Wound Repair and Regeneration

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Contact Pressure Under Traditional Foam and Novel Thermoplastic Elastomer Negative Pressure Wound Therapy Interfaces

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ABSTRACT

Negative pressure wound therapy relies on suction, commonly set to −125 mmHg, to evacuate wound fluid, but dysvascular and pressure injuries often respond unpredictably. Newton's third law indicates that negative pressure applies an equal and opposite contact pressure on the wound surface, and this study quantified this contact pressure across dressing types, wound configurations and suction levels. Using a porcine explant model, central and peripheral contact pressure measurements were obtained beneath black reticulated open cell foam, white foam and a novel thermoplastic elastomer dressing across plexiglass, intact skin, shallow and deep wounds under −50, −75 and −125 mmHg. Contact pressure increased proportionally with negative pressure, and multivariable modelling demonstrated that dressing type, wound type and suction level significantly influenced pressure, with negative pressure explaining most of the variance (0.77 and 0.68). Thermoplastic elastomer at −50 mmHg in deep wounds produced the lowest contact pressure, whereas black reticulated open cell foam and white foam at −125 mmHg generated elevated contact pressures of approximately +125 to +195 mmHg. These findings show that black reticulated open cell foam at conventional −125 mmHg can create hypoperfusion conditions, whereas thermoplastic elastomer consistently produces the lowest pressures and may enhance perfusion at lower suction levels, offering a physiologic explanation for improved clinical outcomes in dysvascular and pressure injuries treated with reduced negative pressure.

1 | Background

Negative pressure wound therapy (NPWT) has become a foundation of complex wound management for more than three decades. Traditional NPWT is delivered using black polyurethane reticulated open cell foam (ROCF) dressings or polyvinyl alcohol white foam. Foam-based NPWT promotes healing through macro-deformation, micro-deformation and exudate evacuation [1–3]. Despite its effectiveness, the mechanical environment at the wound surface remains incompletely defined, particularly regarding the compressive forces (positive or downward pressure) exerted by suction utilised by NPWT [4–6].

According to Newton's third law, 'For every action there is an equal and opposite reaction', NPWT applies a reciprocal contact pressure (CP) against the wound surface proportionate to the NP setting on the pump. When the downward or CP exceeds capillary filling pressure (~30 mmHg) local hypoperfusion can occur [7–9]. ROCF dressings are compressible and contain small, twisting pores (400–600 μm) that increase flow resistance. This resistance

requires high NP to facilitate wound drainage, especially in high exudate wounds [10, 11]. White foam has even smaller pore sizes (60–270 μm) but resists compression more. ROCF at −125 mmHg suction collapses by roughly 80% compared to its relaxed form which increases resistance even more to exudate flow and requires higher vacuum suction levels [4, 12].

A novel thermoplastic elastomer (TPE) NPWT dressing has been developed to overcome the limitations of traditional ROCF. This noncompressible dressing incorporates flow pathways at least 3 mm in diameter that resist collapse. A larger, stable channel radius reduces resistance and improves evacuative flow by the principles of laminar conduit transport, where volumetric flow varies with the fourth power of the radius. A 5× increase in channel radius yields an approximate 625×, or 6250%, theoretical increase in flow for comparable pressure gradients. This calculation does not account for the 80% decrease in volume experienced with ROCF at −125 mmHg which would increase the difference even more.

The TPE dressing resists collapse and maintains hyper-efficient fluid evacuation at lower NP settings [13–17]. Experimental models also demonstrate that dressing stiffness and geometry influence tissue strain, with noncompressible designs maintaining micro-deformation and macro-deformations while limiting excessive compression [2, 18, 19].

The relationship between applied NP, dressing type and the resulting CP at the wound surface remains poorly studied. This study aims to examine wound surface CP (downward pressure) under the three NPWT dressings. Two common foam dressings were compared to a novel TPE NPWT dressing under clinically relevant NP pump settings and relevant simulated wound types. The hypothesis was that wound surface CP rises in proportion to the applied suction and varies by dressing type, with foam producing higher CP than TPE dressings.

2 | Methods

2.1 | Experimental Design

Positive-pressure measurements were obtained to evaluate the forces transmitted to simulated wound beds during NPWT using three wound fillers: black foam (Solventum V.A.C. Granufoam, St Paul, MN), white foam (Solventum V.A.C. Whitefoam, St Paul, MN) and a TPE dressing (PREVENT—Clear Choice Therapeutics Inc., Raleigh, NC) (Figure 1). Each dressing type was tested across four wound conditions: plexiglass (flat, rigid, non-elastic control surface), intact porcine skin (elastic control surface), shallow wounds measuring 5 mm in depth and deep wounds measuring 2 cm in depth. Full thickness porcine explants (Porchetta cut) were harvested from mature Landrace

