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Initial Experience in a Long-Term Acute Care Facility: Using a Novel Thermoplastic Elastomer NPWT Dressing Compared to Traditional Foam

Research Article

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Introduction

A novel thermoplastic elastomer (TPE) dressing (PREVENT®, Clear Choice Therapeutics, Inc., Raleigh, NC) for negative pressure wound therapy (NPWT) has been intentionally designed to improve wound healing through the use of low negative pressure. Unique and proprietary design benefits include transparent, non-absorptive, non-compressible, and non-adhesive properties, all aimed at improving the ease of use and performance of the dressing. The most important differentiation between the TPE dressing and traditional reticulated open cell foam (ROCF), is that the TPE is non-porous. Instead, it has layered multi-directional perforated flow paths (3mm in diameter) constructed from a soft/low-durometer, bio-compatible material that has a clarity that permits direct or augmented (i.e. photometric, like a Moleculight® camera) observation of wound healing while the dressing is in active use. The absence of porosity allows for the elimination of the most problematic element of ROCF NWPT, namely in-growth. The 400-600-micron pore size of traditional ROCF is the ideal architecture to encourage mesenchymal tissue in-growth. So, tissue in-growth into ROCF is not by accident, but rather it is obligated by the properties intrinsic to the material that has essentially defined NPWT for its 30+ year clinical history--foam. Tissue in-growth limits duration of wear time and produces pain and tissue trauma at each dressing change, often sufficient to require use of local anesthetic or even a high-cost trip to the operating/procedural room simply to undergo dressing changes.

The intentional deletion of porosity from the design of the PREVENT®, also provides the following advantages. Without pores, saturation of the dressing is minimal, which has resulted in a notable reduction in dressing odor at dressing changes and during use. Since pain and odor are two of the most important patient reported concerns with NPWT, the ability to mitigate both through one design element is impressive [1]. But most impactful, is that the flow paths through the TPE dressing are exponentially larger and therefore less resistant to flow. With low resistance, the TPE dressing can be run at low negative pressure settings (-50mmHg) [2]. Conversely, it is well established that to achieve optimal evacuation of exudate through a ROCF dressing, NP setting should be set at -125mmHg [3,4].

What has been an under-appreciated consequence of this high NP setting requirement for foam, is that according to Newton's 3rd law of motion, which states that for every action, there is an equal and opposite reaction, when high negative pressure is applied to the dressing a reciprocal high positive pressure is applied to the wound bed [2,5-8]. The amount of positive pressure that is conveyed to the wound bed under an active ROCF NWPT dressing set at -125mmHg continuous is more than 6 times greater than the average capillary filling pressure in the wound bed (i.e. >+180 mmHg vs.~30mmHg) [6,7]. This leads to a hypoperfusion of the wound bed, which has long been known through basic science studies of ROCF NPWT [6,7,9,10].

In the absence of a valid alternative method for applying therapeutic negative pressure to a wound, the clinical consequence has not been fully assessed. Now that a viable alternative has been FDA cleared for use, it is possible to assess if avoidance of the hypoperfusion associated with high NP settings used for foam NPWT, can improve healing outcomes, especially since outcomes in clinical studies evaluating foam NPWT versus standard dressings for the treatment of diabetic ulcers and pressure injuries has been variable [11,12].

The purpose of this study is to compare the wound healing effect

and value of this novel TPE dressing compared to the standard of care black foam NPWT dressing. To assess wound healing effect, in addition to the qualitative absence of infection or gross wound complication, measures of wound healing were compared. To assess the impact on value, the 2 most costly elements of NPWT the duration of treatment and the number of disposable dressings consumed to achieve a final healed wound were also measured. Our working hypothesis is that the beneficial physiological impact of low NP setting NPWT using the TPE dressing will result in greater wound healing, faster with less dressing changes and days of therapy.

