distribution of fluid between the primary and secondary dressings following the “standing” tests (Figure 3A; at the left part of the bar graph) demonstrated that the PVA-based dressing retained 39% of the total fluid and delivered the remainder 61% away from the DHU, into the secondary foam dressing. The CMC-based primary dressing was only able to transport 36% of the fluid into its paired secondary dressing under the same test conditions, thereby leaving substantially more fluid near the wound ( $P < .05$ , Figure 3A; most left-hand-sided bar). Consistently, for the simulated supine position (i.e., for the off-loaded DHU), the PVA-based dressing retained 26% of the fluid and effectively transferred the other 74% of the fluid into the secondary foam dressing, whereas the CMC-based primary dressing only transported 37% of the fluid to its paired secondary dressing ( $P < .05$ , Figure 3A, left two panels). Again, it is demonstrated that the specific technology of the primary dressing is crucial to the capacity of the primary dressing to share fluid with a secondary dressing. However, the technology of the secondary dressing also plays an important role in this process (as demonstrated in the above experiments, where the secondary dressings were those recommended by the manufacturers to use with their own primary dressings).<sup>47</sup>

### 3.1.3 | Multiple simulated wound system

The fluid distribution between a PVA-based, silver-containing primary dressing (Exufiber Ag + by Mölnlycke Health Care) and its corresponding secondary foam dressing (Mepilex Border Flex) was compared to that of a CMC-based, silver-containing dressing used in conjunction with the same secondary foam dressing (Figure 3B). These data are plotted over the time of simulated use, thereby demonstrating the evolution of the fluid sharing from the short to the long usage periods. It is evident that when the primary dressing

was the PVA-based, silver-containing 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 comparison where the primary dressing was CMC-based (Figure 3B). These data further revealed that the reservoir of the secondary dressing began to receive fluid not earlier than 5 hours from the time of the dressing application; however, after 15 hours, the secondary dressing already shared ~54.2% of the retained fluid for the case where the primary dressing was PVA based, but only 36.7% for the CMC-based dressing ( $P < .05$ ; Figure 3B).<sup>54</sup>

## 3.2 | Fibre directionality studies

The digital microscopy image analyses of the primary dressings indicated that the PVA-based, silver-containing dressing had no specific dominant directional preference of its visible fibres. This was evident by the value of the integral bounded between the fibre orientation histogram curve and the 0.5 (midpoint) level for the two primary dressings, which was defined as the fibre orientation index (FOI).<sup>54</sup> When a dressing does not exhibit a directional preference of its visible fibres, the positive and negative areas between the aforementioned histogram curve and the 0.5-level approximately cancel each other, which results in a relatively low FOI value. Correspondingly, the FOI for the PVA-based, silver-containing primary dressing was approximately 3.9-fold lower ( $15.6 \pm 11.8$ ) than that of the CMC-based silver containing primary dressing ( $60.8 \pm 48.8$ ;  $P < .05$  for five different microscope fields of view on each dressing type).<sup>54</sup>

## 3.3 | Durability studies

### 3.3.1 | Sacral pressure ulcer and diabetic foot ulcer phantoms

The tensile tests pointed to considerably distinct failure patterns of the PVA-based versus the CMC-based primary dressings post-simulated use. The PVA-based dressing was shown to be substantially more extensible and structurally stable post use, compared to the CMC-based dressing for which tearing of fibre bundles occurred relatively early during the course of stretching (Figure 4). The stress–strain data of the two primary gelling fibre dressing types (Figure 5A) further revealed that the PVA-based dressing can withstand strains above 150% without detectable loss of fibre integrity, whereas the CMC-based dressing demonstrated substantial fibre bundle failures (associated with fractures in the gel) already below half

