Novel Peel and Place Negative Pressure Wound Therapy Dressing Preclinical Evaluation: Finite Element Modeling of Wound Bed Tissue Strains Expands Upon Biomarker Outcomes

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Introduction

- The use of negative pressure wound therapy (NPWT*) with reticulated open cell foam (ROCF*) has become standard practice for advanced wound care over the past 20 years with well-established mechanisms of action.
- ROCF dressings can promote a robust healing response, but tissue ingrowth may occur if left in place >3days. Dressing changes are recommended no less than 3 times per week.

Purpose

- A novel Peel and Place dressing[§] has been developed for use with NPWT and addresses the challenges of tissue ingrowth with an extended wear time.[1]
- Herein, we report on the novel mechanism of action for this new dressing, which exhibits a modified tissue strain environment and promotes wound healing associated biomarkers (**Figure 1**).

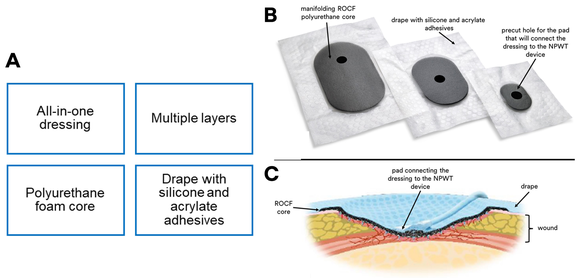

Figure 1. **A**. Characteristics of Peel and Place dressings. **B**. Available sizes, large, medium and small (left to right), and `**C**. cross-section drawing of the Peel and Place dressing applied to a wound.

Methods

- All animal work was approved by the relevant IACUC and complied with applicable national and local regulations, including appropriate pain management and anesthesia methods. Full-thickness excisional paraspinal wounds were created in 11 swine (**Figure 2**).
- Continuous -125 mmHg pressure was applied to both Peel and Place and ROCF dressings for 7 days with a single dressing change on day 4. Biopsies were collected from wound beds at study termination. Total protein was extracted and analyzed using multiplex protein assays.

Methods (Cont'd)

- Finite element modeling of tissue strains was completed using clinically relevant dimensions and mechanical properties. Simulations in this environment were completed for ROCF at -100 mmHg and novel Peel and Place dressings under -125 mmHg. The bottom surface of the model was fixed/constrained. Results of this finite element study are included in **Figure 4**.
- A swine cadaveric computational tomography (CT) study was performed to assess tissue and dressing behavior before and after application of negative pressure. This imaging was used to confirm the translation of theoretical models to a practical scenario.

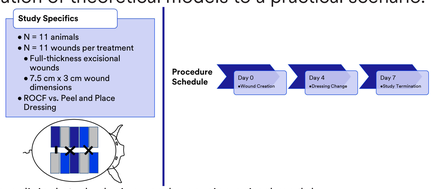

Figure 2. The preclinical study design used a porcine animal model.

Results

- Multiplex protein assays showed a relative increase of growth factors (**Figure 3A**) and cytokines (**Figure 3B**) in tissues managed with the Peel and Place dressing compared to ROCF.
- Significant differences ($p \leq 0.05$) in analyte levels include greater relative concentrations of key analytes in wounds managed with Peel and Place compared to ROCF dressings. Key analytes: Heparin-Binding Epidermal Growth Factor (EGF)-like Growth Factor (HB-EGF), Platelet-Derived Growth Factor AA (PDGF-AA), Transforming Growth Factor alpha (TGFα), Interleukin (IL)-1 alpha (1α), IL-1 beta (IL-1β), IL-8, and IL-1 receptor antagonist (IL-1ra).

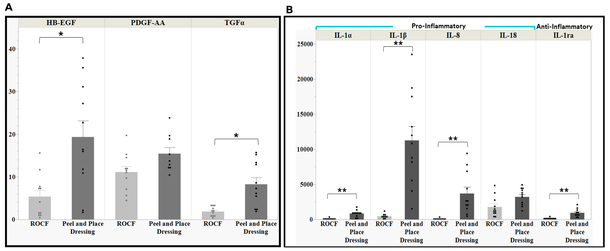

Figure 3. **A**. Growth factor levels for ROCF vs. Peel and Place dressings at Day 7, n=9 to 11. *p<0.05. **B**. Cytokine and chemokine levels for ROCF vs. Peel and Place dressings at Day 7, n= 9 to 11. **p < 0.01.

Results (Cont'd)

- Finite element analysis (FEA) of the Peel and Place dressing under -125 mmHg produced peak and lower tissue strains of 18% and 4%, respectively, that extended several millimeters into the wound bed, while ROCF exhibited peak strains of 40% at shallower depths.[2,3]
- ROCF also produced downward tissue displacement at wound-foam strut contacts (**Figure 4A**).
- Downward displacement was seen in the Peel and Place dressing along the wound edge (**Figure 4B**).
- Overall, Peel and Place tensile strains and displacements were predicted to be more homogenous than ROCF. **Figure 4C** provides a conceptualized image of the tissue displacements at the wound bed surface as informed by the in silico results.

