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CLINICAL EVIDENCE



...with people in mind

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INTRODUCTION

Pressure ulcers (Figure 1) recognise no boundaries; they occur in all healthcare settings, affect all age groups, cause considerable distress and consume significant healthcare resource.

Unfortunately, pressure ulcers are still relatively common¹ with a significant number occurring under clinical supervision². This has lead to a growing tendency to classify pressure ulcers as 'medical errors', rather than simply as an inevitable progression of an existing condition³.

Given that unrelieved pressure is the primary causative factor of pressure ulcers4, the most appropriate interventions must be those designed to mitigate risk by reducing exposure to the degree and duration of pressure. Interventions, such as assisted repositioning regimens, have successfully protected patients for decades and are most effective when used in combination with pressure-redistributing support surfaces.



Figure 1: Pressure Ulcer

The challenge today, is to select the most appropriate support surface from the confusing and expanding array of options and, at the same time, meet the expectations of a diverse group of stakeholders; for example:

- The patient expects: efficacy comfort choice
- The clinician expects: efficacy safety ease of use
- The payer expects: cost efficiency easy access affordability

Active (alternating) pressure redistribution, as a generic modality, may be able to satisfy the above criteria when the critical design characteristics are optimised; however, it cannot be assumed that the critical design principles have been incorporated into all the Active devices available on the market and not all the features encountered will have clinical relevance.

This publication will consider the principal pathology underlying pressure ulcer development and explore the vital link between vulnerability and immobility: a foundation, which has lead to the logical evolution of Active Therapy™ as probably the most efficient, most natural and most effective modality for injury avoidance and treatment. Armed with this knowledge, those involved with therapy provision can make informed decisions for the patients in their care and come closer to realising the goal of pressure ulcers becoming a 'never event'.

Evolution created spontaneous movement as the **natural** and **logical** method for pressure ulcer avoidance.

Our goal is to assist nature at times of increased vulnerability.

ACTIVE THERAPY: defining the term

In 2007 a group of clinicians, engineers, manufacturers and researchers published a series of definitions for support surfaces under the auspices of the National Pressure Ulcer Advisory Panel (NPUAP)⁵. As a result, pressure-redistributing surfaces are now classified into one of two groups (Active or Reactive), as defined by their primary mode of action (Figure 2).

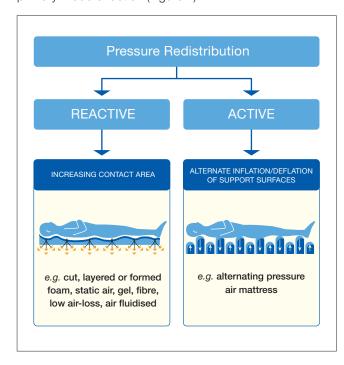


Figure 2: Active and Reactive surfaces

Active mattresses (formerly known as alternating pressure; dynamic; pressure relieving) and Active cushions, are powered devices designed to periodically redistribute pressure away from vulnerable areas even if the patient does not move (Figures 3 & 4).

Active support surfaces

A powered support surface with the ability to change its load distribution properties, with or without applied load.

Figure 3: Definition of an Active surface

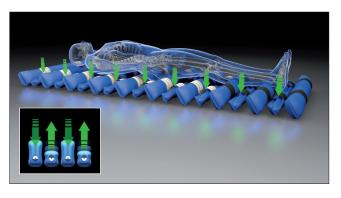


Figure 4: Active surface: periodic cell deflation

In contrast, Reactive surfaces (formerly known as constant low pressure, static, pressure reducing) can be either powered or non-powered and are those that are simply designed to reduce pressure across the whole body by increasing the area of the body in contact with the surface (Figure 5); this is achieved by varying degrees of immersion into, and envelopment by, the supporting media. Unless the patient is physically repositioned on a Reactive surface, the pressure on the body remains constant, albeit lowered. The clinical importance of residual pressure will be covered in the next section.

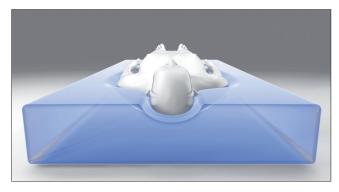


Figure 5: Immersion & envelopment: Reactive surface

PRESSURE ULCER PATHOLOGY: key factors

Overview

Without question, the most significant factor known to be associated with the evolution of pressure ulcers is pressure itself; pressure that may also be associated with shear force within the tissues4. An international, multidisciplinary group of experts reached this conclusion following an extensive review of contemporary literature (Figure 6).

While pressure is a totally natural phenomenon, it can become problematic when it is excessive or prolonged. Exposure to pressure injury is typically associated with individuals who, through age or infirmity, lose the ability to reposition themselves in an appropriate and timely manner.

Aside from immobility, there are other physical and environmental factors that might reduce the skin's ability to withstand pressure such as; nutritional status, co-morbid disease, incontinence, skin temperature and humidity. However, 'the significance of these factors has yet to be elucidated'4.

Pressure and shear force

Pressure arises from the weight of the body pushing down on the mattress or cushion and the inherent resistance exerted by the support surface (Figure 7). There are several factors which influence how this pressure is distributed, such as the type, amount and shape of the tissue present ie (muscle, fat, skin, bone) and body posture. For example sitting, whether in bed or chair, results in higher pressure than lying, while poor posture can increase the impact of shearing forces within the tissue.

Like pressure, shear is a natural phenomenon, which only becomes pathological when it is prolonged or extreme. Shear can be thought of as a nonperpendicular force, which coexists with pressure and, in clinical context, there is always some degree of pressure and shear causing compressive forces within tissues (Figure 8)6.

Although shear is thought to be a contributor in the evolution of pressure ulcers 'the measurement of shear, the role of shear in pressure ulcer formation and strategies to minimise shear remain unclear' (Figure 9)7.

NPUAP-EPUAP Pressure Ulcer Definition (2009)

A pressure ulcer is a localised injury to the skin and/ or underlying tissue usually over a bony prominence, as a result of **pressure**, or **pressure** in combination with shear. A number of confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated.

Figure 6: Definition of a pressure ulcer

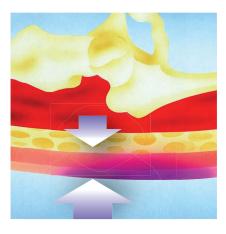


Figure 7: Pressure

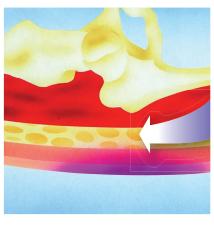


Figure 8: Shear force in deep tissue

What we DO NOT KNOW about shear

- How shear actually causes tissue
- What is the relationship between shear
- Is shear more damaging to muscle, fat
- Which patients are at greatest risk of shear injury?
- The relationship between external and
- What effect postural changes have on shear forces?
- When does shear lead to damage or what is the tissue tolerance to shear?