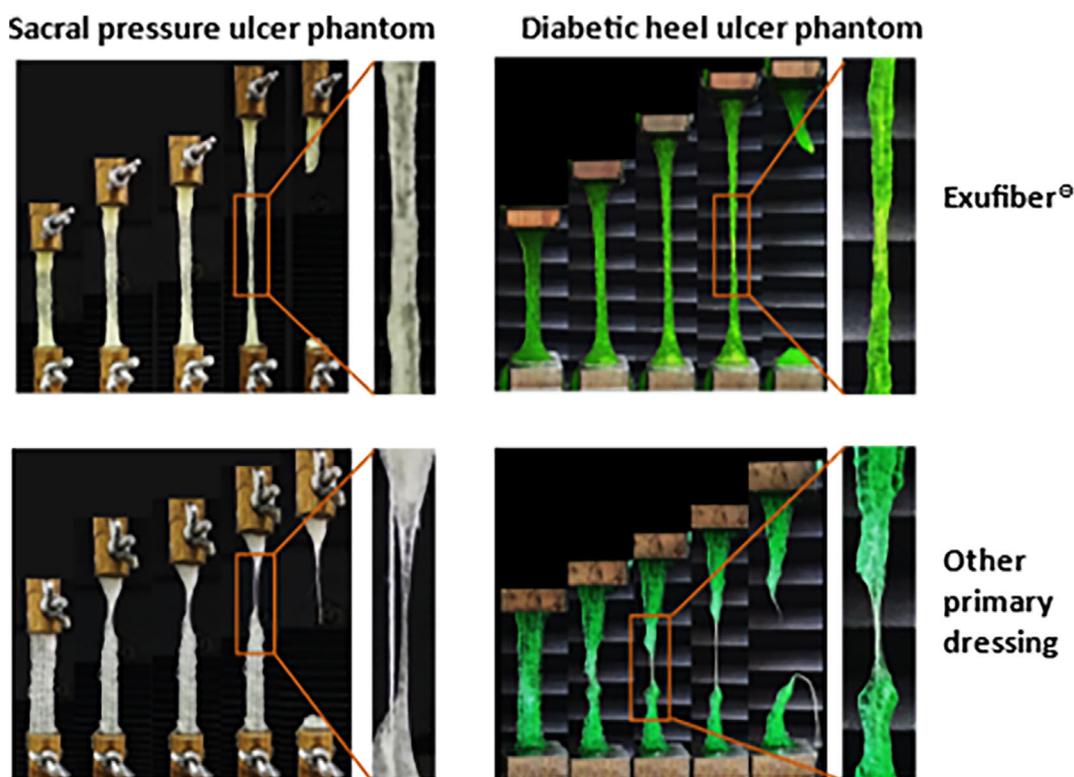
that strain value. Consistent with these stress–strain data, the SED calculations revealed that the PVA-based primary dressing has superior strength and is more enduring than the CMC-based dressing (Figure 5B,C).

### 3.3.2 | Multiple wound system

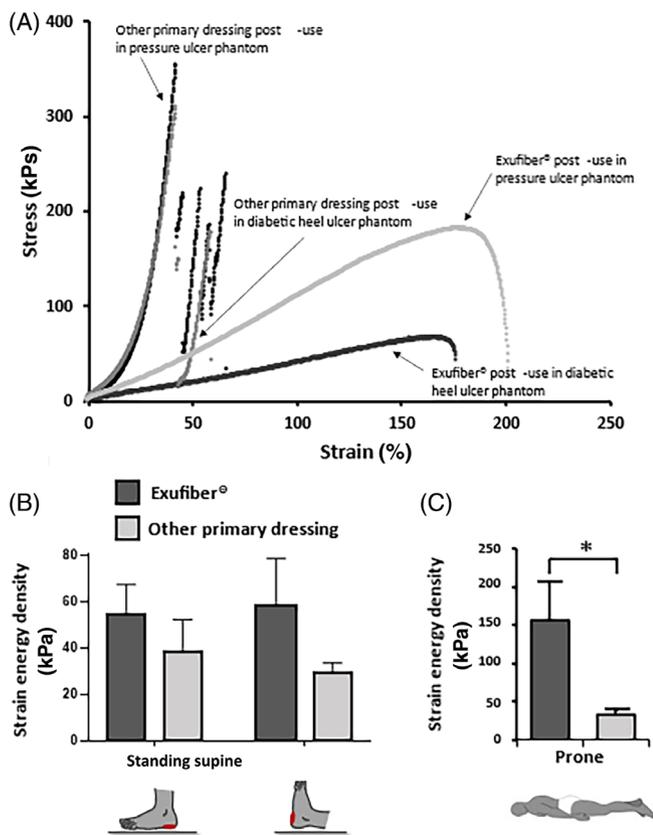
For the mechanical testing of the silver-containing primary dressings post-simulated use, the medium- and long-simulated use periods were considered, as both the PVA-based and CMC-based dressing types transferred fluid to their paired secondary foam dressing at the 10 hours time point and onwards (Figure 3B). Additionally, based on the results of the microscopy analyses of fibre orientation described above, the PVA-based silver-containing dressing was tested as a material without a specific directional preference (i.e., irrespective of the direction by which test specimens were cut from this dressing type). The CMC-based dressing, however, which was identified as having a directional preference of its visible seams and main fibres, was tested in two different configurations: (a) fully aligned with the primary

