Clinical Case Study

Herida Moray Combo™

A Modern Effective Design of a Hybrid Mattress?

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INTRODUCTION AND AIMS

The purpose of commissioning this document is to identify the clinical performance and suitability of Herida Healthcare Manufacturing Ltd.' latest hybrid mattress design – The Herida Moray-Combo™ classified to be used on patient groups being very high risk of pressure damage (including existing wounds up to and including Grade IV). Sincere consideration of using a very high-risk static and dynamic mattress combined in a single product, versus that of independent mattresses (separate systems) is at the height of the papers ethos.

This consideration and design structure, follows a time when many patients are unnecessarily exposed to both systems via over and indeed under prescription of product. The patient utilised in this extensive trial has been exposed to several static (none powered) but mainly dynamic or alternating systems over a 2 - year period. Most of such systems have proven to be none effective for this particular patient' and his associated clinical condition.

The benefits of a hybrid mattress versus the use of both high risk static mattresses and then "stepping up or down" to alternating / dynamic mattresses are well publicised over the last few years. These are points such as reduced moving and handling considerations for both the patient and carer's alike, reduced cleaning and infection control considerations, speedier upgrade to dynamic systems for the patient, enhanced comfort and of course reduced cost (being two systems in one).

There is also evidence to suggest that some designs of alternating mattresses (namely heel cells) can exacerbate heel damage throughout the very alternating cycle that is meant to alleviate pressure damage and other associated factors. As shear and friction forces are becoming increasingly a primary consideration, then the use of alternative methods, in the place of air cells is of high intertest from the author with the Herida hybrid design.

The final part of any evaluation, aside from patient safety throughout is the aim to achieve a better patient outcome, whilst substantiating contributing factors to the healing / care and of course comfort process throughout.

The alternative, very high-risk hybrid mattress system was chosen from Herida Healthcare from a variety of hybrid mattress systems on the market. There are many systems similar to this product on the market, however none with the combination of head care alternation and sloped heel zone with wave technology. This was chosen following multiple attempts to find a suitable dynamic system to suit the needs (clinical, comfort and noise output) for the patient. The patient in question was transferred from system to system and latterly a market leading device that was not fully contributing to the patient's collective healthcare package. Furthermore, the extended purpose was to ascertain its suitability with further patients or group of patients on a wider scale, who had existing and or previous damage, along with other clinical complications thereafter.

Initial Financial Consideration

During the ongoing financial challenges that face the NHS and wider public or even private authorities, due to extended financial constraints. Sadly (or rather sensibly) Clinicians are now being encouraged to look at "best value" solutions more than ever, whilst ensuring that clinical compromise is not achieved, whilst innovation is still championed throughout. As the market (an arena where many companies sell pressure care devices), can become overwhelming as to any

differentiating factors between such equipment and indeed why the cost varies so much.

The original mattresses used prior to changing to the Herida Moray – Combo™ mattress range, varied in both features and price substantially and was identified to be almost four times the cost of the product used during the trial. The patient's condition improved on the Hybrid mattress; however, there was additional contribution via regular levels of nursing care during the evaluation that should also be noted and multidisciplinary team input.

Staffing & Decontamination Challenges

Similarly, as many Care organisations / NHS Trusts are experiencing high levels of staff vacancies, including that of District Nursing and or turnover of care staff within a nursing and residential home setting, further complications can arise, when selecting appropriate equipment. , it is always the opinion of the author that mattress / pressure relieving equipment designs, must be very easy to use and be readily available at an affordable price, whilst delivering ease of moving and handling.

Other

This paper was developed to provide a clinical overview, post paper, product selection guide to those who require guidance, whilst identifying product effectiveness of a hybrid design mattress on a complex patient type. Best value for money was also of sincere consideration at the time of print.

This localised patient evaluation, although conducted on a small basis in this printed instance has been used successfully on many patients since. No arising complications, (linked to the mattress) had been identified throughout.

Clinical disclaimer:

Please note that the use of any mattress system, whether that is of a static, hybrid or dynamic basis, must first and foremost be used alongside a full holistic assessment. These include, but are not exhausted to those of regular skin inspections (searching for reddening / deterioration) and appropriate dressings usage. Where static mattresses and immobility is concerned, regular patient re-positioning must occur whenever possible. Consideration of the patient's nutritional status, including hydration and general care of the skins surface, during moving and handling procedures, plus those of continence aspects must be considered. These are but a few points combined with full comprehensive documentation.