Figure 9: Shear Force Initiative: conclusions

PRESSURE ULCER PATHOLOGY: key factors (continued)

Friction

Although 'friction' per se is no longer considered a primary cause of pressure ulcers4, it does influence the amount of shear exerted. Surfaces with a high co-efficient of friction may be associated with greater shear in, for example, the poorly supported, semi-recumbent posture. As the skin is 'held' in place by the properties of the surface fabric, the skeleton exerts a downward force increasing the tensile stress and strain within the layers of soft tissue. In contrast, surfaces with a very low friction co-efficient allow the body to slide over the surface and so may hinder independent movement and posture control: a balance is required based upon clinical need.

Microcirculation

Although the underlying pathways, whereby mechanical loading leads to tissue breakdown are poorly understood8, advances in mathematical modelling, biomechanics and non-invasive studies now enable researchers to theorise how pressure affects different tissue types. Several mechanisms have been identified that may contribute to the development of pressure damage9 and this understanding is critical in the optimisation of support surface design.

Bloodflow

Blood flows through the tissues from the arterial to the venous system via a complex network of microcirculatory vessels providing the tissues with oxygenated blood (Figure 10). As blood vessels branch, the lumen gets smaller and the vessel walls become thinner, as a result, the pressure of blood flowing through the network drops considerably and vessels become more easily compressed even under relatively low pressure load.

Pressure and shear can significantly affect microcirculation as vessels stretch, kink or tear; resulting in reduced blood flow within the capillary network of the tissue⁶; even very low pressures exerted on the skin can induce an ischaemic state. If the ischaemic state is prolonged, cell death may occur either as a direct result of vessel occlusion or as a result of tissue damage arising at the point blood flow is restored (referred to as the reperfusion event)¹⁰. Reperfusion injury is most commonly observed after a period of prolonged ischaemia¹¹ such as after myocardial and cerebral infarction, critical limb ischaemia and frostbite and is not associated with the short cyclical off-loading characteristic of Active pressure redistribution.

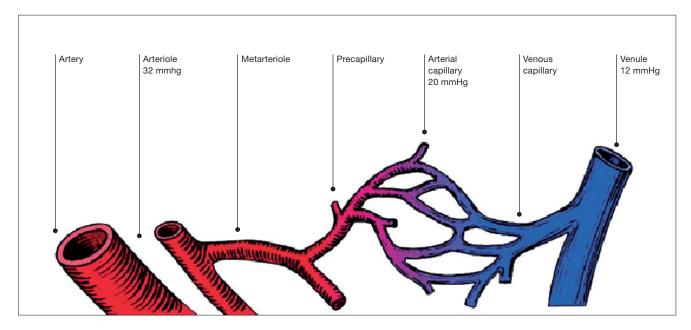


Figure 10: Capillary network

PRESSURE ULCER PATHOLOGY: key factors (continued)

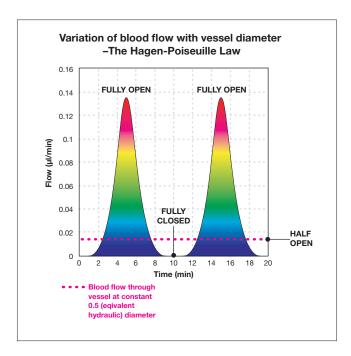


Figure 11: Blood flow in partially closed vessels

In addition, distortion of blood vessels can also disrupt the endothelium and activate the intrinsic clotting mechanism, leading to platelet aggregation (clotting), which can occlude the affected vessel leading to ischaemic necrosis of dependant tissue.

In healthy individuals, homeostatic mechanisms enable capillary pressures to stabilise in response to external pressure (≤ diastolic pressure). However, this mechanism may be diminished in some, and occlusion has been reported with external pressure as low as 17mmHg¹².

Vessels which are even partially occluded deliver significantly less blood to the tissue than fully open vessels¹³ (Figure 11): this is an important determinant in the design of pressure redistributing support surfaces; particularly Reactive surfaces where pressure on the skin remains constant, albeit it lower, until the patient is repositioned.

Lymphatic system

The lymphatic system (Figure 12) is only rarely discussed in relation to pressure ulcers, but there is a growing awareness of importance it plays in the maintenance of tissue integrity. Terminal lymphatic vessels are small, single-cell walled, and collapse easily under even low pressure. As a result, this important drainage system ceases to function effectively,

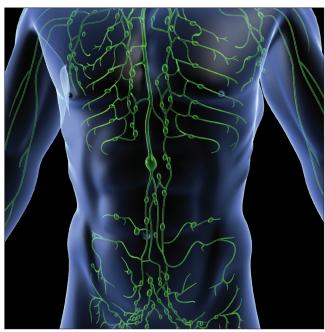


Figure 12: The lymphatic system

leading to a build up of fluid and metabolic waste products in the interstitial space. This, in turn, increases pressure on the micro-vessels of the capillary network. While the exact importance of the lymphatic system is somewhat speculative, studies of lymph flow have proven a very useful tool in defining clear differences between Active and Reactive surfaces in terms of how they affect lymphatic drainage14 and also in demonstrating significant and important performance differences between Active devices that, superficially at least, appear similar¹⁵.

Time

By using contemporary imaging techniques and mathematical modelling of deeper tissue, researchers have refined previously published observational studies in patients¹⁶. It is now believed that, although the pressure:time curve is sigmoidal in shape rather than a classic curve (Figure 13), the relationship between pressure and duration remains critical as even relatively low pressure has been shown to cause muscle cell death if applied for as little as 2-hours^{17,18}.

However, the fact remains that the human body has evolved to respond favourably to its natural environment; this necessarily requires a natural mechanism to deal with

PRESSURE ULCER PATHOLOGY: key factors (continued)

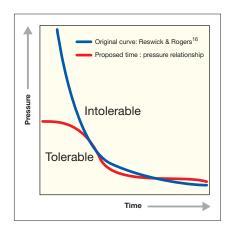


Figure 13: Pressure: time relationship

short periods of relatively high pressure and longer periods of lower pressure. Evolution has provided a raft of protective mechanisms, perhaps the most important being stimulation

exposure to

of spontaneous movement; this serves to ensure that the duration of pressure does not become pathological and that vessels are able to fully reopen after a period of occlusion.

