

The Role of Modern Wound Dressings in Stage I Pressure Ulcers and Patients at Risk of Pressure Ulcer Formation

Helen Shaw, BSc (Hons),
ConvaTec Research and Development

Rachel Mathison, Msc, BSc (Hons),
ConvaTec Medical Affairs Manager Wound Therapeutics UKI



Introduction:

“A pressure ulcer is any lesion caused by unrelieved pressure resulting in damage of underlying tissue. Pressure ulcers are usually located over bony prominences and are graded or staged to classify the degree of damage.”¹

Pressure ulcer incidence is sufficiently high, especially among certain high-risk groups, to warrant concern among health care providers. Pressure ulcers can be a frequent and costly problem and are common in acute care, home care and nursing home environments. An estimated 1.3 to 3 million adults have a pressure ulcer and in 2006 a publication stated a cost estimate of \$70,000 to manage each Stage III or IV pressure ulcer. As prevention of this debilitating condition is strongly considered to be less costly than its treatment, guidelines for health care clinicians to prevent and predict pressure ulcer occurrence have been written to provide effective prevention measures and thus reduce the incidence of pressure ulcers.¹

A series of complex internal causative factors dictate the risk of pressure ulcer formation, including:- malnutrition, age, mobility, mental status and neuropathy. Pressure is the external causative factor in pressure ulcer formation, however additional factors such as:- shear forces, friction, moisture and any other factor that may contribute to the loss of skin integrity should also be considered. Whilst these additional factors alone do not account for the underlying tissue damage, they can accelerate ulceration i.e. progression from Stage I to Stage II. Additionally, the loss of barrier function of the skin increases the complexity of clinical care and increases the risk of infection.

The NPUAP (US National Pressure Ulcer Advisory Panel) and EPUAP (European Pressure Ulcer Advisory Panel) have issued a set of guidelines to assist practitioner and patient decisions about appropriate healthcare. Whilst these guidelines may not be appropriate for use in all circumstances, they provide a good consensus on best practice and cover a wide range of recommendations, including:-

- Risk Assessment
- Skin Assessment
- Nutrition and Pressure Ulcer Prevention
- Repositioning for Pressure Ulcer Prevention
- Support Surfaces
- Special Population: Patients in the operating room

The NPUAP and EPUAP have also agreed on a pressure ulcer classification, Table 1² which classifies pressure ulcers on the level of injury as first proposed by Shea.⁵

Table 1:

Category/ Stage I: Non-blanchable Erythema	Intact skin with non-blanchable redness of a localised area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its colour may differ from the surrounding area. The area may be painful, firm, soft, warmer, or cooler as compared to adjacent tissue. Category I may be difficult to detect in individuals with dark skin tones. May indicate “at risk” persons.
Category/ Stage II: Partial Thickness	Partial Thickness loss of dermis presenting as a shallow open ulcer with a red / pink wound bed, without slough. May also present as an intact or open / ruptured serum-filled or sero-sanguinous filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising.* This category should not be used to describe skin tears, tape burns, incontinence associated dermatitis, maceration or excoriation. * Bruising indicates deep tissue injury
Category/ Stage III: Full Thickness Skin Loss	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining or tunnelling. The depth of a Category / Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and Category / Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category / Stage III pressure ulcers. Bone / tendon is not visible or directly palpable.
Category/ Stage IV: Full Thickness Tissue Loss	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present, Often includes undermining and tunnelling. The depth of a category / stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and these ulcers can be shallow. Category / Stage IV ulcer can extend into muscle and / or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone / muscle is visible or directly palpable.
Unstageable/ Unclassified: Full Thickness Skin or Tissue Loss – Depth Unknown	Full thickness tissue loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, grey, green or brown) and / or eschar (tan, brown or black) in the wound bed. Until enough slough and / or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either a Category / Stage III or IV. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as “the body’s natural (biological) cover” and should not be removed.
Suspected Deep Tissue Injury – Depth Unknown	Purple or maroon localised area of discoloured intact skin or blood- filled blister due to damage of underlying soft tissue from pressure and / or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered in eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

Dressings are used in current practice as part of a protocol of care for the management of pressure ulcers. With a wide range of dressings available, the practitioner will make dressing choices based upon many factors including: ability to absorb exudate, debride sloughy / necrotic tissue, barrier properties, adhesiveness and patient comfort. Hydrocolloid and film dressings are indicated for Stage I pressure ulcers, where the skin is still intact, as stated in table 1, as their function is to protect the vulnerable area from shear force, friction and moisture. The type of adhesive should also be selected carefully so not to cause any additional skin damage or irritation to the area.

