ABSTRACT

“Least costly but most effective” has never been more important to healthcare delivery than in the current healthcare environment of changing reimbursement systems. In wound care, the high costs associated with renting advanced support surfaces may be an area where expenses can be decreased if similar outcomes can be attained by using more affordable mattresses. This article compares the healing rates and eventual outcomes of wounds among two groups of patients randomly assigned to one of two support surfaces. A commonly used low-air-loss mattress was compared with the study mattress, an advanced, non-powered, air and foam surface. Subjects were patients admitted to either of two long-term healthcare settings for the treatment of wounds. The resulting two groups of 10 patients each were evenly matched for average age and percentage of patients who were nutritionally deficient as indicated by albumin or pre-albumin levels. The presence of gastrointestinal tubes and ventilator dependency also was recorded. Consistent wound care protocols were used on both groups, including turning schedules, nutrition, topical medication, and dressings. The study period covered a maximum of 8 weeks; interest was centered on the rate of wound healing and progress toward a goal rather than the length of time to completely close a wound. After 8 weeks, or upon discharge from the study, pressure ulcers in the study mattress group closed at an average rate per week of 9.0% ± 4.8 versus 5.0% ± 3.7 in the low-air-loss mattress group. This study indicates that the study mattress can provide benefits to the wound healing process similar to or better than low-air-loss mattresses at a substantially reduced cost.

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stimulation or pulsed lavage), dressings, and equipment. Xakellis and Frantz reported the mean cost to heal a Stage II pressure ulcer, including hospitalization, was $1,119 ± $4,234. The mean cost to heal a Stage III or IV ulcer, including hospitalization, was $10,185 ± $27,635. The mean cost to heal each ulcer in the Xakellis and Frantz study was $2,731 ± $12,184.

The AHCPR’s Clinical Practice Guideline Number 3: Pressure Ulcers in Adults: Prediction and Prevention states “any individual assessed to be at risk for developing pressure ulcers should be placed when lying in bed on pressure-reducing device such as foam, static air, alternating air, gel, or water mattress.” Medicare has divided mattresses into three distinct groups, each with clinical criteria the patient must meet to qualify for reimbursement. Basically, Group I surfaces include static surfaces that are provided for prevention and for the first line in intervention for pressure ulcers. Group III mattresses include air-fluidized surfaces. This study concentrated on Group II surfaces.

The majority of Group II surfaces are powered mattresses, usually either low-air-loss (LAL) or alternating air surfaces. Group II surfaces are used for those patients who meet one of the following criteria:

• multiple Stage II pressure ulcers on the trunk or pelvis
• comprehensive ulcer treatment for past 30 days with Group I product
• ulcers have worsened or remained the same over the past month
• large or multiple Stage III or IV ulcers on pelvis or trunk
• recent myocutaneous flap or skin graft on trunk or pelvis and the patient has been on a Group II or III surface immediately prior to a recent discharge from a hospital or nursing facility.

Low-air-loss mattresses (designated Group II) were designed to reduce body interface pressure to below capillary closing pressure (32 mm Hg), to distribute weight evenly (pressure relief), and to limit friction and shear. In the literature, several researchers have attempted to prove the efficacy of LAL mattresses in the treatment of pressure ulcers. Some of these studies use interface pressure measurements. Others use reduction in wound measurements rather than final patient outcome with complete wound closure. Some studies show no significant improvement in patient outcomes, such as pressure ulcer healing, when the patient is treated on an LAL mattress. Often a study yields confusing results. For example, in a study conducted by Ferrell et al, an LAL mattress was compared to a 4-inch foam mattress overlay. The study results showed no significant difference in healing rates of deep wounds between the two surfaces, but the researchers did see improved healing of superficial ulcers in subjects treated on an LAL mattress. Mulder et al compared an LAL mattress to a foam overlay. They noted a significant increase in rate of healing among subjects treated on LAL as compared to subjects treated on the overlays. However, in the same study, the researchers found no significant difference in the percentage of wounds that healed completely between the two groups.