Materials and Methods

We performed a retrospective chart review as part of a quality improvement project at a single, high volume long-term acute care (LTAC) in-patient wound care facility (Landmark Hospital of Columbia, Columbia, MO), in an effort to assess the effect and value of a novel negative pressure wound therapy dressing (PREVENT®, Clear Choice Therapeutics, Inc, Raleigh, NC). The PREVENT® TPE product is sold as either a stand-alone wound contact layer or a complete NPWT dressing kit with a mated pump, For this trial, the PREVENT Barrier Wound Contact Layer was trialed on 10 consecutive patients, and the outcomes were compared to a consecutive series of the last 10 patients treated with traditional reticulated open cell foam (ROCF) NPWT dressings, termed "black foam" NWPT. The TPE wound contact layer is a thin (6mm thick), perforated, non-porous, clear, low durometer material, which comes in 3 sizes, analogous to ROCF sizing. It was cut to size and placed in the wound bed, in lieu of ROCF, to fill the "TPE treated" wounds (Figure 1A&B), and then standard clear drapes and vacuum domes (i.e. "Lilly pads") were placed over top and connected to a regulated vacuum pump (Solventum Ulta®) with a collection canister to create a near-airtight wound area in support of negative pressure wound therapy. Thus, the only dressing related variable that was different between TPE and ROCF cohorts was the wound filler. This controlled for confounding effect of variability in dressing materials.

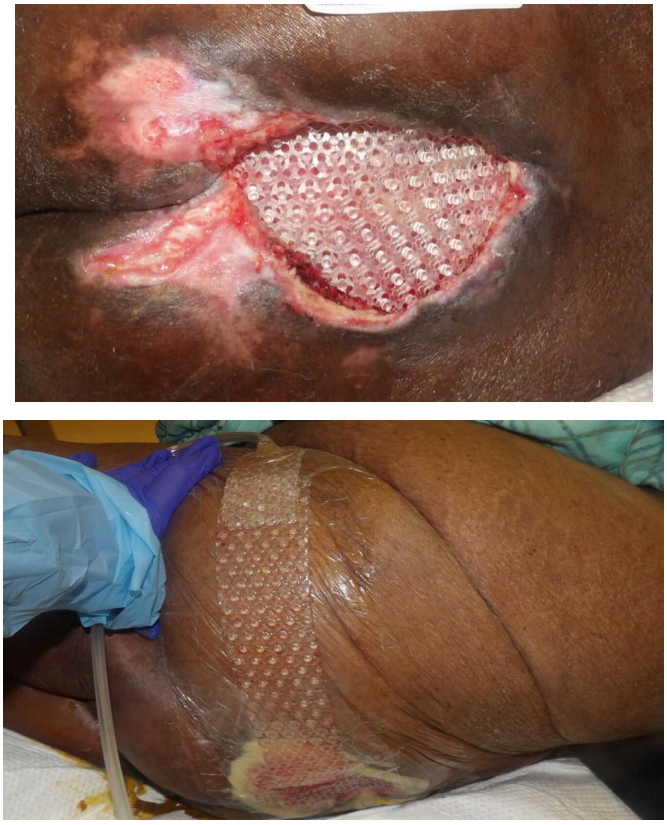

Figure 1: A. Photo showing the TPE dressing cut to the size of the wound and placed into the base of the wound, regardless of wound depth.

B. The TPE dressing in place with TPE bridging to avoid pressure injuries from the dome and tubing. Originally, a foam bridge was used, but this resulted in some fluid stagnation, when the dressing was run at -50 mmHg. This stagnation resolved completely by increasing the negative pressure setting (-125 mmHg), which is a live confirmation of the fact that when using foam in a NPWT dressing to treat a high exudate wound, negative pressure needs to be set at -125 mmHg. Once the bridge was converted to a segment of TPE (placed over drape that have been first applied to the intact skin above which the bridge would lay), the dressing work well at -50 mmHg.

Intervention

The TPE and ROCF wound fillers/contact layers were cut to the areal dimension of the wound and placed within the margins of the wound, to prevent maceration. Measurements including initial wound volume, final wound volume, % volume change were made and the number of days of NPWT and dressing changes were recorded. In terms of eligibility, all patients treated with NPWT during the trial or immediately prior were included, (Initial volume of the wound was at least >10 cm^3). All wound care was conducted under the supervision of an experienced wound care team. All wounds were monitored under their standard wound care protocol for signs of healing and for signs of wound complications, like infection. Any complication was documented.