Barrier products, such as protective emollients and film forming barriers, are also commonly used to maintain good skin integrity and protect the skin in areas that are at risk of pressure ulcer formation. The primary purpose of these products is to provide a barrier to excess moisture or urinary / faecal incontinence and to keep the skin hydrated. Dry skin seems to be a significant independent risk factor for pressure ulcer development.²

This document will consider the external factors which influence the formation of pressure ulcers and the role of a dressing as part of a protocol of care for the prevention of pressure ulcers in areas which are considered to be at risk of pressure ulcer formation and in Stage I pressure ulcers.

Static Pressure

The primary cause of pressure ulcers is static pressure applied to both the skin and underlying tissue. When this pressure is greater than the blood pressure within the capillaries, blood flow is impeded. Maintaining interface pressures below capillary closing pressure (for example 32mmHg) is considered to be the gold standard for pressure relief.⁶ Sustained and sufficient pressure to disrupt blood flow results in hypoxia, localised ischemia and tissue acidosis, leading to cellular necrosis. Pressure ulcers typically occur over bony prominences, however occasionally they can occur in soft tissue areas due to the effect of foreign objects, such as a medical device. Muscle has been shown to withstand pressure loads of around 50mmHg for long periods.⁷

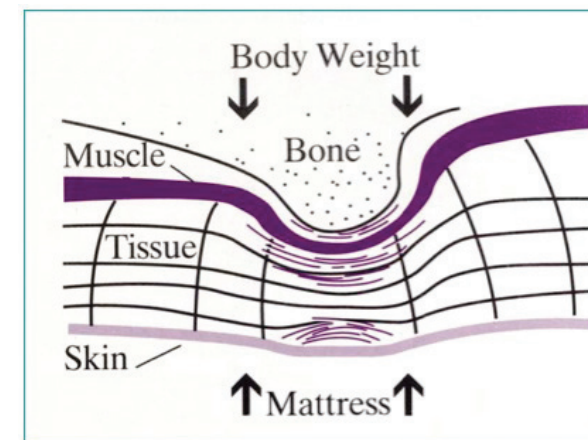


Figure 1: Tissue under Pressure – Adapted from Clinical Practice Guidelines # 3, Agency for Health Care Policy and Research, US Department of Health and Human Services.⁸

For immobile patients, or patients suffering prolonged periods of immobility, dressings alone have a limited (or no) role in alleviating the level of static pressure when compared to the effects of regular patient re-positioning or specifically designed pressure-relieving devices, such as pressure-relieving mattresses or pressure off-loading devices. The phenomenon of “bottoming out” of static support surfaces has been detailed in other papers, and for static foam mattress overlays, thicknesses of 3-4 inches are typical.¹

Torra I Bou et al⁹ conducted an experimental study designed to calculate the level of pressure before and after the application of a Hydrocellular dressing in the area of the sacrum, ischium and heel of three healthy volunteers. Measurements were taken on two surfaces, a viscoelastic foam mattress and a conventional hospital mattress. Pressure was determined by a Talley pressure monitor and repeated through a range of degrees of inclination. The overall average pressure reductions after applying the Hydrocellular dressing, on all volunteers, at all inclinations and on both surfaces were 19.5% in the sacrum, 13.8% in the ischium and 20.15% in the heel.

Dressings may however have a larger role through helping to re-distribute pressure in other circumstances, where a specific off-loading device or support mattress may not be appropriate. For example, this may be worthwhile when the use of another medical device may apply sustained pressure to the patient (e.g. the use of an oxygen mask).