PATIENT OVERVIEW/EVALUATION DETAIL

Mr H is a 67-year-old gentleman with multiple clinical considerations. He was specifically chosen to take part in this evaluation due to his complex requirements and of course failure to achieve both comfort and indeed complete wound healing over a lengthy period. He weighs approximately 72kgs at start of evaluation and his weight remained static throughout and with no dietary / nutritional complications. A Waterlow score of 20+ was identified at start of the trial.

The gentleman's conditions include Hypertension and severe Parkinson's disease. He is also an insulin dependent diabetic and extremely immobile. He has been in care for 5 years in a local nursing home. Although it was not always the case, the patient is now full body - hoist transferred and "controlled sits" in a very specialist chair when out of bed, to try and assist with complete quality of life targets.

He has been nursed on several dynamic mattresses and one very high risk static mattress for approximately 2 years on and off which he found to be uncomfortable and noisy. All systems used throughout this period did not substantiate an improvement towards the clinical situation, outside of excellent, 24-hour nursing care throughout. Having tried many mattresses, he is now being nurses on a Hybrid mattress from Herida Healthcare and a standard electric profiling bed. The profiling bed has also formed part of his care over the last 2 years.

Mr H is able to sit (albeit supported) in a high specification wheelchair for short periods and family still try to take this gentleman home 2-3 times per week for 4-6 hours in the afternoon. Despite being frail he maintains his weight and his general health is good, aside from the reported conditions within this document.

He is at high risk of choking but eats well with assistance. He has suffered a chest infection approx. every 6 months for the last 2 years which does debilitate him massively. This is also a consideration of mattress design and any product selected, must be high angle, profile dependant in accordance with the bed. However, despite it taking a few months to get back to full health, then with the aid of the holistic care package provided, he has delightfully achieved this.

Mr H first developed a pressure ulcer Grade 2 (EPAUP) 18 months ago when very unwell with an undiagnosed infection and has continued to have these recurrent grades 2 to natal cleft/ sacral area (as evidenced by the scar tissue you can

see on the photos). He also has history of heel damage, hence the selection of this design for full product evaluation.

When in bed he is repositioned side to side except when being fed when he is propped up with pillows as he tends to pull his knees up into foetal position when in bed, thus exerting a large amount of pressure to the sacral area. His chair has built in pressure relief and when seated in wheelchair or at home he has a high-risk pressure cushion.

Mr H reports that the hybrid mattress is very quiet and extremely comfortable compared to other equipment that has been used previously. The staff report that the equipment is easy to use, easy to clean and maintain and is quiet thus aiding patient sleep.

TRIAL PERIOD 3 MONTHS

Photo 1 *Trial Start Date, Grade 2 (EPUAP) pressure ulcer combined with moisture.*