orientation of the visible seams and fibres (marked as the “90° direction” in Figure 6) and (b) out of this alignment (i.e., at randomly selected but different from the 90° direction, marked as “0° + 45° direction” in Figure 6).

The SED-to-failure results for the two primary dressing types are plotted in Figure 6A, demonstrating a considerable difference in the strength properties post-simulated use between the PVA-based and CMC-based silver-containing dressings. Again, the PVA-based dressing emerged as being substantially more ductile with respect to the CMC-based dressing.\* It is noted that the PVA-based, silver-containing dressing gained ductility as it absorbed more fluid and gelled, and, accordingly, at the 15-hour time point, it had 1.7-times greater SED-to-failure than at 10 hours. In contrast, the CMC-based primary dressing did not exhibit that its gelling transformation translated into greater ductility, and its SED-to-failure values were indistinguishable between the 10 and 15 hours time-points (Figure 6A). Importantly, these strength tests clearly demonstrated that the main loadbearing structure in the CMC-based silver-containing dressing is the reinforcing (visible) seams and the (near)

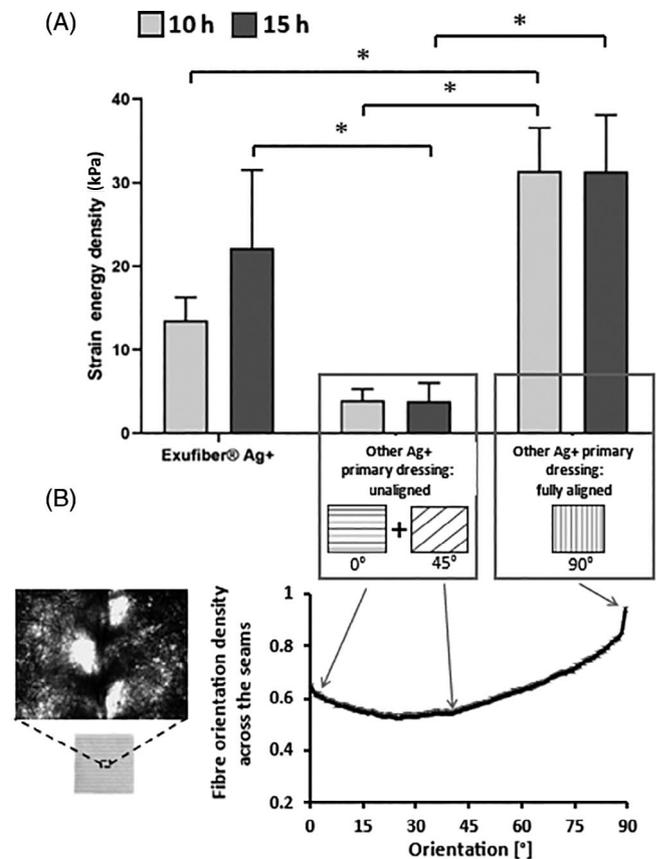


**FIGURE 4** Material strength tests comparing representative failure behaviours of two types of primary, non-silver gelling fibre dressings post-usage in the robotic sacral pressure ulcer system (left column; after 15 hours of simulated use) and the diabetic heel ulcer system (right column; after 5 hours of simulated use). The failure region at the time point preceding the ultimate failure has been magnified for each dressing type (at the right-hand side of each panel), to show the structural integrity and the fibre rupture pattern in each dressing



