Nine Patient Evaluation of a Hyaluronic Acid-Based Wound Dressing

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INTRODUCTION

Over the past two decades, the connection between early granulation tissue formation followed by the synthesis or presence of an extracellular matrix and the healing of full thickness dermal wound has been a major discovery. This understanding has resulted in the development of synthetic and natural connective tissue matrices for managing these wounds.

Wound healing starts with platelet activation, which initiates the cascade of inflammation and progresses towards fibroblast activation and the production of hyaluronic acid (HA), glycoproteins, proteoglycans, and collagen fibers for the extracellular matrix (ECM). The major component of the ECM that is present in almost all tissue is HA. A glycosaminoglycan characterized by a highly polymerized chain of glucuronic acid and N-acetylglucosamine units. The physicochemical and biological properties of HA allow it to interact with other ECM components and participate in a wide range of cell surface receptor interactions. The natural wound management properties derived from HA led to the design of a HA-based wound dressing. In tissue engineering and wound dressing development, benzyl esters of hyaluronic acid (HYAFF) have been extensively studied because HA derivatives show different degradation profiles. The HA-based wound dressing is a bi-layered, sterile, flexible, and conformable wound dressing that acts as an advanced wound care device. It is comprised of a nonwoven pad entirely composed of HYAFF 11, a benzyl ester of HA, and a semipermeable silicone membrane, which controls water vapor loss, provides a flexible covering for the wound surface, and aids increased tear strength to the device. The HYAFF 11 wound contact layer biodegradable matrix acts as a scaffold for cellular invasion and capillary growth. It is indicated for the management of wounds including partial and full-thickness wounds, second degree burns, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undetermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, pediatric, wound dehiscence), trauma wounds (abrasions, lacerations, skin tears), and draining wounds.

The HA-based wound dressing has been used on a variety of wounds, from burns to surgical excision wounds to diabetic foot ulcers. It has been successfully used to treat deep partial thickness burns, some of which also underwent grafting. In patients with diabetic foot ulcers submitted to aggressive debridement with residual bone exposition, complete coverage of the exposed cancellous bone was achieved in most of the patients following the use of the HA-based wound dressing. After skin cancer excision, the HA-based wound dressing was applied on patients with complex clinical conditions, and complete healing was achieved in 8 weeks. From an aesthetic perspective, the skin was smoother, and there were only minor occurrences of hypertrophic or excessive scars, but the healed skin demonstrated flexibility. Furthermore, following the surgical removal of an ulcerated squamous cell carcinoma, the HA-based wound dressing integrated into the wound, and there was no evidence of hypertrophy or excessive scarring. Thus it is abundantly clear that HA has been known for many decades in wound healing research to help manage wounds by providing an environment conducive to natural wound healing.

To further examine the use of a novel HA-based wound dressing, the product was evaluated on nine patients with recalcitrant wounds. The goal of the study was to leave the dressing intact for several weeks to allow for optimal epithelialization of the wound bed. This study also provided an opportunity to non-adherent silicone transfer dressing®, to insure that the HA-based wound dressing and corresponding new growth of epithelial tissue remained intact during the dressing change process associated with the periodic removal of a secondary dressing that is typically used to collect excess wound drainage. The clinical education division of

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REFERENCES


This study was sponsored by:
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**METHODS**

A single application* of a HA-based wound dressing was evaluated in a case series of patients who presented with wounds that had not improved in the 30 days prior to dressing application. Nine patients whose wounds met the indications of use criteria were selected for the study. The study period varied from one to five weeks, depending on when the HA-based wound dressings silicone backing was removed. Prior to product application, the wounds were optimally debrided. The HA-based wound dressing was then placed on the wound according to the manufacturer’s instructions for use and covered with a one-sided silicone transfer dressing for additional protection to ensure the secondary dressing, a silver alginate, did not disturb the wound upon removal, and medical adhesive strips were used to mechanically secure the dressing. When necessary, a no-sting cyanoacrylate liquid skin protectant was applied to the edges of the wound to aid with mechanical occlusion. Four or six weeks prior to application and upon initial application, the wound size was measured. Every week, the absorbent dressing was changed, and the wound periwound areas were examined for adverse events. The HA-based silicone backing was removed after the HA scaffold incorporated into the wound bed. Time to incorporation ranged from one to five weeks, at which time the wound size was measured.

*Patient 3 required a second application of the HA-based wound dressing after one week because on removal of the outer tape, the silicone transfer dressing and the HA-based wound dressing were pulled up.