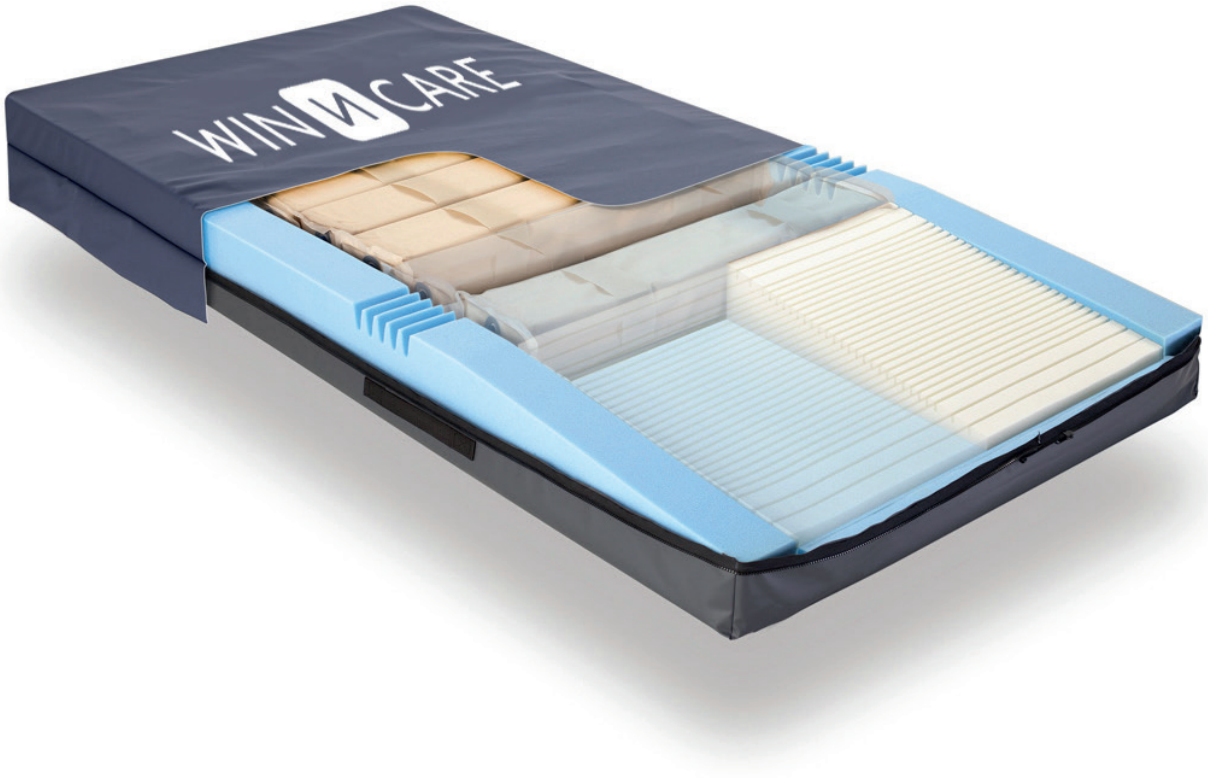
Photo 2 *Mid Trial evaluation - Original lesion healed residual moisture lesion healing*

Photo 3 *End of Trial Image – (close up) Demonstrable healing/scar tissue evident*

NB: No heel damage, including reddening was reported throughout this trail, despite being used on a previously heel vulnerable patient.

“What the Manufacturer Says”

Product Description & Technical Details

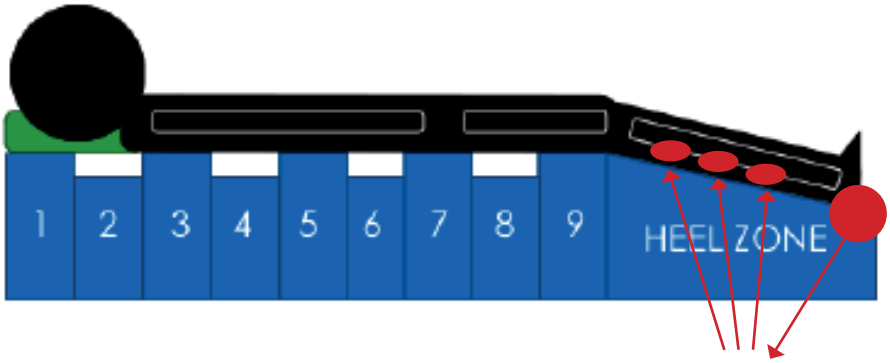


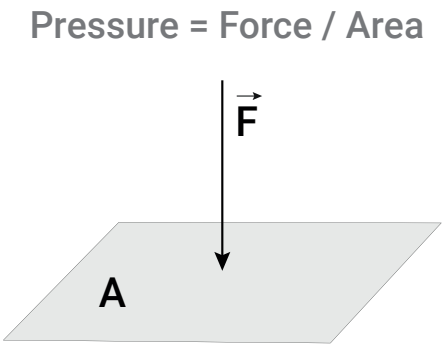
MORAY COMBO™

Herida Healthcare Manufacturing Ltd. have worked with key organisations and partners across the globe, to develop the very latest hybrid mattress technology – Herida Moray - Combo™. Designed, manufactured and sold by Herida Healthcare (Manufacturing) Limited - this amazing new product is designed with specific consideration towards heel damage and comfort for users at the heart of its capabilities.