**FIGURE 5** Durability tests of primary gelling fibre dressings: (A) Example stress–strain curves for two primary dressing types tested under uniaxial tension loading post-usage in the robotic sacral pressure ulcer system (after 15 hours of simulated use) and in the diabetic heel ulcer system (after 5 hours of simulated use). These stress–strain data demonstrate the continuity associated with the robustness of the Exufiber dressing, versus the discontinuity because of the multiple fibre rupture events shown for the comparator dressing. (B) The strain energy density (SED) to failure of the primary dressings after 5 hours of simulated use in the robotic diabetic heel ulcer system. (C) The SED to failure of the primary dressings after 15 hours of simulated use in the robotic sacral pressure ulcer system. There were six repetitions per each test configuration in panels B and C. The error bars are the standard deviations, and an asterisk indicates a statistically significant difference in outcome measures ( $P < .05$ )

90°-oriented fibres. When tested out of alignment, that is, in any direction where the visible seams/primary fibres were not fully aligned with the direction of the applied tensile forces, the strength of the CMC-based primary dressing was more than 8-fold lower than its in-alignment strength (Figure 6A;  $P < .05$ ). With respect to the mechanical strength of the PVA-based, silver-containing dressing, the CMC-dressing had out-of-alignment strength that was ~4-times and ~6-times lower for the 10- and 15-hour time points, respectively (Figure 6A;  $P < .05$ ).



**FIGURE 6** Structure–function analyses of the primary, gelling fibre silver-containing dressings, which were tested in the multiple wound system: (A) The strain energy density to failure of the two tested primary dressing types post 10 and 15 hours of simulated use. (B) The dressing which exhibited a non-uniform normalised fibre orientation in the processed microscopy images (in addition to a longitudinally patterned structure of its visual seams) was consequently tested in two loading configurations, namely, where the tensile loading was applied in full alignment with the principal direction of the fibres of this dressing, or out of such alignment. The error bars are the standard deviations from the mean values ( $N = 6$  repetitions per test configuration), and an asterisk indicates a statistically significant difference in the relevant outcome measure ( $P < .01$ )

## 4 | DISCUSSION

### 4.1 | Robotic wound phantom systems for clinically relevant laboratory evaluations of dressing performance

Exudates play an essential role in any wound healing process, by facilitating cell signalling, proliferation, migration and growth, as well as delivery of protein building blocks for collagen synthesis towards tissue repair. Wounds generally require moisture balance for adequate healing; whilst a moist wound environment is

vital, excess exudate may be irritant, toxic or infectious to adjacent tissues and cause maceration of peri-wound skin.<sup>69</sup> Any excess exudate should therefore be absorbed and retained in effective wound dressings to support the healing process. A common clinical practice for treating cavity wounds is to apply a primary gelling fibre dressing, acting as a “wound filler,” and then cover the wound with a secondary “bordered” dressing, which is typically a foam-based dressing. In such regimes, the role of the primary gelling fibre dressing is to continuously absorb and retain the secreted exudates and transfer those continuously to the secondary dressing, while inducing moisture balance in the wound bed. Other than protecting the wound from mechanical insults and pathogens, the further use of secondary bordered dressings provides an additional reservoir for fluid absorption and retention of the exudate delivered from the primary dressing, through gravity-driven flow or sorptivity (capillary motion) or both, depending on the body posture and activity.<sup>45,53</sup> Combining a primary and secondary dressing should reduce the likelihood of either pooling of exudate in the wound cavity, or leakage and spread of exudate to the peri-wound area, provided that each dressing of the pair is clinically effective and that the two dressings function synergistically.