The observation that mobile individuals remain ulcer free, even if they have multiple risk factors, has lead to the development of Active support surfaces which are designed to effectively manage pressure and to closely mimic the natural pattern of pressure loading and off-loading seen in the able-bodied, ulcer-free, population.

Microclimate

It has been suspected for many years that both tissue temperature and the humidity at the tissue/support

surface interface might be important factors affecting pressure ulcer development^{19,20,21}. While the build up of moisture can increase friction between the skin and the support surface, and so increase the risk of superficial ulceration through mechanical damage, elevated skin temperature has a direct physiological effect by both increasing perspiration and increasing metabolic demand.

If this raised demand for oxygen and nutrients cannot be met, for example when the tissue is under load, damage may occur sooner than if the tissue were normothermic.

Periodic off-loading, through movement or mechanical means, such as Active support surfaces, not only enables the tissue to reperfuse, but also facilitates local cooling²².

Summary

Although it is accepted that the formation of pressure ulcers is complex and not fully understood, the primary aetiology is clearly defined as 'pressure or pressure in association with shear4 with the exact relevance of all other factors yet to be elucidated4.

The fact that individuals, even those with extensive risk factors, remain ulcer free if they regularly offload the pressure through movement, has lead to the development of support surfaces specifically designed to protect patients when, through ill-health or disability, they are at risk of tissue injury.

The priority of any clinical intervention must be the management of pressure.



NATURAL PROTECTIVE MECHANISMS

Spontaneous movement

The human body is constantly exposed to periods of high pressure and, in the healthy person, tissue trauma is avoided by means of frequent spontaneous movement. These movements, which take place both consciously and subconsciously, even during sleep, arise in response to stimuli from the tissue under pressure.

The absolute importance of movement has been studied in the patient population, with elderly²³, spinal injured²⁴ and immobile patients²⁵ being particularly vulnerable to pressure ulceration.

The most indicative risk factor is immobility

Seminal studies show us that the natural movement of healthy individuals, even when sleeping, occurs several times each hour^{26,27,28} (Figure 14) and this gives a clear direction for the development of interventions designed to simulate movement in the event that this reflex is diminished or absent.

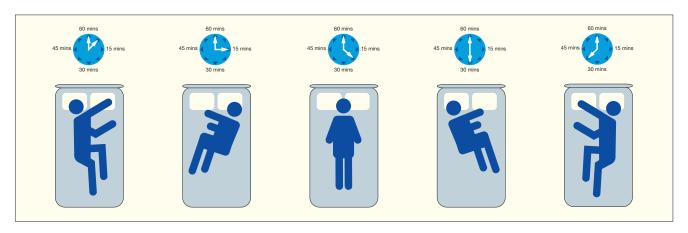


Figure 14: Natural spontaneous repositioning

EFFECTIVE INTERVENTIONS - physical

Pressure off-loading

Given that the primary cause of (non-moisture related) tissue injury is exposure to pressure that is either extreme or prolonged, then the logical, and most effective, intervention is to replicate the natural protection afforded by spontaneous movement. This might be achieved by periodically removing the pressure load through a combination of manual repositioning and Active therapy support surfaces whilst, at the same time,

helping the patient keep as independently mobile as possible. This approach is both important and clinically relevant, as simply reducing the pressure on the skin is not necessarily sufficient to enable tissue perfusion; particularly in patients with complex risk factors.

EFFECTIVE INTERVENTIONS - physical (continued)

Patient repositioning

Patient repositioning, for example 2hrly or 4hrly turning, is no doubt effective and has protected patients for generations. However, today, there is much greater awareness of the risks associated with physical intervention in terms of musculo-skeletal disorders in carers; particularly as the interventions are frequently performed incorrectly (Figure 15).

There is also greater consideration for patient choice. Few individuals would elect to be woken and turned every 2-hours if other, equally effective, options were available. For this reason, evidencebased guidelines suggest that physical repositioning regimens should be individualised and complemented by the selection of an appropriate support surface4; thus optimising sleep intervals and accommodating for pain management, comfort and choice.

Active Therapy support surfaces evolved through the observation and replication of the physiological protective mechanisms inherent in terrestrial mammals. The observation that pressure must be relieved for long enough to make a clinical difference²⁹ has a critical impact on support surface design and performance; with the most effective surfaces likely to be those able to hold pressure as low as possible for as long as possible

However, it is important to recognise that while the design characteristics may be critical to the outcome, not all Active Therapy surfaces provide optimised off-loading profiles.

through each alternating cycle (Figure 16).

"the most effective surfaces likely to be those able to hold pressure as low as possible"



Figure 15: Poor lifting techniques: risk to patient and care giver

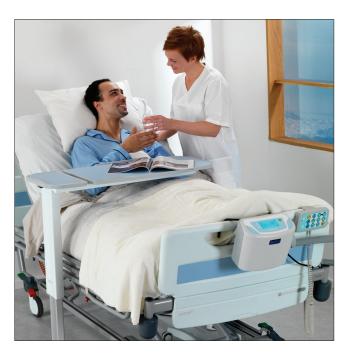


Figure 16: Patient nursed on Active therapy surface

ACTIVE THERAPY - Design principles

Active Therapy surfaces can be described, and differentiated, by several important characteristics: the frequency of off-loading; duration of off-loading; amplitude of the pressure wave and how quickly the pressure is applied and removed⁵. These factors come together to produce a cycle 'signature' which will be different for each support surface.

These performance characteristics are clinically important as laboratory studies clearly indicate that the physiological response elicited by support surfaces varies according to type^{15,30,31}; these distinct effects might have a clinically significant effect on outcome.

Cycle signature

Short interval cycle

Systems with high amplitude (the difference between maximum and minimum pressure) that achieve a low pressure but only for a short duration (Figure 17), are unlikely to allow sufficient reperfusion time; especially in people with compromised central or peripheral vascular function.

Low amplitude (pulsation) cycle

Systems with a low amplitude cycle perform similarly to Reactive devices and off-loading may be insufficient to elicit a normal hyperaemic response (Figure 18)32. This characteristic may be a feature of a particular design, or simply as a result of having insufficient power in the air pump.

Optimised cycle

Systems designed to off-load vulnerable anatomical locations for as long as possible at each cycle (Figure 19), have been shown to deliver superior levels of tissue perfusion and lymph flow compared to both short interval and low amplitude cycles 15,30,32.

