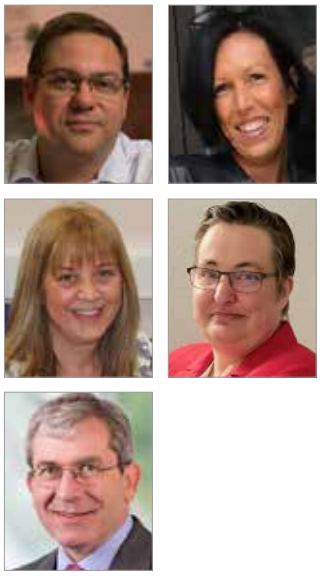
Round table discussion: cellulose fluff dressings — a new dressing technology in pressure ulcer



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Pressure ulcers (also called pressure injuries in the US, Canada and Australia) may develop from beneath the skin, can present themselves rapidly and cause skin and underlying tissue breakdown (European Pressure Ulcer Advisory Panel [EPUAP], National Pressure Injury Advisory Panel [NPIAP], and Pan Pacific Pressure Injury Alliance [PPPIA], 2019; Gefen et al, 2020a), leading to reduced quality of life and increased pain for the patient, plus increasing costs, which potentially can be avoided. These injuries may become life-threatening, for example by leading to sepsis, osteomyelitis or renal failure. Pressure ulcer prevention (PUP) strategies include visual skin assessments, skin care, repositioning and offloading, management of patients' incontinence/excess moisture and optimisation of hydration and nutrition. Recommendations for the use of specific dressings (silicone foam dressings) as a prophylactic to pressure ulcer development have been published and appear in guidelines (Black et al, 2015; EPUAP/NPIAP/PPPIA, 2019). An Expert Panel took place on 20th October 2020 to consider the role of a cellulose fluff core dressing as a prophylactic pressure ulcer dressing. Computer (finite element) modelling of a virtual supine patient suggests that cellulose fluff dressings offer an additional option as a prophylactic dressing (Gefen et al, 2020b).

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Pressure ulcer prevention (PUP) strategies include the identification of pressure ulcer (PU) risk and the application of preventive measures that are individualised for each person. The cornerstones of PUP are routine visual skin assessments, regular repositioning, elevation and offloading of certain body areas (such as the heels depending on clinical judgment), early mobilisation where possible, the use of special support surfaces, positioners and other protective equipment (such as heel suspension boots), and management of co-morbidities and nutrition (EPUAP/NPIAP/PPPIA, 2019). PUP strategies are often led by wound care specialists, but PUP is the responsibility of all clinicians and healthcare staff. PUP requires a multidisciplinary team approach to optimise the patients' conditions, including regular skin inspection and care, dietary support and physiotherapy to help mobilise the patient to the possible extent. There is emerging evidence that the application of dressings with appropriate structure and material composition to areas of the body that are typically at risk of PU, such as the sacral region, may help to prevent PUs. The dressings may reduce friction, shear and pressure, and reduce the likelihood of altering skin moisture to a point where the skin may become fragile and break (World Union of Wound Healing Societies [WUWHS], 2016).

PUP strategies: Challenges in Europe

Efforts to encourage PUP face a number of significant challenges. The Expert Panel identified challenges related to healthcare system funding and clinical knowledge. There is a lack of

awareness in assessing risk of PU development, in correctly identifying PUs and documenting their appearance and progression, which may increase the risk of litigation. PUP is sometimes viewed as low priority and/or is implemented inconsistently within the clinical setting (WUWHS, 2016). International PUP guidelines exist, but non-wound care specialists are not always familiar with such guidance. For example the recently published third edition of the "Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guidelines" (EPUAP/NPIAP/PPPIA, 2019) is available in English, German and French.

A new challenge for PUP in 2020 has been the COVID-19 pandemic. Hospitals and wound care clinics have been overwhelmed, disrupted and/or closed, and, anecdotally, specialist wound care staff have been redeployed to other roles. Guidelines are not easily adjustable, and the implementation of new guidance has not been a priority for services in these changing times. In addition, the rapid set up of wards that exclusively treat patients with COVID-19 and the establishment of emergency/field hospitals in non-medical facilities does not allow straight-forward translation of the preventative protocols and guidelines that were developed prior to the pandemic and did not consider a pandemic situation.

To determine the effectiveness of PUP strategies, including the use of dressings for prevention, the occurrence of PUs needs to be measured so that changes in prevalence can be identified (WUWHS, 2016). Understanding the cost and economic benefit of PUP could encourage healthcare organisations and institutions to prioritise prevention strategies and consider it a worthwhile investment. However, it is typically challenging to accurately identify cost savings against prevention strategies.