The usual benefits of a “hybrid” are naturally evident, providing a speedy delivery from a very high risk static mattress to that of a dynamic in a matter of seconds. As evidence suggests that heel damage can often be exacerbated with the use of true alternating system. Herida has chosen to uniquely combine a static “anti-shear wave management” device. When bed profiling occurs, even when adopting the Fowler position, heel damage can still occur. This unique patent pending design provides an innovative solution for Health care professionals, whilst coupling true comfort for patients.

Alternating mode Image 1A (showing air displacement between alternate cells that reside within the foam core) and 12,5 degree graded heel area - Herida Moray – Combo ™ models

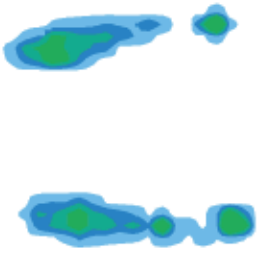




Heel Pressures are naturally displaced from the vulnerable heel areas to the calf muscles

Therefore, using the scientific methodology as above, the greater the surface area, the better displaced is the pressure (Muscle/body mass over calf is wider than that of a vulnerable heel area).

Pressure Mapping Image 1B (right) of Heel Area and Calf area, when using Herida Moray Combo™ and substantiating methodology above.



INITIATION (ALTERNATING MODE)

Simply unzip the base of the mattress, connect to the pump housing to the mains socket and press the On/Off switch for a few seconds. When the pump is started (switched on), all chambers are initially inflated to a maximum 52mmHg (for transfer stability). When removed from static mode to alternating, then alternate chambers deflate for 5 mins and then both chambers inflate for 1.5 mins. This is followed by the adjacent chambers (alternate from initial cycle) deflating for 5 mins. This identifies one complete cycle.

NB: The product automatically initiates on factory set weight limit (approximately 20mmgh) and can be adjusted to relevant patient weight, for clinical and comfort purposes.

CONTRAINDICATIONS

Patients with severe spinal injuries/fractures should not be using alternating systems without specialist Consultant Neurological & nursing advice. This system can be considered safe for use in static mode only for these patient groups, providing clinical risk assessment is conducted beforehand.

Do not attach straps to the fixed part of the bed. Only moving / working parts / bed platform

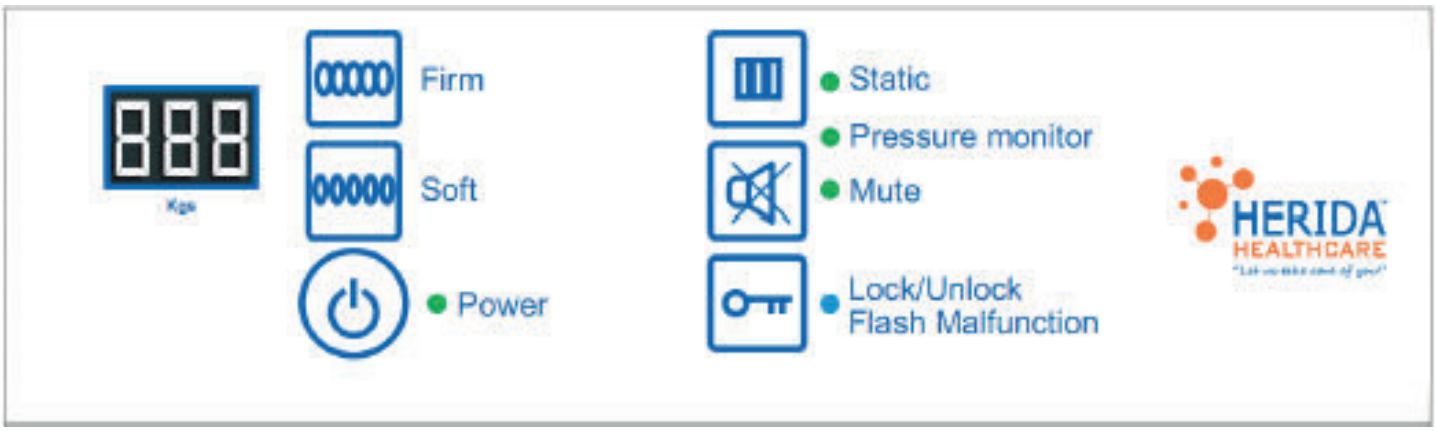


Image (above) *pump face*

- **Soft/Firm:** Pressure adjustment - each push adjusts ±1Kg, long push (hold down 2-3 seconds) adjusts ±10Kg.
- **Power:** Power on or off.
- **Pressure monitor** Light is on when pressure is normal / light is off when the pressure is abnormal / light flashes when alternating.
- **Mute** When pushed, alarm is silenced.
- **Lock/unlock/Flash Malfunction** Lock or unlock the panel when pushing the lock key for 3 seconds. The light flashes when the mattress has air leakage or pressure lower than 6mmHg
- **Noise:** Decibel output – Ultra quiet system - circa 45db