Day and Leonard compared the healing rates of 187 patients on LAL versus a unique foam overlay, the Geo-Matt (Span-America Medical Systems, Inc., Greenville, SC). They found no significant difference in healing rates of pressure ulcers between these two groups.

Goals

The goal of this pilot study was to determine if costs could be decreased by purchasing a less expensive mattress than an LAL while maintaining or improving patient outcomes. In everyday practice, selecting a support surface goes beyond choosing what has worked before and what information is available in the literature. Today’s clinician must weigh the individual needs of the patient.

KEY POINTS

- Because support surface rental costs can be substantial, many facilities are considering their purchase. However, few studies have been conducted to compare the effectiveness and efficacy of different support surfaces.
- To ascertain whether replacing currently used low-air-loss mattresses with nonpowered air and foam surfaces would affect outcomes, the authors conducted a pilot study involving 20 patients with Stage III and IV pressure ulcers.
- Following randomization, outcomes in patients placed on the nonpowered surface were similar or better than those obtained in patients on the low-air-loss mattresses.
- Sample size limitations prohibited statistical analysis of the results obtained, but additional studies, involving a larger sample size, seem warranted, given the potential cost savings.
patient, the drive for positive patient outcomes, the availability of cost-effective products, and the reimbursement for the chosen surface by third-party payors. More than 100 types of pressure-reducing devices are available, ranging from the low-cost foam or static air overlays to the more expensive and widely used LAL mattresses to air-fluidized beds. Rented LAL mattresses can be a great expense. The average rental cost billed to Medicare is approximately $700 per month. Some manufacturers will rent these surfaces for as little as $10 per day or as much as $145 per day. When purchasing a specialty bed, the facility can expect to spend thousands of dollars per bed.

Skyrocketing healthcare costs, recent changes in reimbursement to long-term care under PPS for Medicare patients under Part A, and further changes in Medicare guidelines that will effect reimbursement by third-party payors using the Medicare guidelines for guidance in criteria for payment make it essential for clinicians to evaluate new products that can provide superior pressure reduction and patient outcomes in the least costly manner. Long-term-care facilities can no longer rely on reimbursement from a third party. Under PPS regulations for long-term care, facilities now must pay out-of-pocket for durable medical equipment rental or purchase from a fixed rate they receive for the patient's total care. For many, purchase of equipment that was previously rented will make more financial sense in the long run. This financial investment must be made carefully and must be based on cost-effective outcomes.

The two mattresses compared include a standard, well-known, structurally comparable LAL surface and the PressureGuard® CFT (Constant Force Technology)™ by Span-America Medical Systems Inc. (Greenville, SC), hereafter referred to as “study mattress.” This mattress is nonpowered and comprises a series of interconnected air tubes and elasticized air reservoirs with a Geo-Matt cut foam topper as the patient interface layer. The manufacturer's pressure mappings show that it equalizes pressure over the weight-bearing surface of the patient’s body. Low-air-loss mattresses also equalize pressure but with air intake and outflow rather than movement within a fully enclosed system. The two measurable areas of patient outcomes were:

1. **Meeting the goals of wound treatment as determined by the team.** Goals included progressive closure, preparation for flap, and maintenance of condition. Maintenance of condition is frequently an appropriate goal if the patient's condition is deteriorating and other health concerns are more pressing than skin care. Each wound was rated “achieved,” “not achieved,” or “exceeded.” The goal of progressive closure was considered achieved if the wound showed progress toward closure.

2. **The rate of wound healing over time, with a maximum of 8 weeks.** The goal was to determine the rate of wound closure, expressed as a percentage of the original wound, rather than whether or not the wound fully closed during the study period. The author reports measurements at 3 weeks and at exit from the study to determine if wound healing slowed or accelerated as the wound decreased in size. This helped determine if one mattress outperformed the other at an interim time point as well as at the end point – a consistency that added confidence to the findings.

If the study mattress matched the LAL surfaces in patient treatment, acquisition costs would save the participating facilities thousands of dollars in either rental or purchase of LAL in a very short time.