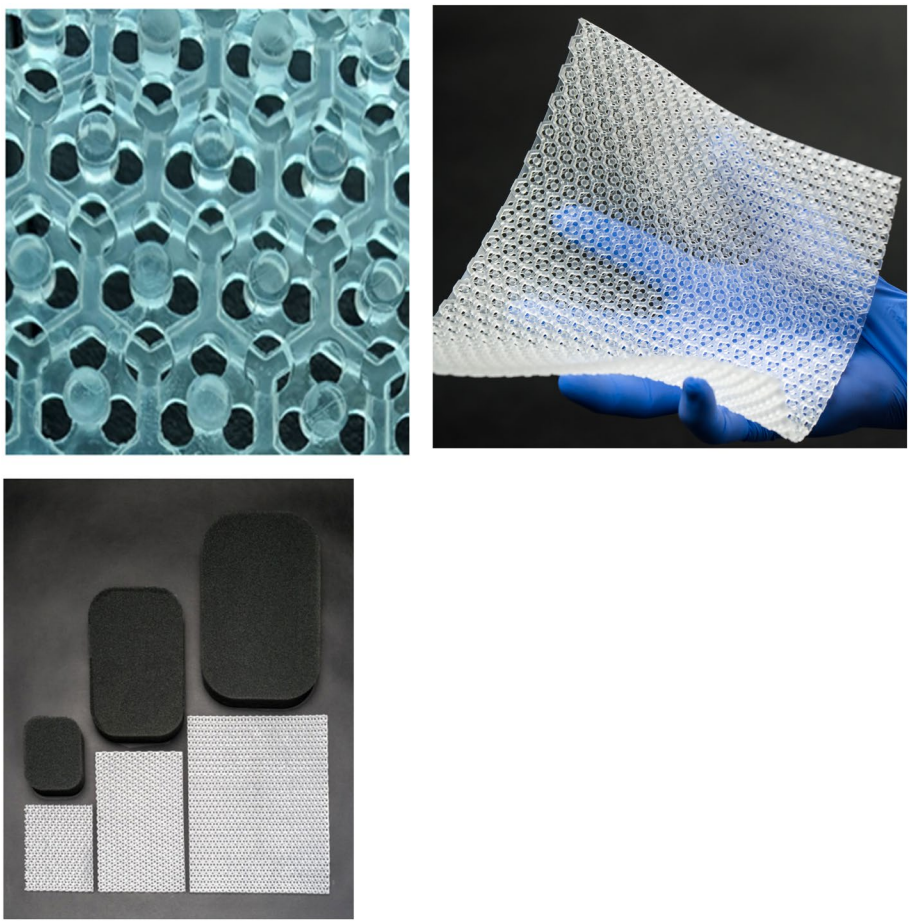

FIGURE 1 | Structural characteristics of the thermoplastic elastomer negative pressure wound therapy filler. Three images depict a magnified and actual size photos (also compared to standard sizes of ROCF) of the TPE dressing, which is a novel, non-porous, perforated, clear, non-compressible, thin (low durometer) NPWT wound filler.

swine weighing approximately 100 kg, as porcine skin most closely replicates the biomechanical and histologic properties of human tissue. Representative images of the experimental setup and wound models are shown in Figure 2.

Twelve matched test conditions were created to include every combination of dressing type and wound model. Each of the three dressings was applied to the four simulated wound beds, producing 12 unique dressing wound pairings tested across all negative pressure (NP) settings. Each dressing was evaluated under three clinically relevant NP settings of −50, −75 and −125 mmHg. For every combination of wound type, dressing and pressure setting, three independent fresh dressings were applied. Each fresh dressing was then tested in three repeated trials, with the system being fully vented to atmospheric pressure between trials to ensure independence of measurements. This resulted in 324 total measurements per pressure measurement location (three pressures multiplied by three dressings multiplied by three repetitions across 12 matched conditions). CP measures were collected using an ultra-thin flexible pressure sensitive film sensor at the central and peripheral wound locations (in g/cm^2, then converted to mmHg), for a total of 648 unique pressure recordings. CP was measured using an ultra-thin flexible pressure sensitive film pressure sensor and display modules (RP-C-MK01X flexible thin film, piezoresistive pressure sensor; Hilitand, China). The sensor reports averaged peak CP across the active sensing area rather than discrete microscale peak pressures from individual struts.

2.2 | Dressing Application and Setup

Dressings were cut to identical dimensions of (7.5 × 15 cm) using a standardised template. Each filler was positioned over the simulated wound and sealed with a clear acrylic adhesive drape to create an airtight environment. NP was applied using the CCT Mini NPWT Pump (Clear Choice Therapeutics Inc.; Raleigh, NC) for the Prevent TPE dressing. KCI ActiV.A.C. pump (Solventum Inc., St. Paul, MN) was used for the black (V.A.C Granufoam, Solventum) and white foam (V.A.C. Whitefoam, Solventum). Once the target pressure was achieved, the system was allowed to stabilise (5 min) before recording CP readings. CP values rapidly fluctuated with a ~5–10 g/cm^2 range and the number recorded was based on the median number within the range. Between each set of trials, all NP was released via tube disconnection and the system was reset. The CP sensors were confirmed to return to zero prior to each trial. For every wound type and pressure level, three new dressings were applied to ensure independent replication.

2.3 | Pressure Measurement and Instrumentation

CP at the wound surface was measured at both the central and peripheral locations using an ultra-thin flexible film pressure display system. Measurements were obtained in grams per square centimetre and converted to millimetres of mercury using a factor of 0.736 (1 g per square centimetre equals 0.736 mmHg). The primary outcome in this study was the magnitude of CP acting on the wound surface at each applied NP setting.

A digital manometer was used to confirm the actual NP delivered at the wound surface. The difference between the pump setting and measured pressure at the wound bed was less than 5 mmHg for all dressings, confirming consistent NP delivery. Because these variations were negligible, manometer validation was performed only on the plexiglass model.

2.4 | Statistics and Data Analysis

Peripheral and central surface pressure measurements were summarised using medians and interquartile range and visualised using boxplots stratified by dressing type, wound type and NP setting. For each matched condition, we estimated mean pressure differences and their 95% confidence intervals (Appendix 1). Specifically, to compare dressing types while accounting for repeated measurements, two linear mixed effects models were fit, one for peripheral pressure and one for central pressure. Each model included a random intercept for NP setting to account for repeated trials within each pressure level. Dressing type, wound type and NP setting were treated as fixed effects. Multiplicative interaction terms between dressing type and wound type were evaluated to determine whether the effect of each dressing varied across wound conditions. This modelling framework follows the recommendations outlined by Detry and Ma, 2016 [20].