There is no doubt clinically, that the cycle needs to be of sufficient amplitude and duration to efficiently 'lift' the body clear of the deflating cell for long enough to allow reperfusion to occur²⁹. While 'pressure relief, below 20-30 mmHg is the cornerstone of the therapy of pressure ulcers'33 ArjoHuntleigh consider this a minimum standard and, unlike many other surfaces on the market, consistently aim to provide pressures at 10mmHg or lower for a substantial proportion of each cycle^{30,34,35}.

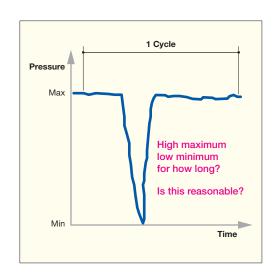


Figure 17: Short interval, high amplitude cycle

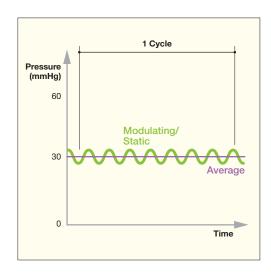


Figure 18: Low amplitude (pulsation) cycle

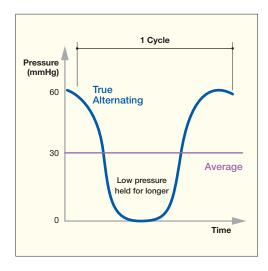


Figure 19: Optimised cycle

ACTIVE THERAPY - Design principles (continued)

Cycle configuration (alternation sequence)

Cell configuration is particularly important for managing tissue integrity in the vulnerable patients who may, because of their age³⁶ and/or underlying condition, have prolonged tissue oxygen recovery times³⁷.

Support surfaces typically operate on an alternating cycle where every second (1-in-2) or, less commonly, every third or fourth cell deflates, while keeping the body supported across the remaining inflated cells (Figure 20).

The ideal cycle will be balanced, such that loading time is matched by recovery time, and this is only mathematically feasible with a 1-in-2 cell cycle. A reasonable alternative to this would be a 1-in-3-cycle system, such as Trinova®, which has been specifically designed to rapidly off-load during the deflation phase and operates on a shorter duration cycle (see below). Those devices which are associated with longer contact times, such as 1-in-4 cell cycles, may be more likely to induce heat build up which can, in turn, lead to sweating (risk of maceration) and greater metabolic demand; a demand which may not be met during the shortened off-loading phase and so leading to progressive tissue ischaemia.

Cycle duration

Healthy individuals enjoy a natural protective mechanism and manage pressure by moving spontaneously at approximately 5-minute intervals, even during sleep²⁷. Similarly, studies of vulnerable patients have shown that those who make significant body movements every seven to twelve minutes rarely develop tissue damage^{38,39}. These observations form the basis for all ArjoHuntleigh support surfaces with the premise that a 7.5 or 10-minute cycle time (5-minutes loaded and 5-minutes off-loaded) most closely resembles the movement patterns associated with that chosen by nature, and so is most likely to provide optimal outcomes: an assumption borne out by extensive field studies40.

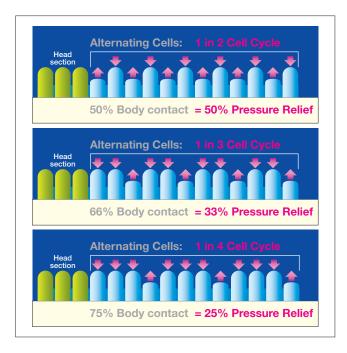


Figure 20: Different patterns of off-loading

Comfort & support

A support surface should be considered a therapeutic modality prescribed to prevent and treat pressure ulcers and so the design must ensure that a careful balance is struck between pressure redistribution (efficacy) and

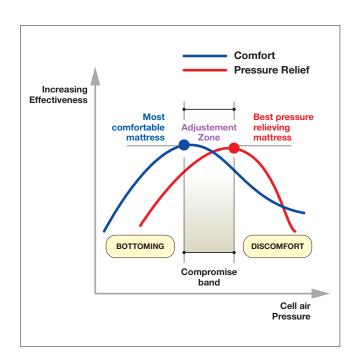


Figure 21: Optimising comfort and performance

ACTIVE THERAPY - Design principles (continued)

comfort⁴¹. There is little point in developing a device that is highly effective, but unacceptable to patients and, by the same token, there is little point in prioritising comfort over efficacy.

In Active air systems, comfort is related primarily to cell inflation pressure and the rate of inflation and deflation during the cycle. A high inflation pressure prevents 'bottoming out', but risks discomfort through high peak contact pressure. While a very soft surface might increase comfort, but may hinder independent movement and increase the likelihood of 'bottoming out' (Figure 21). This explains why a high degree of immersion and envelopment is not necessarily a desirable feature in Active Therapy surfaces.

Fortunately, a balance between comfort and effectiveness can be achieved. A randomised controlled trial, involving almost 2,000 subjects, shows how one type of surface (mattress replacement) can be both more cost-effective and more comfortable than a different type of mattress (overlay)42.

However, optimising the system for each patient is not necessarily straightforward. Devices range from those that have fully automated correction, and so increase or decrease the air in the cells in response to a change in body-mass distribution, to those that require manual adjustment each time the patient alters position.

Automatic, semi-automatic or manual

Manual adjustment

This approach is most appropriate for patients who might be less vulnerable to harm should the device be set incorrectly, for example lower risk patients who are able to make some independent postural changes. However, clinicians are still responsible for setting the device up correctly and this has implications for training, particularly in areas where staff turn-over is high, where the environment is not supervised (home care) or where patient acuity may divert attention e.g. intensive care. However, if used wisely and safely, manually adjusted systems may represent value for money⁴³.

Semi-automatic adjustment

Systems such as the Alpha Response™ mattress replacement and overlay* simply require carer intervention at first installation (selection based on patient weight), after which point the device automatically delivers optimised internal cell pressure: this includes adjustment as the patient moves between a supine and semi-recumbent position. Auto Profile Technology* detects the angle of backrest inclination (Figure 22); reducing the likelihood of user error during use while providing a cost-effective solution for vulnerable patients⁴⁴.