All black foam NPWT wounds were treated using the standard protocol of -125mmHg (-75mmHg on open abdominal wounds) of continuous suction changed twice weekly, in near accordance with the FDA cleared indications (<3) for use. All TPE wounds were treated at a low negative pressure setting of -50mmHg (to -75 mmHg in earlier cases) at continuous suction changed at intervals of up to 7-10days based on the discretion of the wound care team. The TPE is clear, allowing for real time monitoring of the wound, and since it is porous, in-growth into the TPE is not a duration of wear limitation, like it is with ROCF. Furthermore, because of its substantially lower resistance to exudate outflow, TPE NPWT is ideally maintained at -50mmHg to -75mmHg [2], while multiple studies have shown that black foam NPWT requires higher negative pressure settings (i.e. -125mmHg, except over delicate tissues, like in an open abdominal wound) to ef-

fectively evacuate exudate from the wound [4,7,13]. Thus, both dressings were maintained at the ideal negative pressure setting for their respective designs and functions.

Two wounds, which had active infections at the time TPE was initiated, received twice-daily irrigations of 100 mL of 0.25% acetic acid solution through the dressing, by affixing a 2nd dome to the dressing and using that as an in-flow port (Figure 2). The dome tubing was then connected by luerlock to an IV line which conveyed the irrigation to the wound bed, under the pull of active negative pressure, producing an "irrigation" effect, as opposed to "instillation". Instillation is an asynchronous process of dripping fluid into the wound filler, allowing for a dwell time and then turning on the negative pressure, to remove the instilled fluid. Vera-flo instillation (0.25% Dakins solution) was used in two of the black foam treated patients, due to high bioburden and slough. Thus, some manner of fluid instillation/irrigation was used in 2 of the 10 patients in each cohort.

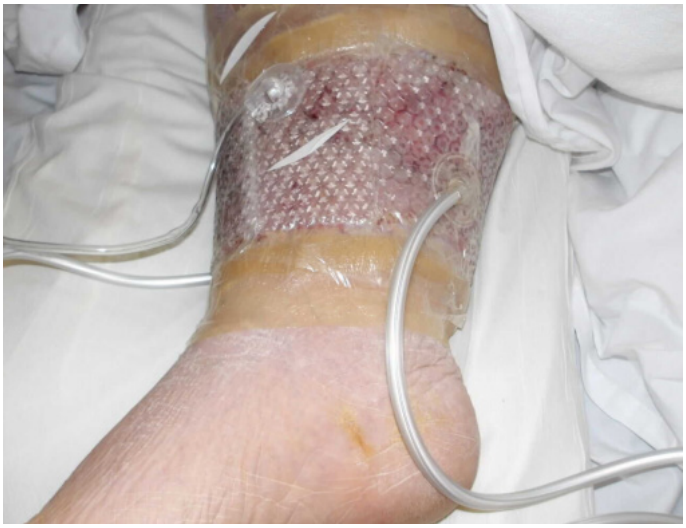

Figure 2: Photo showing two suction ports on each side of the wound. One is used for inflow and the other for traditional suction outflow, to allow for surgical grade irrigation of the wound at bedside, under the sealed dressing.

Measurements

One of 3 experienced wound care nurses, performed and documented all measures to minimize inter-observer error, utilizing the most used method for measuring wound area (L x W) and wound volume (L x W x D) in clinical practice. The simple ruler method includes a measurement of the longest length in the longitudinal axis of the body part (L) and the largest width axis (W), which is tangential to the length axis measurement [14]. Depth (D) is measured with a ruler or cotton swab applicator placed into the wound in a clean fashion to measure the deepest depth margin compared to the normal skin surface. Measurements were performed and recorded at each dressing change.

Primary outcome measure is duration of care (termed "NPWT Days") until the wound had healed sufficiently to no longer require active wound care (i.e. = end of NPWT, which commonly is defined as < 0.5cm wound depth at the LTAC) or in which NPWT care was no longer supported (i.e. due to discharge from LTAC or insurance limitations), which explains the variation in final wound volumes between cases at the "end of treatment" date. All wounds that achieved this outcome healed to completion without complication or resumption of active wound care, except for 2 patients, one in each cohort, which are detailed below.