Adjusted mean pressure differences between dressings were estimated using marginal means. Pairwise contrasts were

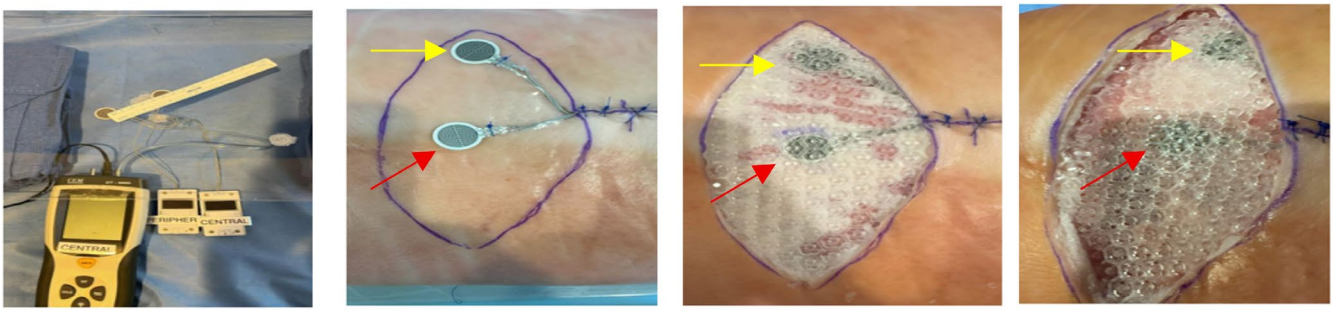

FIGURE 2 | Experimental setup and simulated wound bed models for contact pressure measurement. Representative images of the experimental setup demonstrating the four wound bed models: Plexiglass, intact skin, five-millimetre shallow wound, and two-centimetre-deep wound (left to right) before and after placement of the TPE dressing. The central measurement zone is indicated with red arrows and the peripheral measurement zone is indicated with yellow arrows.

then constructed within each wound type and NP setting. For each contrast, the model-based difference in pressure was reported together with the corresponding 95% confidence interval. These contrasts were displayed graphically to show the pattern of dressing specific effects across wound types and NP settings.

To quantify the relative contribution of each factor to variability in pressure measurements, we calculated semi-partial R^2 from multilevel models that included wound type, dressing type and pump NP setting as fixed effects. Separate models were created, one for peripheral pressure and one for central pressure. For each model, the proportion of variance uniquely attributable to each factor was estimated after adjusting for all other predictors.

All analyses were performed in R version 4.5.1 using the lme4, emmeans and partR2 packages. Statistical significance for mixed model contrasts was defined using 95% confidence intervals.

3 | Results

CP measurements at the wound surface increased proportionally with higher NP settings across all dressings (Figure 3).

3.1 | Peripheral Pressure

The distribution of peripheral pressures is shown in Figure 4. TPE consistently produced the lowest median peripheral

