Nimbus® range of pressure-redistributing mattresses

Healthcare providers face unprecedented challenges with higher-acuity patients, budget cuts, public demand for better health care and a growing recognition that some healthcare-acquired injuries, such as pressure ulcers, could be avoided. Given that pressure is a primary causative factor in pressure ulcer development, the latest guidelines (EPUAP-NPUAP, 2009) provide recommendations for patient repositioning, the allocation of either an Active or Reactive pressure-redistributing support surface and, for some, complete and permanent off-loading of the tissue.

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Wound Valve™ Technology
Active therapy (alternating pressure)
Pressure ulcer

There are a number of major drivers behind the need to improve the way pressure ulcer risk is managed: higher acuity patients; resource-limited healthcare systems; a growing emphasis on patient preference, clinician safety and a nosocomial pressure ulcer rate that has changed little over time (Buttery and Phillips, 2009). The challenges are clearly complex and demand an evidence-based and timely prevention strategy. For example, patient risk has to be established at first clinical contact, a comprehensive plan of care implemented in order to optimise the tissue's tolerance to applied pressure, and pressure must be redistributed away from the most vulnerable areas (European Pressure Ulcer Advisory Panel-National Pressure Ulcer Advisory Panel [EPUAP-NPUAP], 2009). This latter element is perhaps most critical, as it tackles the fundamental cause of harm — unrelieved pressure.

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Pressure ulcers in context

While the underlying pathology of a pressure ulcer is not fully understood, there is little doubt that injury primarily arises when pressure is of sufficient intensity and duration to effect vessel occlusion, ischaemia and cell death (EPUAP-NPUAP, 2009). The inverse relationship between time and pressure has been widely studied in both the field (Reswick and Rogers, 1976) and in the laboratory. For example, Linder-Gantz et al (2006) demonstrated that constant lower pressure (67mmHg) over two hours or more, can be as harmful as high pressure (240mmHg) held for between 15 minutes and one hour. Laboratory findings are also supported by early field studies which serve to illustrate the important and beneficial relationship between periodic pressure off-loading (spontaneous movement) and pressure ulcer outcomes (Exton-Smith and Sherwin, 1961).

These basic principles have been used to guide preventative measures through the adoption of largely effective, yet labour intensive, routine repositioning. Other factors, such as complex comorbidities, continence, nutrition and microclimate (temperature and humidity at the skin surface) are also important in terms of tissue perfusion, cell regeneration and the skin's ability to withstand pressure (tissue tolerance). However, these are unlikely to be considered a primary cause of pressure injury when viewed in isolation, and become most important when associated with immobility or other exposure to high or prolonged pressure.

Managing the risk associated with pressure

Given that the human body is constantly exposed to periods of high pressure, it is not surprising that evolution has provided a complex, subconscious, yet effective strategy to avoid pressure injury. Even during sleep, an individual will make several significant movements each hour in response to pressure stimuli. This movement periodically replaces periods of pressure loading (vessel occlusion), with periods of pressure off-loading (reperfusion); a normal physiological process which safely maintains tissue integrity.

In clinical practice, however, spontaneous movement may be absent or diminished, with the patient unable to sense the stimulus for movement and/or unable to make an adequate compensatory position change. As vulnerability increases, the level of intervention required to manage

the risk will also increase, and this typically translates into an increased turning frequency as well as the use of pressure-redistributing equipment.

While these pressure management strategies are no doubt beneficial, there are some drawbacks. Physical repositioning risks injury to the care-giver and, if too frequent, will repeatedly disturb the patient which may affect sleep, pain control, day-time energy and comfort. In practice, prescribed repositioning regimens may also be difficult to implement and so may not actually be carried out as scheduled. For these reasons, repositioning is usually combined with a pressure-redistributing support surface so that individualised repositioning regimens can be sympathetic to the patient's overall care needs, and rest periods can be extended without compromising outcomes (Phillips, 2000; Defloor et al, 2005; Krapfl and Gray, 2008).

