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Fluid management and strength postsimulated use of primary and secondary dressings for treating diabetic foot ulcers: Robotic phantom studies

Adi Lustig | **Amit Gefen**

Department of Biomedical Engineering, Faculty of Engineering, Tel Aviv University, Tel Aviv, Israel

Correspondence
Amit Gefen, The Herbert J. Berman Chair in Vascular Bioengineering, Department of Biomedical Engineering, Faculty of Engineering, Tel Aviv University, Tel Aviv 6997801, Israel.
Email: gefen@tauex.tau.ac.il

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Mölnlycke Health Care, Gothenburg, Sweden

Abstract

Non-offloaded diabetic heel ulcers and the wound dressings used to treat them may be subjected to considerable bodyweight forces. A novel robotic foot phantom with a diabetic heel ulcer was designed and constructed to test the combined performances of applied primary and secondary dressings, in simulated non-offloaded (standing) and offloaded (supine) postures. We specifically compared the performances of the primary Exufiber dressing (Mölnlycke Health Care) combined with the secondary Mepilex Border Flex dressing (Mölnlycke) against a corresponding pair from an alternative manufacturer. Fluid retention and distribution between the primary and secondary dressings of each pair were determined using weight tests, and mechanical strength of the primary dressings was further measured postsimulated use through tensile testing. The Exufiber and Mepilex Border Flex pair performed similarly in the two simulated postures (retention = ~97%), whereas the comparator pair exhibited a 13%-decrease in retention for a supine to standing transition. Furthermore, the Exufiber dressing delivered up to 2-times more fluid to its paired secondary dressing and endured 1.7-times greater strain energy than the corresponding primary dressing before failure occurred. The present robotic foot phantom and associated methods are versatile and suitable for testing any dressing, in consideration of the relevant clinical factors and practice.

KEYWORDS

exudate absorption and retention, laboratory testing standards, material durability, non-offloaded diabetic heel ulcer model, wound dressings

Key messages

- diabetic foot ulcers and the applied dressings are exposed to the body forces
- we developed a robotic foot ulcer phantom for simulating such dressing use
- we compared two pairs of primary and secondary dressings using this phantom

- the tested dressing pairs differed significantly in retention performances
- the primary dressing products also differed in the strength post-simulated use

1 | INTRODUCTION

Diabetic foot ulcers are one of the most common and devastating complications of diabetes.[1] With the ongoing spread of the disease, which currently impacts the lives of more than 1 of every 10 Americans, these wounds have become an extreme clinical, social and economic concern and burden.[2-4] Among other tissue damage pathways induced by diabetes, the chronic state of hyperglycaemia causes pathological changes in collagen fibres within the connective soft tissues of the plantar feet; the collagen thickens and fuses, resulting in stiffer plantar tissues with a compromised capacity to effectively dissipate bodyweight loads through tissue deformations.[5] This leads to sustained or repetitive plantar tissue stress concentrations adjacent to bony prominences of the foot at weight-bearing postures and during gait, respectively.[6,7] When combined with the peripheral neuropathy in these patients, which disables their pain signalling that is essential for protecting tissue health and integrity, the intense, concentrated mechanical loading injures the plantar tissues, typically under the calcaneal (heel) bone or the metatarsal heads (toe and forefoot).[1] The skin consequently breaks down, allowing pathogens to penetrate the foot in at least half of the cases,[8] leading to a diabetic foot ulcer in approximately (at least) 1 of 4 diabetic neuropathic patients over a lifetime.[2] Noteworthy, a recent report estimated that this risk has increased to 1 in 3 patients in the last few years.[9]

Foot ulceration is a highly disabling condition and is detrimental to the quality of life of patients and their families. The innate healing processes in patients with diabetic neuropathy are usually delayed, incomplete or uncoordinated as the disease has considerable negative impact on both the vascular and immune (inflammatory) system functions.[1] This leads to frequent hospitalisations and lower-limb amputations.[10-12] The incidence of lower extremity amputations in the diabetic population ranges from 78 to 704 per 100 000 person-years and the relative risk between diabetic and non-diabetic patients varies between 7.4 and 41.3.[13] The escalating costs of treating diabetic foot ulcers have been estimated in 2014 to range from 9 to 13 billion USD annually, in addition to the expenditure associated with managing the diabetes itself.[14,15]

Diabetic heel ulcers (DHUs) are a common type of diabetic foot ulcers, although the exact incidence of heel ulcers in patients with diabetes is still unclear.[16,17] Out of the different possible diabetic foot ulcer locations, the heel introduces substantially greater challenges in treatment and prevention of deterioration into gangrenes or calcaneal osteomyelitis. This is because the anatomical location of the hind foot is constantly exposed to intense, sustained or dynamic and repetitive pressure and shear, corresponding to either standing or gait.[11,18] Of note, although DHUs may be slightly less frequent than metatarsal ulcerations, they are clearly more challenging to treat due to the above reason, with limb salvage success rates that are 2 to 3 times less likely than those seen with diabetic forefoot metatarsal ulcerations.[19] In other words, DHUs constitute a more significant medical problem than diabetic forefoot ulcers. Accordingly, patients with DHUs will preferably have their wounds partially or completely offloaded, by means of an offloading (plantar pressure redistribution) device such as a total contact cast, or by lifting their legs where possible, to alleviate the loads at the wound area.[20] Nevertheless, ambulatory patients are unlikely to comply with complete immobilisation and furthermore, the immobilisation itself is known to increase the risk of thrombosis, muscle atrophy, depression and pressure ulcers elsewhere. Hence, a DHU and any treatment dressing that is applied to its surface will, in fact, be exposed to bodyweight forces.[10,11]