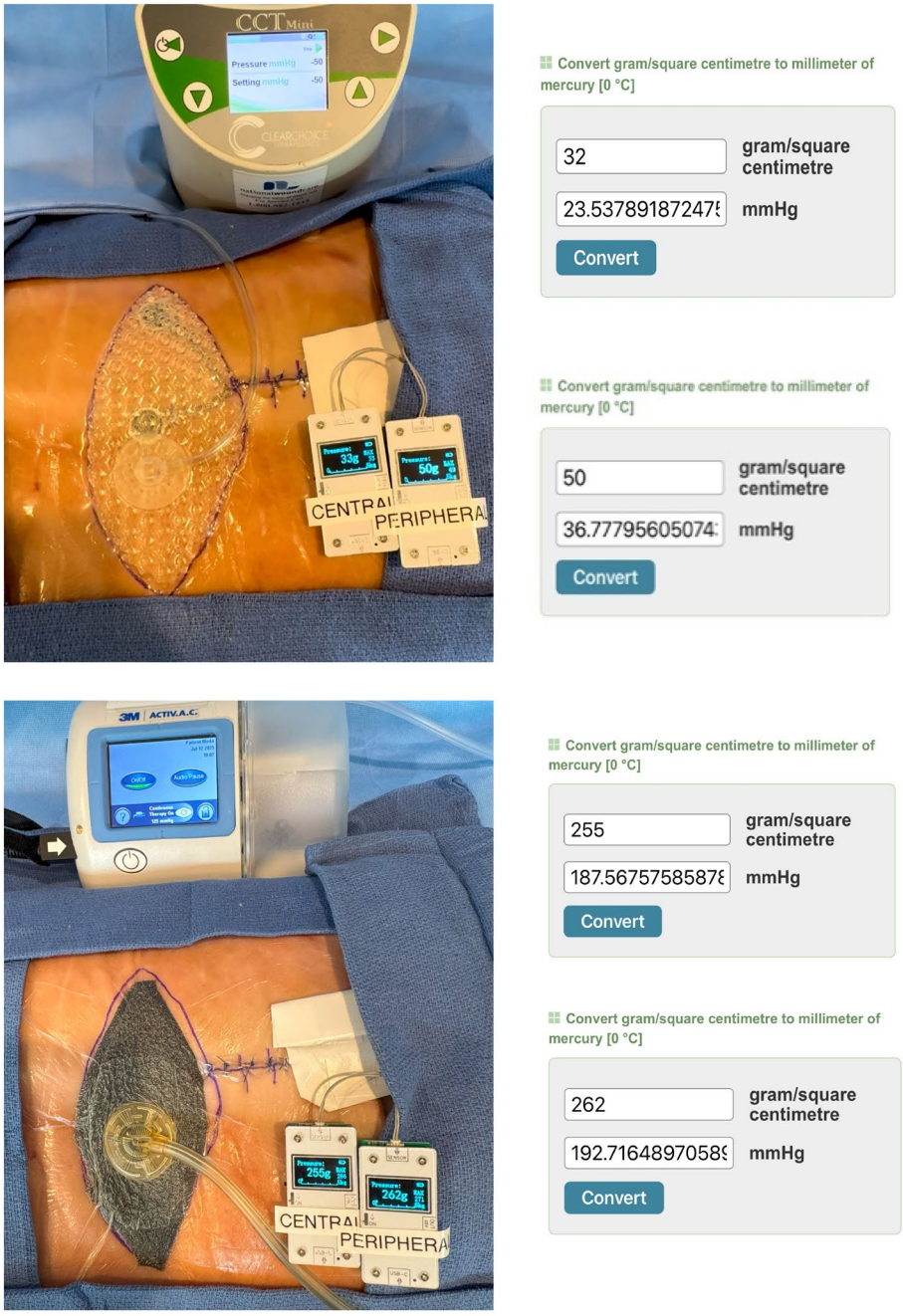

FIGURE 3 | TPE at −50 mmHg and foam at −125 mmHg. Conversion from g/cm^2 (on screen) to mmHg shown to the right.

pressures across all wound types and NP settings other than for 2 cm deep wound at −50 mmHg pressure setting (see Figure 1 for more details).

At 50 mmHg, TPE–Black contrasts were significant for intact skin (−9.73 mmHg; 95% CI, −18.04 to −1.41) and plexiglass (−11.77 mmHg; 95% CI, −20.08 to −3.46), while TPE–White was significant only on plexiglass (−16.59 mmHg; 95% CI, −24.90 to −8.28). At 75 mmHg, significant reductions were observed for 5-mm SQ wounds (TPE–White: −29.26 mmHg; 95% CI, −37.57 to −20.95; TRE–Black: −17.00 mmHg; 95% CI, −25.31 to −8.69) and intact skin (TPE–White: −21.66 mmHg; 95% CI, −29.97 to −13.34; TPE–Black: −30.89 mmHg; 95% CI, −39.21 to −22.58), with TPE–Black also significant in these wounds. At 125 mmHg, differences were most pronounced, with TPE producing substantially lower pressures across all surfaces, including plexiglass (TPE–White: −83.85 mmHg; 95% CI, −92.17 to −75.54; TPE–Black: −78.62 mmHg; 95% CI, −86.94 to −70.31). See Figure 2 and Appendix 1 for more details. Multi-variate model-based peripheral contrasts are shown in Figure 5.