Shear Force

Shear force is another example of pressure than can be exerted onto the body of a patient. Shear forces are produced when surfaces are slid across one another. In the case of a patient, examples of shear forces are: when the angle of a bed or chair is changed, or when a patient slides up or down a bed. These movements can result in pulling and stretching of the underlying tissue and blood vessels.

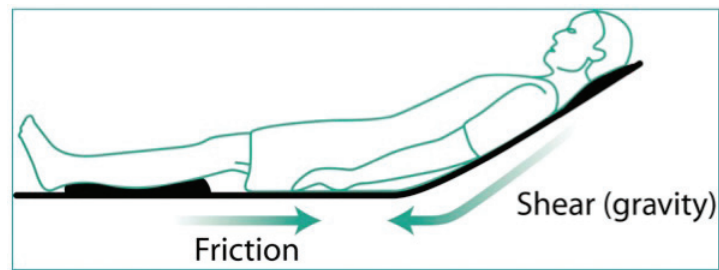


Figure 2: Adapted from Clinical Practice Guidelines # 3, Agency for Health Care Policy and Research, US Department of Health and Human Services.⁸

Friction is created by movement of the patient across surfaces, such as clothes or bed linen. Repeated movements can result in the superficial loss of epidermis and outer layers of the *stratum corneum*. This can result in abrasion-type wounds, which can produce considerable amounts of exudate. The contents of this exudate can contribute to the adhesion of skin to a surface and thus can further increase shear forces. Areas subject to friction force are likely to develop wounds (or skin breakdown around wounds). Areas identified as at risk of friction forces include the heels, buttocks, sacrum, elbows and trochanters.¹⁰

AQUACEL® Foam dressing is designed to help reduce the risk of skin breakdown by absorbing exudate and providing a low co-efficient of friction.

Nakagami et al¹¹ compared interface pressures and shear forces over the heel in a pressure ulcer preventative dressing and a thin film dressing in a clinical setting. In the study 30 hospitalised elderly patients participated. The results of the study showed that a dressing with a low friction external surface can significantly reduce shear force, however it did not significantly reduce interface pressures.

Ohura et al¹² developed an *in vitro* model to assess the impact of an external shear force and pressure on a superficial layer of skin and subcutaneous tissue with an underlying bony prominence. The model incorporated porcine skin, a Predia sensor capable of measuring shear and pressure simultaneously and a small strain gauge shear sensor buried in the superficial dermis, as illustrated in Figure 3. An external 1Kg force with a cotton cloth interface was applied to this skin model. This external force was attached to a friction pull tester which pulled at a rate of 10cm per 30 seconds.

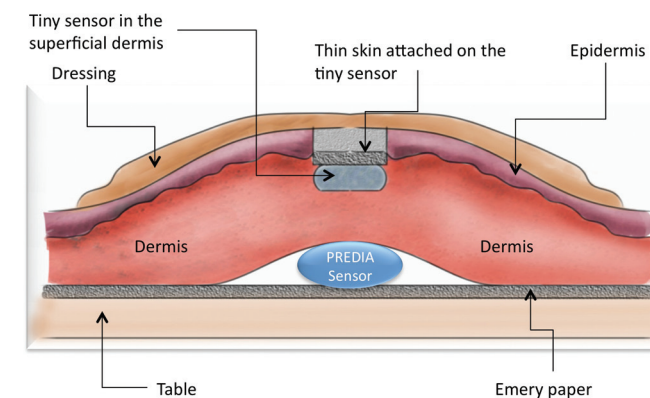


Figure 3: Illustration of Ohura et al¹² pig skin model

Five dressings were evaluated in this model: ALLEVYN™ ADHESIVE (Smith and Nephew), TIELLE™ (Systagenix), Tegaderm™ (3M Healthcare), Development Opsite™ (product under development, Smith and Nephew) and DuoDERM® CGF dressing (ConvaTec).

The static pressure recorded under the test dressings remained the same as the control (no dressing) within a range of 6.1 - 7.2mmHg. During weight movement, the pressure of the control raised to 16.36mmHg, all dressings tested were shown to produce a 26-46% reduction compared to the control pressure in the subcutaneous layer.