Effective conservative treatment of a DHU, using appropriate wound dressings and an offloading regime where clinically applicable, involves exudate management as a critical component of the care plan. As in any wound, exudate serves as the transport medium for essential molecules and cells involved in the healing process, for example, nutrients, inflammatory mediators, electrolytes, proteases, growth factors and leukocytes. Nevertheless, excess amounts of exudate may disturb the healing,[21] pointing to the fundamental role of wound dressings in maintaining a moist but not wet environment in the wound bed. Adequately performing dressings effectively absorb and retain excess wound fluids, thereby preventing exudate from pooling in the wound cavity which would delay healing, or spillover of the exudate to the wound margins that may lead to maceration of the peri-wound skin, or exudate leakage which can be distressing to patients and care providers.

Gelling fibre dressings are a primary dressing type designed for the above purposes; they are widely used

clinically, among other indications, for treating diabetic foot ulcers.[22] Made from tightly packed fibres of blended superabsorbent materials, gelling fibre dressings absorb excess exudate, causing the dressing material to swell and take the form of a gel which closely conforms to the wound cavity shape. After inserting a gelling fibre dressing into the wound cavity, the common clinical practice is to cover the wound with a secondary, 'bordered' foam dressing (ie, a dressing having a wound contact foam pad surrounded by an adhesive border).[23] The secondary dressing provides an additional reservoir for the exudate absorption and retention; supports the maintenance of a moist environment by preventing dehydration of the wound; prevents excessive heat loss from the wound bed; and protects the wound from further mechanical trauma and pathogens. Therefore, primary and secondary dressings function together, as a pair, which is how their performances should be evaluated in bench testing.[24]

In this study, we developed a novel robotic foot phantom with a DHU, to facilitate complex bioengineering testing of the individual and combined performances of primary and secondary dressings used for treating these wounds. We specifically focused on the synergistic fluid management properties of the primary and secondary dressing pairs under investigation, at simulated non-offloaded (standing) vs offloaded (supine) postures, as well as on the mechanical durability of the tested primary dressings postsimulated use sessions. The present robotic foot phantom and associated test methods are versatile and suitable for evaluating and rating any wound dressing or dressing combinations used or intended for treating diabetic foot ulcers, in consideration of the relevant clinical factors and practice.

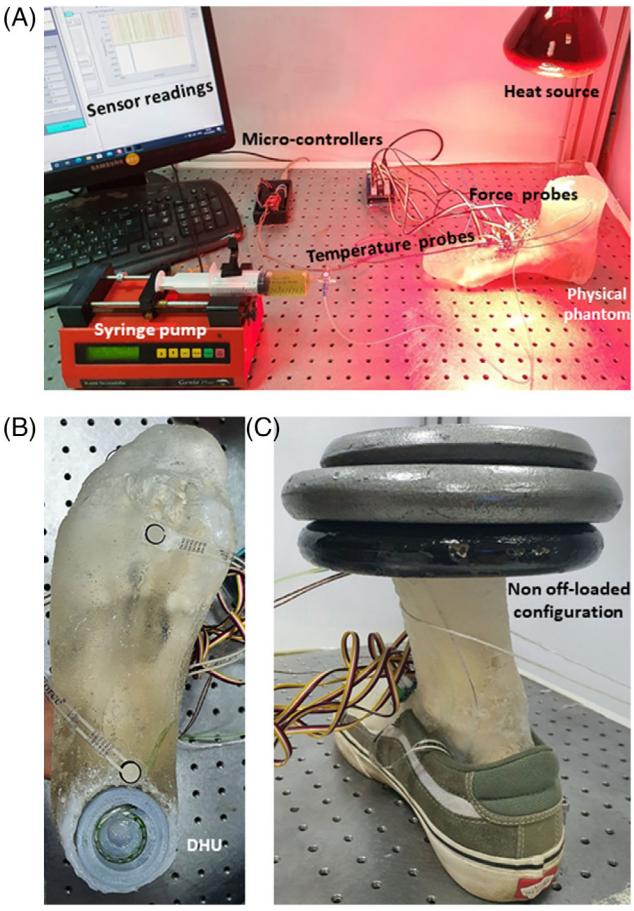

FIGURE 1 The robotic phantom of a diabetic heel ulcer (DHU) and its control setup (A) and example test configurations representing lying without shoes (B) and standing with shoes (C). The phantom system includes an exuding DHU model which allows controlled release of a simulated exudate fluid into the 'wound', so that dressing products and clinical protocols can be tested in physiologically and clinically relevant scenarios which represent real-world mechanical and thermodynamic conditions that may affect dressing performances in fluid management and mechanical integrity