PUP strategies: new proposed technologies

PUP technologies to redistribute pressure and shear and alleviate focal loads to at-risk areas of the body (e.g. the buttocks, the heels and other bony prominences). While the range of different technologies can be confusing, variety drives critical thinking. This in turn drives science and efficacy research, leading to published evidence that will eventually support clinical decision-making.

Ideal characteristics of a PUP dressing

A dressing suitable for PUP must protect the skin and underlying soft tissues from mechanical loads and moisture damage.

- **Mechanical loads** – A PUP dressing must share or absorb some of the mechanical loads instead of the skin and underlying subdermal soft tissues, which are subjected to the compressive, tensile and shearing forces associated with the bodyweight (or in some cases, with application of a medical device). When there is effective load sharing by a dressing, there is less load on the skin and within the deeper tissues.
- **Moisture damage** – A PUP dressing must also protect the skin from moisture, such as sweat, urine, faeces or exudate, and ideally, perform equally well when dry and wet. Many parameters of the dressing's structure affect this, including the dressing materials, their organisation within the dressing structure, the thermal conductivity of the dressing materials and the thicknesses of each layer in a layered dressing.

There is currently one family of dressings formally indicated for PUP – the soft silicone multi-layered foam dressings, referred to in the Clincal Practice Guidelines (EPUAP/NPIAP/PPPIA, 2019). Multi-layer silicone foam dressings are available from different manufacturers, and each design has its own material composition, numbers of layers, components and sizes. Gefen et al (2020b) used the well-established finite element modelling computer method (FEM; Box 1) to compare conventional silicone foam dressing designs made by different manufacturers with an alternative dressing design, that of a soft cellulose fluff dressing with a superabsorbent polymer (SAP) core (RespoSorb® Silicone Border/Zetuvit® Plus Silicone Border, Paul Hartmann AG).

Summary of work by Gefen et al (2020b): silicone foam versus cellulose fluff dressing

Dry and moist sacral dressing performances were compared on an anatomically realistic computer FEM of a supine female patient. Rigorous experiments were conducted prior to the modelling work to determine the relevant dressing properties of four silicone foam sacral dressings versus the RespoSorb® Silicone Border/Zetuvit® Plus Silicone Border cellulose fluff dressing:

- **Protective efficacy index (PEI): how much the applied dressing reduces exposure to mechanical loads in soft tissues:** Silicone foam dressings have an approximately stable, steady performance when dry and moist. Cellulose fluff dressings, though, delivered a better load sharing with tissues and received a

higher PEI than silicone foam dressings.

- **Protective endurance (PEN): how effectively the load sharing remains when there is exposure to moisture.** The cellulose fluff dressing had a slightly lower PEN than silicone foam dressings.
- **Prophylactic trade-off design parameter (PTODP % = PEI x PEN): the trade-off performances when one considers the dry and wet performances altogether.** Cellulose fluff dressings performed better than silicone foam dressings. Although cellulose fluff dressings had a lower PEN, they have a higher PEI so delivered a greater PTODP.

The cellulose fluff dressing effectively protected the sacral tissues, and more so when dry with respect to silicone foams (Gefen et al, 2020b). The results by Gefen et al (2020b) also showed that different silicone foam dressings are not equal in their prophylactic performances, but rather, the base technology, the specific material components, and their unique interfaces and arrangement in the dressing structure shape the quality of the delivered tissue protection (Gefen et al, 2020b). Critical thinking and analysis are required to review the potential and possibilities beyond silicone foam dressings.

Box 1. Three-dimensional computational finite element modelling in wound care.

Professor Amit Gefen's laboratory at Tel Aviv University uses advanced computer modelling/simulation approaches and methods to determine performances of dressings and other medical devices in different situations. The human anatomy is reconstructed digitally (e.g. from MRI or CT scan data) and is divided from a complex anatomical structure into an extremely large number of smaller 'elements' (in the order of hundreds of thousands or sometimes millions), which are known as finite elements. This division of a complex body/device structure to small (finite) elements facilitates calculations, made by powerful work stations and dedicated engineering software packages. These calculations are aimed at determining the magnitudes and distributions of the mechanical loads and thermal conditions within the tested dressing (or other device) and also, importantly, within the nearby body tissues, including with regards to how these mechanical and thermal loads change over time or during changing circumstances. For example, when a dressing becomes moist, that can be considered in the computer simulations through a-priori knowledge concerning the changes in the dressing properties (e.g. the stiffnesses of its components) and the effects on the tissue loading state are then calculated. The impact of a technology or the performances of a product (either existing or new) can therefore be assessed. Importantly, the ability to compare technologies in a standardised, objective manner before entering into clinical trials in patients, or the insights gained from the modelling work to interpret results of clinical research, can help to make informed decisions by industry research and development groups, by purchasers and administrators in medical facilities, by regulators and insurance bodies (e.g. health maintenance organisations), and by clinicians in choosing the best dressings for their patients.

