LOW-AIR-LOSS THERAPY: New Product Design Overcomes Modality's Long-Recognized Limitations

Low-air-loss (LAL) mattress systems have been used for the treatment and prevention of pressure ulcers since 1971 when the first design in clinical use was recorded in literature¹. In the absence of an accepted definition of LAL, product designs have multiplied, and misconceptions of mechanisms of performance have been propagated.

This article will explore the topic of low-air-loss mattresses; their designs, commonly held beliefs and fallacies in how they work, results reported in literature, problems with current designs, and solutions provided by one product, the PressureGuard Easy Air by Span-America Medical Systems.

I. What is Low-Air-Loss?

<u>PURPOSE</u>: The goal of the original design, and all subsequent LAL designs, is to reduce the incidence of pressure ulcers, and to help to treat existing ulcers.

Pressure ulcers are caused by the a combination of pressure, shear, heat, and moisture. There are many support surface technologies that assist with pressure management by distributing the load of the body over as large an area as possible. These technologies include the use of foam, air, and gel in their construction, and may include the use of motors to move air in and out of the system.

LAL is differentiated from all other surface technologies in that it can *help reduce the accumulation of heat and moisture on the skin (maceration)*. Excessive heat and moisture negatively affects the microclimate of the skin, making the skin more susceptible to the damaging effects of pressure and shear, and decreasing the resiliency of the epidermis to these external forces.^{2,3}Therefore, controlling the microclimate of the skin is necessary in the prevention of the development of pressure ulcers. LAL mattresses were developed, and are used in the belief that, they help to control the microclimate of the skin.^{24,5}

<u>CONSTRUCTION</u>: LAL was first described in medical literature in 1971 by Scales et al.¹ They described a system of interconnected air chambers with a flexible, vapor-permeable film between the skin and the support air. The goal of this bed was to minimize the volume of air and the size of the pump compared to high-air-loss surfaces, thereby achieving uniform load distribution to "accommodate body forms", evaporate water from the support area, and control temperature and humidity.

Since that first description, the number of available products claiming to be LAL have multiplied rapidly. Currently, there are dozens of products on the market, with nearly a corresponding number of construction methods. Since there has never been a definition of LAL put forth by an independent body that is agreed upon in the medical and manufacturing communities, clinicians have been left with assumptions of how a LAL mattress is designed, and how it performs.

A literature search for a description of LAL reveals some common characteristics: a) a series of interconnected air cells or pillows that allow air to escape^{3,5} b) an adjustable pump that maintains air inflation,^{23,5} c) a coverlet that goes over the mattress that is of a material that is air and moisture permeable, bacteria impermeable, and waterproof, and that reduces shear and friction.^{2,6} In addition, it has been proposed that the coverlet provides thermal insulation to prevent excessive loss of body heat, have high moisture vapor permeability to prevent accumulation of excess moisture on the skin and high air porosity for removal of excess body heat through air flow.^{2,3,6}

II. How Does Low-Air-Loss Function?

MECHANISM OF EFFECTIVENESS: Since air escapes from the support cells and is leaked to the area under the coverlet, and the coverlet is supposed to be air and moisture permeable, people assume that LAL works by allowing air to escape through the coverlet and move against the skin to decrease moisture and heat on the skin.^{1,2,5,6} However, this is not true.

An examination of LAL surfaces on the market, and a review of construction patents and manufacturer literature reveals that the majority of LAL mattress coverlets are not air permeable,^{7,8} as the original design put forth; rather than air moving against the patient's skin, heat and moisture from the body diffuse through the vapor-permeable cover and into the air bladder. The blower then pushes the air, moisture, and heat out of the support system.

Therefore, the mechanism that allows most LAL surfaces to decrease heat and moisture from the support area of the body is diffusion through the moisture vapor permeable coverlet to the underlying air,^{3,6} not evaporation from the skin surface, as is commonly believed.

III. How Well Does Low-Air-Loss Work?

<u>LITERATURE REVIEW</u>: Many articles have been written attempting to document the effectiveness of LAL in various settings, age groups, and conditions; results have been mixed.