**Methodology**

This pilot study was set up as a prospective, randomized clinical trial involving 20 patients who had Stage III or IV pressure ulcers on the trunk or pelvis.

**Inclusion criteria:**
1. The patient was admitted as an inpatient to one of the two test sites.
2. The patient had pressure ulcer(s) at Stage III or IV on the trunk or pelvis.
3. The patient was bedridden, necessitating pressure distribution off of bony prominences and ulcer site(s).

If a patient was admitted to the study with more than one pressure ulcer, only the deeper ulcer was followed in the study. Poor health status of a patient negatively affects wound healing on all of that patient’s wounds. One patient with many wounds would have an unequally large effect on the results for that mattress, either positive or negative.

**Sites.** Two facility sites were used. Vencor Hospital is a 70-bed, acute care hospital in San Diego, California specializing in ventilator-dependent patients and patients with extensive wound care needs. Horizon Health and
Sub-Acute Center in Fresno, California, is a 225-bed long-term and subacute care center. These two sites have relatively homogenous patient profiles and lengths of stay, wound care protocols including use of LAL mattress replacements, and employ moist wound healing with nutrition intervention. Certified enterostomal therapy (ET) nurses direct their wound care programs and each facility has developed a reputation in their respective geographic area for excellence in wound care.

**Mattress assignment.** For simplicity, each facility used a brand of LAL most familiar to its staff and equally approved as reimbursable, Group II surfaces under Medicare Guidelines. Each LAL surface vented air in the same manner and the capacity of the pumps to generate airflow through the mattresses (approximately 130 L/minute) was nearly equal. The two brands are widely used in the United States.

Patients who met the inclusion criteria were randomly assigned to one of the two groups, the study mattress or LAL, in an alternating pattern as they were admitted. The first patient admitted, who required a special support surface as part of ulcer treatment, was placed on the LAL, the second patient admitted was placed on the study mattress, the third patient on the LAL, and so on. Ten patients were placed on the study mattress and 10 were placed on the LAL.

Unfortunately, as often happens in patient-oriented research, two of the LAL patients were switched to the study mattress during their treatment upon physician’s orders, despite inclusion in the study. Hence, the numbers of patients in the results show 10 on the study mattress and only eight on LAL. The outcomes of these two patients are discussed separately in the results that follow; they are not included in the data analysis.

**Data collection.** Data collected on each patient included: age, albumin or pre-albumin, g-tube, ventilator dependency, site and size of ulcer, presence of eschar, and the goal for wound healing.

**Albumin/pre-albumin.** Albumin or pre-albumin determined nutritional status. A normal albumin range of 3.3 g/dL to 4.5 g/dL was used for this study. An albumin level of less than 3.5 g/dL indicates the need for detailed nutritional assessment and possible intervention. Albumin levels below 3.0 g/dL have been associated with poor wound healing outcomes. A normal pre-albumin range of 20 g/dL to 40 g/dL was used for this study.

**G-tube/ventilator dependency.** These features were recorded because patients with g-tubes for enteral feedings or who are dependent on ventilators are more medically fragile. A concentration of these fragile patients in one of the two groups could negatively affect the comparison of outcomes.

**Wound measurements.** Length, width, and depth, in centimeters, were taken at 3 weeks and at end of the study and weekly as clinicians were able. The data were used to determine percent of wound healing that occurred over the initial 3-week time period and over the entire time the patient was in the study, up to the 8-week limit. The interim 3-week measurement was included to see if wound healing accelerated over time and to note if one mattress outperformed the other at an interim time point as well as at the end point.

**Goal for healing.** Each subject was evaluated and the wound care team established a goal for wound healing – progressive closure, maintenance, or preparation for flap surgery – rather than completion of the wound healing process. The team included the patient and/or family, the ET nurse, nursing staff, and the patient’s primary physician. These goals were established according to the patient’s medical condition, prognosis, quality of life, age, and level of debilitation. At the end of the study, patients were rated as having achieved their goal, not having achieved their goal, or having exceeded their goal. For example, if the patient’s condition made maintenance of the wound a reasonable goal, but the patient showed progress toward closure of the wound, the patient was scored as having exceeded his/her goal.