Pressure-redistributing mattresses: defining the difference

Now reclassified based upon their primary mode of action (EPUAP-NPUAP, 2009), pressure-redistributing mattresses are designed to manage pressure in one of two ways.

To reduce the pressure applied to the most vulnerable areas — Reactive therapy

Reactive mattresses (such as foam, gel or static air, powered low-air-loss or air fluidised systems) are designed to allow the patient to immerse into, and be enveloped by, the supporting medium. As a result, the surface area bearing the weight of the patient is increased, leading to a reciprocal decrease in contact pressure. Pressure, though lower, is not relieved unless the patient is repositioned and may not be low enough to prevent capillary occlusion. However, despite their previous popularity, powered systems were developed predominantly to manage patients presenting with conditions such as burns or highly exuding wounds, and not specifically for the prevention and treatment of pressure ulcers. As such, the evidence base may be weak (Clark, 2008) and largely out of date. Very soft surfaces can also hinder self-repositioning and rehabilitation, while systems associated with air flow may affect skin and systemic hydration (McNabb and Hyatt, 1987; EPUAP-NPUAP, 2009).

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To reduce the duration of exposure to pressure — Active therapy

By contrast, Active therapy has been developed primarily to manage pressure ulcer risk. Active mattresses are designed to simulate the effects of normal spontaneous movement by systematically redistributing pressure away from vulnerable areas, even if the patient does not move. Off-loading is generally achieved through the cyclical inflation and deflation of air cells across the mattress surface at a typical frequency of between 6–8 times each hour; a rate similar to spontaneous position change during sleep (Johnson et al, 1930; Keane, 1978). The technical performance can also be characterised by describing the amplitude of the cycle (EPUAP-NPUAP, 2009) or, put simply, the difference between the maximum pressure observed over an inflated cell and minimum pressure observed when the cell deflates and moves away from the body. Mattresses designed to hold the cell pressure as low as possible for as long as possible, while supporting the patient, may optimise the physiological response to off-loading, and have shown superiority in terms of both tissue perfusion (Goossens and Rithalia, 2008) and lymph flow (Gunther and Clark, 2000).

The clinical benefit derived from this measurable physiological response has been validated through clinical outcome studies and randomised controlled trials (RCT) conducted in some of the most challenging environments such as burns (Still et al, 2003), critical care (Phillips, 2000; Malbrain et al, 2010), patients with existing wounds (Wallenstein 2002; Clark et al, 2005) and spinal injury (Finnegan et al, 2008).

Active or Reactive... the evidence base?

Mattress selection should be based

Figure 1: Nimbus Professional mattress (ArjoHuntleigh).

on the needs and goals identified for each individual patient. Reactive mattresses, such as foam, may be ideal for first-line protection in vulnerable patients and the treatment of superficial ulcers (National Institute for Health and Clinical Excellence [NICE], 2005), while powered Reactive surfaces may be particularly helpful for pain management and patients with problematic spasm or insomnia, given the possibility for envelopment and warming without movement. Mattresses, both Active and Reactive, which incorporate low air loss, may be beneficial in the management of patients who require management of the microclimate at the mattress:skin interface. However, the significance of these and other confounding factors, in terms of pressure ulcer prevention, has yet to be determined (EPUAP-NPUAP, 2009).

While the evidence base for either modality is arguably weak, recent studies have clearly demonstrated the clinical benefit of Active therapy in some of the most challenging circumstances. Finnegan et al (2008) reported the results of an RCT comparing Nimbus 3 Professional mattress (*Figure 1*, ArjoHuntleigh) with air-fluidised therapy in the care of para/quadraplegic, post-operative myocutaneous flap patients (*Figure 2*). In the Nimbus mattress group, a specialised device, Wound Valve™ Technology (ArjoHuntleigh) (*Figure 3*), was used to isolate and permanently deflate the mattress cell directly beneath the graft. This enabled the operative site to be continuously off-loaded without requiring the patient to adopt an unnatural position. Neither group developed tissue damage at either the graft site or the heel despite being very high risk; while the Nimbus 3 Professional attracted a significantly lower rental and running costs compared to the air-fluidised therapy.