**CASE STUDIES**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Gender</th>
<th>Diagnosis</th>
<th>Location</th>
<th>Chronicity</th>
<th>Previous Tx</th>
<th>Length of Use</th>
<th>Type of Wound Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>Diabetic foot, VLU</td>
<td>L anterior leg</td>
<td>4 months</td>
<td>Collagen/oxidized cellulose</td>
<td>3 weeks</td>
<td>Bordered foam dressing</td>
</tr>
<tr>
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<td>Hypertension, L VLU</td>
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<td>CMC silver dressing</td>
<td>2 weeks</td>
<td>Bordered foam dressing</td>
</tr>
<tr>
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<td>L anterior leg</td>
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<td>4</td>
<td>M</td>
<td>Chronic venous disease, CMC</td>
<td>L anterior leg</td>
<td>1 month</td>
<td>CMC silver dressing</td>
<td>4 weeks</td>
<td>Bordered foam dressing</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>Rheumatoid arthritis, L VLU</td>
<td>L anterior leg</td>
<td>2 months</td>
<td>Bordered foam dressing</td>
<td>1 week</td>
<td>Bordered foam dressing</td>
</tr>
<tr>
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<td>M</td>
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<td>Honey</td>
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<tr>
<td>8</td>
<td>M</td>
<td>PVD, VLU</td>
<td>L anterior leg</td>
<td>3 months</td>
<td>Honey</td>
<td>3 weeks</td>
<td>Bordered foam dressing</td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>Rheumatoid arthritis, L VLU</td>
<td>L anterior leg</td>
<td>3 months</td>
<td>Honey</td>
<td>3 weeks</td>
<td>Bordered foam dressing</td>
</tr>
</tbody>
</table>

**RESULTS**

**Figure 1: Wound Area over Time**

HA-derived wound dressing was applied at Time = 0.

**Figure 2: Percent Area Reduction**

The cohort studied consisted of chronic or non-healing wounds of mixed etiologies presented for an average of 3.3 months.

At the endpoint of this nine patient cohort, there was an average 68.90% reduction in wound area. For all nine patients, the total initial wound area was 26.32 cm² and total final wound area was 8.59 cm², which gives a total wound area reduction of 67.36%. No adverse reaction to the HA-based wound dressing was observed. For all patients, the silicone transfer dressing effectively maintained the HA matrix in place, and it did not damage epithelized tissue on removal.

As shown in Figure 1, the wound size was stagnant or increased for the evaluated chronic wounds for the weeks prior to the application of the HA-based wound dressing. Following a single application, or two for patient 3 because the HA-based wound dressing was pulled up, there was a significant decrease in wound size (p = 0.009). The wounds of patients 7 and 9 closed completely following the first application, and the wounds of patient 3 and 8 had fully healed. Though patient 1’s wound had decreased 69% after one application, the wound size continued to decrease an additional 30% in the month after the HA-based wound dressing’s backing was removed. Similarly, two weeks after the removal of the silicone backing, patient 3’s wound had decreased an additional 94% for a total decrease of 97%. Due to resumed pressure at the wound site, patient 8’s wound has not healed to date. For all patients, the silicone transfer dressing was used for additional protection to ensure the secondary dressing did not disturb the wound upon removal, and since the silicone transfer dressing is non-adherent, the epithelialized tissue was not damaged on removal. These results may speak to the need for multiple applications of the HA-based wound dressing. Also, many of the patients’ underlying etiologies were complex, which could explain the variation in results.

**DISCUSSION**

The average time the patients’ wounds were open prior to the application of HA-based wound dressing was 3.3 months. Following the application of the HA-based wound dressing, there is a definite positive wound healing trend even after weeks and months of stagnant wound healing. The wounds of patients 7 and 9 closed completely following a single application. One month after the HA-based wound dressing removal, the wounds of patient 3 and 8 had fully healed. Though patient 1’s wound had decreased 69% after one application, the wound size continued to decrease an additional 30% in the month after the HA-based wound dressing’s backing was removed. Similarly, two weeks after the removal of the silicone backing, patient 3’s wound had decreased an additional 94% for a total decrease of 97%. Due to resumed pressure at the wound site, patient 8’s wound has not healed to date. For all patients, the silicone transfer dressing was used for additional protection to ensure the secondary dressing did not disturb the wound upon removal, and since the silicone transfer dressing is non-adherent, the epithelialized tissue was not damaged on removal. These results may speak to the need for multiple applications of the HA-based wound dressing. Also, many of the patients’ underlying etiologies were complex, which could explain the variation in results.

**CONCLUSION**

All the patients, except patient 2, experienced a reduction in wound size. Overall, there was a significant decrease in wound size (p = 0.009). The average reduction in wound size was 68.90%, and the wounds of patients 7 and 9 closed completely. Of the patients available for measurement one month after removal of the HA-based wound dressing , patient 3’s and patient 6’s wounds closed within a month post HA-based wound dressing backing removal. The majority of wounds were set on a healing trajectory after a single HA-based wound dressing application. No adverse reaction to the HA-based wound dressing was observed. For all patients, the HA-based wound dressing was securely placed, and it did not damage epithelialized tissue on removal.