**Exit criteria.** Eight weeks was the maximum time for participation in this study. Again, the goal was to determine differences in rate of wound closure and progress toward the stated goal. Therefore, a defined endpoint was necessary to calculate final size percentages. Other than the 8-week time limit, study exit criteria also included death, discharge from inpatient status, or flap surgery. Data for those patients who did not complete the full 8-week time period are calculated using the number of weeks they did participate.

**Topical wound care.** The topical wound care protocols in each facility were similar. These protocols were based on the principals of moist wound healing, as described in the AHCPR Clinical Practice Guidelines for the Treatment of Pressure Ulcers and the Clinicians Pocket Guide to Chronic Wound Repair (see Table 1 for a description of the topical wound protocols).
The protocols also included patient positioning in bed, including positioning off of the ulcer site at all times if able, and employing the 30-degree, side-lying oblique position. This position provides pressure relief for the sacrum and both trochanters. Position changes were performed at regular 2-hour intervals.

Comparison of study groups. Upon admission to the study, the two groups were evenly matched in average age (see Table 2). The two groups were also evenly matched in the percentage of patients who were nutritionally deficient as indicated by albumin or pre-albumin levels. The average albumin level, taken at the time of admission was 2.5, significantly below the 3.5 threshold cited above. The average pre-albumin was 14.7, significantly below the threshold of 20 cited above. The two groups were also fairly evenly matched in the numbers of patients who used g-tubes – seven of 10 in the study mattress group and five of eight in the LAL group. The LAL group had more ventilator-dependent patients than the study mattress group – five of eight (63%) versus four of 10 (40%).

Meeting wound treatment goal. Data gathered summarize the results, comparing goals, results, and average rate of wound closure of the two groups (see Table 3). This chart includes data on the two patients who were switched from LAL to constant force technology. These data were not analyzed statistically as these patients are presented for added information only; they did not complete the study on the same mattress, but their results are of interest as case studies. Two wounds on one patient who switched surfaces are described in the results, although only one wound per patient was followed in the patients who started and completed the study on the same mattress.

Under “Goal for Wound,” “Achieved” included those patients who fully met or were progressing toward meeting their established goal of progressive closure or maintenance, whether the wound was completely closed or not at the end of the 8-week study. “Exceeded” included those patients who had maintenance as their goal and

### Table 1: Topical Wound Care Protocols

| Irrigate all wounds with 120 cc of normal saline using a 35-cc syringe and 20-gauge angiocath. |
| Apply appropriate topical dressing based on the following criteria: |
| - **Superficial wounds with minimal amount of drainage**<br>Perform one of the following:<br>  - Apply hydrogel to wound bed, cover with gauze<br>  - Cover wound with thin foam dressing<br>  - Cover wound with transparent film<br>- **Wounds with depth or cavity with minimal amount of drainage**<br>  Pack wound with hydrogel impregnated gauze and apply cover dressing<br>- **Superficial wounds with moderate to large amount of drainage**<br>  Cover with foam dressing, with or without calcium alginate<br>  Apply calcium alginate and cover with hydrocolloid dressing<br>- **Wounds with depth or cavity with moderate to large amount of drainage**<br>  Pack wound with calcium alginate, cover with gauze, foam dressing, or hydrocolloid |