These 2 patients were the only two that failed NPWT treatment, as defined as a wound that did not heal following discontinuation of NPWT. In one extremely ill, obese patient with peritonitis, his open abdominal wound failed to heal with any treatment provide, which was felt to be related to his overwhelming systemic disease burden. His wound was starting to granulate following conversion to the TPE dressing, better than it had previously when treated with black foam NPWT treatment. His wound dimensions were difficult to reliably obtain due to his obesity (especially in the lateral decubitus position, which gapped the open wound some), severe illness and open abdomen with intermittent significant abdominal distension. Regardless, his absolute LxWxD dimensions recorded were larger than at the initiation of TPE NPWT, so it was considered a failure of healing. Thus, the dressing was discontinued, and he is pending hospice transition. In the other patient, the one treated with black foam NPWT, the patient refused to comply with weight bearing and turning restrictions for his sacral pressure injury, and this wound failed to heal.

The primary process measure was % volume reduction (% Volume Redux = (Initial Volume - Final Volume)/Initial Volume x 100). Additional outcome measures are absolute differences in volume, as well as the following process measures: number of days of NPWT and number of dressing changes over the course of care.

Statistical Analysis: Descriptive statistics (average, % differences) were calculated using the Microsoft Excel 2025 workbook formulas. Since the distribution of values within each comparator group was not normal, we used the Mann Whitney U-test for comparing non-parametric data from two independent groups. When analyzing for statistically significant ($p < 0.05$) difference between groups regarding the following measures: % volume reduction, total and per day, as well as the number of dressing changes and the total length of NPWT care.

Results

The TPE dressing produced an average decrease in wound volume of 59% (median: 79%), compared to 55% (median: 71%) with black foam over the course of treatment. When compared to days of treatment, this computed to a 5% reduction in wound volume per day for the TPE dressing versus 2% volumetric reduction per day for black foam. While the difference in total and daily volumetric reduction of the wound was not significant ($p > 0.17$), the average number of treatment days required to reach the point of discontinuation of NPWT was significantly different, with this endpoint being achieved 2.3x faster with TPE vs. black foam (14.6 days vs. 33.9 days; $p=0.009$ = 19.3 days saved). Furthermore, 90% of black foam NPWT treated patients required at least 2 weeks of NPWT dressing compared to only 50% for the TPE dressing. In addition to the significant reduction in treatment days, 4x fewer dressing changes were needed to achieve this treatment goal (2.0 TPE vs. 7.9 black foam; $p=0.009$). Thus, the 2 most expensive and directly quantifiable costs of in-patient NPWT wound care (days of treatment and number of dressing used per patient) were both sig-

nificantly reduced with the TPE dressing.

Full patient-level data and group averages are presented in Tables 1through 3.

Table 1: TPE Dressing (PREVENT) - Patient-Level Data (all volumes reported in cm3).

Wound Location	Vol, Initial	Vol, Final	Vol, Change	Vol Change/ Dressing	Volume Change/ Day	% Volume Redux	% Volume Redux/ Day	Dressing Changes	NPWT Days	> 2 weeks NPWT
Abdomen	232	6.3	225.7	112.9	9.4	97%	4%	2	24	Yes
Lower extremity	627.7	488.25	139.5	69.8	15.5	22%	2%	2	9	No
Abdomen	20.29	34.01	-13.715	-6.9	-1.1	-68%	-5%	2	13	No
Lower extremity	307.5	8.05	299.45	99.8	12.5	97%	4%	3	24	Yes
Lower extremity	9.75	4.875	4.875	1.6	0.2	50%	2%	3	23	Yes
Lower extremity	199.8	14	185.75	61.9	9.3	93%	5%	3	20	Yes
Lower extremity	152.8	15.4	137.35	68.7	9.8	90%	6%	2	14	Yes
Lower extremity	403.2	128	275.2	275.2	45.9	68%	11%	1	6	No
Lower extremity	443.7	1	442.7	442.7	63.2	100%	14%	1	7	No
Foot	9.9	5.83	4.07	4.1	0.7	41%	7%	1	6	No
Avg						59%	5%	2	14.6	50%

Table 2: Traditional Black Foam NPWT - Patient-Level Data (all volumes reported in cm3).