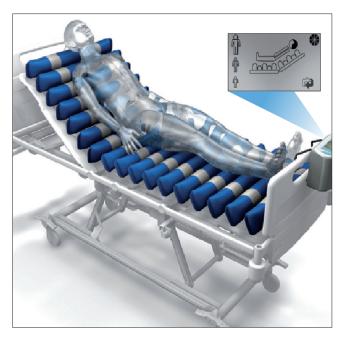


Figure 22: Semi-automatic pressure adjustment

Automatic adjustment

The safest option, and the one most likely to deliver optimal outcomes in the most vulnerable patient, is the fully automated surface. Automatic systems optimise internal cell pressure to maintain high levels of comfort and effective pressure redistribution regardless of patient weight or posture. Mattresses such as the Nimbus® range and Auto Logic® range are both fully automated systems and are consistently shown to be clinically effective in the most challenging circumstances⁴⁰.

ACTIVE THERAPY - Design principles (continued)

Automatic adjustment (continued)

It is important to note however, that not all devices labelled as 'automatic' have a dynamic function. Many surfaces do not use the comprehensive algorithms and micro-processor feedback to control the inflation pressure, but simply revert to a pre-determined 'default' pressure in response to the load changing. This fundamental difference has been demonstrated in a study comparing the Nimbus 3 mattress with surfaces from three other suppliers, all of whom claimed to have a fully 'automated' system⁴⁵. The study revealed that only the Nimbus 3 mattress demonstrated true adjustment to changes in body mass distribution and the physiological effects of these subtle, but nevertheless clinically relevant, design attributes can be further studied in vivo using non-invasive Doppler imaging (see page 16)30,46,47.

Safety features and performance optimisation

In addition to a full range of alarms, cable management and easy clean surfaces, many of the Active Therapy surfaces from ArjoHuntleigh have additional design features aligned closely to patient and care-giver safety.

Heel Guard (Nimbus range)

Uses very simple yet effective cell design (Figure 23) to ensure off-loading over the most vulnerable heel area as low as possible for as long as possible.

AutoMatt sensor pad (Nimbus range)

A pressure sensitive pad located beneath the mattress in the torso section; automatically detects and prevents 'bottoming out'.

Wound Valve Technology (Nimbus range)

The prevention of heels ulcers is particularly problematic. as is the healing of existing wounds. Contemporary guidelines suggest⁴ that heels should be permanently off-loaded in vulnerable patients and existing pressure ulcers off-loaded to facilitate healing - both can be achieved using Wound Valve Technology (Figure 24)



Figure 23: Nimbus mattress range: specialised Heel Guard for enhanced off-loading



Figure 24: Wound Valve Technology: enables complete and permanent off-loading

deflated for as long as necessary, without causing discomfort to the patient and without hyper-extending the knee; a position associated with popliteal vein occlusion⁴⁸ and potential DVT risk. It is believed that complete off-loading of the heel before damage occurs is more effective than merely reducing pressure⁴⁹.

Seat cushions (all ranges)

ArjoHuntleigh designs Active Therapy cushions to the same exacting standards as the bed surfaces and cushions include side-to-side cell alignment and contouring to help promote and retain sitting posture. Studies have shown that the off-loading provided by Active seat cushions can match the tissue perfusion obtained by repositioning50 and so, while these cushions don't replace the need for repositioning, they add an important element of safety in any 24-hour risk management programme.

ACTIVE THERAPY - Performance measurement

Index'.

Given the design differences between surfaces, it is important for clinicians to have information in order to be able to differentiate between apparently similar systems and thus select the most suitable surface for the patient. These differences should not be underestimated, as the impact on blood flow can be significant. Mattresses, such as the Nimbus⁴⁷ and AUTO Logic³⁰ systems, which are designed to adjust automatically to individual patient characteristics, have been shown to deliver significantly greater blood flow to the tissue compared to other surfaces. Some of the possible performance metrics are described in this section.

(PRI) Unlike Reactive therapy, an Active support surface is designed to limit the degree of immersion and envelopment in order to support the patient clear of the

deflating cell. Hence it is possible to track the off-loading

profile as each cell deflates over time (Figure 25).

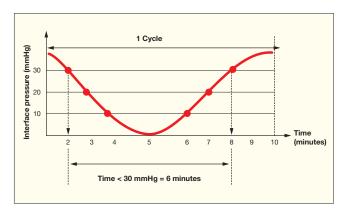


Figure 25: Typical Pressure Redistribution Curve

Measuring critical performance characteristics

Cycles have typically been described by reporting the maximum, minimum and/or average pressure recorded at the mattress:skin interface (interface pressure); however, on its own, this is misleading and unhelpful. As figures 18 and 19 show, the average pressure can be identical and deliver very different, yet clinically important, physiological responses. It is for this reason that average pressure should not be used to describe Active systems⁵¹. Similarly, reporting maximum pressure is largely meaningless as it is neither extreme nor prolonged and so of little clinical relevance if regularly relieved.

The clinically important measurement criteria for Active Therapy systems are therefore minimum pressure and time, and specifically how long the lowest pressures are maintained for: this can be reported by

Pressure Redistribution Index

calculating a time-dependent 'Pressure Redistribution

PRI Calculation

If pressure is <20 mmHg for 4-minutes in every 10-minute cycle the data can be reported as either:

PRI per hour = 24-minutes @ <20mmHg

Figure 26: Calculating the Pressure redistribution Index

Although it is impossible to determine an absolute safety threshold in the clinical setting, the goal is to achieve pressures as low as possible for as long as possible and certainly to aim for pressures below thresholds that are most likely to be clinically relevant i.e. 30 mmHg, 20 mmHg and 10 mmHg^{52,53} (Figure 10): these pressures relate approximately to the closing pressures of blood vessels at heart level⁵⁴.

PRI can be reported either as the percentage time below certain thresholds for each cycle or perhaps, more relevant, as the percentage off-loading per hour; this enables comparison between surfaces with different cycle times (Figure 26).

In seated individuals, the pressures exerted by a seat surface are higher due to the smaller contact area; blood pressure is also higher since a column of blood exists between the heart and the buttocks. The proposed reporting criteria for PRI over the ischial tuberosities, is therefore 60 mmHg, 40 mmHg and 20 mmHg.

ACTIVE THERAPY - Performance measurement (continued)

By sustaining a high PRI performance, **Active pressure redistributing support** surfaces will ensure blood vessel diameters remain as large as possible for as long as possible.

The potential advantage of holding pressure 'lower for longer' (high PRI) has been reported in both healthy subjects^{30,31} and those with impaired neuro-vascular response⁵⁵.