WEIGHT PRESSURE TBALE (GUIDE)

Patient Weight (kg)	30	50	120	150	180+
Pressure MMgh	10	15	25	35	52

"WAVE" DESIGN GRADIENT HEEL AREA (NON-CASTELLATED)

The design of the 12.5 degree tapered heel area is developed of such in order to remove direct heel pressure and displace on a wider surface area, (being the back of the calF). Naturally the equation Pressure=Force/Area heel achieves better re-distribution over a wider body surface area.

The wave cut, high density - visco foam works with any movement of the heel and indeed the multi stretch, vapour permeable cover. This unique design, reduces shear and friction forces and when coupled with the graded heel area has proven to be effective on very high-risk patient groups, who are otherwise susceptible to prospective heel damage.

No movement from cell alternation is evident in this region and therefore reduces shear and friction forces, otherwise exposed to patients when in full alternating mode.

The sloped design also allows the use of other pressure relieving devices as may be deemed necessary. However, it should be noted that this product has been used effectively on many patients with existing heel damage.

Image 1C (right) Arrows provide a demonstration of actual shear and friction forces that naturally occur. The unique heel design (profile cut left to right, along with multi stretch, vapor permeable fabric, significantly reduces the "dragging impact" and as such relevant shear and friction forces. NB image shown is without a cover present for illustration purposes only).

The image shown represented a 3cm "drag force" reduction on this subject and represents an average of between 3 and 5cm drag distance when profiling a bed into the fowler position. See clinical reference below: ****Can pressure ulcers be prevented by using different support surfaces?*

CLINICIAN'S OVERVIEW OF MANUFACTURER'S STATEMENT

There is nothing really to contraindicate what the manufacturer is suggesting within its literature. The images within, clearly demonstrate a very difficult scenario of attempting to measure shear forces in a simplistic manner.

The technical features of the pump, albeit much lower reported pressures are similar (in use) to many others on the market. The rapid ventilation of the cells, use of alternating cells up to the head section (for use on specific patient groups - occiput) and unusually effective heel area is considered unique and has been thoroughly effective throughout this evaluation.

The patient weight setting at the lowest level is particularly useful. It is unusual but demonstrably effective in that a 10mmgh setting would be available of true alternating or hybrid systems such as this (in the author's experience). When used with frail and highly immobile patients (such as Mr H), whereby comfort and body mass size is of consideration, this proved to be a popular function with the carer's, when prompted. Whilst initially the 52mmgh pressure exertion setting at the highest level was questioned. Upon further investigation, lots of dynamic systems are exposed to much higher cell pressures (MMGH – not to be confused with interface pressures). The patient used for the subject study was not of a larger body mass. However, he it was identified be comfortable throughout.

SUMMARY

This Hybrid mattress design is another product to choose from the ever-growing portfolio of mattresses, which are available from a multitude of suppliers in the modern pressure care market of today. The Herida Moray Combo™ hybrid mattress combines the benefit of a static and dynamic system.

Aside from excellent feedback from the patient and his family, the evident improvement to the wound was deemed significant. What proved to be interesting was the comments from a variety of nursing staff throughout this trial. The feedback was both consistent and positive throughout. This was mainly due to reported ease of use (stepping up and down to alternating mode as required), reduced moving and handling, reduced infection control concerns (not having to clean two or sometimes 3 mattresses, when stepping up and down). Multiple reports of how quiet the pump unit was in comparison to all other units within the care environment were also a key matter brought to my attention. This was deemed a contributing factor to improved sleep patterns experienced by the patient and alongside other factors, could also be linked as a contributory matter to the wound healing process.

