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Meeting report: Addressing risk factors with evidence-based technologies for the prevention and treatment of pressure injuries in different healthcare settings

Implementing evidence-based strategies for the prevention and treatment of pressure injuries (PIs, also called pressure ulcers) that include the use of dressings, positioners, and turning and positioning systems can deliver optimal, cost-effective care to at-risk patients. This meeting report summarises the proceedings of an expert panel-led symposium at the European Wound Management Association (EWMA) Conference, Gothenburg, Sweden, in June 2019, during which the findings of recently undertaken research relating to technologies for PI prevention and treatment were presented.

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The huge economic, health-related and social burden of pressure injuries (PIs) *[Box 1]*, also called pressure ulcers, is well-known and has resulted in considerable global efforts to reduce their occurrence. The key to establishing a comprehensive prevention programme is through the thorough understanding of evidence-based strategies that can be translated and embedded into clinical practice, and that are instilled throughout organisations and across different health care settings, i.e. from acute care to community care.

Latest clinical research into PI prevention

Prophylactic dressings

An international guideline from the National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP), and Pan Pacific Pressure Injury Alliance (PPPIA) (2014) states that clinicians should consider applying a preventive dressing to areas that are subjected to bodyweight forces, such as bony prominences (e.g. heel and sacrum) for the prevention of PIs, *in addition* to (not instead of) standard preventive measures.

Supported by a plethora of published research evidence, Mepilex® Border Sacrum (Mölnlycke Health Care) is a biomechanically and clinically effective preventive option for PIs when used as a component of standard preventive regimens. Professor Nick Santamaria opened the symposium describing the history behind Mepilex Border for PI prevention, which spans nearly 20 years' of work involving in the region of 1000 patients. The journey began with the work of Brindle and Wegelin (2012) who assessed the impact of Mepilex Border dressings on PI formation in intensive care unit (ICU) and cardiac surgery patients in a controlled clinical trial.

Following the positive results reported by Brindle and Wegelin (2012), the 'Border Trial' was undertaken in Australia: a randomised controlled trial (RCT) which investigated the effectiveness of Mepilex Heel and Mepilex Border Sacrum compared to standard care alone in the prevention of PIs. In total, 440 high-risk ICU patients were included, with Mepilex Heel dressings applied to the heels and Mepilex Border Sacrum dressings applied to the sacrum of patients while they were in the emergency department prior to transfer to an ICU. A 10% difference in PI incidence between the dressings and standard care groups was observed (3.1% versus 13.1%, respectively). For every 10 patients treated, one PI was prevented (i.e. the number needed to treat [NNT] equated to 10) (Santamaria et al, 2015a). To put this into context, the NNT for aspirin to prevent

Box 1. Pressure ulcer and pressure injury.

Terminology regarding pressure ulcers/pressure injuries is evolving. The term "pressure injury" is used by the Pan Pacific Pressure Injury Alliance (PPPIA) and has recently been adopted by the National Pressure Ulcer Advisory Panel (NPUAP) (WUWHS, 2016). In the UK, NHS Improvement recently held a consensus event where clinicians voted strongly in favour of using the term "pressure ulcer". For the next version of the International Classification of Disease (ICD-11), the World Health Organization will use the term 'pressure ulceration'.

a further acute myocardial infarction is 1667 (Antithrombotic Trialists Collaboration, 2009).

These results changed clinical practice at The Royal Melbourne Hospital (RMH) in Australia; a 5-year PI prevention project was implemented, which resulted in the prevalence of hospital-acquired PIs decreasing from 6.6% in 2010 to 2.5% in 2014 (Santamaria et al, 2015b), and a relative risk reduction of 65% across the whole hospital. Interestingly, of the remaining 2.5% of PIs, 80% were medical device-related, which has been consistent since 2013. This suggests more bioengineering and clinical work needs to be done to reduce the occurrence of medical device-related PIs.

The 'Border Trial' has now been replicated in different care settings, such as long-term care (LTC) facilities and nursing homes, which are associated with high rates of PI prevalence and incidence (Santamaria et al, 2018). In a study involving 288 patients in a LTC facility, a reduction in PI incidence similar to that observed in the 'Border Trial' was observed with Mepilex Heel and Mepilex Border Sacrum dressings: an 8% difference in incidence between the dressings (2.1%) and standard care groups (10.6%) (Santamaria et al, 2018). Improvements in quality of life (due to a reduction in preventable PIs and associated morbidity and mortality) was also observed. This is especially important for LTC facility residents and the elderly who are at high-risk for PI.

