ASSESSMENT OF A NOVEL BIOMATRIX WOUND CONTACT LAYER USING SIMULATED NPWT

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INTRODUCTION
Chronic wounds by definition, are particularly difficult to heal by conventional means. One therapeutic tool that has been successfully applied to such wounds is negative wound pressure therapy (NPWT), during which negative pressure is applied in order to withdraw fluids from the wound and increase blood-flow to the site, promoting healing. Typically, a wound is layered with three components: a wound contact layer (WCL), a reticulated foam, and a transparent film to seal the wound.

The reticulated foams can lead to tissue ingrowth and wound bed disruption that can cause patient discomfort upon removal. A WCL often added to foam but not into gauze during NPWT, Wounds, 2009;21(11):302–309. A WCL should not cause patient discomfort, either during use or at dressing changes. A perforated, collagen-based, biomatrix WCL has been developed to provide the protection of a low-adherent WCL with the wound healing benefits of a collagen dressing. The WCL was designed to act as a sacrificial substrate for excess matrix metalloproteinases (MMPs) that can inhibit wound healing.

The objective of this study was to understand the compatibility of the biomatrix WCL† with negative pressure wound therapy (NPWT) in vitro. The biomatrix WCL was tested using saline as well as simulated viscous wound fluid in order to gain a more realistic understanding of the impact this product may have on NPWT (including compatibility with negative pressure and fluid flow). Identical tests were also performed on a competitor silicone WCL to provide a basis for comparison.

METHODS
An in vitro NPWT model has been developed based on the publication from Thomas et al., which describes an in vitro simulated wound model. The model was modified to be compatible with NPWT by using a flow rate of 20 g/h with simulated wound fluid solutions (Table 1). The WCLs were placed on the model wound bed, followed by a NPWT foam, transparent polyurethane film, and then connected to a vacuum pressure of 120 mmHg.

The results of this study demonstrate the novelty and efficacy of a biomatrix WCL. Utilizing patented crosslinking technology allows for reinforcement of the collagen matrix enabling it to withstand strong negative pressure, leaving the WCL intact, protecting the wound.

CONCLUSIONS
The simulated NPWT experiments demonstrated that the use of a biomatrix WCL will not interfere with the extraction of fluid from a wound, thereby allowing for the maintenance of an ideal wound-healing environment. The biomatrix WCL performed as well (or better than) the competitor when it came to fluid transfer, and has the added benefit of acting at the biological level of wound healing.

RESULTS
• A vacuum pressure of 120 mmHg was achieved and maintained in the NPWT apparatus in the control (without WCL), the competitor WCL and in the presence of the biomatrix WCL.
• The quantity of fluid collected via NPWT simulation with saline was similar with or without a biomatrix WCL in place, indicating zero impedance of vacuum or fluid transfer by the presence of a WCL. The results for the silicone WCL showed a decrease in the amount of saline able to be removed.
• Higher viscosity simulated wound fluid was removed at a lower rate.
• The biomatrix WCL provided similar results to the competitor WCL when simulated wound fluid was used.

DISCUSSION
The in vitro data for the biomatrix WCL suggests:
• Optimal negative pressure can be achieved and maintained in the presence of the novel WCL, therefore it may be used to decrease patient discomfort, and aid in wound healing without disrupting the application of NPWT.
• Fluid transfer is not impeded by the biomatrix WCL. An optimal level of moisture can be maintained in the wound without build-up of water and, subsequently, to the perforations in the biomatrix WCL and the natural porosity of collagen, that can become sponge-like in the presence of moisture. The competitor silicone WCL does not have the porous structure of the biomatrix WCL, which from the saline results, can impact fluid removal.
• The biomatrix WCL demonstrated similar performance with simulated viscous wound fluid compared to the competitor product with the added benefit that the biomatrix WCL is bioresorbable and therefore does not need to be removed in its entirety from the wound bed, reducing the likelihood of tissue damage at dressing changes.
• The results of this study demonstrate the novelty and efficacy of a biomatrix WCL. Utilizing patented crosslinking technology allows for reinforcement of the collagen matrix enabling it to withstand strong negative pressure, leaving the WCL intact, protecting the wound.

REFERENCES

Table 1: Simulated wound exudate formulation.

<table>
<thead>
<tr>
<th>Saline (g)</th>
<th>Simulated Wound Fluid (g)</th>
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<tbody>
<tr>
<td>1000</td>
<td>water</td>
</tr>
<tr>
<td>5</td>
<td>g sodium chloride</td>
</tr>
<tr>
<td>0.184</td>
<td>g calcium chloride</td>
</tr>
<tr>
<td>4.418</td>
<td>g sodium chloride</td>
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Table 2: Results for a simulated NPWT in vitro wound model; each entry indicates the quantity of fluid that was drained from the apparatus over 3 hours under the given conditions. A4 results for the simulated viscous wound exudate are relatively similar to each other indicating that the use of either a silicone or biomatrix WCL does not impede flow. There is a reduction in the flow rate of the competitor WCL, this supports the use of a porous biomatrix WCL for even distribution of fluid removal.

Figure 1: in vitro NPWT model. Fluid is delivered to the simulated wound bed. The WCLs are placed on the model wound bed, followed by components of a standard NPWT kit: reticulated NPWT foam, adhesive polyurethane film, and finally an adhesive connector that leads to a vacuum at 120 mmHg.