In a second pilot RCT, 16 high-risk patients were recruited (Malbrain et al, 2010) from within an intensive care population. Half the subjects were randomly assigned to receive the Nimbus 3 mattress, while half were allocated a non-powered, air-filled Reactive surface (control group). The results demonstrated superior performance for the Active therapy group in terms of prevention of pressure ulcers, particularly category 2 and above. Where ulcers were present on admission, 82% of wounds in the Active therapy group were clinically rated as 'improved' based on a compound assessment tool (Pressure Ulcer Scale for Healing [PUSH], NPUAP, 1998), compared to none in the Reactive group (p=0.002), while 67% of wounds in the Reactive group were considered to have deteriorated (p=0.006).

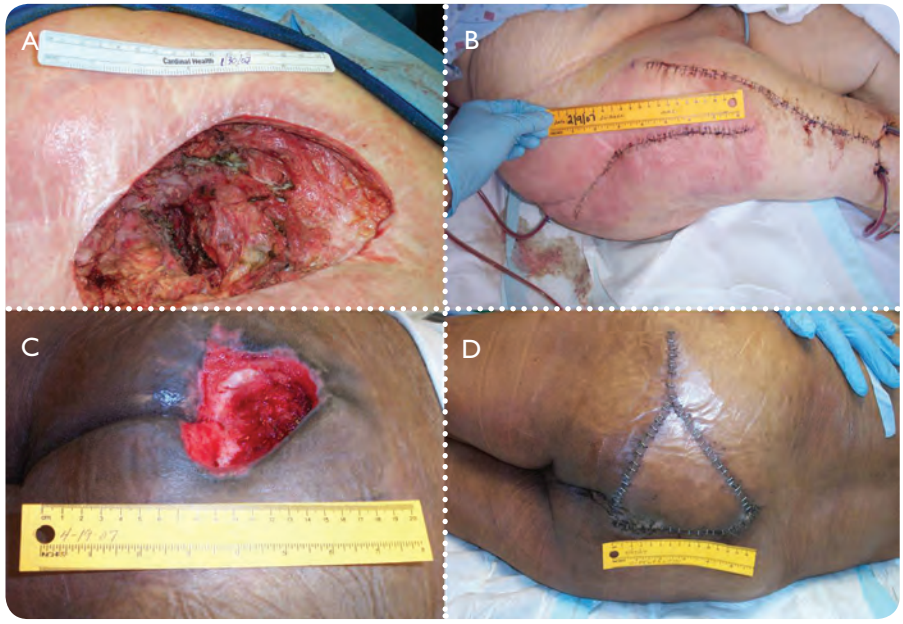
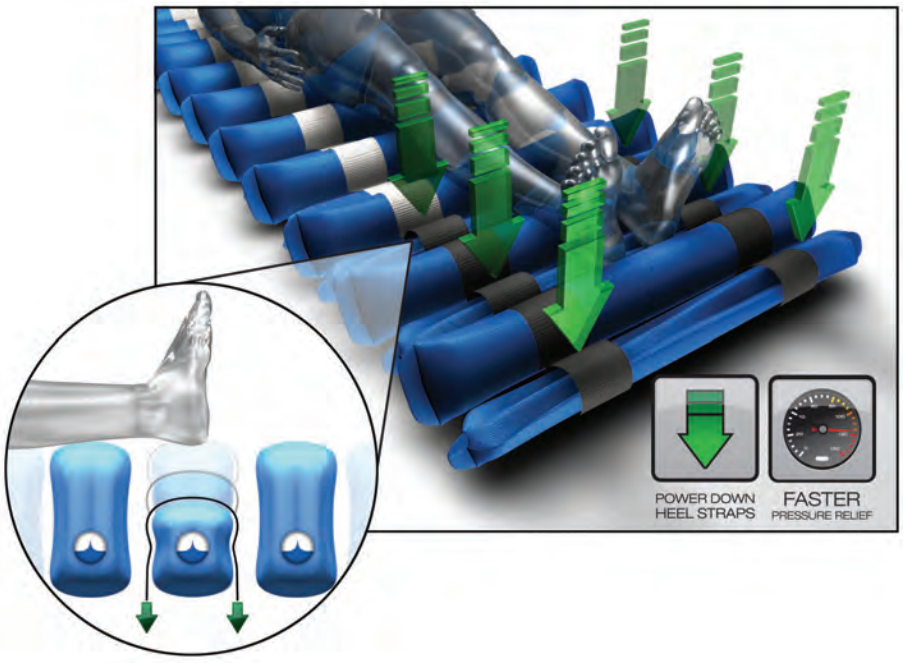