Ferrell reported that the rate of pressure ulcers healing among elderly in nursing homes was three times faster on LAL than on a 10-cm. thick egg-crate foam mattress.9 However, in a follow-up article, Ferrell et al concluded that LAL is cost-effective for patients with "good healing characteristics and 'mild' ulcers".¹⁰ Inman et al reported a significant decrease in the number of nosocomial pressure ulcers in ICU patients on LAL compared to those on "standard hospital surfaces".¹¹ They found no differences with regard to resolution of existing ulcers. Pulsating LAL resulted in decreased lengths of stay in ICU and clinical benefits for patients with posterior burns, as reported by Yarbrough et al.¹² In a review of support surfaces, Holzapfel indicated that LAL should be used in the treatment of Stage III and IV ulcers on multiple body surfaces, and for the prevention of ulcers, especially if drainage from the patient can be controlled or contained.⁵ Charles et al found LAL to be effective in reducing the size of stabilized pressure ulcers Stages II-IV in bed-ridden patients who have either acute or chronic medical conditions.13

Other articles indicate no benefits to the use of LAL. Hardin et al reported no significant difference in the development of nosocomial ulcers in postoperative heart or liver transplant patients between LAL and static fluid.¹⁴ Jesurum et al found no statistical difference in the development of ulcers in cardiovascular surgical patients between LAL and "standard ICU pressure-reducing foam mattress replacements".¹⁵ Warner showed no statistically significant differences in pressure ulcer outcomes between LAL and foam mattresses with loose-fitting top covers.¹⁶ As written above, Ferrell et al concluded that LAL bed cost-effectiveness compares poorly with other accepted health treatments in the treatment of patients with severe ulcers and poor healing characteristics, unless the cost of leasing or renting these surfaces is "substantially reduced".¹⁰

Two articles done in literature review format point to the lack of well-designed, scientifically rigorous studies available in the literature, and to an inability to draw conclusions from the studies as results have been mixed.^{17,18}

NEED FOR QUANTIFICATION: Many methods of measuring physiological effects, including cutaneous pressure mapping devices for interface pressures, and thermography and Doppler for microcirculatory blood flow have been devised. However, none has been validated as a reproducible method for predicting clinical effectiveness.^{19,20} Until now, the only fairly objective and quantifiable method of comparing mattresses or possibly pre-determining mattress effectiveness has been interface pressures. However, skin-resting interface pressures do not actually reflect the bone-tissue interface pressures, or capillary closure pressures,² and should not be used as the sole reason for clinical acceptance of any support surface.

As medical costs rise, and health care facilities search for the most effective and least costly methods of patient management, objective criteria for comparison of product effectiveness, as well as controlled scientific evidence of the therapy's relative value in clinical intervention, are necessary.¹⁹

Since the distinguishing feature of LAL is the removal of heat and moisture from the patient and from the patient-mattress combination, a test method to quantify the amount of moisture removed has been developed at Clemson University; a full description of the test and the results on six LAL mattress products have been reported at scientific conferences²¹ and will soon be published. A graph of the results shows large variances among the six products. (See Fig. 1)

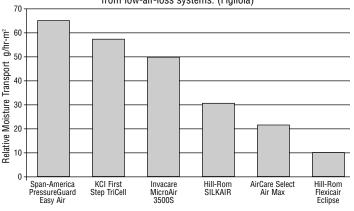
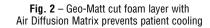


Fig. 1 – Comparative g/hr-m² of moisture removed from low-air-loss systems. (Figliola)

IV. LAL Shortcomings: Can They Be Overcome?

LAL systems have clinical and practical shortcomings that have been identified over the 30 years that these surfaces have been used in patient care. These shortcomings have been answered by the PressureGuard Easy Air.

1. <u>Makes the user cold</u> On typical systems, users commonly complain that they are always cold. There are two reasons for this. First, the user lies on a thin cover that almost puts him in direct contact with airfilled cylinders that are cooler than body temperature; laying in contact with them causes conductive heat loss from the user's body. Second, many systems are ineffective at eliminating moisture. Moisture collects at the surface, soaks into the top fabric, and gets trapped in the polyester batting, reforming there as liquid. This now-saturated cover remains in contact with the user, causing his perception of being cold. *Easy Air solution*: <u>Maintains body temperature</u>. First, the top Geo-Matt foam surface acts as an insulating layer, protecting the body from direct contact with the air cylinders. (See Fig. 2) Second, the Easy Air is documented to be more effective than any leading LAL system in removing excess moisture.²¹ Combined, the Easy Air's Geo-Matt along with superior moisture removal keep the user feeling comfortable, not cold.