The mean control (no dressing) for shear force in the subcutaneous layer was 0.47N. The shear forces were reduced by 31 - 45% compared to the control, depending upon which dressing was applied, but with no significant differences between dressings. For all dressings tested, the shear force in the subcutaneous layer was reduced compared to the shear force within the superficial layer. DuoDERM® CGF dressing was shown to have the lowest shear force in the superficial layer, when compared to the other dressings tested.

In vitro testing was performed at ConvaTec, Deeside, UK to determine the ability of AQUACEL® Foam and Mepilex™ Border dressings to reduce shear force transmitted from a force applied to the dressing surface through to the underlying tissue.

The test method was based upon the work performed by Ohura et al¹², using a sled to create the surface shear force, the speed of the testing and the same Predia pressure and shear force sensor were replicated. This model has been limited to comparing the reduction in shear force transmitted through the dressing alone, thus eliminating the variability of using porcine skin. The pressure range used within the model to determine the ability of a dressing to decrease shear forces with increasing applied load was increased.

Within this *in vitro* model, the data shows at a 99.9% confidence level, significantly less shear force was transmitted through the AQUACEL® Foam dressing to the Predia sensor compared to Mepilex™ Border dressings ($p < 0.001$).¹³

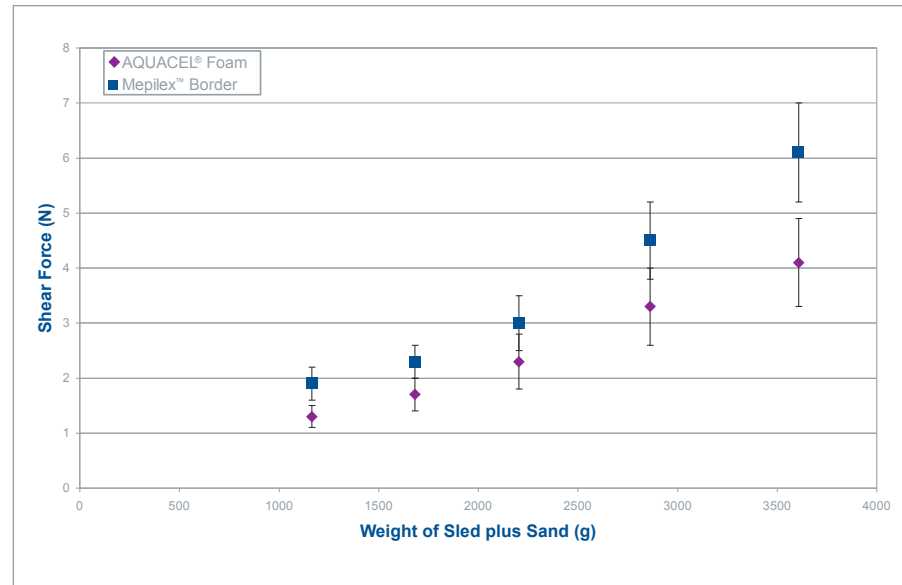


Figure 4: *in vitro* shear force measured under dressing.¹³

AQUACEL® Foam dressing is designed to protect against skin breakdown caused by excess moisture, friction or shear force.

Skin Protection

If skin is exposed to excess moisture, it may become excoriated, macerated, denuded or broken (Figure 5). Perspiration, faeces and urine are all common sources of excess moisture, with the corrosive nature of urinary and faecal incontinence potentially leading to chemical damage and skin breakdown. In the case of sacral pressure ulcers, the importance of protecting the skin from urinary and faecal incontinence is well documented.¹ Although moisture on the skin does not directly cause pressure ulcers, it softens or macerates the skin, making it more susceptible to damage from friction or shear.¹⁴



Figure 5: Maceration with damage from friction or shear.

Just as the skin acts as a barrier, a product that provides a barrier to liquids offers a form of protection to help maintain good skin integrity and to protect skin at risk from the damaging effects of incontinence, moisture and friction.