Figure 2: Using Wound Valve Technology to off-load reconstructive surgical sites both pre (A and C) and postoperatively (B and D).

While these studies are small and would benefit from further investigation, the findings are borne out by a multi-centre prospective clinical outcome study. Clark (2001) reported the outcome of 2,507 patients and concluded that the Active mattress replacement is more cost-effective than other strategies for prevention in the highest risk population and treatment of the most severe pressure ulcers.

Combining the published evidence with expert opinion lead the EPUAP-NPUAP (2009) guideline committee to conclude that Active therapy is the treatment of choice for patients who cannot be regularly repositioned. A similar proposition from this group has also suggested possible benefit from Active cushions when used with caution for spinal-injured patients. This latter proposal demonstrates that the value of Active therapy may not be restricted only to bed surfaces. In 2008, Stockton and Rithalia studied tissue perfusion to demonstrate the role of the AURA® cushion (ArjoHuntleigh) in matching the perfusion achieved by physical off-loading, while Zoller (2002) explored the longer-term benefit in a survey of paralysed USA veterans.

Yet, when selecting a support surface, it is important to recognise that the technical performance of an Active mattress is intrinsically linked to the physiological response it elicits and, as the response varies considerably (Goossens and Rithalia, 2008), surfaces cannot be substituted with confidence. A simple illustration arises from a RCT which set out to test the hypothesis that there is little difference between a mattress overlay and a mattress replacement, other than asset cost (Iglesias, 2006). While the outcomes in raw terms were similar, the overlay group developed ulcers 10.6 days sooner, attracted higher treatment



costs and lower patient satisfaction. The report concluded that the chance of the overlay proving more cost-effective is a conservative 10–20% (Iglesias, 2006).

The additional challenge of heel ulcers

In 2009, Buttery and Phillips reported audit data from 44 hospitals across the UK and showed that more than half the pressure ulcers were facility-acquired, 24% of these involved the heel. Although all pressure ulcers are problematic, heel ulcers are associated with additional risk factors related to both prevention and healing. The demographic shift in the population predicts more patients with underlying comorbidities, such as age, obesity, diabetes, peripheral vascular disease, immobility and high acuity. Those that go on to develop heel ulcers may have significant issues with subsequent healing, mobilisation and rehabilitation, as the effects on footwear and gait can be life-long if deep tissue loss or amputation has occurred.