How PRI is measured

PRI is typically measured using a small (1-2 cm) calibrated sensor placed directly between the apex of a cell and a bony prominence, usually heel or sacrum (Figure 27). However, until recently, there has been

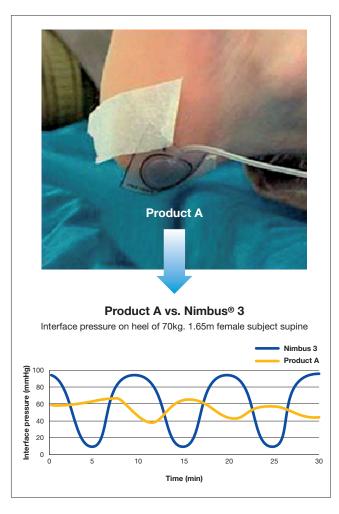


Figure 27: Comparing the performance (PRI) of different Active Therapy surfaces

little attempt to standardise the test protocol. This, plus the morphological variation introduced by human subjects, renders comparison between different test centres virtually meaningless. To address this, in 2009, an international group partnered with the Tissue Viability Society (UK) in order to define an appropriate test methodology for Active surfaces.

In 2011, the group have begun to report their findings^{56,57}; this includes the development of a standardised test mannequin, a reporting mechanism for performance characteristics (based on PRI) and the acknowledgement that existing tests for 'immersion and envelopment', as used for Reactive surfaces, are inappropriate for application to Active surfaces.

It is important to note that performance measurements such as PRI, while useful descriptive tools, can only be used to measure pressure redistribution. Used alone, they cannot give an indication of clinical outcome and so should be used in combination with evidence from laboratory or field trials in order to more reliably inform decision-making.

Tissue perfusion studies

Tissue perfusion can be studied in the laboratory and can provide an indication of how the microcirculation responds to tissue off-loading. This might be considered a surrogate measure of clinical performance and certainly enables differentiation between different support surfaces³⁰. Those Active surfaces with high PRI values (off-load lower for longer) are associated with significantly higher blood flow as they are less likely to diminish the normal homeostatic response to off-loading: reactive hyperaemia⁵⁸.

Microclimate

In recent years, despite the fact that the exact relevance is 'yet to be elucidated'4, much has been made of the importance of temperature and moisture control at the interface between the mattress and body; much of this being related to the assumed requirement for air flow (air loss) across the mattress

ACTIVE THERAPY - Performance measurement (continued)

surface. However, this is not necessarily the case. If it is accepted that moisture associated with incontinence is managed by means other than the mattress, then moisture associated with sweating might be managed by temperature control.

movements. This enables air to flow beneath the skin and cool the interface (Figure 28); at the same time, some surfaces have air flow beneath the cover to promote a temperature gradient away from the body, while the inflated cells are in contact with the skin.

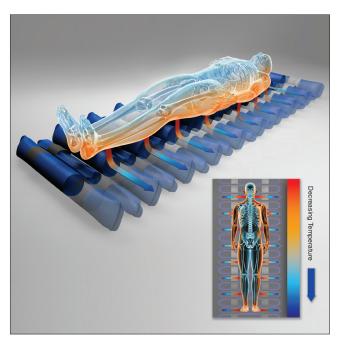


Figure 28: Heat dispersal hypothesis: conduction and convection

Active Therapy systems have one distinct advantage when it comes to temperature control, particularly those with a high profile PRI. Active surfaces periodically remove contact with the skin, much as an individual would when making spontaneous

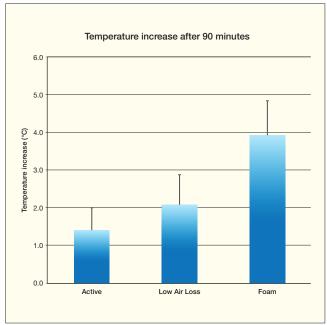


Figure 29: Active therapy: superior temperature control

Laboratory studies clearly show the beneficial effect of Active Therapy on temperature regulation, with the AUTO Logic 200 mattress outperforming both foam and low air loss (Reactive) surfaces (Figure 29)22.

ACTIVE THERAPY - Clinical application

Aside from the general management of pressure ulcer risk and treatment of existing wounds there are some specific applications particularly suited to Active Therapy surfaces; the following recommendations are drawn from both contemporary guidelines⁴ and relevant literature.

- Active Therapy surfaces are recommended for patients who cannot be frequently repositioned⁴. Repositioning can be tailored to the patients' choice and their need for rest and sleep without compromising tissue integrity⁵⁹. Using an Active surface with an individualised repositioning programme promotes well-being as well as reducing caregiver exposure to musculo-skeletal disorder.
- Active cushions may be beneficial for patients who are immobile and seated or have developed wounds on Reactive surfaces (e.g. air filled, gel, foam)⁴. These may be particularly helpful if the patient is likely to be non-concordant with regular repositioning regimens⁵⁰. All patients with a therapeutic mattress should have a cushion when seated.
- Consider the care setting when allocating equipment. Use enhanced safety features such as battery back-up in low-supervision environments.
- Off-load heels and existing pressure ulcers⁴. Ideal application for Active surfaces with Wound Valve Technology.

ACTIVE THERAPY - Summary

Active surfaces, as opposed to powered Reactive devices, evolved directly in response to the recognition of 'unrelieved pressure' as the principal cause of pressure ulcers; this simple foundation remains true today and may explain why Active surfaces have out-performed Reactive surfaces in some of the most challenging environments^{60,61.62}.

This is perhaps also the reason why the international consensus group, who developed the NPUAP-EPUAP Pressure Ulcer Prevention Guideline (2009), recognised the value of Active Therapy as the modality of choice for the most vulnerable patients – those who cannot be frequently repositioned. Overall, Active mattress studies have delivered perhaps the strongest evidence base over the past 50-years and within some of the most challenging environments⁴⁰: this is particularly true for Active surfaces with a high PRI index⁴⁰. Evidence suggests that this modality is perhaps the most effective

and cost-effective solution for managing the highest risk and treating the worst ulcers in vulnerable patients⁶³.

A final point is to reflect on the fact that, although many Active devices exist, their effectiveness is not uniform even though they appear to be of similar construction. The key principle of pressure off-loading is not always understood and design may be driven by manufacturing and pricing considerations rather than by clinical relevance. By employing leading edge technology to develop and test support surface functionality, Active Therapy surfaces from ArjoHuntleigh are continuing to push the boundaries of design and performance keeping patient safety, care-giver safety and budgets firmly in mind.