2. <u>Air flow blocked by compressed fabric</u> For maximum effectiveness, moisture removal should be occurring beneath the entire surface of the top coverlet. But in typical low air loss systems, this cannot happen. Such systems rely on polyester batting to create a lofting layer between the top fabric and the air escaping from the cylinders below. In theory, this lofting layer holds moisture vapor—which has passed downward from the patient through the top fabric—until rising air can carry it out of the system. However, the polyester lofting material is compressed under the user's weight. This allows the top fabric to lie directly on the perforations in the cylinders below, effectively closing them off. Moisture removal can then only occur around the periphery of the user, not directly under him, greatly decreasing the amount of moisture the system can remove. Systems that use no lofting material at all have the same problem.

Easy Air solution: Un-compressable "Air Diffusion Matrix" **fabric**. Easy Air uses a proprietary, three-dimensionally woven fabric that will not completely compress beneath a user's weight. (See Fig. 3) This fabric is used in both the top coverlet and in the airflow cover of the mattress itself to ensure an uninterrupted path for air flow directly beneath the user. This tremendously increases the Easy Air's capacity to remove excess moisture, especially from areas like the sacrum that typical LAL systems fail to address.





3. <u>Moisture control compromised by adjustments</u> Many caregivers don't realize this, but lowering the weight or comfort setting on most LAL systems compromises the system's ability to control moisture. Laboratory testing reveals that choosing the lowest comfort setting on some leading LAL systems reduces the air flow from the controller unit by as much as 60% below the maximum setting. Which should the caregiver choose: the best comfort setting, or maximum air flow for moisture control?

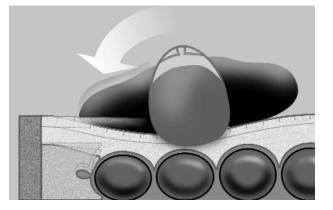
Easy Air solution: Moisture control always maximized. On the Easy Air, there is no need to compromise. Its comfort/weight adjustment takes place in the underlying cylinders and is completely independent of its "on/off" air flow control through the upper Air Diffusion Matrix. So, if the air flow is "on", it is operating at 100% of its moisture controlling capacity even at the lowest comfort setting.

4. <u>Thick and unstable surface.</u> Many LAL surfaces are designed around the mistaken belief that deep immersion into tall air cylinders is the only way to achieve effective pressure management. As a result, these surfaces tend to engulf the user, often disorienting them. A thick layer of air is inherently unstable, making it difficult to perform position changes, dressing changes, and other activities of daily living (ADLs). In addition, extreme surface heights of 9" or more make transfers and self mobility difficult, and can enhance the possibility of entrapment under siderails.

Easy Air solution: Low, stable surface that also addresses shearing. The Easy Air achieves its outstanding pressure management without the use of extra-tall air cylinders. At just 7" tall, the Easy Air is about the same height as a typical, non-specialty mattress. And it is just as stable, by virtue of its patented PressureGuard integrated foam shell/air cylinder design that incorporates the anti-shearing and pressure management properties of the Geo-Matt cut foam top layer.²² The Easy Air is easily the most stable low air loss surface ever designed, making it simple to perform dressing changes and other ADLs.

5. <u>Compromised safety</u>. Most LAL systems do an excellent job of equalizing pressures. But most are simply not made to withstand a user's concentrated body weight in any one spot on the surface. The edge of the mattress can collapse when the user rolls, or shifts sideways. With the siderails up, this collapse can leave a dangerous gap beneath the siderail. Such gaps pose an entrapment danger, as they have caused several suffocation deaths when the user's head has become entangled under the rail. In light of pending FDA legislation on this issue, entrapment poses a serious patient safety, regulatory, and liability risk. A collapsing edge can also pose a serious hazard when the user sits on the edge of the mattress during transfers.