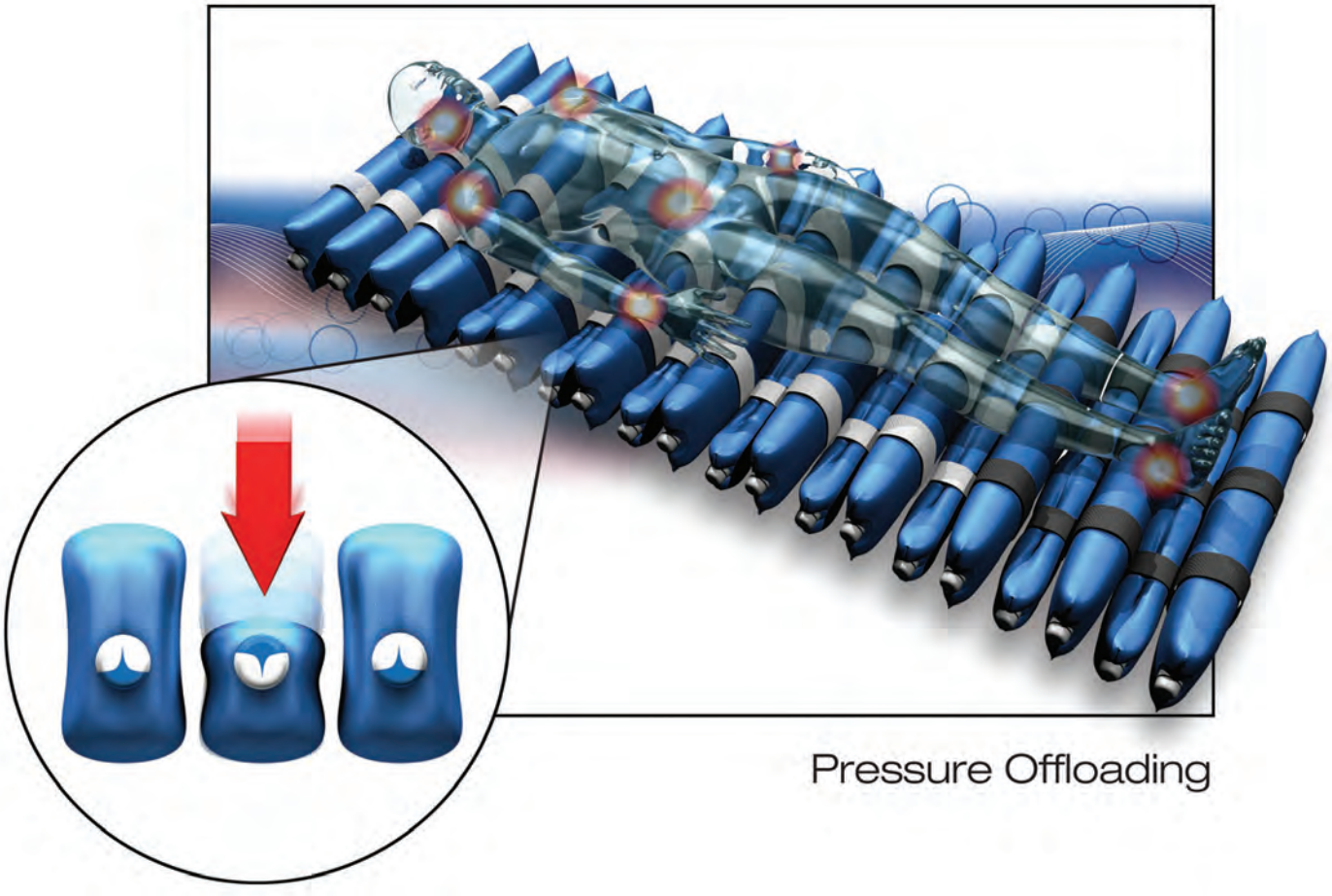


Figure 3: Heel Guard™ and Wound Valve™ Technology

Figure 4a: Pre-treatment: life-threatening category 4 pressure ulcer.

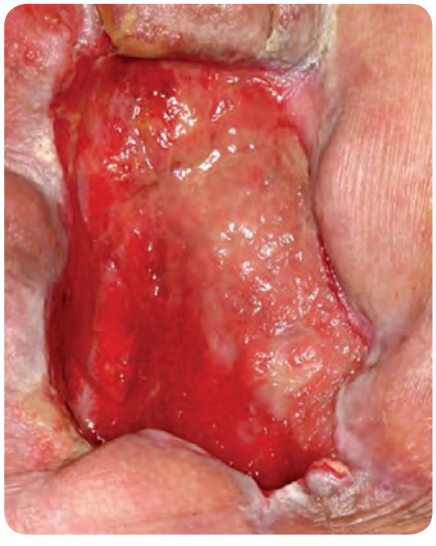


Figure 4b: Post-treatment.

