CASE SERIES

Sepaderm for the Management of Acute and Chronic Wounds

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Abstract: The following case series includes a surgical excision, a burn wound, and a chronic venous ulcer that were successfully treated with Sepaderm®, a new wound management system. Sepaderm was chosen for its ease of use and its ability to remove excess exudate from the wound bed. The system also limits exudate leakage onto periwound tissue and protects against direct contact with the wound bed. These cases provide initial evidence that the Sepaderm system performed well and facilitated healing of different wound types, including a previously nonhealing venous leg ulcer.

There have been many new advances in wound dressings and treatment technologies, such as collagen/oxidized regenerated cellulose dressing, cross-linked hydrogels, biological dressings, platelet-derived growth factor-based therapy, synthetic matrices, and human cell-derived skin substitutes (eg, Dermagraft® [Advanced BioHealing, Westport, CT], or Apligraf® [Organogenesis, Canton, MA]). Despite such product advances, a need remains for cost-effective wound treatments that 1) require less frequent changing; 2) provide an adequate moist environment; 3) absorb exudate; 4) prevent leakage onto periwound skin; and 5) do not adhere to or damage healing tissues. A new wound care system called the Sepaderm Wound Management System (Aalnex, Inc., Irvine, CA) was specifically engineered to incorporate these desirable properties.

It is composed of three distinct components: 1) an adhesive circular-frame support cushion made of an ultra-soft, closed-cell, nonabsorptive polyolefin foam that is biologically fluid-resistant; 2) an exudate wicking strip that surrounds the outer wound edge and acts as a protective barrier against exudate overflow onto the periwound area, which also transfers exudate away from the wound and upward to the third part of the system (the reservoir); and 3) a reservoir above the wound surface for isolation of absorbed exudates and to minimize any contact with the healing epithelium and granulation tissue in order to prevent damage. Additionally, the system is completely covered with a low-friction, velvet style, breathable, polyurethane membrane that maintains a physiologic moisture vapor transfer rate and also func-
tions as a bacterial barrier (Figure 1). A prospective, randomized, double-blind, clinical trial would provide the best level of evidence regarding clinical efficacy of this new system. This preliminary study reports three cases of three different wound types using the Sepaderm system without parallel controls or comparative treatments.

Case Reports

Case 1: A 55-year-old white man (Patient 1) had a left lower leg burn wound measuring 72 cm². He was treated with Mesalt® dressing (Möllycve, Norcross, GA) with daily dressing changes. Seventy-eight days later, the wound had decreased to 22.1 cm² (69% decrease) with moderate exudation and robust granulation. Treatment with the Sepaderm system was then initiated (defined as day 0) and was changed every 3–4 days with no noted additional pain. Healing progressed with continued moderate exudation, minimal maceration, and robust granulation (Figures 2, 3). The time to 50% wound closure was achieved 12 days following the initiation of Sepaderm treatment (Figure 3). After nearly 7 weeks of Sepaderm treatment, the wound was nearly 90% closed and was

Figure 1. The Sepaderm Wound Management System.

Figure 2. Healing of lower left leg burn wound with the use of Sepaderm system. Wound closure was 19% on day 7, 66% on day 14 and 100% by week 11.

Figure 3. Percent wound healing: A) prior to Sepaderm system and B) with the use of Sepaderm system.
then transitioned to standard dressings [Mesalt covered with Mepilex® border dressing (Möllycke)]. The wound completely closed 4 weeks later.

**Case 2:** A 67-year-old African American man (Patient 2) had surgical excision of an infected cyst in the scapular muscle area measuring 21 cm². He was treated with Mesalt dressing with daily changing. After 4 weeks, 53% of the wound had healed (9.9 cm² remaining). Defining this point as day 0, a 16-day treatment with Sepaderm system was then initiated. The system was changed every 3–4 days. Similar to Patient 1, wound healing continued to improve with the use of Sepaderm and reached nearly 50% closure at day 9 (Figures 3 and 4) and 80% closure at day 16 (Figure 3). Sepaderm treatment was discontinued at day 17 after 80% of the wound had closed and was then transitioned to standard dressings (Normlgel®, Mölnlycke) and covered with Mepilex border dressing. The wound healed completely by day 28.

**Case 3:** A 77-year-old African American man (Patient 3) had a chronic venous leg ulcer on the lower left leg that failed to show any closure after 8 months of prior treatments, which included compression wraps, various dressings, and Apligraf. The wound measured 2.8 cm² with robust granulation and a small amount of serosanguinous exudate. The site was cleaned with soap and water before the Sepaderm system treatment along with compression was initiated. The wound was not painful and it began to heal within two weeks (Figure 5). Healing accelerated and continued with normal periwound tissue and no pain (Figures 3 and 5). The wound reached 50% closure at 31 days (Figure 3) and was considered healed completely after 66 days.