Easy Air solution: Unequaled edge-of-bed safety. Like all PressureGuard models, the Easy Air is equipped with the patented Safety Edge^M. This two part bolster system will not allow the edge of the mattress to collapse. The inner bolster has a carefully placed "crumple zone". (See Fig. 4) When a user approaches the edge of the mattress, the crumple zone allows the bolster to tip inward, directing the user's weight back toward the center of the mattress. The Safety Edge works the same way during patient transfers, adding a measure of safety by directing the user's weight onto the mattress, rather than off the edge of the bed, and giving a stable surface to push off from.

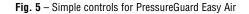


6. Loss of inflation during power interruption: Most low air loss systems go flat in the event of a power outage. Some have a thin layer of foam at the bottom as an emergency backup, but this is clearly insufficient to protect the user for any length of time.

Easy Air solution: Never loses inflation. The underlying air cylinders that supply the main support of the Easy Air are not perforated. They are connected to the controller unit by dual air lines that immediately seal off the system when power is interrupted. In the event of a power failure, the cylinders will remain inflated at a therapeutically effective level for literally days or weeks, not minutes.

7. <u>Overly complicated controls.</u> On most systems, caregivers are forced to make a number of decisions in order to properly program the control unit. Some products require employees of the manufacturer (e.g., a nurse provided by the bed rental company) to correctly adjust all settings for a given user.

Easy Air solution: Simple controls. The Easy Air was designed to deliver maximum performance with minimal caregiver input. Its controller unit has a simple dial for setting the comfort level from "softest" to "firmest". (See Fig. 5) One pair of "On/Off" buttons activates the alternating pressure feature, while the other pair activates the air flow. All three controls are clearly marked, and large icons make the controls accessible even for those with poor vision or minimal ability to read English.





8. <u>Gatching negatively affects performance</u>. Computerized pressure mapping of typical systems reveal significantly higher pressures in the sacrum when the head of the bed is elevated. To address this, some systems require use of special "Fowler Boost" or "Seat Inflate" settings to keep the user from bottoming out in this position. Others simply do not address it.

Easy Air solution: Gatching has minimal effect. The longitudinal (head-to-foot) orientation of its support cylinders, combined with the presence of the Geo-Matt therapeutic top surface, keeps sacral pressures at a safe level even with the head of the bed elevated. Pressure mapping confirms that seat pressures are nearly unaffected when the head of the bed is raised, despite the user's weight, and without need of any special setting.

9. <u>Infection control</u> On typical systems, infection control is an issue only in how difficult it is to clean the entire system thoroughly. A few systems attempt to differentiate themselves from the typical design by incorporating perforations in their covers that allow air to blow directly on the user. This air is constantly being re-circulated from within the room, making it likely to be contaminated.

Easy Air solution: <u>Uncompromised infection control</u>. The Easy Air differentiates itself from typical systems in a wide variety of ways, but blowing recirculated room air directly on a patient's skin is not one of them.

10. Difficult to clean. Because they are designed to be uncovered, deflated, and rolled up for transfer, thorough cleaning of typical LAL systems is a challenge. When deflated, these systems have dozens of small "nooks and crannies" between air cylinders, making the cleaning process both time consuming and difficult.

Easy Air solution: Simple, thorough cleaning. The Easy Air is designed to be *used*, not to be stored or transported. Its entire surface is wiped clean while in place, using the same mild detergents and disinfectants used on standard facility mattresses. The mattress itself is never disassembled for cleaning. Instead, it is sealed inside a wipe-clean inner cover. The outer coverlet can be wiped clean for everyday use, and can be machine washed in warm water when necessary.

V. Summary

Maceration due to the combination of heat and moisture on the skin makes the skin more vulnerable to the negative effects of pressure. Low-air-loss mattresses are unique among the vast array of support surfaces, in that they are designed to reduce maceration of the skin. The appropriate use of low-air-loss surfaces should include the need to decrease maceration if the patient's condition causes excessive heat and moisture to collect on the skin. A study describing a proposed test method for quantifying the ability of low-air-loss systems to remove heat and moisture from the patient is described. Many commonly used low-air-loss mattresses do a poor job of handling moisture due to design flaws. The PressureGuard Easy Air removes heat and moisture better than the other five products used in the study. The unique design of the PressureGuard Easy Air also solves ten of the most common problems associated with the use of low-air-loss.

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