2 | METHODS

2.1 | The robotic phantom of a diabetic foot ulcer

To simulate the clinical use of the investigated dressing combinations (primary and secondary dressing pairs), we have designed and constructed a robotic foot phantom with a DHU (Figure 1A), which was fabricated similarly to a recently reported robotic sacral pressure ulcer phantom developed in our laboratory as described in Reference 24. The current foot phantom system simulates an active DHU in physiologically and clinically relevant scenarios which represent real-world mechanical and thermodynamic conditions that may affect dressing performances in exudate fluid management and mechanical integrity. This robotic foot phantom includes rigid plastic replicates of the foot and ankle bones, including the entire foot skeleton and the distal tibia and fibula. The soft tissue substitute was made of two-component silicone rubber (RTV615, Momentive Performance Materials Inc, Waterford, New York) which had been cast in the shape of the foot of an adult male (with foot length that is equivalent to a shoe size of 42.5EU/8.5UK/9US). The elastic modulus of the aforementioned silicone was measured through uniaxial unconfined compressive testing (Instron electromechanical testing apparatus model 5944, Instron Co, Norwood, Massachusetts) and found to be 2.5 MPa. A cylindrical cavity was carved into the plantar heel region of the foot phantom, directly under the calcaneus bone replica, to a depth of 2 cm which exposed the (plastic) calcaneus, thereby simulating a grade-3 DHU as defined by the Wagner and the University of

Texas classification systems.[25-28] Within the above-mentioned cavity, we placed a 3D-printed custom-made component, which simulated the exuding wound bed. This wound bed simulator had a truncated conical shape, forming a crater-shaped 'wound' 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).

To simulate the continual exudation of the above DHU model, a spiral perforated irrigation tube was incorporated in the 'wound bed' and tunnelled through the phantom structure to connect to an electromechanical syringe pump (Genie Plus model, Kent Scientific, Torrington, Connecticut). This setup facilitated pre-defined, controlled release of exudate-substitute fluids into the simulated DHU. The effective wet surface area of the simulated wound bed was approximately 13 cm^2. The margins of the simulated DHU were not irrigated, that is, the minimal irrigation depth was ~1 cm. The simulated DHU described above, including its effective wet area and irrigation depth, is consistent with descriptions and presentations of DHUs documented in the clinical literature.[29-31]

A safe and reproducible exudate substitute fluid formula, formerly developed in our laboratory,[24] was used to simulate the exudation of the above DHU in the foot phantom system. The formula for the exudate substitute facilitates control of the fluid viscosity and pH and specifically contains food-standard Xanthan gum powder at a concentration of 0.1%, mixed with distilled water and a green food dye (for visualisation purposes). This formula, as used in the present study, resulted in fluid viscosity of 0.23 Pa·s, density of 1.01 g/cc and pH of 5.5 which are all representative of protein-containing biological fluids reported in the literature.[24]

The temperature, to which the DHU in the robotic phantom and the tested dressing products were exposed to during the simulated use periods, was also controlled and monitored. This is an important consideration in representing real-world use of dressings given the effects of temperature on fluid viscosity, flow regime and the material behaviours of the dressings under investigation. An infrared lamp was therefore stationed above the foot phantom as a heat source (Figure 1A), using an adjustable setup that allowed tuning of the simulated wound cavity temperatures within the range of 31°C to 35°C, as reported for diabetic foot ulcers monitored through infrared thermography.[32,33] Three thermocouples were embedded around the simulated DHU to monitor the spatial temperatures and record these to the controlling computer once per second (1 Hz).

Lastly, to simulate the physiological bodyweight loads acting on the DHU of a standing person, we placed weights on top of the foot phantom (Figure 1C) corresponding to a body mass of 60 kg. Seven flexible, paper-thin resistive force sensors (FlexiForce, Tekscan Inc, Boston, Massachusetts) connected to a microcontroller board (Arduino-mega 2560, Ivrea, Italy) measured the effective reaction forces applied on the DHU region during the above 'standing' tests (Figure 1A). Five of these sensors were embedded within the cast silicon beneath the calcaneus bone replicate, another sensor was attached at the planter hindfoot (adjacent to the DHU and towards the posterior arch) and the remainder sensor was attached to the plantar forefoot (Figure 1B). All these sensors were pre-calibrated using precision calibration weights to obtain the resistance-weight (Ω/Kg) calibration curve for each sensor. Force measurements were also conducted continuously during all experiments at a sampling frequency of 1 Hz.

2.2 | Simulated treatments of the DHU

2.2.1 | Dressings

In the experiments reported below, we tested the individual and combined performances of a primary and secondary dressing applied to the DHU in the robotic foot phantom for a simulated treatment period, to allow the primary and secondary dressings to function together as a synergistic fluid retention system. Specifically, we used the commercially available Exufiber primary gelling fibre wound dressing (Mölnlycke Health Care AB, Gothenburg, Sweden) combined with the secondary multi-layer absorbent foam dressing Mepilex Border Flex (also manufactured by Mölnlycke Health Care AB). We compared the performances of the above dressing pair to a pair of a primary gelling fibre dressing and secondary multi-layer absorbent foam dressing from a different market-leading manufacturer (both these primary and secondary dressings were of the same alternative commercially available brand). The latter comparator dressings are referred to here as the 'other primary dressing' and 'other secondary dressing', respectively.