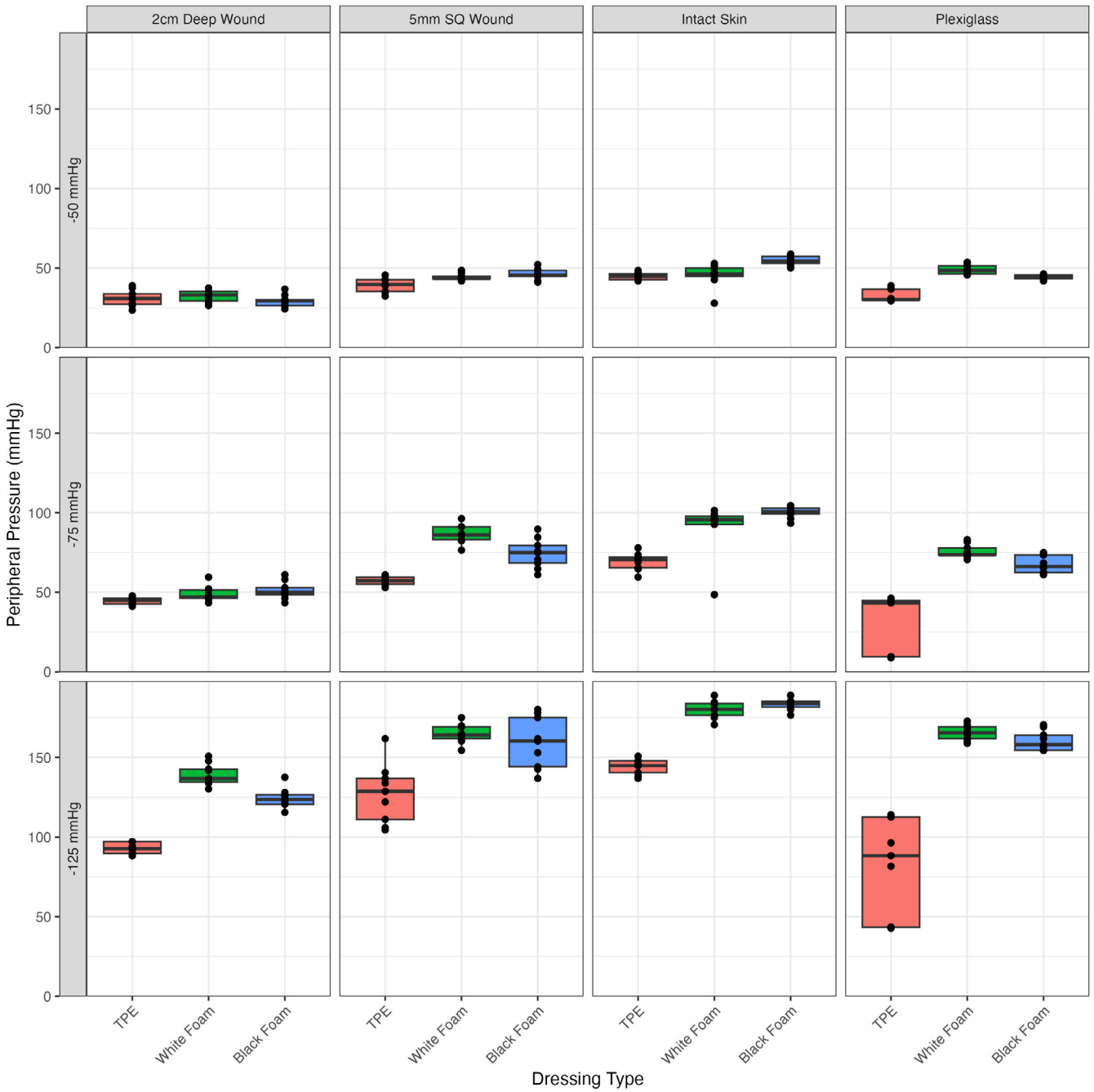

FIGURE 4 | Peripheral pressure by dressing, wound type, and NP setting. Boxplots show peripheral pressures for each dressing across wound types at 50-, 75-, and 125 mmHg. The boxplot height represents the interquartile range; the horizontal line indicates the median; and points beyond the whiskers indicate outliers.

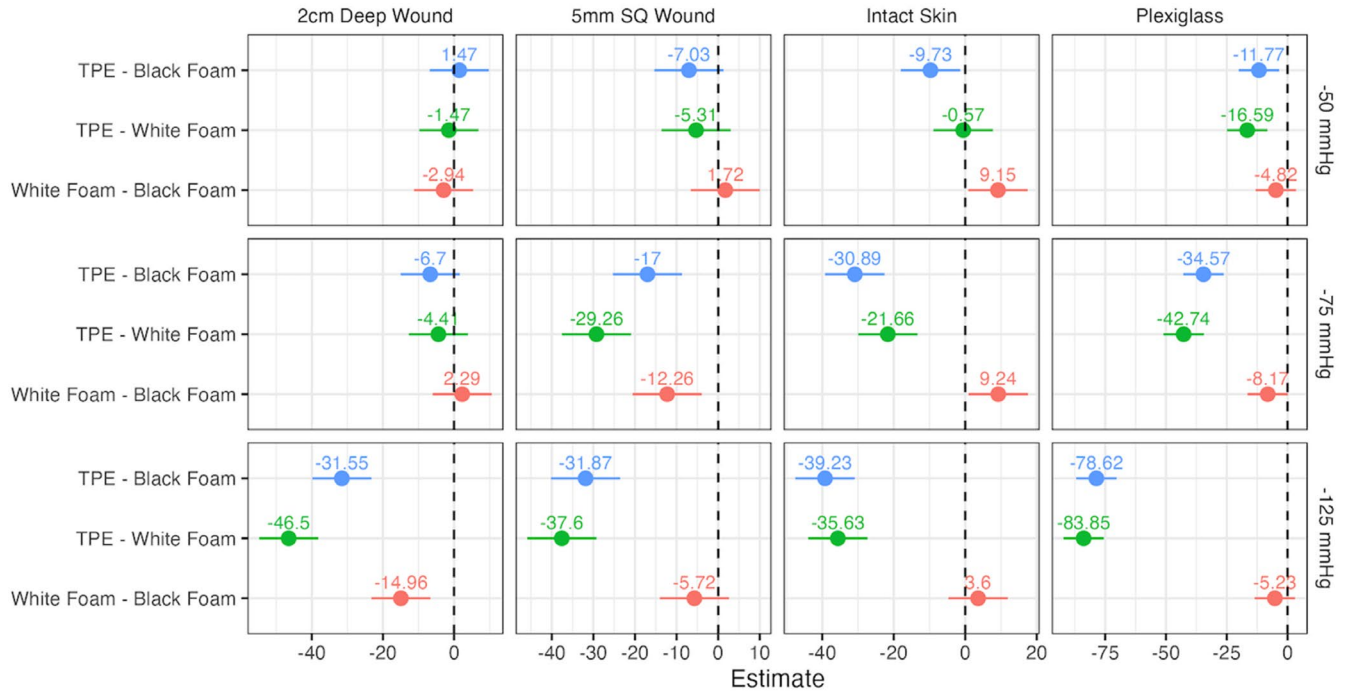

FIGURE 5 | Model based peripheral pressure contrasts. Model based contrasts and 95% confidence intervals (CIs) of peripheral pressures between dressings across wound types and pressure settings. The width of the horizontal lines through the point estimates represents the 95% CI; intervals that cross zero indicate that the estimate is not statistically significantly different from zero.

3.2 | Central Pressure

The distribution of central pressure measurements is shown in Figure 6. TPE consistently produced the lowest peripheral pressures across all wound types and NP settings. See Figure 4 for more details.

