Surface Contact Pressure for Novel Thermoplastic Elastomer Wound Filler

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BACKGROUND

- **Negative pressure wound therapy (NPWT) using reticulated open cell foam (ROCF)** fillers has been the **standard of care for more than 3 decades** without effective alternatives
- A **novel FDA cleared thermoplastic elastomer (TPE) dressing** has been developed as an **alternative to ROCF**
- **Newton's 3rd Law: For every action there is an equal and opposite reaction**- NPWT results in a Positive Pressure on the wound surface
- **Positive pressures above 30mmHg exceed capillary filling pressure** and can lead to **hypoperfusion**
- **Foam collapses under suction**, reducing effective pore size and **increasing flow resistance**, which **amplifies positive pressure** on the wound surface
- **Traditional ROCF systems often require very high suction levels (-125mmHg) to maintain flow**, which can unintentionally **increase tissue compression** and contribute to poor wound response

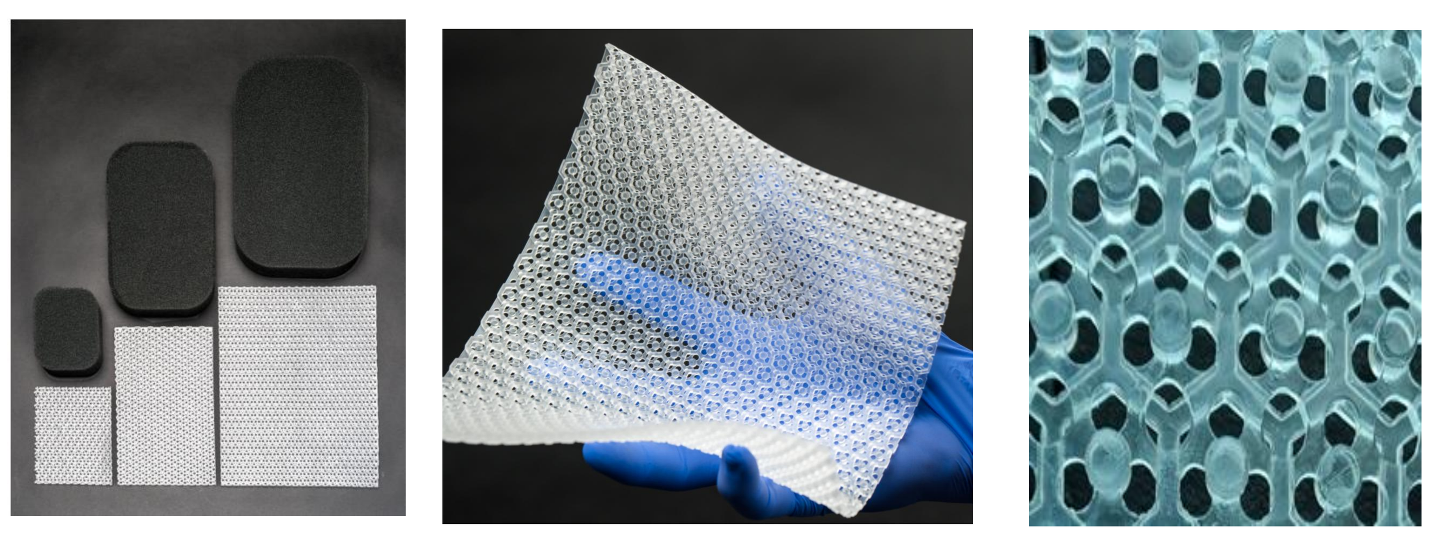

Figure 1: *Size options and structural design of the TPE dressing*

AIM

- **The current study aims to examine positive pressures applied to wounds** by ROCF and the novel TPE NPWT dressings under **clinically relevant negative pressure settings**
- To determine how **NP setting, dressing type, and wound type** each **contribute to variation in wound surface pressure**.