### Table 2: Patient Profiles

<table>
<thead>
<tr>
<th>Study Mattress</th>
<th>LAL</th>
<th>Switched from LAL to Study Mattress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Number of wounds</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Age range (years)</td>
<td>36-100</td>
<td>48-90</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>72.8</td>
<td>70.5</td>
</tr>
<tr>
<td>Albumin &lt; 3.5 or pre-albumin &lt; 18</td>
<td>8 (80%)</td>
<td>7 (88%)</td>
</tr>
<tr>
<td>G-tube</td>
<td>7 (70%)</td>
<td>5 (63%)</td>
</tr>
<tr>
<td>Ventilator dependent</td>
<td>4 (40%)</td>
<td>5 (63%)</td>
</tr>
<tr>
<td>Ulcer site</td>
<td>Sacrum/coccyx</td>
<td>7 (70%)</td>
</tr>
<tr>
<td>Trochanter</td>
<td>3 (30%)</td>
<td>1 (12%)</td>
</tr>
<tr>
<td>Ulcer stage</td>
<td>III</td>
<td>3 (30%)</td>
</tr>
<tr>
<td>IV</td>
<td>7 (70%)</td>
<td>6 (75%)</td>
</tr>
</tbody>
</table>
who progressed toward closure during the study. “Not achieved” included those patients who did not meet their goals for either progressive closure or maintenance. Table 4 compares the goals for wound healing with the results achieved for each of the two groups.

In the study mattress group, the goal for four of the 10 patients was progressive closure, five had maintenance as the goal, and one patient received wound care as preparation for flap surgery. In the LAL group, the goal for five of the eight patients was progressive closure, two had maintenance as their goal, and one received wound care in preparation for flap surgery.

All 10 patients on the study mattress (100%) achieved or exceeded their goals during the study period. Five of the eight patients treated on the LAL achieved or exceeded their goals.

**Rate of wound healing.** The rates of wound closure at 3 weeks and at the end of the study are summarized in Table 5. These rates were determined by comparing the total change in wound volume in cm³ and in the percentage of change from the original wound. The author used wound volume rather than area, so length, width, and depth were recorded on each wound.

In the following equations used as part of this process, \( X = \) either 3 weeks or the number of weeks in the study (see Table 6). The number of weeks in the study was a maximum of 8-weeks as discussed earlier in this article (see Table 5).

The resulting numbers in each group were averaged. At the end of 3 weeks, wounds in each group had closed by nearly the same volume (17.0 cm³ and 17.1 cm³ respectively) and, therefore, at the same rate per week
(5.7 cm³). However, as a percentage of the total wound closed in 3 weeks, the study mattress group outperformed the LAL group 43% to 21.8%.

At the end of the study period, the average volume closed was nearly equal (25.8 cm³ versus 22.2 cm³). However, the average rate of closure per week was higher on the study mattress (3.5 versus 2.8) as was the average percentage closed (60% versus 39.6%).

At 3 weeks, the average rate of wound closure per week as a percentage of the original wound was 14.4% ± 11.1 on the study mattress and 7.2% ± 7.6 on the LAL. At 8 weeks, or the end of the study (whichever came first for the individual patient) the average rate of wound closure per week as a percentage of the original wound was 9.0% ± 4.8 on the study mattress, compared with 5.0% ± 3.7 on the LAL.

During the study, two of the subjects, whose wounds had reached a plateau in their healing, were switched from the LAL mattress to the study mattress at the insistence of their physicians. Data on two wounds on one patient and one wound on the other are included in the patient data tables to indicate the effects of each of the two surfaces. One patient's goal was for wound closure of both sites, and the other patient's wound was being prepared for myocutaneous flap surgery.

On each of the two surfaces, Patient 1 showed short-term improvement, then reached a plateau. During each plateau period, the physician switched surfaces. Each change in surface resulted in a 1-cm reduction in wound depth; Patient 1 showed no difference in healing between surfaces. It is believed that healing was impaired due to history of pelvic radiation. The patient subsequently had myocutaneous flap surgery to close the wound.

Patient 2 had two Stage IV pressure ulcers. This patient was on LAL for approximately 5 weeks. During the first 2 weeks, the ulcers closed by 50% (trochanter) and 86% (coccyx), respectively, then both stagnated in their closure process. No contributing factors such as significant change in health status, medications, or nutrition were observed to account for this occurrence. The physician ordered the switch to the study mattress. Progressive healing was again observed; after 4 weeks on the study mattress, the wounds closed by 100% and 71% of the size of the respective ulcer at the time the surface was switched to the study mattress. No patients developed new ulcers on either the study mattress or the LAL mattresses.