TPE also consistently reduced central pressure relative to White and Black foams. At 50 mmHg, significant reductions were observed in intact skin (TPE–White: −19.04 mmHg; 95% CI, −26.58 to −11.51; TPE–Black: −14.96 mmHg; 95% CI, −22.49 to −7.42) and plexiglass (TPE–White: −35.96 mmHg; 95% CI, −43.50 to −28.43; TPE–Black: −27.46 mmHg; 95% CI, −35.00 to −19.93). At 75 mmHg, significant reductions were seen across most wounds, including 5-mm SQ wounds (TPE–White: −32.61 mmHg; 95% CI, −40.14 to −25.07; TPE–Black: −20.84 mmHg; 95% CI, −28.38 to −13.31) and intact skin (TPE–White: −48.71 mmHg; 95% CI, −56.25 to −41.18; TPE–Black: −29.34 mmHg; 95% CI, −36.88 to −21.81). At 125 mmHg, the largest reductions occurred, particularly on plexiglass (TPE–White: −127.66 mmHg; 95% CI, −135.20 to −120.13; TPE–Black: −106.25 mmHg; 95% CI, −113.78 to −98.71), with several White–Black contrasts also significant but of smaller magnitude. See Figure 4 and Appendix 1 for more details and Figure 7 for mixed model-based results.

3.3 | Variance Contribution

NP setting explained the majority of variation in pressure measurements (Table 1). In the peripheral model, NP setting accounted for 77% of the variation and in the central model accounted for 68%. Wound type and dressing each explained up to 11% individually. Combined variable models showed that wound plus dressing explained 18% of central pressure variance, wound plus pressure explained 84% of peripheral variance and 74% of central variance, dressing plus pressure explained 83% of peripheral variance and 80% of central variance and the full model explained 90% of peripheral variance and 86% of central variance.

4 | Discussion

In this porcine explant model, wound surface CP rose proportionally as suction increased, making pump NP setting the primary determinant of CP tissue loading. These findings are consistent with prior manometry work demonstrating accurate transmission of pump settings to the wound interface. NP setting explained 77% of the variance in peripheral pressures and 68% of the variance in central pressures.

Across all wound types, the TPE dressing generated the lowest wound surface pressures, whereas both black and white foams produced markedly higher pressures. These differences were largest at −125 mmHg, where ROCF created surface pressures in the range of 125 to 195 mmHg, consistent with the peak foam interface pressures reported by Biermann et al. [9]. At −75 mmHg, TPE again produced lower surface CP than both foam dressings in intact skin and shallow wounds.

At −50 mmHg, TPE generated approximately +15 to +30 mmHg of surface pressure in the centre of the wound. This pressure range (+15 to +30 mmHg) is associated with increased microvascular perfusion when applied as external compression measured by laser Doppler and thermodiffusion modalities [4, 5, 21, 22]. This also is the range of CP exerted on superficial tissue by