Importantly the patient, along with family input, reports that the mattress was comfortable and much quieter than any system he has used in the past, allowing many good night's rest for longer periods throughout the trial, when compared to previous products used. Additionally, comments that he was handled less that when using alternative designs were also highlighted. Comfort when using the technology of foam and air at very low pressures, where also identified by all parties.

Cost as mentioned within the report previously is always a contentious issue, whether in scrutiny of public sector budgets or indeed an individual purse of the user. When taking the cost of an alternating system and a very high risk static system

in addition to associated decontamination and staffing costs linked to moving and handling, then this product provided outstanding value for money. When this clinical information was presented to the budget managers on the relevant units, when combined financially against its clinical performance, these factors determined the selection of which company or product they would look to standardise and or use again in the future. To that extent, Herida's products were chosen for a wider application of use, beyond the trial.

In summary, both patient, family and nursing staff alike could not have reported a more positive outcome of the trial. As overall Clinical supervisor of the evaluation, I can substantiate that the aims set out prior to evaluation were exceeded in all aspects. The design considerations for the Herida Moray Combo ™ mattress proved to be as good as any very high-risk system used. In the instances of this patient, the selection proved to be superior.

A wider evaluation and extension to this study is ongoing based on the effectiveness of product evaluation.

RELEVANT COSTS & APPROPRIATE REFERENCES

It has been estimated that the cost is between s£363,000 / £543,000 to treat a Grade 3 pressure ulcer and that of £447,000 - £668,000 to treat a grade 4 pressure ulcer. Estimated treatment cost of chronic wounds in the UK is *£2.3bn - £3.1bn. This Figure equates to an estimated 3% of the total NHS Expenditure (Department of Health 2010).

Nearly 700,000 people are affected by pressure ulcers each year across all care settings, including patients in their own homes with the most vulnerable patient over 75. Around 186,617 develop a pressure ulcer in hospital each year and each pressure ulcer adds up to over £4000 additional costs. (Ref: Hope 2014)

***Can pressure ulcers be prevented by using different support surfaces?
Pressure ulcers (also called bed sores, pressure sores and pressure injuries) are ulcers on the skin caused by pressure or rubbing at the weight-bearing, bony points of immobilised people (such as hips, heels and elbows). Different support surfaces (e.g. beds, mattresses, mattress overlays and cushions) aim to relieve pressure, and are used to cushion vulnerable parts of the body and distribute the surface pressure more evenly. The review found that people lying on ordinary foam mattresses are more likely to get pressure ulcers than those lying on a higher-specification foam mattress. In addition the review also found that people who used sheepskin overlays on their mattress developed fewer pressure ulcers. While alternating-pressure mattresses may be more cost effective than alternating-pressure overlays, the evidence base regarding the merits of higher-specification constant low-pressure and alternating-pressure support surfaces for preventing pressure ulcers is unclear. Rigorous research comparing different support surfaces is needed: 3 September 2015 : Authors - McInnes E, Jammali-Blasi A, Bell-Syer SEM, Dumville JC, Middleton V, Cullum N.

N.I.C.E : Pressure ulcers: prevention and management - Clinical guideline (CG179) Published date: April 2014

Excerpt: "Adults considered to be at high risk of developing a pressure ulcer will usually have multiple risk factors (for example, significantly limited mobility, nutritional deficiency, inability to reposition themselves, significant cognitive impairment[3]) identified during risk assessment with or without a validated risk assessment tool. Adults with a history of pressure ulcers or a current pressure ulcer are also considered to be at high risk".

A guide to the treatment of pressure ulcers from grade 1–grade 4. Wound Essentials 2007; 2: 106-13 – Author: Wicks.

Public domain - Costs and Shaming Ref (archive):
http://www.telegraph.co.uk/health/ healthnews/8613764/Hospitals-namedand-shamed-on-bedsores-record-whichcosts-NHS- 4bn-a-year.html (accessed 10 October 2011). Ref: Daily Telegraph print 4th July2011: Hospitals 'name and shamed' on bedsores record which costs NHS £4bn a year.

NOTES

In the interests of transparency, it should be noted that the Herida Healthcare mattresses used within this evaluation were provided on a zero-cost basis to the establishments using them, post-evaluation.

NB: This product has been designed and manufactured by Herida Healthcare Manufacturing Ltd. This is a separate company to that of Herida Healthcare Ltd.