For more information about the support surfaces available from ArjoHuntleigh and the clinical evidence supporting the product range, please contact your local representative or visit www.arjohuntleigh.com

References

- 1. Vanderwee K, Clark M, Dealey C et al. Pressure ulcer prevalence in Europe: a pilot study. Journal of Evaluation in Clinical Practice. 2007; 13: 227-235
- 2. Phillips L. Pressure ulcer audit: a paradigm shift. In: Cherry GW, Hughes MA (Eds). Second Oxford European Wound Healing Course Book. Positif Press, Oxford. 2010: 159-165
- 3. Shreve J, Van Den Bos J, Gray T et al. The Economic Measurement of Medical Errors. The Society of Actuaries Health Section. 2010. Milliman.
- 4. NPUAP & EPUAP Pressure ulcer prevention and treatment guideline. 2009. www.npuap.org (accessed January 2011)
- 5. NPUAP Terms and Definitions Related to Support Surfaces. NPUAP, Washington DC. 2007 www.npuap.org (accessed January 2011)
- 6. Kottner J, Balzer K, Dassen T et al. Pressure ulcers: A critical review of definitions and classifications. Ostomy Wound Management. 2009; 55(9): 22-29.
- 7. Edsberg L, Perla J, Call E. Shear Force Initiative. World Union of Wound Healing Societies Conference. Toronto, Canada. 2008
- 8. Bader D. Oomens C. Recent advances in pressure ulcer research. In: Science and Practice of pressure ulcer management, 2006. Springer Ltd, London.
- 9. Berlowitz DR, Brienza DM. Are all pressure ulcers the result of deep tissue injury? A review of the literature. Ostomy Wound Management. 2007; 53(10): 34-38.
- 10. Stadler I, Zhang R, Oskoui P et al. Development of a simple, non-invasive clinically relevant model of pressure ulcers in the mouse. Journal of Investigative Surgery. 2004; 17: 221-22.
- 11. Nyhlen B. Bedsores Origin, Prophylaxis as well as conservative and surgical treatment. SPRI report No. 4. 1979; 122-137. Stockholm
- 12. Guyton AC. Textbook of Medical Physiology. 8th Ed. Saunders &Co. 1991: 170-183
- 13. Mayrovitz HN, Regan M, Larson P. Effect of rhythmically alternating and static pressure support surfaces on skin microvascular perfusion. Wounds. 1993; 5(1): 37-55
- 14. Gunther R, Brofeldt B. Increased lymphatic flow: effect of a pulsating air suspension bed system. Wounds. 1996; 8(4): 134-140
- 15. Gunther RA, Clark M. The effect of a dynamic pressureredistributing bed support surface upon systemic lymph flow and composition. Journal of Tissue Viability. 2000; 10(3 suppl): 10-15
- 16. Reswick JB and Rogers JE. Experience at Rancho Los Amigos Hospital with devices and techniques to prevent pressure sores. In: Kenedi RM. Cowden JM and Scales JT eds. Bedsore Biomechanics: 1976. Macmillan Press London.
- 17. International review. Pressure ulcer prevention: pressure, shear, friction and microclimate in context. A consensus document. London: Wounds International, 2010.

- 18. Linder-Ganz E, Engelberg S, Scheinowitz M et al. Pressuretime cell death threshold for albino rat skeletal muscles as related to pressure sore biomechanics. J Biomech. 2006; 39(14): 2725-2732.
- 19. Romanus EM. Microcirculatory reactions to controlled tissue ischaemia and temperature: a vital microphagic study on the hamster cheek pouch. In Kenedi RM (ed). Bedsore Mechanics, Macmillan Press, 1976. London.
- 20. International review. Pressure ulcer prevention: pressure, shear, friction and microclimate in context. A consensus document. London: Wounds International, 2010.
- 21. Lachenbruch C. Skin cooling surfaces. Estimating the importance of limiting skin temperature. Ostomy Wound Management. 2005; 51(2): 70-79.
- 22. Goossens R & Phillips L. Effects of support surface design on skin temperature. NPUAP Biennial Conference (poster). 2011. Las Vegas
- 23. Barbenel J C. Movement studies during sleep. Pressure Sores - Clinical Practice and Scientific Approach, Bader D L (Ed.) MacMillan (London). 1990; 249-260.
- 24. Noble P C. The prevention of pressure sores in persons with spinal cord injuries. World Rehabilitation Fund, 1981. New York
- 25. Norton D, Maclaren R, Exton-Smith A, N. An investigation of geriatric nursing problems in Hospital. Churchill Livingstone, 1962. Edinburgh.
- 26. Johnson M et al. In what position do healthy people sleep? JAMA. 1930; 94: 2058-2062.
- 27. Laird D A. Did you sleep well? Rev.Rev. 1935; 91(Feb): 23-70.
- 28. De Koninck J, Cagnon P, Lallier S. Sleep Positions in the Young Adult and Their Relationship with the Subjective Quality of Sleep. Sleep. 1983; 6(1):52-59
- 29. Mawson A R et al. Risk factors for early occurring pressure ulcers following spinal cord injury. American Journal of Physical Medical Rehabilitation. 1988; 67: 123-127.
- 30. Goossens RH, Rithalia SVS. Physiological response of the heel tissue on pressure relief between three alternating pressure air mattresses. J Tissue Viability. 2008; 17(1): 10-14
- 31. Mayrovitz HN. Effects of different cyclic pressurization-relief patterns on heel skin blood perfusion Advances in Skin and Wound Care. 2002; 15(4): 158-164
- 32. Rithalia S, Heath GH. Alternating pressure redistribution mattresses: appearances can be deceptive. MedTex Conference. 2007
- 33. Robertson J, Swain I, Gaywood I. The importance of pressure sores in total healthcare. Pressure Sores - Clinical Practice and Scientific Approach, (Ed.) Bader D, MacMillan 1990. London.
- 34. McLeod A, Rithalia SVS, Gonsalkorale M. Development of a system for evaluating dynamic air mattresses. Journal of Tissue Viability. 1994; 4(4): 133