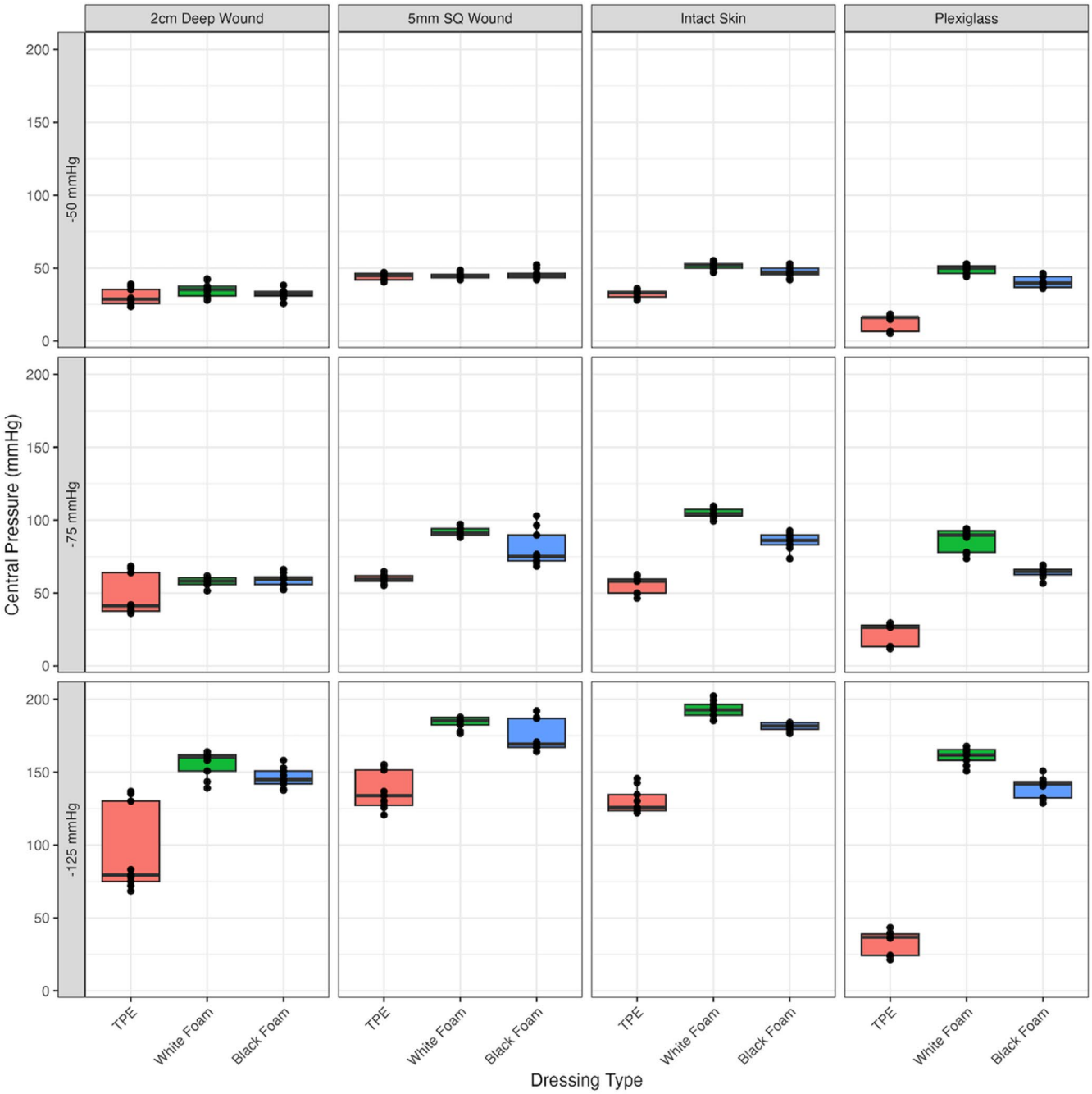

FIGURE 6 | Central pressure by dressing, wound type, and NP setting. Boxplots display central pressures for each dressing across wound types at 50, 75 and 125 mmHg. The boxplot height represents the interquartile range; the horizontal line indicates the median; and points beyond the whiskers indicate outliers.

commonly prescribed compression stockings and athletic compression sleeves, which are worn to improve local perfusion.

Central CP exceeded peripheral CP for every dressing. Both foam dressings produced the greatest rise in central compression as suction increased. These observations align with prior studies showing that increasing NPWT increases underlying surface CP. The magnitude of foam compression scales with the applied pump setting in animal and human tissue experiments [7, 23, 24]. Combined factor models indicate that filler mechanics modify, but do not completely override, the effect of suction intensity. The TPE dressing resulted in a reduction in CP compared to NP setting on the pump. The foam resulted in higher CP values when compared to the pump setting. However, at −125 mmHg, the CP under the TPE was still multiples over the capillary filling pressure (~30 mmHg). The compressive nature of ROCF and its attempts to recoil to its relaxed form amplify CP on the wound bed under active NP and reduce microvascular perfusion near the wound [1, 4].

Multiple independent investigations demonstrate that traditional ROCF NPWT systems apply a positive compressive force at the wound surface with concomitant reductions in perfusion during active suction. Biermann et al. [9] documented foam

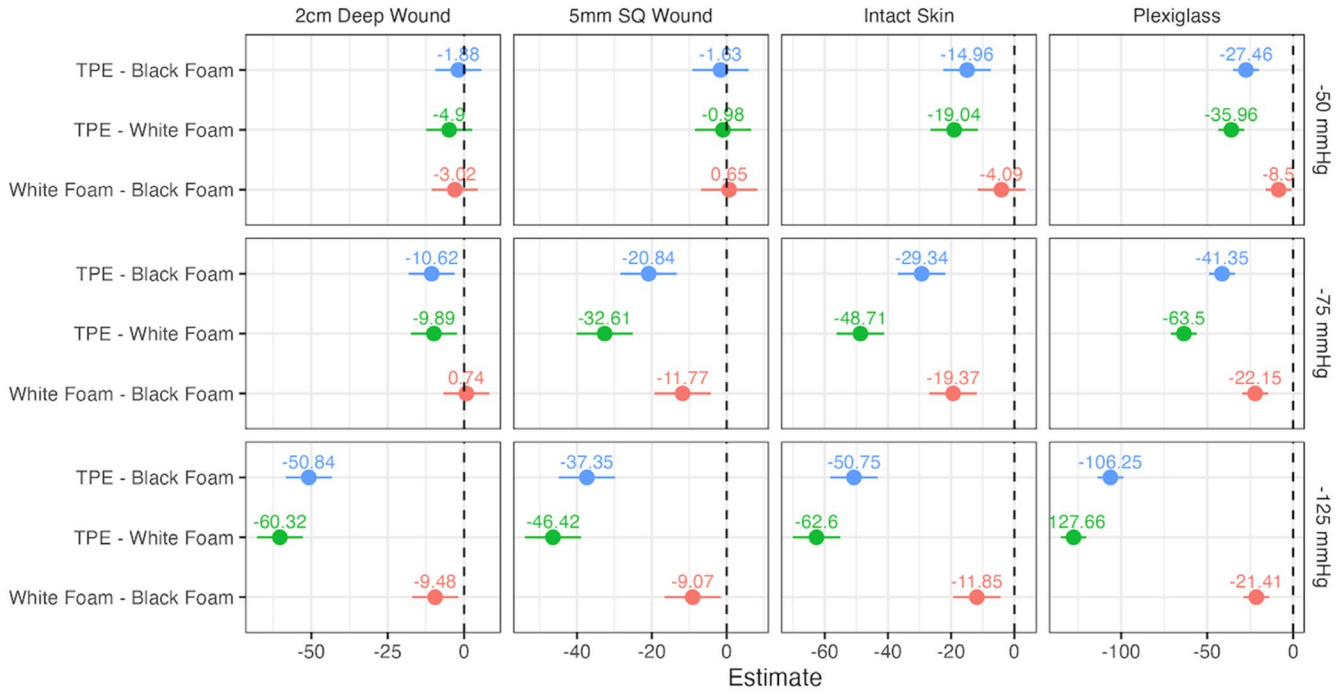

FIGURE 7 | Model based central pressure contrasts. Model based contrasts and 95% confidence intervals (CIs) of central pressures between dressings across wound types and pressure settings. The width of the horizontal lines through the point estimates represents the 95% CI; intervals that cross zero indicate that the estimate is not statistically significantly different from zero.

TABLE 1 | Variance contribution.