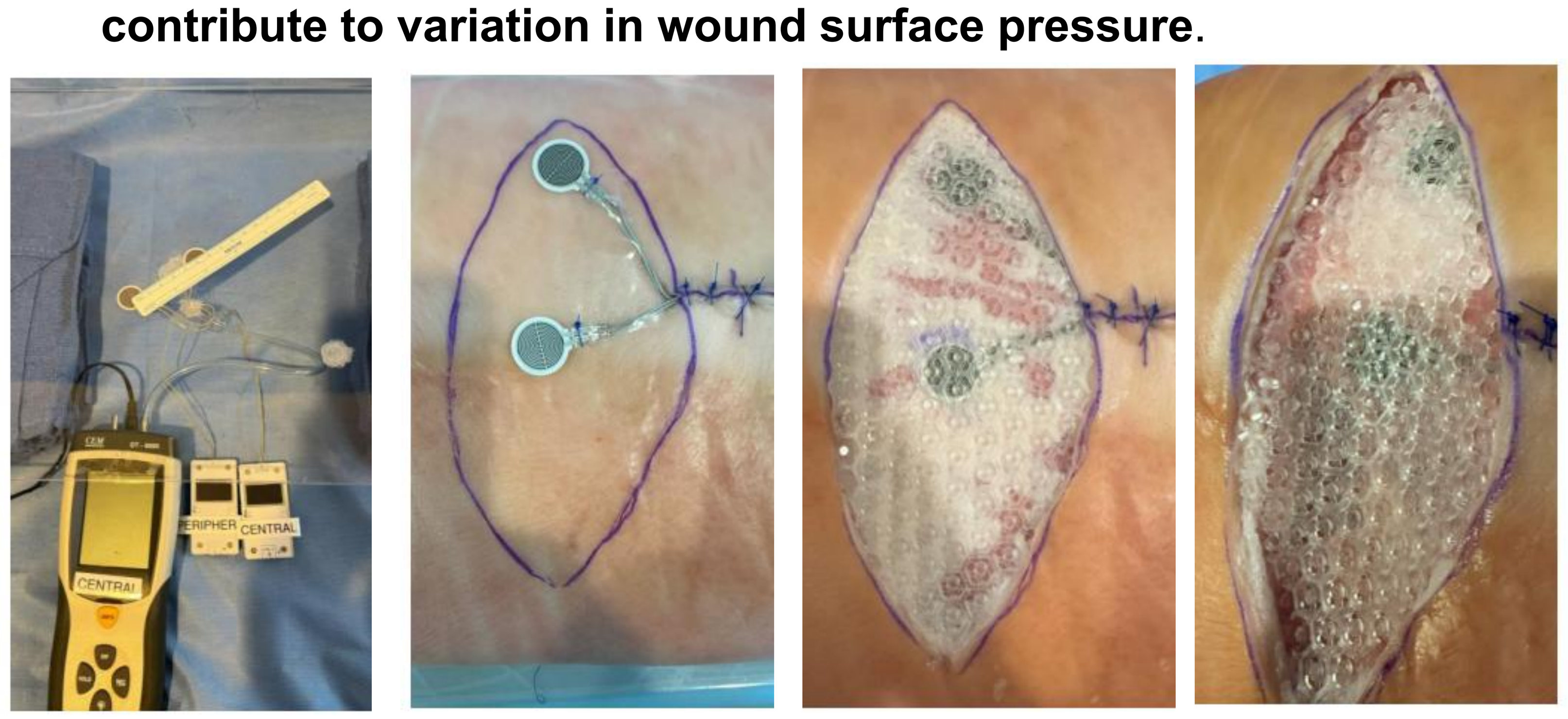

Figure 2: *Representative images of experimental setup: plexiglass, intact skin, 5mm shallow wound, 2cm deep wound (before and after placement of the TPE dressing in place) (left to right)*

METHODS

- **Positive pressure measurements were recorded at the center and periphery** of the wounds using a **thin film pressure display system** (g per cm2).
- Three dressings (**black foam, white foam, and TPE**) were applied to **4 simulated wound beds** (plexiglass, intact skin, 5 mm shallow wounds, and 2 cm deep wounds) using a **porcine explant model**.
- Three clinically relevant **negative pressure settings** were examined (**negative 50mmHg, negative 75mmHg, and negative 125mmHg**).
- A total of **648 unique central and peripheral pressure measurements** were collected.
- Each combination of **dressing type, wound type, and pressure setting** was repeated across **three fresh dressing applications**.
- **Manometer readings confirmed accurate delivery of negative pressure**, remaining within **5mmHg** of the programmed pump setting for all dressings.

RESULTS

- Positive pressure on the wound surface **increased proportionally** as the negative pressure (NP) setting increased across all dressings.
- The TPE dressing generated **significantly lower positive pressure** than black and white foam at **−125 mmHg** (**p < 0.05**)
- At **−75 mmHg**, the TPE dressing produced **significantly lower central and peripheral pressures** than both foams on intact skin and 5 mm wounds (**p < 0.05**).
- At **−50 mmHg**, TPE surface pressures were within a physiologic range consistent with compression sleeves (**+15 to +30 mmHg**), which has been shown to improve perfusion.
- Black and white ROCF foam at **−125 mmHg** produced elevated positive pressures (**+125 to +200 mmHg**) that may result in clinically significant hypoperfusion.
- Negative pressure setting was the dominant determinant of wound surface pressure, explaining **77%** of peripheral pressure variance and **68%** of central pressure variance. Dressing type and wound type contributed smaller but statistically significant effects.
- In deep wounds (>2 cm), the TPE dressing at **−50 mmHg** produced the **lowest median positive pressure** of any condition measured.