The European Pressure Ulcer Advisory panel and National Pressure Ulcer Advisory Panel. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide recommends

“Use a structured approach to risk assessment that includes a comprehensive skin assessment to evaluate any alterations to intact skin. (Strength of Evidence = C) Consider individuals with alterations to intact skin to be at risk of pressure ulcer development.”

Alteration in skin condition may include, dry skin, erythema, and other alterations. The presence of non-blanching erythema also increases the risk of further pressure ulcer development.

“Protect the skin from exposure to excessive moisture with a barrier product in order to reduce the risk of pressure damage. (Strength of Evidence = C)”

The mechanical properties of the *stratum corneum* are changed by the presence of moisture and as a function of temperature.

Strength of Evidence

A	The recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans (or humans at-risk for pressure ulcers), providing statistical results that consistently support the guideline statement (Level 1 studies required)
B	The recommendation is supported by direct scientific evidence from properly designed and implemented clinical studies on pressure ulcers in humans (or humans at-risk of pressure ulcers), providing statistical results that consistently support the recommendation. (Level 2, 3, 4, 5 studies)
C	The recommendation is supported by indirect evidence (e.g. studies in normal human subjects, humans with other types of chronic wounds, animal models) and / or expert opinion.

Figure 6: Strength of Evidence Rating - The European Pressure Ulcer Advisory panel and National Pressure Ulcer Advisory Panel. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide

AQUACEL® Foam dressing provides a waterproof, viral and bacterial barrier¹⁶ and is designed to protect the skin from excess moisture and incontinence episodes.*

*As demonstrated *in vitro*

Alternatively, to maintain the skin's normal softness and pliability, a 10-20% water content is needed within the skin.¹⁵ When skin loses moisture, it becomes dry, flaky, chapped and less pliable (Figure 7). Ulcers are more likely to develop in dry skin.¹⁴ If the *stratum corneum* is removed, the skin's barrier capability is lost, increasing water vapour loss (Transepidermal water loss) through the damaged area and potentially allowing external fluid or agents (e.g. bacteria) into the tissue. Studies have shown that if the *stratum corneum* is removed, that the water vapour loss of forearm skin increases 100-fold, to approximately that of a water layer alone.¹⁵



Figure 7: Dry skin

AQUACEL® Foam dressing provides a controlled Moisture Vapour Transmission Rate,¹⁷ which may help to reduce Trans Epidermal Water Loss (TEWL)*

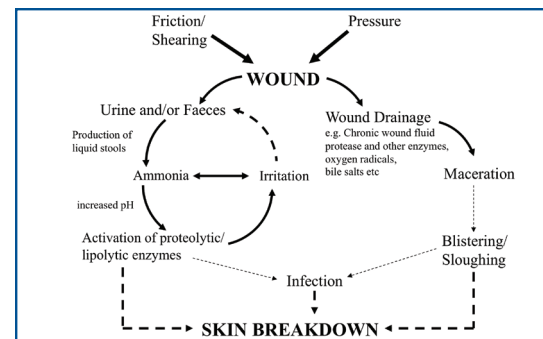


Figure 8: Schematic of a WET skin environment and how internal / external factors can cause skin breakdown.

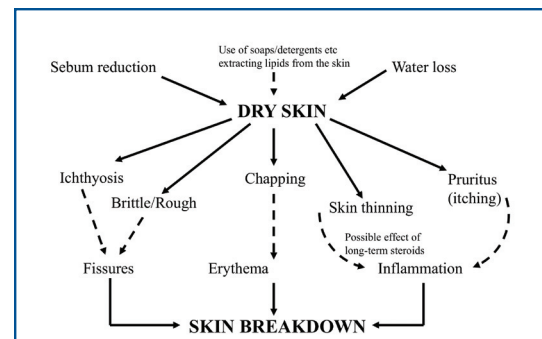


Figure 9: Schematic of a DRY skin environment and how internal / external factors can cause skin breakdown.

Practitioners have a plethora of product choices to protect the skin from faecal and urinary incontinence, including petrolatum-based barrier creams and film-forming barrier creams which can increase the hydration of at-risk skin.