Similar findings have been observed in research recently carried out at the Charité University Hospital in Berlin, Germany, and presented by Dr Jan Kottner ahead of publication. An RCT, similar to the Australian protocol and in-line with the clinical realities of high-risk adult patients throughout the hospital, was conducted. The intervention group had standard preventive care according to local protocol (including risk assessment, skin assessment, allocation of support surfaces) plus dressings applied to the sacrum (Mepilex Border Sacrum) and heels (Mepilex Border Heel), while the control group had standard preventive care only.

Over a 3-year period, 422 patients were included in the RCT and followed up with regards to the primary outcome: PI category II, III, IV, unstageable or Deep Tissue Injury (DTI) to sacrum and/or heel (for more information on the protocol, see ClinicalTrials.gov NCT02295735). The primary outcome was only observed in 2.8% of the intervention group, compared to 11% of the control group. Additionally, the absolute risk reduction of the intervention versus control was approximately 80%. These results are similar to the findings of Professor Santamaria from Australia, and build on the accumulating knowledge and strengthen the evidence-base for the prophylactic use of Mepilex Border dressings for sacral and heel PIs in high-risk patients.

Over 60 publications refer to reductions in PI rates associated with the use of Mepilex Border dressings. The clinical results and cost-benefit analysis have provided implementation teams with strong bioengineering and clinical evidence to support the addition of Mepilex Border dressings to the PI prevention protocol in many facilities. The results associated with the prophylactic use of Mepilex Border dressings cannot be translated to other multi-layer foam dressings, as the dressings are uniquely designed, formulated and structured *[Figure 1]*.

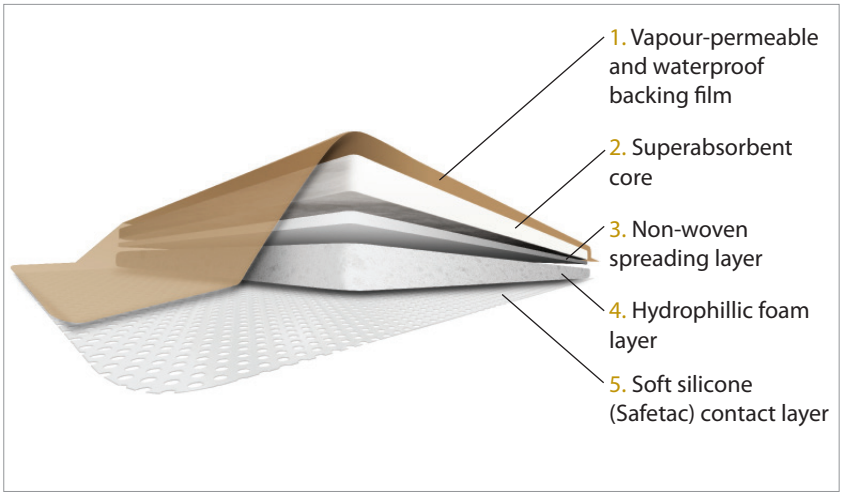


Figure 1. Diagrammatic representation of a multi-layer foam dressing with Safetac (Mepilex Border Sacrum).

Cost-benefit analysis of Mepilex Border dressings for PI prevention

In a cost-benefit analysis undertaken in Australia, treatment costs of patients receiving prophylactic Mepilex Border dressings were 3.6 times less than for those who were not treated with the preventive dressings (Santamaria et al, 2015c). Professor Santamaria referred to the findings (ahead of publication) of a multi-national cost-benefit analysis of Mepilex Border dressings, when used as part of a quality improvement bundle in nursing facilities in the USA and Australia. In the USA, a saving of US$7,915 in treatment costs per patient was determined, equating to US$12.7bn in total cost savings, with similar

Table 1. Comparison of the effectiveness of Mölnlycke® Z-Flo™ Fluidised Positioner and standard pillows in the positioning of patients in a 30 degree position (Kapp et al, 2019).