Poorly performing wound dressings or dressing pairs may cause suboptimal moisture balance, sharp tissue temperature gradients, mechanical damage to tissues, foreign body reaction or a combination of these unwarranted events.<sup>70</sup> It is therefore surprising that existing laboratory tests for evaluating the fluid management performance and mechanical durability of wound dressings, e.g., the commonly used European EN 13726 family of standards for wound dressings,<sup>52</sup> typically neglect the fundamental physiological and clinical aspects that determine the environment in which dressings function. Among the major topics that are ignored in the abovementioned and similar testing standards are: (a) the anatomical configuration relevant to the wound aetiology, (b) exposure to physiological mechanical forces that may influence the performance of dressings, (c) the directionality of the exudate flow from the wound into the applied dressings, (d) the forces and clinical technique of removal of the dressings and (e) the biophysical behaviour of the exudate, particularly the range of possible exudate viscosities.<sup>51,71,72</sup> With regards to the latter point, one of the important gaps between laboratory tests and clinical reality is that in the typical testing of wound dressings, including in the European EN 13726 testing standards (in particular parts #1-4 and #6 of this set of standards), aqueous solutions such as the sodium/calcium ion “Solution A,” saline or Ringer's solutions are

used, as opposed to protein-containing or other viscous solutions.<sup>46,73</sup>

To overcome all the above limitations of existing testing standards and protocols, a variety of novel computer-controlled robotic phantoms that include simulated wounds of different aetiologies has been recently developed in the group of the senior author (AG), to form the basis for a new and clinically relevant testing platform for wound dressings (Figure 1). These versatile phantom systems have been designed and constructed specifically for testing the individual and combined performances of primary and secondary wound dressings, considering all the above-listed, real-world factors which were absent in previously used testing methods. By exposing wound dressings to an exudate-like fluid and simulating important mechanical, thermodynamic and clinical practice conditions, objective, quantitative, standardised and clinically relevant laboratory comparisons of wound dressing performances become feasible.

## 4.2 | The concept of sorptivity of dressings and its importance in fluid management

In 1957, Dr. John Philip introduced the term sorptivity and the sorptivity parameter “*S*,” which he defined as *a measure of the capacity of a solid, porous medium to absorb or desorb liquid by capillarity*.<sup>74</sup> He noted in his published work that as *S* is a measure of the capillary uptake or removal of water, it is essentially a property of the medium (with some resemblance to permeability in this regard, however, sorptivity is specific to capillary motion). His work was seminal in the field of soil and water sciences and can further be extrapolated for describing any other porous material which absorbs fluid through capillary action, including wound dressings. Indeed, a primary mechanism of action for many wound dressings including gelling fibre dressings is capillary motion, where exudates are being lifted and moved away from the wound surface through a capillary effect.<sup>75</sup> The ability of an absorbent material to transfer a certain viscous fluid by capillary action is generally described as<sup>76</sup>:

$$V = AS\sqrt{t}, \quad (2)$$

where *V* is the cumulative volume of the liquid absorbed through a cross-sectional area *A* of the absorbent material at time *t*, and *S* is the sorptivity of the absorbent material. The sorptivity *S* (defined in<sup>74</sup>) is formulated as<sup>77</sup>:

$$S = \left( d \sqrt{\frac{\gamma}{\mu}} \right) \left( \frac{\varepsilon}{\lambda} \sqrt{r} \right) \left( \frac{\cos\theta}{2} \right), \quad (3)$$

where  $d$ ,  $\gamma$  and  $\mu$  are the density, surface tension and viscosity of the fluid undergoing the capillary motion, respectively,  $\varepsilon$  is the effective porosity of the dry absorbent material,  $\lambda$  is the average tortuosity factor of the absorbent material,  $r$  is the average pore radius and  $\theta$  is the contact angle of the interface between the liquid and pore walls.

Good sorptivity of the primary dressing is essential for clearing any excess exudate away from the wound bed, into the primary dressing structure, and from there, onwards to the secondary dressing, and finally, to the environment through evaporation from the surface of the secondary dressing. The sorptivity performance feature becomes even more critical if the dressing should absorb wound fluids against the gravitation, as some patient positions may require. Poor sorptivity of the primary dressing, not allowing effective transfer of exudate between the primary and secondary dressings will cause a so called “plugging effect.” Such plugging occurs when the primary dressing has relatively low sorptivity and, thereby, is essentially acting as a plug above the wound bed, promoting exudate accumulation at the bottom of the wound cavity, but not facilitating the sufficient transfer of fluid into the secondary dressing reservoir, from which it can evaporate. The plugging phenomenon further limits the maximal fluid volume that can be absorbed in the pair of the dressings, to the capacity of the primary dressing alone, and thus, increases the risk for backflow of exudate that was already absorbed in the primary dressing when it becomes excessively wet or may lead to leakage from the dressing that can cause maceration.