Wound dressings with low friction, waterproof barriers offer an alternative option to the practitioner. Dressings can be indicated for up to 7 days wear time, meaning that the practitioner does not need to regularly re-apply barrier products such as emollients, which may rub off on bed linen or clothing. Furthermore, when faecal or urinary incontinence is present, the dressing backing may be wiped clean, negating the need to use cleaning products which may themselves cause skin damage, together with the cleansing process itself potentially causing further breakdown of the *stratum corneum*.

*As demonstrated *in vitro*

AQUACEL® Foam dressing is designed to stay in place for up to 7 days.

When choosing a dressing, it is important that removal of the dressing does not strip the *stratum corneum* or increase the risk of skin breakdown. *In vitro* bioadhesion studies^{18,19} have evaluated the adherence of fibroblast cells involved in the wound healing process to a wide range of wound care products. To mimic peri-wound adherence, a modification of these studies has used epidermal keratinocyte cells to assess the potential for a dressing to cause skin trauma upon removal.

Adult human keratinocyte cells were obtained and transferred into a sterile dish containing Hank's balanced salt solution (HBSS). The tissue was washed and cut into small (3–5mm²) pieces which were then placed into 25cm² tissue culture flasks containing media (Dulbecco's Modified Eagle Medium (DMEM), supplemented with 10% foetal calf serum (FCS) (Sigma, UK), 20 mM Hepes buffer, 100µg/ml gentamicin and 0.5µg/ml amphotericin B). Cell cultures were incubated at 37°C in a 5% CO₂ / 95% air environment. Readiness for sub-culturing was determined by the extent of keratinocyte cell outgrowth (5–10 days). Cells were farmed successively in a 1:4 split ratio to passage 3–8 before experimental use. Keratinocytes were harvested from stock dishes and plated out at 2x10⁵ cells/ml in 6 well plates. A 1cm² piece of each test dressing was cut from adhesive area and applied dry. All cut dressings were placed onto the monolayer of keratinocytes and pressed gently in place. After 24 hours, the dressings were carefully removed from the surface of the culture, using minimal force to avoid damaging the cells or causing any additional cells to detach from the dressing. The cell numbers on each dressing were determined through trypsinisation and counting using a Neubauer cell counting chamber.

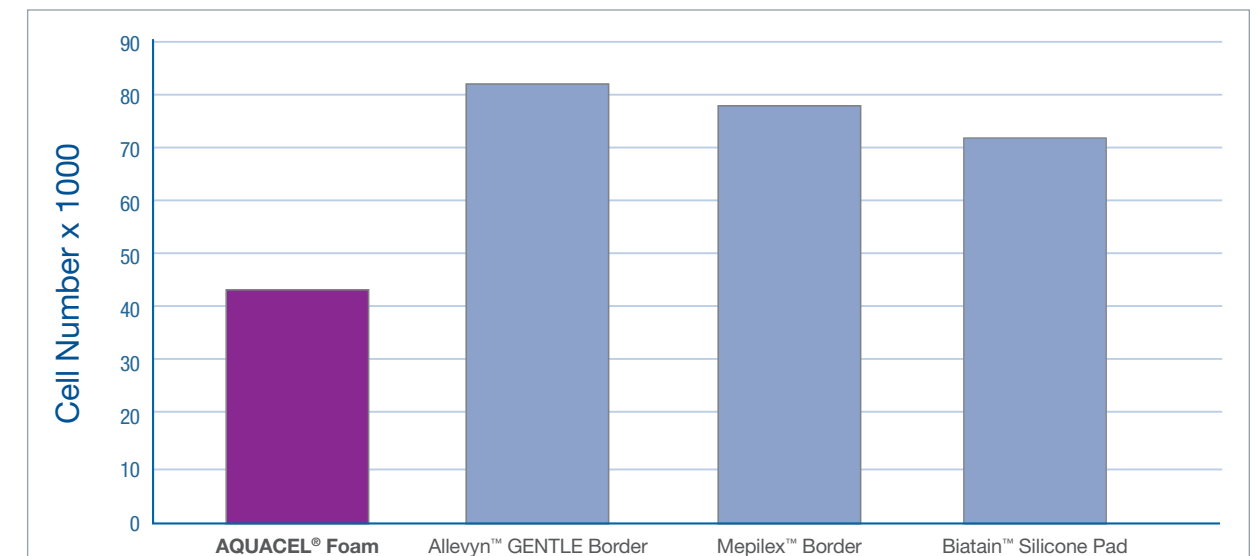


Figure 10: Number of Keratinocyte cells adhering to dressing.