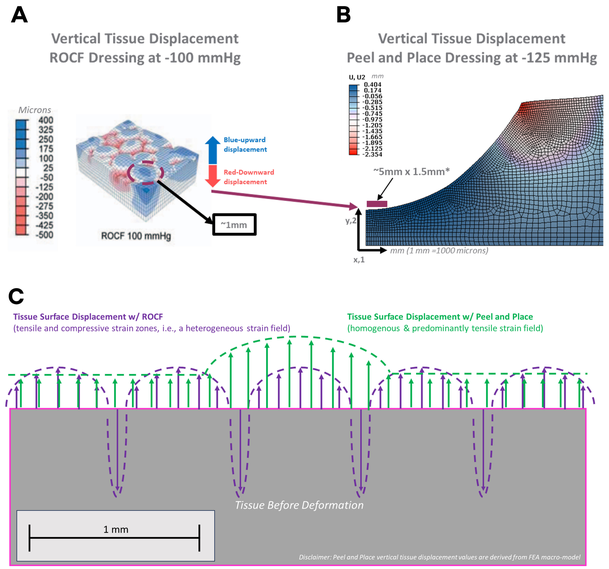

Figure 4. Finite element models depicting vertical tissue displacements along the wound base. **A**. ~5 mm width x 1.5 mm height vertical tissue displacement model for ROCF. **B**. 28 mm deep wound model for Peel and Place dressing. The purple rectangle represents the ROCF model size compared to the Peel and Place model. **C**. Illustration of vertical tissue displacements for Peel and Place dressing (green lines), ROCF dressing (purple lines), and tissue before deformation (gray box with pink outline) drawn to scale given in silico results.

Results (Cont'd)

- Cross sectional CT images of ROCF and Peel and Place treated 4 cm deep wound confirmed compression occurs at the superficial wound edge and vertical tissue distension at the base of the wound.
- Compared to the ROCF dressing (**Figure 5A**), tissue displacement at the base of the wound appeared more homogenous in the wound managed with Peel and Place dressing (**Figure 5B**).

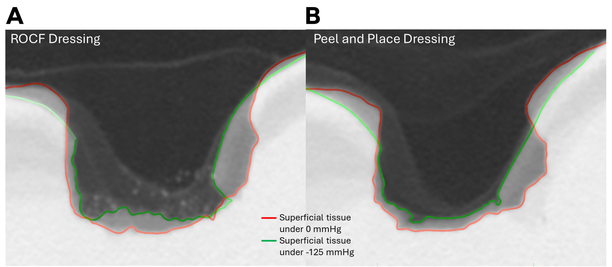

Figure 5. Superimposed images of tissue surface deformations before and after application of negative pressure and **A**. ROCF or **B**. Peel and Place dressings. Note: Preclinical experiments were performed in thawed swine cadavers following completion of an unrelated study. In-life CT results may differ.

Conclusions

- Cells respond to imposed forces/strains by producing biochemical stimuli.[4] The homogenous tissue strains and deep propagation of tensile strains seen in the novel dressing FEA model could explain the greater levels of cytokines/chemokines and growth factors compared to ROCF.

References

1. Allen D, Robinson T, Schmidt M, Kieswetter K. Preclinical Assessment of Novel Longer-Duration Wear Negative Pressure Wound Therapy Dressing in a Porcine Model. *Wound Repair Regen*. Apr 19 2023.
2. Wilkes RP, Kilpadi DV, Zhao Y, Kazala R, McNulty A. Closed incision management with negative pressure wound therapy (CIM): biomechanics. *Surg Innov*. 2012 Mar 2012;19(1):67-75.
3. Wilkes R, Zhao Y, Kieswetter K, Haridas B. Effects of Dressing Type on 3D Tissue Microdeformations During Negative Pressure Wound Therapy: A Computational Study. *J Biomech Eng*. 2009 Mar 2009;131(3):031012.
4. Dunn SL, Olmedo ML. Mechanotransduction: Relevance to Physical Therapist Practice—Understanding Our Ability to Affect Genetic Expression Through Mechanical Forces. *Phys Ther*. 2016;96(5):712-721.

Presented at the Symposium on Advanced Wound Care/Wound Healing Society Spring Meeting, May 14-18, 2024, Orlando, FL

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*3M™ V.A.C.® Therapy; [§]3M™ V.A.C.® Granufoam™ Dressing; [$]3M™ V.A.C.® Peel and Place Dressing (Solventum Corporation, Maplewood, MN)

The authors thank Maritza Quintero (Solventum) for assistance with poster preparation.