It is important to note that the level of sorptivity achieved by a certain dressing that is applied to a specific wound is influenced by both the individual wound characteristics and the dressing materials and microarchitecture. For example, referring to the right-hand side of Equation (3) in this regard, the first term (from left to right) comprises of biophysical properties (e.g., the surface tension  $\gamma$  and viscosity  $\mu$ ) of the exudate. The second term contains the microstructure properties of the absorbent material of the dressing (such as the porosity  $\varepsilon$  and the pore radius  $r$ ), and the third term is an interaction term that includes parameters concerning the interface between the absorbent dressing material and the exudate.

### 4.3 | Fluid management performance of gelling fibre dressings in robotic wounds

The robotic wound systems described here are powerful in simulating clinically relevant scenarios and the

associated fluid handling performance of dressings, including with regards to patient positioning. For example, prone positioning of the sacral PU phantom (Figure 1A) allowed to isolate the sorptivity performance of the primary gelling fibre dressings, revealing that the Exufiber dressing has greater sorptivity with respect to the comparator gelling fibre dressing when required to act in a capillary motion mode of fluid transfer, i.e., opposing the gravitational forces (Figure 2A). Such high sorptivity clears absorbency and retention capacity in the primary dressing for additional, newly secreted exudate, as the inflowing exudate is continuously being transferred to the upper, secondary foam dressing, thus preventing a “plugging” effect (where the primary dressing maxes out its capacity).<sup>45</sup> In other words, good sorptivity of a primary dressing enables the retention reservoirs of both the primary and secondary dressings to be adequately utilised. The above finding, of greater sorptivity of the Exufiber dressing, was consistent with the results from the DHU phantom (Figure 1B). In the DHU phantom, the Exufiber dressing demonstrated not only superior absorbency for flow conditions that were fully gravity-driven (i.e., standing, where the dressing was placed right under the simulated wound bed, allowing the exudate to drip directly into the dressing), but also, under mixed gravity/capillary-force induced fluid motion, which occurred for the supine posture (Figures 2B and 3A).

Another important factor influencing the fluid management performance of wound dressings is the occurrence of bodyweight or external forces that deform the dressings, and, thereby, affect their effective reservoirs. This was particularly illustrated by the DFU phantom study results, which considered both standing and bed-rest (supine) conditions.<sup>47</sup> While offloading DFUs is currently the mainstream treatment approach,<sup>78</sup> not all DFUs are off-loaded in practice, and even wounds that are generally offloaded are occasionally exposed to bodyweight forces. For example, when transferring out of bed to a standing or sitting posture, ambulatory diabetic patients are likely to be at least partially weight-bearing on their plantar DFU, even if they would normally use an offloading device. Moreover, the proportion of patients with DFUs who do not use any offloading devices is reported to be on the rise.<sup>79</sup> Non-off-loaded DHUs may be exposed to considerable mechanical forces, exceeding twice the bodyweight during the occurrence of each heel-strike.<sup>80</sup> A dressing pair applied to treat a DFU must therefore be able to perform satisfactorily under the large compressive dressing deformations associated with such intense forces, which should be expected in nearly all real-world usage scenarios. An important observation in this regard was that the Exufiber and Mepilex Border

Flex pair performed similarly (i.e., their absorbency and retention performance = ~97% were statistically indistinguishable) between the simulated standing and supine postures. In contrast, the comparator dressing pair exhibited a statistically significant decrease (13%,  $P < .05$ ) in the fluid retention of the pair for a standing position with respect to the supine performance (Figure 2B), indicating that the non-off-loaded performance of this dressing pair was compromised compared to its fully off-loaded performance. This is not ideal, as a stable performance of the dressing pair is warranted across the life-cycle of the dressings and regardless of the type of patient activity.