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

Prior to applying the dressing products to the simulated DHU, we weighed the new out-of-package dressings and documented their initial (dry) weight. We then cut the primary dressing to fit the 'wound bed' of the DHU and fill the wound cavity as in clinical practice, following which the DHU was covered with the corresponding secondary dressing (of the same manufacturer).

In experiments simulating supine lying, the foot phantom was positioned accordingly without a shoe (Figure 1B), whereas in the tests representing standing with shoes, a casual walking sports shoe was put on the robotic foot phantom and the phantom was then positioned in a 'standing', non-offloaded configuration on a rigid table (Figure 1C). A set of weights was then added onto the tibia and fibula replicates to simulate weight-bearing standing, so that the force readings near the DHU were in the 5 to 10 kg range. Finally, the foot phantom system was activated after setting the flow rate of the simulated exudate to 1.5 mL/hour, corresponding to 2.7 mL/cm^2/24-hours which is representative of moderately to highly exuding foot ulcers.[28,34] The duration of the simulated use was 5 hours across all tests. The tests were repeated six times for each primary and secondary dressing pair.

2.3 | Testing the dressings postsimulated use

2.3.1 | Retention and fluid distribution tests

Following each simulated use session, both the primary and secondary dressings were removed and reweighed. Next, any excess simulated exudate which remained in the wound bed was carefully collected using dry gauze pads. The total exudate volume (TEV) was then calculated, as the fluid volume retained in the primary dressing (the wet minus dry dressing weight divided by the fluid density) plus the fluid retained in the secondary dressing and the remaining fluid collected from the wound bed. The calculated TEV was always lower, by 12% on average, than the theoretical TEV which is the product of the flow rate and simulated use time, due to evaporation and residual fluid in the tubing of the foot phantom system.

We determined the fluid retention in the primary and secondary dressings (considered together) after the simulated supine lying or standing sessions as the wet minus dry dressing weight difference divided by the fluid density. We then further evaluated the distribution of the retained fluid mass between the primary and secondary dressings of each pair (ie, brand) type, per each test, as the ratio of the fluid volume retained in each dressing (primary or secondary) over the total fluid retained by the pair of dressings in the respective test.

2.3.2 | Material strength tests

The two primary dressing types under investigation were tested for their tensile strength immediately postsimulated use, by means of the abovementioned electromechanical material testing system and following the ASTM D-638-14 testing standard. A load cell with capacity of 2 kN was used for these tests. Dressing specimens, prepared according to the aforementioned testing standard, were stretched at a 50 mm/minutes deformation rate until ultimate failure (ie, total rupture) occurred. Stress–strain curves were then plotted, based on the recorded force-deformation data. The strain energy density (SED) to failure,[35] that is, the area under the stress–strain curve until the first major failure event (defined as a minimum of 10% sudden decrease in the stress level) was calculated for each tensile test, using a dedicated computer code (Matlab software suite ver. R2019b, MathWorks, Inc, Natick, Massachusetts).

2.4 | Statistical analyses

Descriptive statistics of the following outcome measures were determined as means ± SDs and compared between the two types of the dressing pairs and the two postures of the foot phantom: (a) fluid retention in the primary and secondary dressings; (b) the distribution of fluid mass between the primary and secondary dressings; and (c) the SED-to-failure of the primary dressings post the simulated use. Two-way analysis of variance (ANOVA) tests, followed by post hoc Tukey–Kramer pairwise comparisons, were used to statistically compare the above outcome measures between the possible combinations of dressing pair types and phantom postures. The level of statistical significance was set as $P < 0.05$.

3 | RESULTS

Fluid retention in the primary and secondary dressing pairs and the distribution of the fluid mass between the primary and secondary dressing postsimulated use, for the dressing pairs which have been tested here, are shown in Figure 2. A comparison of the retention performances between the investigated dressing combinations after 5 hours of simulated use in the standing and supine positions (Figure 2A) demonstrated superior performances of the Exufiber and Mepilex Border Flex pair, over those of the comparator combination, for both foot postures. Specifically, when the foot phantom was used in a standing configuration (ie, the simulated DHU was in a non-offloaded position), the direction of the fluid flow aligned with the gravity vector, effectively causing the simulated exudate fluid to be pulled directly onto the primary dressing. Under these 'standing' test conditions, the dressing pairs should theoretically have presented