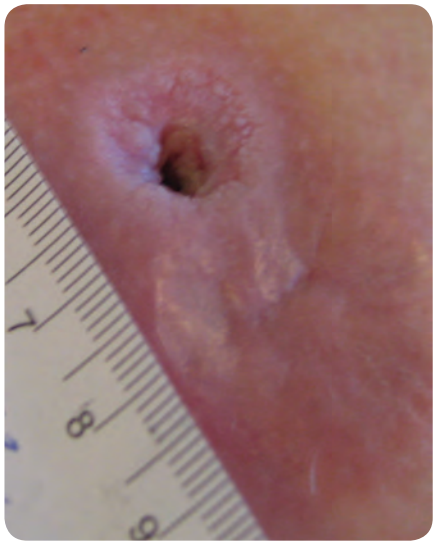


Figure 5a: Pre-treatment: recurrent category 4 trochanteric ulcer.

Figure 5b: At eight weeks the graft site was intact.

Figure 6a: Pre-treatment: clinically-infected ulcer over the Achilles tendon.

Figure 6b: Post-treatment, 12 days later.

Figure 7a: Pre-treatment: category 4 sacral pressure ulcer.

Figure 7b: Post-treatment of debridement, off-loading, TNP therapy and honey dressings.

Protecting the heel with HeelGuard™ Technology

Although most Active mattresses are designed to off-load efficiently, the Nimbus 3, Nimbus 4 and Nimbus Professional mattresses (ArjoHuntleigh) are further enhanced to protect the increasing number of vulnerable patients with sub-optimal blood flow to the limbs or low reperfusion indices. These surfaces have specialised heel zones incorporating HeelGuard™ Technology (ArjoHuntleigh) (*Figure 3*). This simple, yet effective device extends the degree and duration of cell deflation over the most vulnerable heel area, and has proven particularly beneficial for avoiding heel ulceration in those patients who have complex comorbidities, such as spinal injury, or those requiring critical care (Finnegan, 2008; Malbrain, 2010).

'Floating' the heel and complete pressure off-loading with Wound Valve Technology

Finally, there are some patients for whom any degree of pressure can induce injury or complicate wounds or surgical sites, such as those presenting with critical limb ischaemia, recent grafts, burns or complex wounds. These patients may require complete and permanent off-loading. For pressure ulcers at least, the EPUAP-NPUAP (2009) guideline is clear in its recommendation that vulnerable patients may need their heels permanently 'floated' clear of the bed, and that existing pressure ulcers should not bear weight. However, this is not always easy to achieve.

Typically, patients with wounds may be prevented from assuming a favoured position, such as no sitting or no side lying. Alternatively, to protect the heel, they may be required to use a supplementary off-loading device such as a wedge, trough, or pillows placed behind the calf. If not fitted properly, these can be associated with

side-effects such as persistent pressure which risks damage to the Achilles tendon, heat, sweating, discomfort and displacement. Again, both of these strategies, i.e. having to maintain an unusual posture to avoid pressure or use an offloading device to off-load the wound may have further drawbacks. The former may not be acceptable to patients particularly over a longer period of time, while the efficacy of positional devices, such as pillows, inflatable boots, troughs, wedges, etc has not been fully established (Junkin and Gray, 2009). In addition, raising the foot and lower leg in patients with arteriopathy can cause ischaemic pain. While for others, a device that hyper-extends the knee may cause popliteal vessel occlusion, a condition hypothetically linked to an increase in deep vein thrombosis (DVT) risk (Huber and Huber, 2009). Similar concerns may be levelled at putting a pillow behind the calf. These complex clinical challenges require simple, yet effective solutions.

Illustrative case reports: complete off-loading with Wound Valve™ Technology

The following case reports reflect typical challenges faced by clinicians and show how the Nimbus 4 and Nimbus Professional mattresses with Wound Valve Technology can simplify the care of patients without compromising comfort or safety.