In this *in vitro* model, significantly less keratinocyte cells were observed to adhere to the AQUACEL® Foam dressing than to the other dressings tested.²⁰

AQUACEL® Foam dressing is designed to help reduce pain and trauma upon removal.^{20, 25}

The European Pressure Ulcer Advisory panel and National Pressure Ulcer Advisory Panel. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide recommends

“Inspect skin regularly for signs of redness in individuals identified as being at risk of pressure ulceration. The frequency of inspection may need to be increased in response to any deterioration in overall condition. (Strength of evidence = B)”

Ongoing assessment of the skin is necessary to detect early signs of pressure damage.

One potential drawback of the use of dressings for skin protection in the case of pressure ulcer prevention is the balance between skin inspection and the cost of dressing removal/replacement. With the advancement of adhesive technologies, certain dressings can now be re-positioned,^{19*} allowing regular skin inspection without the increased cost of dressing changes.

AQUACEL® Foam dressing is designed to be re-positionable,²¹ allowing inspection of intact skin.

Clinical Practice

A clinical study implementing a comprehensive prevention program has been shown to reduce pressure ulcer incidence by 87%. Since the current cost of treatment is estimated at \$500 to \$50,000 per ulcer, such prevention programs could significantly reduce healthcare costs.²²

According to a publication from the US Agency for Healthcare Research and Quality (AHRQ), the ConvaTec Solutions® Algorithm for Pressure Ulcer Prevention was described as a proven technique that can be used to enhance patient outcomes.²³

Organisations are encouraged to develop a comprehensive program to prevent the development of chronic wounds. These wounds can be quite costly, both financially and in terms of their impact on a patient’s quality of life.

*Skin inspection without dressing change would only be recommended for intact skin.

The information contained within Figure 11 is to help understand the risk factors associated with skin breakdown and to develop care plans to reduce the likelihood that a clinically and economically costly wound will develop.

In addition to the risk factors identified by ConvaTec Solutions® Algorithms, other factors may pose further risk for the development of chronic ulcers.¹ Several scales may be used to assess an individual’s risk, including the well-known Braden and Norton scales, or the lesser known Gosnell scale.²⁴