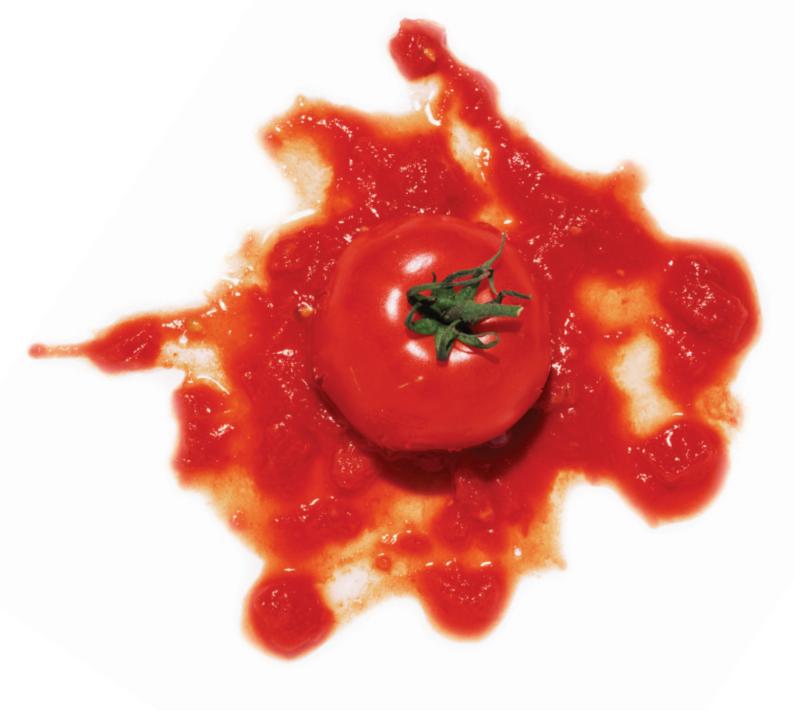
References

- 35. Rithalia S V S, Hevari B, Hutchins S. Measurement of Pressure Relief Index in dynamic air cushions. Abstracts of In-vivo measurement: scientific, commercial and clinical aspects, (3-4 April): Manchester Metropolitan University. 1996
- 36. Sanada H, Kanagawa K, Inagaki M et al. A study on the prevention of pressure ulcers: the relationship between transcutaneous PO2 in the sacral region and predictive factors for pressure ulcer development. Wounds. 2005; 7(1): 17-23
- 37. Inagork M, Nishimura M, Sanada H. Study of the prevention of pressure sores - relationship between transcutaneous PO2 in the sacral region and the length of applied pressure. J. Jpn. Acad. Nurs. Sci. 1985; 5(2): 92-93.
- 38. Exton-Smith AN, Sherwin RW. The prevention of pressure sores - significance of spontaneous bodily movements. Lancet. 1961; 2(7212): 1124-1126
- 39. Keane F X. The minimum physiological mobility requirement (MPMR) for man supported on a soft surface. Paraplegia. 1978; 16: 383-389.
- 40. Optimising and Measuring Outcomes in Pressure Ulcer Prevention and Management: clinical evidence. ArjoHuntleigh. 2010; isssue 6. www.arjohuntleigh.com (accessed January 2011)
- 41. Rithalia S V S. Comparison of performance characteristics of the Nimbus and Airwave mattresses. International Journal of Rehabilitation and Research. 1995; 18: 182-185
- 42. Iglesias C, Nixon J, Cranny G et al. Pressure relieving support surfaces (PRESSURE) trial: cost effectiveness analysis. BMJ. 2006; 332(7555): 1413-1415
- 43. Clifford I, Candler S, Starling M. Twenty-four hour pressure area management: study report. British Journal of Nursing. 1995; 4(22): 1308-1314
- 44. Ward C. The value of systematic evaluation in determining the effectiveness and practical utility of a pressure-redistributing support surface. J Tissue Viability. 2010; 19(1): 22-27
- 45. Rithalia S. V. S, Heath G. H. A change for the better? Measuring improvements in upgraded alternating - pressure air mattresses. Journal of Wound Care. 2000; 9(9): 437-440
- 46. Rithalia S. Assessment of patient support surfaces: principles, practice and limitations. Journal of Medical Engineering Technology, 2005; 29(4):163-9
- 47. Rithalia S, Taylor A and Gonsalkorale M. "A change for the better?" EPUAP (oral presentation) Aberdeen, Scotland. 2005
- 48. Huber DE, Huber JP. Popliteal vein compression under general anaesthesia. Eur J Vasc Endovasc Surg. 2009; 37(4): 464-469
- 49. Donnelly J (2001). Hospital acquired heel ulcers: a common but neglected problem. Journal of Wound Care; 10 (4): 131-136
- 50. Stockton L, Rithalia SVS. Is dynamic seating a modality worth considering in the prevention of pressure ulcers? J Tissue Viability. 2008; 17(1): 15-17

- 51. Bliss M. Letter to the Editor British Medical Journal. 1995; 310: 126
- 52. Eriksson E. Etiology: microcirculatory effects of pressure. Pressure Ulcers: Principles and Techniques of Management, Constantian M B (Ed.) Little Brown & Co. (Boston). 1980; 7-14
- 53. Kemp M G, Krouskop T A. Pressure ulcers: reducing incidence and severity by managing pressure. Journal of Gerontological Nursing (Sept). 1994; 27-34
- 54. Landis E M. Micro-injection studies of capillary blood pressure in human skin. Heart. 1930; 15: 209-228
- 55. Van Schie C, Ragunathan S, Rithalia S et al. Heel blood flow studies using alternating pressure air mattress systems in diabetic patients. Manchester Diabetes Centre, School of Health Care Professions, University of Salford. 2004
- 56. Tissue Viability Society. Laboratory measurement of the interface pressures applied by active therapy support surfaces: A consensus document. Journal of Tissue Viability. 2010; 19(1): 2-6
- 57. Goossens R, Clark M and Philllips L. Developing a standardised test methodology for active therapy support surfaces. EPUAP conference (3 oral presentations). 2010. Birmingham, UK
- 58. Husain T. An experimental study of some pressure effects on tissues, with reference to the bed-sore problem. The Journal of Pathology and Bacteriology. 1953; 66: 347-358
- 59. Defloor T, De Bacquer D, Grypdonck MH. The effects of various combinations of turning and pressure-reducing devices on the incidence of pressure ulcers. Int J Nurs Stud. 2005; 42(1):
- 60. Finnegan MJ, Gazzero L, Finnegan JO et al. Comparing the effectivenss of a specialised alternating air pressure mattress replacement system and an air-fluidised integrated bed in the management of post operative flap patients: a randomised controlled pilot study. Journal of Tissue Viability. 2008; 17(1): 2-9
- 61. Gebhardt KS, Bliss MR, Winwright PL et al. Pressure-relieving supports in an ICU. J Wound Care. 1996; 5(3): 116-121
- 62. Malbrain M, Hendriks B, Wijnands P et al. A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients. Journal of tissue viability. 2010; 19(1): 7-15
- 63. Clark M. Models of pressure ulcer care: costs and outcomes. British Journal of Health Care Management. 2001; 7(10): 412-416

Notes

Notes



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