	Base	1-hour	2-hour
Pillow angle degradation	26.7	21.5	16.6
Positioner angle degradation	30.7	29.3	26.8

P<0.001 for time, angle and combined effect.

cost savings per resident in Australia. Health care costs are expected to increase in the future as population age increases and chronic diseases that increase PI risk, such as diabetes, spread, hence the importance of cost-effective interventions that can reduce PI occurrence cannot be overlooked.

Positioning devices

Repositioning of an individual is undertaken to reduce the durations of exposures to localised pressures and shear stresses on skin and the resulting tissue deformations and distortions over vulnerable areas of the body and to contribute to comfort, hygiene, dignity and functional ability. Positioners are designed to maintain effective positioning and alignment, provide comfort, avoid causing additional pressure and shear, be user friendly and cost effective. Protocols guide that a person should be at a 30-degree angle with the bed in a side lying position (unless inconsistent with the patient's condition and other care needs that take priority). Pillows, wedges or more advanced technologies like fluidised positioners can be used.

Professor Santamaria shared the experiences from the Royal Melbourne Hospital in Australia where a fluidised positioner (Mölnlycke® Z-Flo™ Fluidised Positioner, Mölnlycke Health Care *[Figure 2]*) was compared with standard pillows to maintain patient position. Here, the fluidised positioner provided a significantly improved consistency of the 30-degree angle compared to the pillows (*[Table 1]*; Kapp et al, 2019).

A RCT is to be undertaken at the Royal Melbourne Hospital to determine the clinical effectiveness of a turning and positioning system (Mölnlycke® Tortoise™ Turning and Positioning system *[Figure 3]*) compared to usual care devices for PI prevention in the ICU setting. This builds on earlier published bioengineering research such as magnetic resonance imaging (MRI) studies of sacral soft tissue deformations when the Tortoise system is used (Peko Cohen et al, 2018), and computer modelling of scalp tissue stresses at the occipital region when the head is supported by different head positioners, including the Z-Flo Fluidised Positioner (Katzengold & Gefen, 2018). The final aim is to combine all the bioengineering and clinical research results characterising these preventive technologies in order to determine their efficacy as a bundle, following the approach of Peko Cohen, Gefen and colleagues (Peko Cohen et al, 2018).

Biomechanical efficacy of PI prevention strategies

RCTs are potentially able to statistically confirm that an intervention works, but they cannot explain the mechanisms and modes of action for the clinical outcomes that are achieved. Professor Amit Gefen presented an overview of the scientific rationale and biomechanical efficacy of the Mepilex Border dressings in PI prevention and treatment.

Finite element (FE) modelling, a well-established computer modelling methodology in medical device research and development, is currently being used extensively in the wound prevention and care arena. In PI prevention, in particular, it is used to examine the complex interactions between the skin, deeper tissue layers and the applied dressing, depending on the unique shape, material composition and structure of the dressing, as well as the mechanical forces imposed by the bodyweight and the environment (e.g. friction with the support surface, bedsheets or garments). Since the most serious PIs are DTIs that develop internally, and given that in such cases, the extent of tissue damage is not visible on the skin surface until massive irreversible damage has already been caused, FE modelling can be used to map and simulate the mechanical forces, deformations and stresses that develop internally in the tissues. This helps to identify the specific biomechanical efficacy of the tested dressing design and its role and contribution in prevention strategies that reduce exposure of soft tissues to mechanical loads, which then explains the clinical observations.

The research group of Professor Gefen has also developed and utilised technology to create an artificial controlled pelvis environment, which contains a simulated sacral wound, where every measurement

Figure 2. Mölnlycke® Z-Flo™ Fluidised Positioner.

Figure 3. Mölnlycke® Tortoise™ Turning and Positioning system.

can be controlled and digitally monitored, such as temperature, (substitute) exudate fluid volumes, exudate viscosity, pH, and rate of exudate inflow into the simulated sacral wound bed. With this artificial (phantom) patient, nicknamed the 'Robobutt', primary and secondary dressings, plus the interaction when they are used in combination (as well as the influence of other treatment methods and/or preventative or treatment devices) can be analysed. Dressings can be tested, for example, for fluid retention and the strength of the dressing material after use, and the 'Robobutt' therefore allows to compare between existing and future products, as well as product bundles and treatment protocols.