Over the 8-week study period, the daily rental cost of the LAL mattresses was approximately $35.00/day, resulting in a total rental cost of $1,960.00 per patient over the 8 weeks. In comparison, the purchase price (manufacturer’s suggested retail price) of the study mattress is $1,080.00, or approximately 50% of rental costs over 8 weeks. Over time, further savings will be realized because the study mattress will be available for future use.

**Discussion**

The goal of this study was to determine if the cost of an LAL mattress was justified in improved patient out-

<table>
<thead>
<tr>
<th></th>
<th>End of 3 Weeks</th>
<th>End of 8 Weeks d/c from study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average Size at Start (cm³)</td>
<td>Average Size at 3 weeks (cm³)</td>
</tr>
<tr>
<td>Study Mattress</td>
<td>32.5</td>
<td>15.5</td>
</tr>
<tr>
<td>LAL</td>
<td>50.44</td>
<td>34.57</td>
</tr>
<tr>
<td></td>
<td>6.6</td>
<td>25.8</td>
</tr>
<tr>
<td></td>
<td>24.6</td>
<td>22.2</td>
</tr>
</tbody>
</table>

*d/c = discharged*
comes or whether similar or better outcomes can be achieved by using technology that was less costly. The results of the study showed that improved patient outcomes, as seen by improved healing rates, can be achieved when using an alternative pressure-reducing device, without incurring costly rental or purchasing bills.

The study randomization yielded two groups that were evenly matched for nutritional deficiencies (low albumin or pre-albumin), nutritional source (enterally fed), and location of ulcers caused by pressure secondary to immobility. Although the majority of the subjects were elderly, each group had one relatively young subject (the study mattress group had one 36-year-old; the LAL group had one 49-year-old).

Dressing changes at both facilities follow similar protocols based on the AHCPR guidelines and the principles of moist wound healing. Nursing care included routine turning and re-positioning every 2 hours and nutritional supplementation when needed. Protocols guided the staff to keep the ulcer sites as free of pressure as possible with frequent turning and appropriate positioning.

Without pressure testing each patient in every possible position on each weight-bearing bony prominence on both surfaces, making the generalized statement that “surface X provides lower interface pressure than surface Y for all patients” is impossible. From the results of this study, likewise, this conclusion cannot be reached because the author and her colleagues did not have access to pressure mapping or sensors that would accurately measure the interface pressures for the mattresses used.

The small sample size is an acknowledged limitation of this study that may affect the conclusive results. Additional randomized controlled studies consisting of a larger patient sampling, comparison of support surfaces across surface categories, including the study mattress, and a longer period of study ending with full wound closure may prove to be of value.

Another limitation of this study is the use of two different LAL mattresses, even though they are nearly identical in structure, method of venting air to the environment, and capacity of blowers to move air through the mattresses (approximately 130 L/minute). Using only one brand of LAL mattress would eliminate the possible factor of one LAL mattress performing differently from the other and negatively affecting all LAL results.

Conclusion

In relation to the two stated goals:

1. Meeting the goal of wound treatment: 100% of the subjects on the study mattress met or exceeded their goal for wound healing versus 63% of the LAL group.

2. Rate of wound healing over time: after 3 weeks, pressure ulcers on subjects on the study mattress closed at an average rate per week of 14.4% ± 11.1, while the LAL subjects’ pressure ulcers closed at an average rate per week of 7.2% ± 7.6. After 8 weeks, or upon discharge from the study, the pressure ulcers on subjects in the study mattress group closed at an average rate per week of 9.0% ± 4.8, as opposed to 5.0% ± 3.7 on the LAL.

This study suggests that the study mattress is an effective and lower cost alternative to the LAL mattresses in positively affecting the rates of wound healing in patients with Stage III and IV pressure ulcers.

Acknowledgment

The mattresses used in the study were provided by Span-America Medical Systems Inc., Greenville, SC.
References