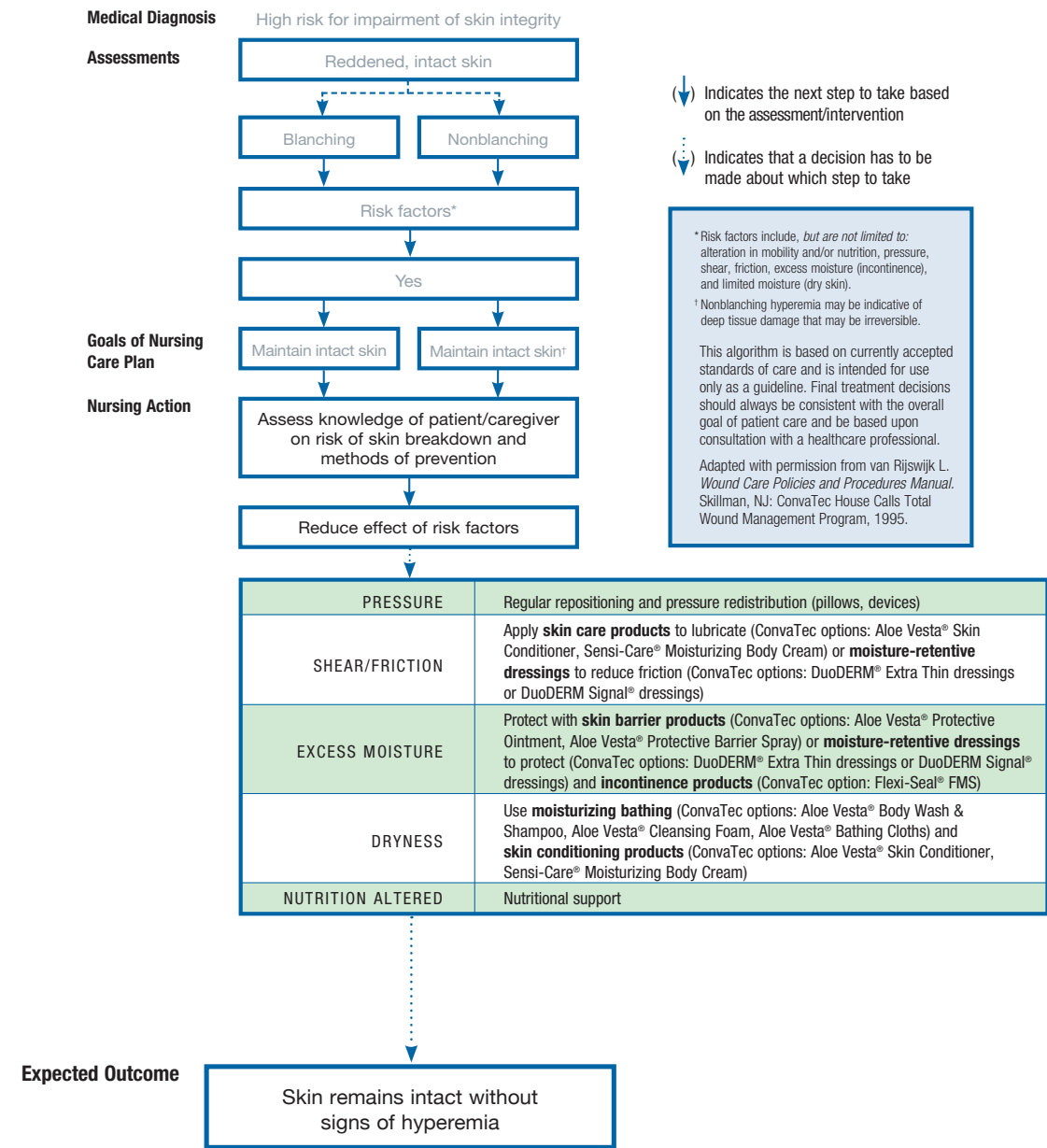


Figure 11: ConvaTec Solutions® Algorithm (An updated pressure ulcer prevention algorithm is being validated and will be available in 2013.)

Conclusions

The incident rates, economics, and impact on the quality of life to the patient for pressure ulcers are well documented and understood. As the primary cause of pressure ulcer formation is static pressure, the caregiver's primary concern is to remove pressure from at-risk areas in order to help prevent pressure ulcer formation, however several other factors also have a role to play in pressure ulcer formation.

The roles of shear forces and excess moisture as secondary contributing factors are well documented. Whilst these factors alone do not directly cause pressure ulcers, they do soften and damage the skin, making it more susceptible to further damage.

Hydrocolloid Dressings and skin care products have played a role in the prevention of pressure ulcers for many years, with their primary functions being either to protect the skin from friction and excess moisture by forming a barrier, or to maintain skin moisturisation so that the skin maintains its natural barrier function.

Dressing technologies have further now developed, with newer adhesives that are designed to ensure low trauma upon removal and which have the ability to be re-positioned.²² These new technologies allow the caregiver further product choices to reduce the skin damage caused by friction and excess moisture with the confidence that an at-risk area of intact skin can be inspected without causing further skin damage or incurring the cost of a dressing change upon each inspection.

AQUACEL® Foam dressing is designed to protect against skin breakdown caused by excess moisture, friction or shear force and may be used as a part of a comprehensive protocol of care to protect at-risk areas and help prevent skin damage.

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