Dressings should be designed to follow the 'Goldilocks rule'. That is, they should not be too stiff, nor too soft, and should be compatible in their structure and stiffness behaviour with the body anatomy, tissue composition and the expected principal directions of the bodyweight forces (Schwartz and Gefen, 2019). A dressing that is too soft will not shield the body tissues from excessive deformations, as it will transfer the (nearly) full extent of the distorting forces to the tissues, instead of absorbing the majority of these forces within the dressing structure in order to protect the tissues. A dressing that is too stiff will over-shield the tissues, in the sense that it may minimise tissue distortions under the centre of the dressing, but at the same time inflict focal, localised tissue distortions at the perimeter of the dressing, since its stiff nature is unable to conform to the body contours, and, therefore, will indent the tissues and create stress concentrations at the edges of the (stiff) dressing. Likewise, a dressing needs to have a balanced fluid retention capacity — not too little, as excess exudates compromise tissue integrity and viability, and not too much, as the wound bed needs to be moist to allow repair. Overall, the design of a good dressing should bridge the continuum between prevention of further damage and treatment of the existing wound itself.

Mepilex Border in clinical practice

Professor Paulo Alves rounded off the symposium with a series of case studies showcasing the role of Mepilex Border in PI treatment *[Box 2]* . In the hospital setting, PI prevention begins at admission and ends at discharge, where there is the support of the multidisciplinary team and regular monitoring and reviews.

It can be a challenge to prevent and treat PIs once patients return to the community, where resources may be minimal and the latest tools not always available. Professor Alves presented cases of patients who had developed PIs following discharge, and the strategies and treatment plans implemented to treat and prevent further damage.

Conclusion

Professor Joyce Black summarised the session. Published bioengineering as well as clinical research evidence for the effectiveness and efficacy of PI prevention strategies, including the use of prophylactic Mepilex Border dressings, positioners and turning systems, continues to grow. Figures suggest that such interventions reduce cost significantly while also improving patient outcomes and quality of life (Santamaria et al, 2015a; 2015b; 2015c), which is also evident in the case studies presented here.

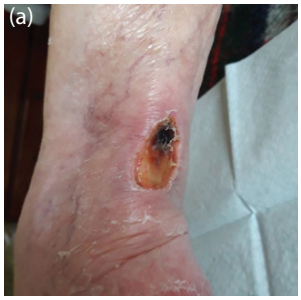
Box 2. Case studies courtesy of Paulo Alves.

Case 1: Medical device-related PI

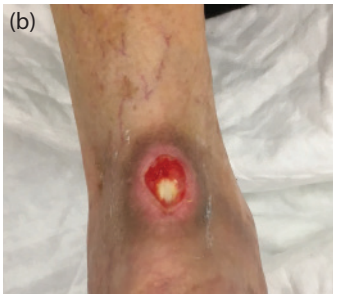
A 75-year-old female with a complex vascular and pulmonary history had a 6-day hospital stay after orthopaedic surgery. On post-operative day 3, there were signs of a category IV PI on the left Achilles tendon. Pre-surgery, she was mobile and independent in daily life activities; however, on discharge she had a long period of immobilisation.

Four months later, the PI measured 5cm x 2cm with necrotic tissue and a macerated periwound skin, which was severely painful. The PI was in a very mobile area that was difficult to dress. Previous dressings had peeled off and there had been fluid strikethrough on the dressing. Sharp curette debridement was performed to prepare the wound bed; Mepilex® Border Flex was used to dress the wound and maintain a moist wound environment.

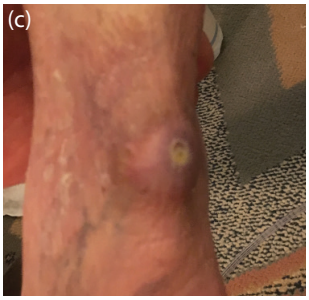
Mepilex Border Flex conformed to the heel and its Exudate Progress Monitor (a grid of equidistant dots that can be used to track and record exudate) helped to determine when a dressing change was required. As the wound progressed to healing and moisture levels reduced, less frequent dressing changes were required. After 5 months of treatment, the wound healed.



(a) Baseline.



(b) Day 1 of treatment with Mepilex Border Flex.

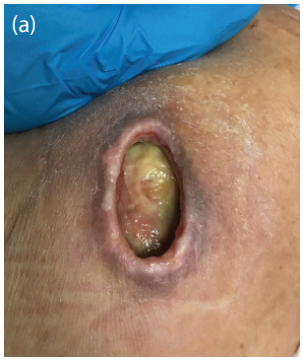


(c) Healed 5 months after treatment began.