Variable	Peripheral: Variance Explained*	Central: Variance Explained**
Wound	0.07	0.06
Dressing	0.06	0.11
Pressure Setting	0.77	0.68
Wound+Dressing	0.13	0.18
Wound+Pressure Setting	0.84	0.74
Dressing+Pressure Setting	0.83	0.80
Wound+Dressing+Pressure Setting	0.90	0.86

Figure 3: *Images of the TPE at -50mmHg and foam at -125mmHg. Conversion from g/cm² (on screen) to mmHg shown to the right*

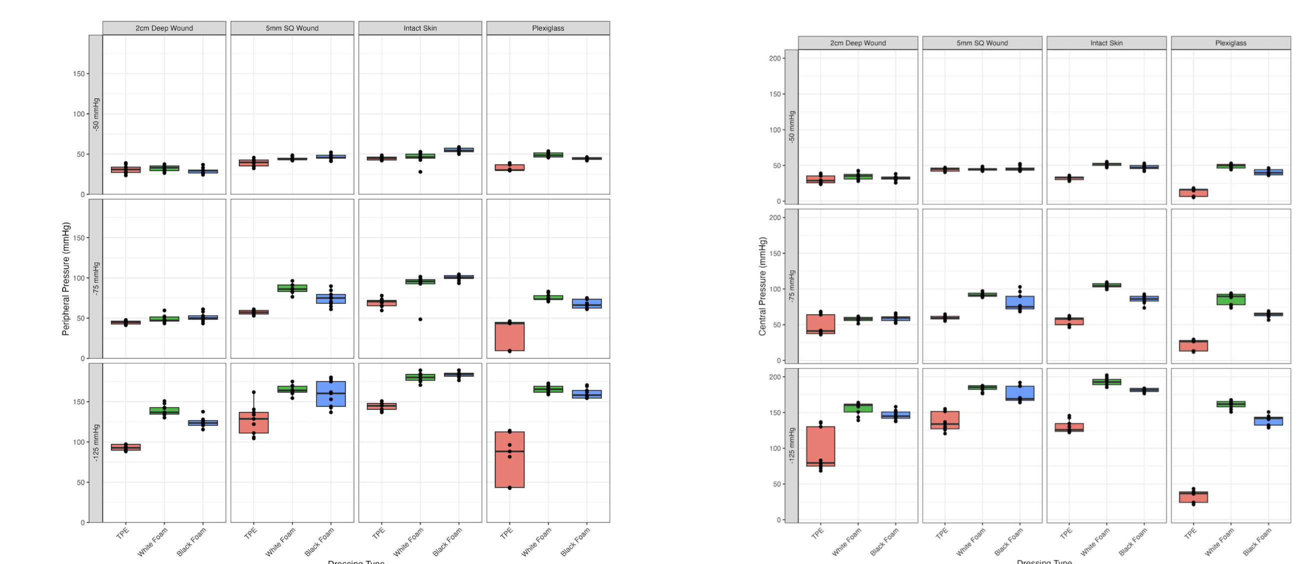

Figure 4: Peripheral & Central Pressure by Dressing, Wound and NP

CONCLUSIONS

- **Traditional NPWT with ROCF produces very high positive pressures** on the wound surface, often **above + 125mmHg**, which can create **clinically significant hypoperfusion** of the wound bed
- The **TPE dressing** was engineered as an optimized NPWT filler. Its **nonporous, nonopaque design** avoids tissue ingrowth and **eliminates the flow resistance seen in foam**, which allows for optimal performance at low negative pressure (-50mmHg) in continuous or intermittent mode.
- **Pressure injuries and dysvascular wounds often respond poorly to ROCF based NPWT**. The requirement for continuous **-125mmHg** in foam systems may explain **suboptimal outcomes** in wounds that already have limited perfusion
- **The TPE dressing** specifically at **-50mmHg** applies +10 to +40mmHg which is consistent with compression dressings that improve perfusion, which may contribute to its early **clinical success in treating pressure injuries and dysvascular wounds**

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