Variable	Peripheral variance[a]	Central variance[a]
Wound	0.07	0.06
Dressing	0.06	0.11
Pressure setting	0.77	0.68
Wound + dressing	0.13	0.18
Wound + pressure	0.84	0.74
Dressing + pressure	0.83	0.80
Wound + dressing + pressure	0.90	0.86

[a]Semi-partial R^2 statistic from the peripheral and central pressure models. Values represent proportion of variance in pressure measurements explained by each predictor or combination of predictors.

interface pressures up to 187 mmHg at a suction of −125 mmHg with concurrent blood flow reduction and stepwise oxygen decrease as suction rose [8]. Kairinos et al. [7, 24] demonstrated proportional reductions in perfusion in the wound bed as suction increased and directly measured increases in tissue pressure beneath circumferential and noncircumferential dressings in vivo. Transcutaneous oxygen, radioisotope imaging and perfusion probe studies support that perfusion falls as suction increases, with larger losses at higher programmed levels [23, 25]. Microvascular mapping in porcine wounds shows a characteristic pattern of hypoperfusion within 0.5 cm of the wound edge and hyperperfusion at distances beyond 2.5 cm during therapy, independent of filler type, although the hypoperfusion zone is less pronounced with inelastic gauze than with elastic foam [1, 21, 22]. Importantly, preclinical optimization studies suggest that many biologic benefits such as granulation formation reach near maximal effect around 80 mmHg compared to higher settings [4, 5]. However, multiple studies have also shown fluid evacuation with ROCF requires a minimum of −125 mmHg [4, 26–28].

Polyurethane ROCF collapses up to 80% at −125 mmHg, which reduces effective pore size; ROCF's compression exponentially increases flow resistance. Porcine data showed greater hypoperfusion near the wound edge with foam than with gauze or pathogen binding mesh [1, 22]. In contrast, the TPE dressing maintains open channels of approximately 3 mm that do not collapse under suction. Similar advantages have been observed with pressed membrane and pathogen binding mesh systems that demonstrated less hypoperfusion compared with foam in preclinical work [13, 15, 29].

These findings support consideration for lower suction settings with a non-collapsing, channelized, conformable interface for wounds treated with NPWT, especially those with poor blood flow or high-pressure risk. The Prevent TPE dressing produced the lowest surface pressures across all conditions and, at a programmed suction of −50 mmHg, generated a physiologically favourable CP range consistent with perfusion-enhancing external compression seen in preclinical models [4, 5, 21, 22, 30, 31]. By reducing wound bed CP while maintaining effective fluid evacuation, this design may lower hypoperfusion risk. Additionally, the lack of ingrowth polymer design and lack of compression may improve tolerance during intermittent or variable modes, which have shown microcirculatory and granulation benefits in preclinical and early clinical studies [4, 5, 30, 31]. Further randomised clinical evaluation focused on perfusion endpoints,

pain and infection related outcomes are needed to validate a clinical effect of the significant mechanistic observations in this study. Furthermore, elevated CP and ischemic conditions associated with traditional ROCF may explain poor wound healing in dysvascular wounds, pressure injuries and wounds over bony prominences. Specifically, these findings may help explain why pressure injuries, which are caused by compression, do not respond to traditional NPWT management.

4.1 | Limitation

Our study used a porcine explant model, which lacks blood flow and normal vascular responses. Our thin film sensors measured only surface CP, not microvascular perfusion or oxygenation. Despite being a common device used for measuring CPs in clinically relevant situations, a known limitation of thin film pressure sensors is that the geometry of the material in contact with the sensor can alter pressure measurements. This effect may be compounded at the wound periphery, where the depth may be more shallow (saucerised) or supported by the adjacent intact tissue. Additionally, the material upon which the thin film pressure sensor is secured, can also impact pressure reading, with higher pressure readings anticipated when the sensor is secured to a hard surface (i.e., plexi-glass) as opposed to a compliant one (i.e., tissue). Lastly, this was a basic science study, aimed at establishing a mechanistic explanation for variable performance of NPWT in different wound types, and therefore we only measured mechanical pressure and did not assess clinical outcomes like: pain, granulation, bacterial load or the resultant impact bacterial overgrowth has on odour and infection control.

5 | Conclusion

Traditional ROCF requires high levels of NP, which directly generate elevated CP at the wound surface. The data show that ROCF magnifies this effect, to levels of CP that can create hypoperfusion/ischemic conditions under the dressing, consistent with prior literature. In contrast, the TPE dressing produced the lowest CP. Because the TPE dressing has improved flow characteristics and functions effectively at low pump settings (−50 mmHg), the TPE applies CP similar to compression stockings and athletic sleeves which improved perfusion. These findings suggest the novel TPE dressing may be particularly beneficial for wounds over bony prominences, pressure injuries and dysvascular wounds where preservation of blood flow is essential. However, clinical studies are needed to validate these empirical findings.

Disclosure

This work has not, in whole or in part, been previously published or presented elsewhere.

Conflicts of Interest

Shuler & Freedman are co-founders of Clear Choice Therapeutics the manufacturer of the TPE dressing (The PREVENT). Greenberg is paid by Clear Choice Thearpeutics. There are no other conflicts.

Data Availability Statement

The data that supports the findings of this study are available in the Supporting Information of this article.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Appendix 1:** Model based pairwise contrasts of peripheral and central contact pressure across dressing types, wound conditions and negative pressure settings. This appendix presents adjusted mean differences in contact pressure between dressing types at each negative pressure setting and wound condition. Estimates are derived from linear mixed effects models with random intercepts for pressure level and fixed effects for dressing type, wound type and pressure setting. Values are reported as estimated mean differences in mmHg with 95% confidence intervals and corresponding *p* values. Negative values indicate lower contact pressure for the first dressing listed in the contrast. Peripheral and central wound surface pressures are presented separately.