Case report 1

This case represents one of the most significant clinical challenges (Ward, 2009). An 81-year-old patient was admitted with a life-threatening category 4 (EPUAP-NPUAP, 2009) pressure ulcer, vast tissue loss (*Figure 4a*), septicaemia, diabetes and ischaemic heart disease. It was felt that she was unlikely to survive. As repositioning was difficult due to the patient's condition, she was nursed mainly in her preferred semi-recumbent position on a Nimbus Professional mattress with the cell beneath the wound permanently deflated. Despite her grave condition, the combination of systemic treatment, expert wound care and complete off-loading lead to such improvement (*Figure 4b*) that the patient recovered sufficiently to be transferred for rehabilitation.

Case report 2

A 38-year-old paraplegic presented with a recurrent category 4 trochanteric ulcer (*Figure 5a*). The ulcer had recurred following reconstructive surgery for an earlier ulcer, and the patient's refusal to lie in any position other than on the wound was problematic. He had previously refused a pressure redistributing mattress but was willing to try the Nimbus Professional mattress with the cell beneath the wound permanently deflated. The wound improved and further reconstruction was undertaken after 18 days. The patient was discharged with the mattress to minimise the risk of recurrence and at eight weeks the graft site was intact (*Figure 5b*). The ability to off-load a specific section of the mattress enabled the patient to enjoy his preferred resting position and exercise choice without risk to his skin.

Case report 3

A 60-year old immobile patient was admitted with a large, clinically infected ulcer over the Achilles tendon (*Figure 6a*), complicated by diabetic neuropathy, poor vascular status and human immunodeficiency virus (HIV). The patient had been wearing a foam heel boot before admission and the wound had not progressed. The wound was debrided, treated with advanced wound dressings and systemic antibiotics and then off-loaded permanently by deflating the cell beneath the foot. Within 12 days the patient was fit for discharge (*Figure 6b*).

Case report 4

A 64-year old tetraplegic lady with myelodysplasia was admitted with an intractable category 4 sacral ulcer (*Figure 7a*) that had failed to respond to a range of advanced wound care therapy, including topical negative pressure (TNP) (Ashton and Sturges, 2006). The approach was 'back to basics'; the wound was debrided, completely off-loaded by sub-wound cell deflation and treated with two short courses of TNP followed by honey dressings. The wound healed to just 1 cm^2 within 90 days and fully epithelialised three weeks later (*Figure 7b*).

Key points

- Reactive and Active (alternating therapy) are new terms used to categorise support surfaces based on the pressure-redistributing properties and mode of action.
- Active mattresses each have different performance profiles and so stimulate a different physiological response. This may impact on clinical outcome so device substitution requires caution.
- Active therapy, e.g. the Nimbus range, will complement patient repositioning regimens and is the preferred modality for those patients who cannot be moved regularly (EPUAP-NPUAP, 2009). Large-scale studies (Clark, 2001; Iglesias, 2006) suggest that Active therapy mattresses may be more cost-effective than mattress overlays or Reactive surfaces.
- Wound Valve Technology provides targeted and sustained pressure elimination (floatation) over the most vulnerable areas, avoiding drawbacks associated with traditional methods.

Conclusion

Pressure ulcer prevention begins with the first principle: if the patient cannot move — move the patient, or move the pressure... and act as soon as the risk is recognised. The combination of a support surface and a patient-focused, rather than ritualistic repositioning regimen can reduce the risk of harm to both the patient and

the care-giver. This has both clinical and economic benefits.

Individual care packages, which are driven by holistic assessment, are sensitive to the physical, social and emotional well-being of the patient while avoiding the time burden of unnecessary procedures. At the same time, this approach may reduce the risk of care-giver injury through the avoidance of unnecessary and often physical intervention. Such injuries can be associated with substantial cost, for example, sick leave, workers' compensation and the loss of skilled personnel from the service.

Where healthcare providers seek a solution which is practical, effective, affordable and acceptable to the patient, Active therapy mattresses and cushions, such as those from ArjoHuntleigh, are a strong contender. WUK

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