

SoftCloud[™] Dynamic Mattress Range

Clinical Evaluation

The SoftCloud[™] [™] Dynamic mattresses have been developed and built following the principles set down in published clinical papers, freely available in the public domain.

These papers are available to be used as an additional tool for clinical nurse advisers and should be used in conjunction with the results of local evaluations of the SoftCloud[™] products.

With regard to the SoftCloud[™] dynamic mattress, this is a re-branded version of the Softair which in turn is a rebranded version of Sidhil Trio mattress, for which there is a published clinical paper (see file copy).

Pending the arrival of production models of the SoftCloud[™] products, the clinical evaluation is based on published papers on alternating pressure support, and the Trio paper. Once production model are received, a separate clinical evaluation of the SoftCloud[™] product by a recognized clinician will be initiated.

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A pressure ulcer is localized 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 contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated.¹

Pressure ulcers continue to present a major health problem.

- Up to 1 in 5 patients in Europe are incurring tissue damage in acute care²
- In the United Kingdom, up to 4% of the healthcare budget is spent on pressure
- ulcer management³
- Pressure ulcers pose a significant threat for patient comfort and morbidity with
- associated factors such as pain, loss of mobility and loss of self-esteem having a
- negative impact on patient wellbeing
- Pressure ulcers pose a significant burden to the healthcare provider; increased cost off care, length of stay, nursing time and litigation.

Pressure ulcers are considered preventable and correct management can reduce the risk of occurrence. Pressure ulcer avoidance is a main concern for clinicians and healthcare providers alike.

FORMATION OF A PRESSURE ULCER:

A pressure ulcer can be described as an ulceration resulting from the combined effects of pressure or pressure in combination with shear.

The formation of pressure ulcers is complex and not fully understood, however the basic process involves the constriction of small blood and lymph vessels, as a result of external compression and distortion of the soft tissues. This causes an insufficient supply of essential nutrients and oxygen, together with a buildup of waste products from cell metabolism.

These forces can cause a significant reduction in blood flow as vessels stretch, kink or tear⁴ resulting in reduced blood flow, ischemia and vessel occlusion, which can lead to pressure damage.

Why use Alternating Pressure for pressure ulcer management?

Traditionally, average capillary closing pressures have been used to predict the pressures beyond which tissue damage may occur: 32 mmHg in the arterioles, 20 mmHg in the capillary bed and 12 mmHg in the venules⁵. However, studies that are more recent suggest that the average 'functional' operating pressure in the capillary bed is 17 mmHg NOT 32 mmHg⁶ and may be as low as 6 mmHg in the venous end of the capillary.

Fortunately, evolution has equipped the body with a natural ability to manage high pressures for short periods of time, by initiating normal spontaneous movement which stimulates reactive hyperaemia: a process that restores the blood flow to the tissues⁷.

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WHO IS AT RISK?

• Patient groups, such as the elderlys and paraplegics9 move less frequently and have related tissue structure that predisposes them to pressure ulcers.

- Those under the influence of sedatives or strong analgesics.
- Patients with neurological disorders, leading to impairment of sensation.
- Patients with microvascular disease e.g. diabetes, arteriopathy etc.
- Incontinent patients moisture macerates the skin increasing the risk of pressure ulcers.
- Age, not an independent risk factor alone but associated with high risk co-morbidities.

HOLISTIC WAYS TO HELP PREVENT PRESSURE ULCERS DEVELOPING:

Traditionally a care plan is devised following a risk assessment of the patient – measures should include:

A 24 hour, individualized, repositioning regime¹⁰, which includes; early mobilization, good nutrition, management of incontinence, restricted time spent seated, the provision of a pressure redistributing support surface for both bed and chair and daily skin inspection.

ALTERNATING PRESSURE: THE NATURAL METHOD OF RELIEVING PRESSURE

Alternating pressure air mattress (APAM), alternating overlay, dynamic, active mattress. Alternating Pressure systems, typically consist of rows of horizontal cells that alternate; with the 1:2 or 1:3 cycle offering the greatest degree of pressure off-loading. The ideal movement pattern is one which resembles that of healthy individuals - approximately one movement every five minutes11. This facilitates restorative blood flow to the tissues, which is usually accompanied by a measurable hyperaemic response.