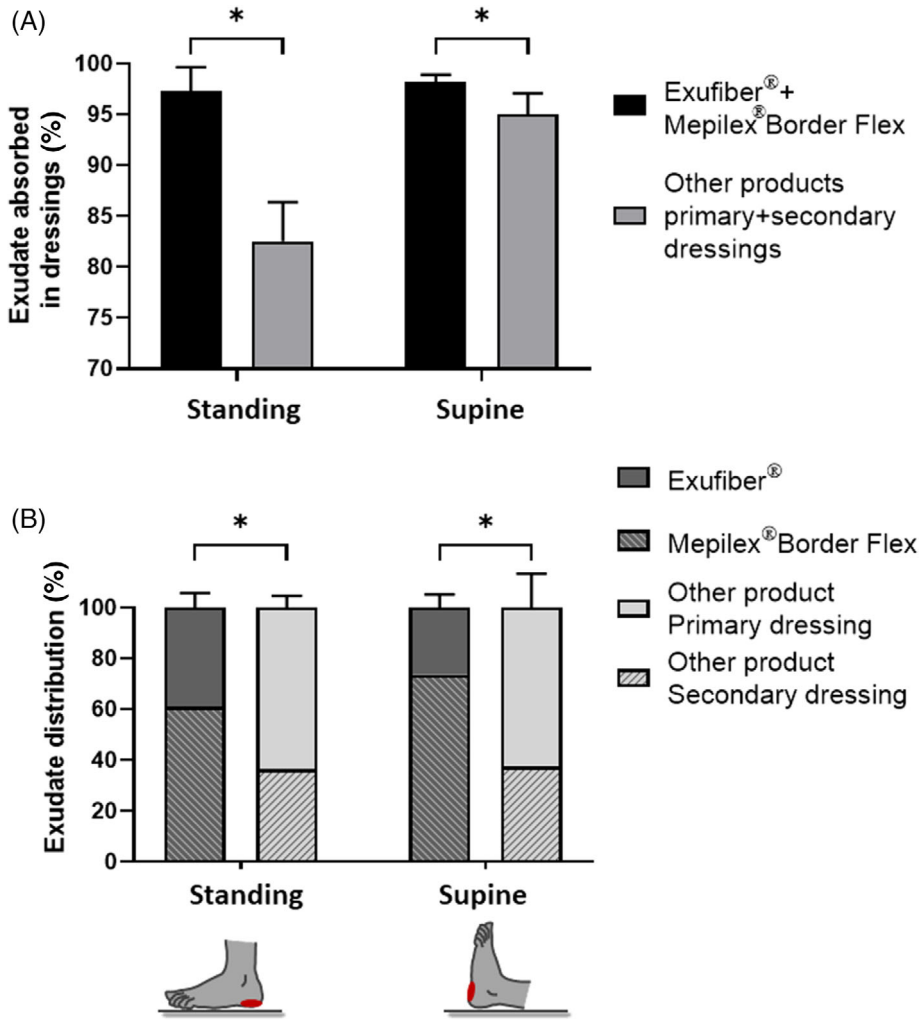

FIGURE 2 Fluid management data for the tested dressing pairs: A, Fluid retention in the primary and secondary dressings (considered together) after the simulated standing or lying sessions. Values are the percentages of the total fluid mass delivered to the simulated diabetic heel ulcer. B, The distribution of fluid mass between the primary and secondary dressings. Values are the percentages of the total retained fluid mass in the pair of the primary and secondary dressings after the simulated standing and lying sessions. Each simulated use session lasted 5 hours and tests were repeated six times per test condition. The error bars are the standard deviations and asterisks indicates $P < 0.05$

their best fluid handling performances, as there is no need for capillary action or active transfer of exudate fluids by the dressings rather than a simple absorption process. In this testing scenario, the Exufiber and Mepilex Border Flex pair retained 97.3 ± 2.3% (mean ± SD) of the exudate substitute fluid, compared with the fluid retention of 82% ± 3.8% in the other pair, which was a statistically significant difference ($P < 0.05$; Figure 2A). Positioning the foot phantom to represent supine lying demonstrated a similar trend with greater (98.2% ± 0.7%) retention for the Exufiber and Mepilex Border Flex dressing pair than for the comparator pair for which the retention (95% ± 2.1%) was likewise statistically significantly lower ($P < 0.05$; Figure 2A).

Importantly, in the 'standing' test configuration, the applied weights representing the body mass (Figure 1C) caused the investigated dressing pair (particularly the secondary dressing which was outside the wound cavity and therefore, directly subjected to the ground reaction forces) to perform under compressive deformations, which may have affected the total retention reservoir of the pair. Of note, the Exufiber and Mepilex Border Flex pair performed similarly in the two simulated postures, whereas the comparator pair exhibited a 13%-decrease in retention for a supine to standing transition, representing, for example, getting out of bed (Figure 2A).

The fluid distribution between the primary and secondary dressings was measured after 5 hours of simulated use, separately for the 'standing' and 'supine' positions (Figure 2B). Following the 'standing' tests, the Exufiber dressing retained 39% of the total fluid and delivered the remainder 61% away from the DHU, into the secondary dressing. The other primary dressing was only able to transport 36% of the fluid into its paired secondary dressing under these simulated standing conditions, thereby leaving substantially more fluid at the proximity of the wound ($P < 0.05$; Figure 2B). Consistently, for the simulated supine position (ie, the off-loaded DHU), the Exufiber dressing retained 26% of the fluid and effectively transferred the other 74% of the fluid into the secondary dressing, whereas the other primary dressing only transported 37% of the fluid to its secondary dressing ($P < 0.05$; Figure 2B).