What does this mean for PUP?

The finite element computer modelling method maps and quantifies the mechanical loads of each element of dressing (or any other device that contacts the skin) and of the skin and underlying tissues, and in particular, how a dressing or positional aid impacts on the mechanical and thermal loads in tissues. By applying a 'virtual dressing' to a 'virtual patient' in the computer, it is possible to calculate the standardised performances of any dressing in any environment for any patient, and their position, and its impact on the dressing–tissue load share. This is true for commercially available dressings as well as for future dressings under development.

How do we currently classify PUP dressings?

While support surfaces used for PUP are broadly classified as active, reactive or foam, currently there is no classification or agreed definition of a PUP dressing. Clearly, no single dressing can fit all clinical needs, but there are advantages to dressings with multiple indications (e.g. logistics of storage, stock and training on the uses of one dressing type). Silicone foam dressings were originally designed for treatment of, rather than the prevention of, wounds. Compared to dressings utilising acrylic, hydrocolloid and polyurethane adhesives, soft silicone dressings are atraumatic to the wound and the surrounding skin and minimise pain at dressing change and risk of maceration (Rippon et al, 2007). After research conducted nearly a decade ago exploring prevention of surgical PUs by employing the use of silicone based dressings – an innovative concept at the time – it was concluded that at-risk body areas can be protected by application of such dressings on intact, non-injured skin (Brindle and Wegelin, 2012). The use of these dressings prophylactically, alongside other PUP strategies has been shown to reduce the risk of intensive care unit (ICU)-acquired sacral and heel PUs (Santamaria et al, 2015; Hahnel et al, 2020). However, being treatment dressings by their origin, there are some characteristics of silicone foam dressings that are not required for PUP. The group agreed that it would be fortuitous to design a dressing specially for PUP, or to remove features of dressings that are not required for PUP. For example, is a highly absorbent core a necessary requirement for a PUP dressing? Excess moisture is a risk factor for sacral PUs, so a dressing with an absorbent core with strong moisture handling properties alongside continence management could be beneficial. However, an absorbent core might not be necessary when used to prevent PUs on the

heels of patients during surgery or in the ICU. A single-indication PUP dressing would need to perform better than the current multi-indication dressings available. Staff would also have to be educated on the importance of continuing other PUP strategies – even if there is a specifically designed PUP dressing, all other PUP strategies must continue. A dressing alone, as good as it may be, cannot prevent all PUs.

Next steps

The Expert Panel has agreed that a next step for the development of PUP dressings would be to define the ideal characteristics of a PUP dressing. Gefen et al (2020b) has shown that cellulose fluff dressings work equally or outperform some standard silicone foam dressings for sacral PUP. The group also agreed that more work is needed to investigate how a specifically designed, single-indication PUP dressing and 'dual-purpose', multi-indication dressings work with other PUP initiatives, as part of a multi-step approach (e.g. use of support surfaces, repositioning and optimisation of patient hydration and nutrition). Effective PUP requires a combined, multi-disciplinary approach, so a PUP dressing cannot prevent PUs in isolation.

Education is required to reframe the mindsets of clinicians that PUP is as important as treatment. Identifying the specific clinical settings where PUP dressings may be most beneficial will help to target such PUP strategies. Patients in emergency departments and retirement/home care/outpatient facilities are at high risk of PU development. The availability of PUP dressings in these settings is inconsistent. In the community setting, there requires further research, cost-benefit studies and involvement of the outpatient healthcare professional community.

Conclusions

Cellulose fluff dressings, such as RespoSorb® Silicone Border/Zetuvit® Plus Silicone Border, could offer an alternative to silicone foam dressings in PUP as their biomechanical parameters showed they perform equally well (Gefen et al, 2020b). Any prophylactic dressing needs to be part of a multi-disciplinary, multi-factored approach for PUP. In other words, PUP dressings are an additional tool within a PUP strategy, not the magic bullet. The next steps include developing of a clear definition of a prophylactic dressing and understanding the impact of prophylactic dressings alongside other PUP initiatives to improve patient outcomes. Efforts are underway in this regard, for example the Prophylactic Dressing Standards Initiative (PDSI) of the NPIAP & EPUAP for which Professor Gefen is a Co-Chair, has been established (www.epuap.org/prophylactic-dressing; Wound Management & Prevention, 2020). WINT

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