The loading cycle needs to be of sufficient amplitude and duration to both mimic normal movement and to'lift' the body clear of the deflating cell long enough to allow reperfusion. Systems that have a low amplitude cycle may be unable to stimulate blood flow and, if pressure relief is ineffective, may have an adverse effect on clinical outcome.

The ability of an APAM to relieve pressure below clinically relevant thresholds is measured by calculating the Pressure Relief Index (PRI). Choosing thresholds close to arteriolar, capillary and venule operating pressures (30, 20 and 10 mmHg) indicate an APAM's performance. Clearly, the greater the time spent under each threshold... the better! In particular, the 20 and 10 mmHg thresholds12,13 are clinically more important.

Pressure Relief Index can be used to measure and compare the performance of alternating surfaces such as mattresses and cushions. Interface pressure (the pressure existing between the support surface and the test subject) is recorded using a single sensor such as an Oxford Pressure Monitor then digitally analyzed and expressed as a graph. Other outcome measures such as blood flow can also be measured and can clearly illustrate the relationship between off-loading and blood flow.

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OPTIMISING CLINICAL OUTCOMES USING ALTERNATING PRESSURE:

The function of an effective APAM is to hold contact pressures as low as possible for as long as possible, particularly under the most vulnerable areas such as the heel.

- Ensure staff know how to correctly set up the device and adjust cell pressures accordingly for nonautomatic systems – use fully automatic systems where possible to avoid the risk of error.
- Minimize the use of tightly fitted sheets and padding in order to optimize the beneficial effects of pressure off-loading but, at the same time, actively manage incontinence.
- Take particular care when moving and handling the patient to avoid friction and shear.
- Ensure effective pressure management continues when the patient is seated in a chair.
- Use mattress replacements rather than an overlay on top of a base foam mattress where; the patient is at the upper weight limit for an overlay, the base mattress is of questionable quality, or where side rail height is an issue.

Alternating mattress replacements have been found to be the most cost-effective way to assist in the management of pressure ulcers₁₄.

References:

1. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Australia; 2014.

2. European Pressure Ulcer Advisory Panel (1999). Guidelines on the treatment of pressure ulcers; 1(2): 31-33.

3. Bennett G, Dealey C and Posnett J (2004). The cost of pressure ulcers in the UK. Age and Aging; 33(3): 230-235.

4. Bliss MR and Thomas JM (1993). An investigative approach: An overview of randomised controlled trials of alternating pressure supports Prof Nurs; 8: 292 – 296.

5. Williams SA et al (1988). Dynamic measurements of Human Capillary Blood pressure. Clinical Science; 74: 507-512.

6. Landis EM (1930) Micro-injection studies of capillary blood pressure in human skin Heart; 15: 209-228.

7. Reswick JB and Rogers JE (1976). 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: Macmillan Press London.

8. Conine TA, Daechsel D and Lua MS (1990). The role of alternating air and Silicore overlays in preventing decubitus ulcers. Int J Rehab Res; 13: 57 – 65.

9. Gebhardt KS, Bliss MR, Winwright PL and Thomas JM (1996). Pressure-relieving supports in an ICU. JWound Care; 5(3): 116-121.

10. Image adapted from www.geriatricssyllabus.com.

11. Grindley A and Acres, J (1996). Alternating pressure mattresses: comfort and quality of sleep. Brit J Nurse; 5(21): 1303-1310.

12. Guttman L (1976). The prevention and treatment of pressure sores. In: Kenedi RM, Cowden JM and Scales JT eds. Bedsore Biomechanics: Macmillan Press London.

13. Rithalia S (2004). Evaluation of alternating pressure air mattresses: one laboratory based strategy. Journal of Tissue Viability; 14(2): 51-58.

14. Clark M and McLeod A (2003). A sore point. HES; p28-29.

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