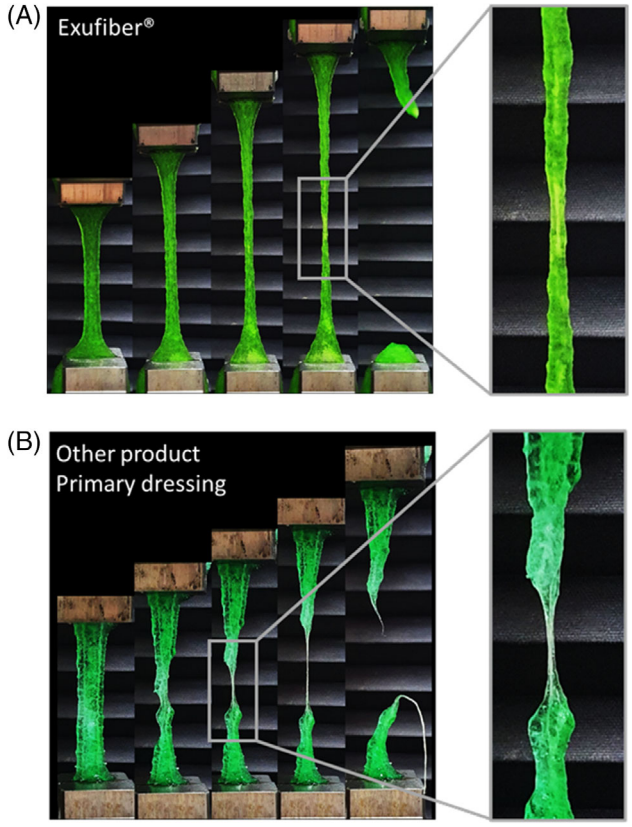

FIGURE 3 Tensile tests documenting the failure behaviours of the two primary dressing types under investigation. The failure regions at the time points where structural integrity of the dressings was lost have been magnified

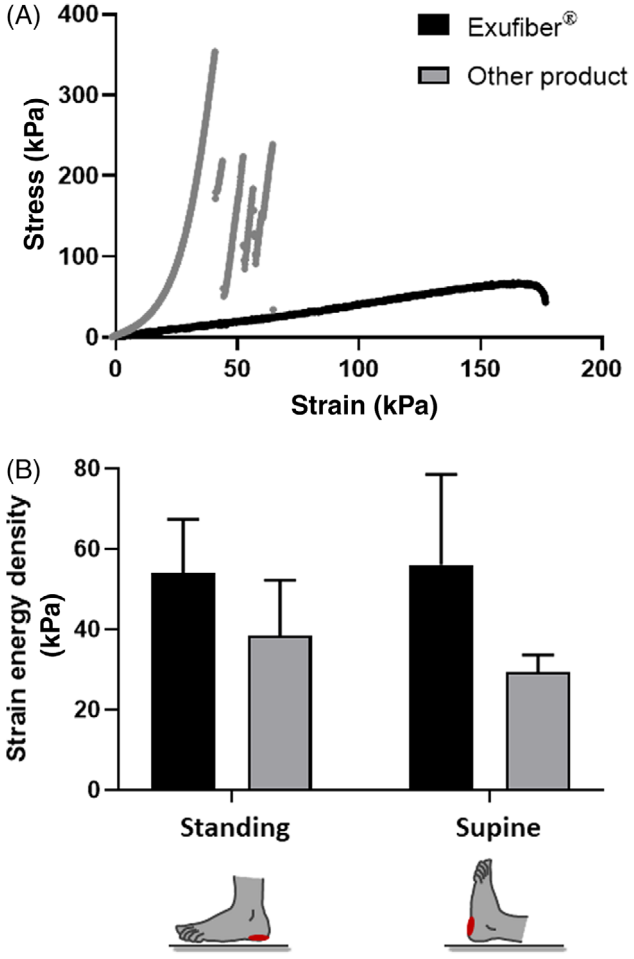

FIGURE 4 The strain energy density (SED) to failure of the primary dressings postsimulated use: A, Example stress–strain curves for the two dressing types under investigation, showing extensibility for the Exufiber dressing vs a rupture pattern caused by a series of fibre tear events for the other tested primary dressing product. B, The SED-to-failure of the two dressing types for the simulated standing and lying test configurations. Each simulated use session lasted 5 hours and trials were repeated six times per test condition. The error bars are the standard deviations

The two primary dressing types, tested for their tensile strength immediately after the simulated use sessions, demonstrated highly distinct mechanical failure behaviours. The Exufiber dressing was shown to be remarkably more extensible and structurally stable postuse with respect to the other primary dressing, which demonstrated an escalating rupture pattern caused by a series of fibre tear events (Figure 3). The latter dressing lost its structural integrity at approximately a quarter of the ultimate tensile strain of the Exufiber dressing (Figure 4A). Also notable is that, once the first fibre bundle had failed, loading the dressing material further caused nearly instantaneous failure of additional reinforcing fibres (Figure 4A), which further broke the absorptive gel that surrounds these fibres and structurally depends on their integrity (Figure 3). The SED-to-failure data consistently showed that the Exufiber dressing had superior strength and, in addition, that the failure strengths of both dressing types were not significantly influenced by the simulated posture (Figure 4B), which justified pooling of the SED-to-failure data for the two postures per each primary dressing type. Comparison of the aggregate SED-to-failure data between the primary dressing types following the above pooling for postures, demonstrated that the Exufiber dressing was significantly, 1.7-times, more durable than the comparator primary dressing ($P < 0.05$).