The healing rate for all three patients in this study reached levels that would predict the likelihood of complete healing for these wounds (Table 1). Patients 1 and 2 had healing rates of 0.6 and 1.0 cm/week after 1 week of treatment, respectively. Patient 3 (initially a nonhealing venous ulcer) reached a healing rate of 0.15 cm/week after 2 weeks of Sepaderm treatment.

**Discussion**

Newer wound dressings such as collagen/oxidized regenerated cellulose, negative pressure dressings, biological extracellular matrices, and silver alginate wound dressings, have been introduced with mixed results. For example, in randomized controlled trials, a collagen/oxidized regenerated cellulose dressing did not yield signif-

**Table 1.** Sepaderm treatment produced initial healing rates above the healing-predictive initial healing rate of ≥ 0.1 cm/week.

<table>
<thead>
<tr>
<th>Initial healing rates (cm/week)</th>
<th>Patient 1 (Burn wound)</th>
<th>Patient 2 (Surgical excision)</th>
<th>Patient 3 (Venous ulcer)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Week</td>
<td>0.6</td>
<td>1.0</td>
<td>NA</td>
</tr>
<tr>
<td>2 Weeks</td>
<td>1.6</td>
<td>1.2</td>
<td>0.15</td>
</tr>
<tr>
<td>3 Weeks</td>
<td>1.1</td>
<td>1.1</td>
<td>0.10</td>
</tr>
<tr>
<td>4 Weeks</td>
<td>NA</td>
<td>NA</td>
<td>0.13</td>
</tr>
</tbody>
</table>

*Nonhealing ulcer prior to Sepaderm treatment; NA = not available
icantly better outcomes opposed to the standard treatment of moistened gauze, a negative pressure dressing was not significantly better than a static pressure dressing in skin graft healing of the radial forearm free flap donor site, and a silver alginate wound dressing was not significantly better than a standard alginate dressing. Therefore, there is a continuing medical need for improved wound dressings that promote wound healing.

The Sepaderm wound management system was selected to treat three different wound types based on its ability to remove excess exudate from the wound bed, which limits exudate absorption onto periwound tissue while maintaining a moist environment for the wound bed, and its ease of application. Its ability to promote wound healing in previously treated wounds, including a chronic venous ulcer that failed to heal following all previous treatments, a burn wound, and a fresh surgical wound was assessed. Complete wound closure of chronic, nonhealing venous leg ulcers has been demonstrated if 50% wound closure is achieved in less than 60 days (Michael L. Sabolinski, personal communication, January 2010). Both the acute, surgical, and the burn wound had similar healing rates reaching 50% closure at days 9 and 11, respectively. In Case 3, where the chronic venous ulcer had failed to heal using best care treatment prior to the use of the Sepaderm system, reached 50% closure at day 31 subsequent to the use of the Sepaderm system. Falanga and Sabolinski and Sabolinski et al had determined that within the first 4 weeks an initial healing rate of ≥ 0.1 cm/week and ≥ 0.075 cm/week would predict complete healing of venous ulcers and diabetic foot ulcers, respectively. All three wounds treated with Sepaderm achieved healing rates above these lower limits that predict complete wound healing (average of 1.1 cm/week for both burn and surgical wounds and average of 0.13 cm/week for the venous ulcer). It is important to note that with the use of the Sepaderm system, the wound edges were not disrupted by a dressing or at the time of dressing change, and the wound edges were free of contact disturbances. There was no wound, or peri-wound infection or inflammation, and a permissive wound-healing environment was achieved. All three wounds healed completely with normal periwound tissue and minimal maceration during the entire healing process and the healed skin returned to normal pigmentation. The Sepaderm system stayed in place for the duration between changing and there was no exudate leakage.

Sepaderm does not contain any medically active ingre-
tem can stay in place for multiple days requiring fewer visits to the clinic, and fewer telephone calls to health-care providers. Most importantly, the Sepaderm system demonstrates the ability to achieve complete wound closure in nonhealing wounds.

Conclusion
In this case series, each of the three wound types (burn, surgical excision, and a non-healing venous ulcer) treated with the Sepaderm System showed excellent healing results. The treatment was well accepted by both patients and clinicians. It was easy to use, could be left in place for extended periods, managed exudate without leakage, maintained a moist wound environment, and did not allow exudate to pool on the treated site. Wound healing improved and led to complete closure in a burn wound, surgical excision, and a venous ulcer. The authors' limited experience with Sepaderm in reducing the need for multiple dressing changes, return visits or calls to address exudate leakage, pain, or discomfort, and the successful treatment of a long-term venous ulcer will need to be substantiated in larger studies. Further clinical trials are underway.

References