The study of time courses of the fluid distribution between the primary and secondary dressings (Figure 3B) revealed that the fluid sharing process between the dressings in the pairs initiated between 5 and 10 hours after application of the dressings and the sharing grew subsequently. However, consistent with the results reported above, the performance of gelling fibre dressing products produced by different manufacturers was remarkably different in this fluid sharing aspect as well. Specifically, the Exufiber Ag + primary dressing delivered greater fluid volumes for absorbency and retention by the secondary foam dressing, approximately 2-fold and 1.5-fold the amounts of the exudate simulatant at the 10- and 15-hours time points, respectively, compared to the comparator dressing pair (Figure 3B). Again, the more fluid that is transferred from the primary gelling fibre dressing to the secondary foam dressing, the greater is the available capacity of the primary dressing for handling newly secreted exudate. Overall, all the above experimental results demonstrated that the fluid management performance of wound dressings depend on the specific dressing materials and composition, which are naturally unique to each dressing manufacturer and brand. This further indicates that there are optimal and less optimal choices of primary-secondary dressing combinations, even if the primary dressing is defined as a “gelling fibre dressing” and the secondary dressing is foam-based; not all dressings belonging to the same family of products are made equal (Figure 3B).

#### 4.4 | The ability of gelling fibre dressings to remain fully intact during removals

Wound dressings are designed primarily to absorb and retain exudates, yet, it is vital that used dressings maintain their mechanical strength and structural integrity while in the wound and importantly, when they are being removed from the wound for a dressing change. The latter requirement is challenging to meet from a

materials engineering perspective because, at the instant of removal, the dressing is typically exposed to an intense, instantaneous tensile force applied by either the gloved fingers of the wound care clinician or by means of the forceps they are using, both of which result in stress concentrations in the dressing at and around the grip site. This occurs after the dressing was exposed to the aggressive wound environment for days, including the wetness with non-neutral pH, various enzymatic agents and elevated (above-room) temperatures. If a dressing disintegrates upon removal (or prior to that, e.g., because of the occasional forces that apply on the wound because of accidental rubbing with an object, or as a result of the bodyweight forces), macroscopic or microscopic residues of the dressing materials may remain in the wound cavity. Any dressing debris left on the wound surfaces, or which migrates into the wound bed, may result in a “foreign body response”<sup>81</sup> which prolongs the inflammatory phase and consumes biological resources of tissue-repairing cells and proteins, thereby delaying the wound healing.<sup>44,49,50</sup>

In the above context, the Exufiber dressing demonstrated superior durability and moreover, a desirable, “rubber-like” material behaviour under tensile loading, as opposed to the “peak-and-drop” failure pattern for the competitor gelling fibre dressing (Figures 4 and 5A). The microscopy image analyses (Figure 6), conducted for the silver-containing versions of the PVA-based versus the CMC-based dressings, helped clarifying the reason for these distinct failure behaviours of the two tested product types from a structure–function perspective, specifically pointing to the distinct directionality of the visible fibres in the two dressings as the underlying cause for the above difference. The PVA-based Exufiber Ag + dressing did not exhibit a specific directional preference of its visible fibres, thereby indicating low dependence of its strength on the direction of pulling. Contrarily, the CMC-based silver-containing dressing, for which the microscopy image analyses did demonstrate a strong directional preference associated with its weave structure, specifically towards the visible reinforcing seams of this dressing type (Figure 6B), has a strong preference for strength that is aligned with the direction of its visible seams and fibres. The durability test results were indeed consistent with the aforementioned microscopy findings (Figure 6A), demonstrating poor mechanical strength of the CMC-based dressing when the direction of the pulling forces did not fully align with that of the visible reinforcing seams and fibres (Figure 6A). Of note, in clinically relevant, real-world scenarios, a clinician removing a primary gelling fibre dressing by pulling it out of the wound cavity cannot be aware of the directional strength preference of the used dressing, or the primary orientation of

its fibres because the dressing is folded within the cavity and much of it is not visible, and in addition, it often takes the colour of the exudate which makes it even harder to identify a weave pattern or seams. The CMC-based dressing with the inferior strength (Figure 6A) is therefore more probable to disintegrate in the wound. The likelihood of such dressing failure events may increase further when a wound has undermining, is tunnelled, or has sticky or rough surfaces, implying that the wound care clinician would need to apply greater pull-out forces to release the dressing that needs to be changed.