4 | DISCUSSION

Exudates play an essential role in any wound healing process, by facilitating cell signalling, proliferation, migration and growth, as well as the delivery of protein building blocks (amino acids) for collagen synthesis towards tissue repair. Wounds generally require moisture balance for adequate healing; excessive amounts of

exudate may be irritant, toxic or infectious to adjacent tissues and cause maceration of peri-wound skin, resulting in deterioration of the wound.[12] Any excess exudate should therefore be absorbed and retained by means of an effective wound dressing 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, for mechanical and contamination protection as well as for additional fluid management. In such configurations, the role of the primary gelling fibre dressing is to continuously absorb, retain and transfer (to a secondary dressing) secreted exudates, while inducing an adequate hydration balance in the wound bed, through the moist gel-like consistency of the dressing. The further use of secondary bordered dressings provides an additional reservoir for fluid absorption and retention for exudate delivered from the primary dressing through gravity-driven flow or capillary motion (sorptivity), depending on the body posture and activity (Figure 2).[24,36] Combining a primary and secondary dressing reduces 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 dressings function synergistically.

Poorly performing dressings or dressing pairs may cause suboptimal moisture balance, excessive tissue temperature changes, mechanical damage to tissues, foreign body reaction to debris from disintegrated dressings or a combination of these unwarranted events.[23] Any and all these factors have potential consequences on patient safety and wellbeing, progression of healing (or the lack of), the quality of care and the treatment costs. It is therefore surprising that laboratory testing to evaluate the fluid management performances and mechanical integrity and endurance of wound dressings, for example, the commonly used European EN 13726 family of standards for wound dressings[37] typically neglects the physiological and clinical aspects that determine the environment in which dressings function. Among the topics that are ignored in the abovementioned and similar testing standards are: (a) the anatomical configuration relevant to the wound; (b) physiological levels of mechanical forces that may impact on the wound and dressings during usage; (c) the directionality of flow from the wound bed into the applied dressings; (d) the biophysical behaviour of the exudate which may be viscous, not watery as the sodium/calcium ion 'Solution A', saline or Ringer's solutions that are often used according to the above and similar testing standards and protocols; and (e) the clinical practice of application and removal of dressings (and dressing pairs).[38-40]

To overcome the above limitations of existing testing standards and protocols for dressings used for diabetic foot ulcer treatments, we introduced here a novel robotic diabetic foot phantom that includes a simulated DHU and which is described here for the first time in the literature. This phantom system has been specifically designed and constructed for testing the individual and combined performances of primary and secondary wound dressings that are commonly used for treating diabetic foot ulcers, considering all the above-listed real-world factors which were absent in previous testing methods (Figures 1 and 2). By exposing dressings to an exudate-like fluid and simulating important mechanical, thermodynamic and clinical practice conditions, objective, quantitative, standardised and clinically relevant laboratory comparisons of dressing performances become feasible.

In our recently reported work utilising a robotic sacral pressure ulcer phantom,[24] we introduced for the first time the concept of sorptivity in the context of wound dressings; sorptivity is the ability of a dressing material or structure to transfer a viscous fluid through capillary motion, via its internal porous microstructure.[24,41-43] We established in Reference 24 that good sorptivity of a primary dressing is critical for maintaining excess exudate away from the wound bed, irrespective of the patient position and regardless of whether the direction of the exudate flow aligns or opposes that of the gravity vector. When a pair of primary and secondary dressings functions synergistically, adequate sorptivity of the primary dressing indicates that there is effective fluid transfer from the primary to the secondary dressing so that the absorption and retention capacities of both dressings are used effectively. The more fluid that is transferred from the primary to the secondary dressing, the better the primary dressing can absorb newly secreted exudate from the wound without maxing out its absorption capacity. Suboptimal transfer of exudate from the primary to the secondary paired dressing may lead to a so-called 'plugging effect', in which the primary dressing retains most of the fluid in the system and approaches saturation while the secondary dressing remains relatively dry.[24] A lower share of the secondary dressing in the total amount of fluid retained by the dressing pair indicates a growing likelihood that the primary dressing will become a 'plug' in the wound (Figure 2B). If such a 'plugging effect' occurs, the cumulative reservoir of the dressing pair will not be exploited; also, exudate volume will build up at the interface gaps between the nearly saturated primary dressing and the wound bed, which negatively impacts the healing process.[24]

Individual posture and mobility are critically important when evaluating diabetic foot ulcer dressing performances, as indeed demonstrated in our present findings