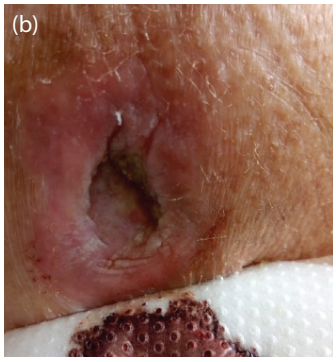
Case 2. Category IV PI on the right trochanter

A 77-year-old female patient developed a category IV PI on the right trochanter. She had had a stroke 6 months ago and was immobile, with joint and muscular rigidity. The patient was dependent on care support for repositioning, which had not been adequate, and she required nutrition supplementation. The PI had evolved over 2 months, and measured 12cm x 5cm with a cavity and tunnelling present.

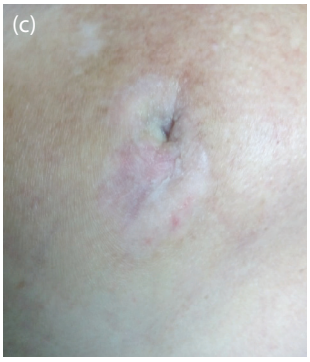
The wound was highly exuding, leading to dressing strikethrough and degradation, so the main aim was to manage exudate while maintaining a moist environment. The cavity was filled with Exufiber® gelling fibre dressing to absorb exudate and transfer moisture to the secondary dressing (Mepilex Border Flex). In the last 2-week phase of healing, Granulox® (Mölnlycke Health Care; a topical haemoglobin-based spray) was used on the clean wound bed. The wound healed after 6 months of treatment.



(a) Baseline.



(b) Four months later.



(c) Healed 6 months after treatment began.

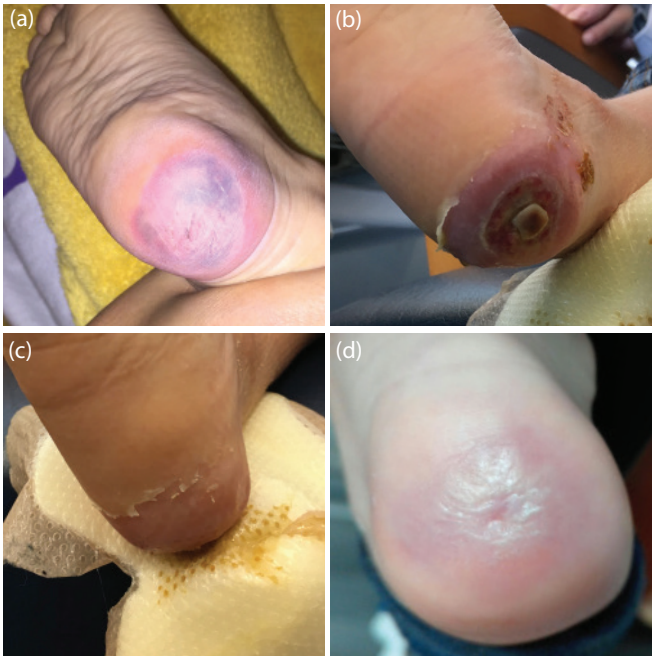
Box 2 cont. Case studies courtesy of Paulo Alves.

Case 3: Category IV PI on heel of young boy

A 20-month-old boy had fractured his tibia and fibula and was in a cast. However, he had stopped walking and reverted to crawling. After 25 days, the cast was replaced with a plaster splint due to severe heel pain. On removal of the cast, a category IV PI on the heel (6cm x 6cm) was identified.

It was difficult to gain parent consent to debride, so Mepilex Border Flex dressings were adapted to conform to the heel. In 3 months, the wound had healed. Over this time, there was a reduction in pain and the child regained trust when walking and running. Parents were able to apply dressings while on holiday.

(a) Baseline.
(b) 1.5 months into treatment.
(c) Adapted heel dressing.
(d) Wound healed 3 months after treatment began.



As this peer-reviewed evidence builds, clinicians are being given the data they need to change current protocols to minimise incidence and prevalence of PI, and to secure much-needed resources for prevention programmes. WINT

Declaration
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