#### 4.5 | Concluding remarks

The effectiveness of wound dressing performance in exudate management is commonly gauged in simple, non-realistic laboratory setups, typically, where dressing specimens are submersed in vessels containing aqueous salt solutions, rather than by means of clinically relevant test configurations. Specifically, two key fluid–structure interaction concepts: *sorptivity*—the ability of wound dressings to transfer exudate, including viscous fluids, away from the wound bed by capillary action and *durability*—the capacity of dressings to maintain their structural integrity over time and particularly, at dressing removal events, have not been properly addressed in existing test protocols. The present article reviewed the recent published research concerning the development of clinically relevant testing methods for wound dressings by our group, focussing on the realism of the tests as well as on the standardisation and automation of the laboratory measurements of dressing performance. A second objective of this work was to compile the experimental results characterising the performance of gelling fibre dressings, which were acquired using the advanced testing methods described here, to demonstrate differences across products that apparently belong to the same “gelling fibre” family, but differ remarkably in materials, structure and composition and, thereby, in performance. We conclude that not all wound dressings belonging to the same family of products are “born equal,” which requires product-specific performance evaluations relevant to the wound aetiology that the dressings should treat, or, if the products are intended to function in combination, such as for primary and secondary dressings, then the combined performance should also be measured.

Future laboratory research to improve the robotic phantoms of cavity wounds described here may include robotic variants of additional wound aetiologies such as VLUs or burns; embedding more sensor types in the simulated wounds such as pH sensors and improvements in

the exudate-like fluids used with the robotic systems. For example, as the fluid handling properties of wound dressings are most likely to be affected by both proteins and electrolytes, developing new test fluids that contain combinations of proteins and salts is a useful research direction to pursue. For calibrating such test fluid properties against the real-world biophysical properties of wound exudates, particularly their viscosities for different wound aetiologies, investigations of native wound fluids should be conducted in parallel, to be able to represent the range of viscosities seen in typical clinical settings. A next step can be to incubate bacteria in the test fluids, for future testing of the behaviour of bacterial cultures in the wound dressing microstructure and the performance of silver-containing, anti-microbial dressings in the robotic phantoms. Such bacteria can be selected from those that are safe to eat, e.g., those used for producing yogurt or cheeses (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*), as the growth of these bacterial species has been shown to be inhibited by silver nanoparticles.<sup>82</sup>

In closure, the recent developments of robotic wound phantoms which are reviewed here, and the associated standardised experimental platforms and protocols, facilitate investigations of dressing performance under clinically relevant scenarios, where the dressing technologies interact with the wound aetiology and the related clinical practice. The methods and systems described here offer a high degree of realism of performance testing with respect to all prior art. The current tests further reflect technological progress, enabling the incorporation of evaluations of primary/secondary dressing pairs, according to how they are being used clinically, and as opposed to some of the oversimplifying testing procedures where dressings are evaluated in isolation (e.g., by soaking them in vessels that contain aqueous solutions). The innovative robotic phantom studies reported here are pivotal for improving the decision-making process of clinicians, hospital administrators and regulatory personnel, by basing their choices of wound dressings on quantitative efficacy research, rather than on marketing assertions. This should improve patient safety, the effectiveness of treatments and the overall quality of the delivered wound care.

#### ACKNOWLEDGEMENT

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#### DATA AVAILABILITY STATEMENT

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

## ENDNOTES

\* Ductility is the degree to which a material can sustain plastic/irreversible deformations and continue to absorb strain energy under tensile loading before a catastrophic failure occurs.

† Tortuosity is the ratio of the length of a flow path between two points in the absorbent material to the corresponding straight-line distance, which relates to the porosity and interconnectivity in the microstructure of the absorbent material. For all practical porous materials,  $\lambda > 1$ .

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