(Figure 2). While offloading is a fundamental treatment approach for patients presented with diabetic foot ulcers,[20] not all foot ulcers are off-loaded and even those which are offloaded are not offloaded continuously, for example, when transferring out of bed to a standing (or sitting) position, ambulatory patients are likely to be at least partially weight-bearing on their plantar wound, even if they would normally use an offloading device. Moreover, the percentage of patients without any offloading devices has been reported to be on the rise.[44] Non-offloaded diabetic foot ulcers, and DHUs in particular, are exposed to considerable mechanical forces, exceeding two-times the bodyweight at each heel-strike event (which is equivalent to fourfold the loading magnitude applied in our present study to represent a two-legged standing posture).[11] These intensive bodyweight forces require the applied dressing pair and specifically, the secondary dressing attached to the plantar foot surface to be able to perform satisfactorily under the large compressive deformations associated with real-world usage. An important observation in this context is that the Exufiber and Mepilex Border Flex pair performed similarly (ie, with no statistically significant difference) in the two simulated postures, standing and supine, retaining approximately the same fluid masses and volumes released by the simulated DHU (~97%). Contrarily, the comparator pair exhibited a significant (13%) decrease in fluid retention of the pair for a standing position (where the secondary dressing was deformed), with respect to the retention of this pair for the supine lying position (Figure 2A). The above difference between the performances of the two investigated dressing pairs serves as an excellent example for why dressings should generally be assessed in a clinically relevant context, reflecting real-world usage scenarios and clinical practice, so that the synergistic function of the dressing pair is measured (Figure 2), as opposed to examining each dressing in isolation.

Other than exhibiting adequate fluid absorption and retention across varying body conditions and postures, it is essential that dressings remain intact at all times while in use or during application or removal. The latter requirement is the most challenging one to meet from an engineering design perspective, since at the time of removal, the dressing materials have experienced prolonged exposure to aggressive exudates having non-neutral pH and which contain enzymatic agents (for periods of hours to days), at above-room (wound and peri-wound) temperatures. Moreover, intense localised mechanical forces act on a dressing during removal, by either the forceps or the gloved fingers of the healthcare professional, at the grip sites. Nevertheless, a dressing must not disintegrate at such times, to avoid an adverse event where macroscopic or microscopic residues of the dressing materials are left in the wound bed. Any dressing debris that remains in the wound bed may result in a 'foreign body response',[45] characterised by persistent inflammation, macrophage infiltration and fusion to form foreign body giant cells, followed by fibrotic capsule formation. This cascade prolongs and/or intensifies the inflammatory phase and therefore, delays the healing. In this regard, we found that the Exufiber primary dressing was substantially more extensible and endured 1.7-times greater mechanical loads up to failure with respect to the comparator (Figure 4B).

The above remarkable difference in postuse mechanical strength between the two tested primary dressing products relates to their distinct structures. The Exufiber dressing does not rely on reinforcing fibres for its structural strength (Figure 4A). The other primary dressing, however, fully depends on fibre reinforcement, resulting in a classic composite material behaviour where the (moist) matrix cannot bear loads on its own and hence, with each ruptured fibre, the stress in the dressing suddenly drops and rises again on the remaining intact fibres, leading to tearing of additional fibres and so on and so forth, until total failure occurs (Figures 3B and 4A). As the gel matrix of the comparator product is clearly unable to tolerate mechanical stresses by itself and completely depends on the reinforcing fibres for structural integrity (Figures 3B and 4A), there is a risk for disintegration of the moist matrix, for example, as a result of bodyweight forces acting on the wound area or during dressing removals or both. Noteworthy is that we tested these dressing products by applying tensile forces that were exactly aligned with the direction of the reinforcing fibres, thereby allowing the tested dressings to exhibit their maximal strength. It is highly unlikely that a practicing clinician would pull out a fibre-reinforced dressing precisely along the direction of the reinforcing fibres while removing a dressing for wound cleaning and change. An isotropic primary dressing such as the Exufiber dressing, which does not have any specific directional strength preferences, is highly advantageous in this regard, as it will effectively resist pull-out loads irrespective of the angle and orientation at which a clinician is attempting to extract it from the wound.

To summarise, a robotic phantom of a foot with an active exuding DHU, which mimics multiple relevant mechanical and thermodynamic wound conditions, has been developed here to facilitate complex testing of the performances of primary and secondary dressings used for treating diabetic foot ulceration. This robotic foot phantom was specifically used in order to compare the performances of two commercial dressing pairs in simulated standing and supine positions. The foot phantom

facilitated investigations of the sorptivity of the two studied primary dressings and the synergy in fluid handling when coupling these primary dressings with their matching secondary dressings, at the simulated non-offloaded and offloaded foot positions. The tested dressing pairs and the primary dressing products demonstrated remarkable differences in fluid management and postuse mechanical strength, respectively, pointing to the unique structure-function properties of each product (and pair) and also, to the need for more clinically relevant testing standards. Gelling fibre dressings are not all made the same and likewise, foam dressings each have their unique structure and composition related to the engineering design and manufacturing techniques which are always product-specific.[46] Accordingly, dressings belonging to the same family of products, for example, gelling fibre or foam, would still exhibit distinct features and efficacy outcomes. Evidence-informed clinical decision-making must always rely on published, peer-reviewed quantitative data detailing these product-specific features and efficacy parameters. It is further essential that all bioengineering laboratory measurements of these product specifications are made clinically relevant and reflect the pathophysiology of the patient and wound and the appropriate clinical practice of treatment. Our recent approach of using robotic phantoms of wounds[24,36] has proven to be extremely effective for this purpose and should therefore be used in newly developed testing standards for wound dressings.

DATA AVAILABILITY STATEMENT

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

ORCID

Amit Gefen https://orcid.org/0000-0002-0223-7218

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