Wound Location	Vol, Initial	Vol, Final	Vol, Change	Vol Change/ Dressing	Volume Change/ Day	% Volume Redux	% Volume Redux/ Day	Dressing Changes	NPWT Days	> 2 weeks NPWT
Sacral	51.5	27.9	23.6	1.8	0.5	46%	1%	13	45	Yes
Sacral	458	425.6	32.6	16.3	0.7	7%	0%	13	45	Yes
Foot	125.6	18.3	107.2	53.6	7.7	85%	6%	4	14	Yes
Lower extremity	195.8	9.2	186.6	93.3	9.8	95%	5%	3	19	Yes
Foot	13.2	0.4	12.8	4.3	0.4	97%	3%	4	32	Yes
Abdomen	789.6	722	67.6	22.5	7.5	9%	1%	2	9	No
Abdomen	268	11.2	256.7	85.6	9.5	96%	4%	4	27	Yes
Sacral	250	315.3	-65.4	-32.7	-1.1	-26%	0%	14	58	Yes
Sacral	122.9	53.2	69.7	5	1.2	57%	1%	14	58	Yes
Abdomen	709.2	99.2	610	76.3	19.1	86%	3%	8	32	Yes
Avg						55%	2%	7.9	33.9	90%

Table 3: Cost Analysis Model.

	Cost per kit	Number of Dressings Used	Total Dressing Costs	Number of Treatment Days	Estimated Facility Internal Cost/ In-patient Day	Estimated Facility Total Cost for In-patient Stay	Estimated Total Cost of Care
TPE	$840	2	$1,680	14.6	$1,250	$18,250	$19,930
Black Foam	$40	7.9	$316	33.9	$1,250	$42,375	$42,691

Discussion

Cost Analysis Model

The cost for a ROCF NPWT dressing varies by user and contract. This is business confidential information, but for purposes of forecasting and demonstrating the potential for cost savings of one treatment method compared to another, we can make a general assumption that the price of a single ROCF NPWT dressing is $40/kit, and we can assume that the vacuum pump rental fee and canister cost/use is identical between the treatment groups, thereby negating the impact of these 2 factors on the model. If we further assume that the TPE dressing garners a premium price per disposable kit given its unique and proprietary features, and this a 20x innovation premium, meaning that the price per disposable TPE kit would be $800 each, then we can use the actual data for days of use and number of dressing changes to compute a cost analysis model. While the PREVENT® TPE is avail-

able as a complete NPWT system, including its own proprietary drape, dome and pump, this LTAC trialed the TPE as a stand-alone wound contact layer and therefore there was an additional $40 per dressing, to account for the black foam kit that was also opened to obtain the drape and tubing needed to mate to the vacuum pumps used in this LTAC (black foam filler was discarded). Days of use can be converted to a cost by multiplying by the average estimated internal facility cost per in-patient day. This is a metric that is available and used by healthcare administrators routinely for financial forecasting. The LTAC facility in which the trial was completed reported an internal cost of $1250/in-patient day. This is on par with publicly available data. Lastly, while not shown in Table 3, the sensitivity of the dressing price on total cost of care savings is very minimal (<8%).

Since the facility reimbursement for essentially all LTAC (and acute hospital) in-patient stays is at a capitated rate, total cost of care is the most relevant metric, since the cost of all care related activity directly reduces the margin for the facility. Thus, cost analysis modelling such as this, provides important information to decision makers, that is far more informative than simple direct price comparisons. If a higher priced premium product results in faster healing time, and the most important factor in the total cost of care is the facility resources used while in-patient (i.e. hospital bed and possible operating/procedure room for dressing changes), then it is a more valuable option. This model shows that despite 5.3x greater total dressing costs ($1680 TPE vs. $316 black foam), the total cost of care was 2.1x cheaper for TPE compared to black foam, resulting in an average absolute estimated cost savings of $22,761 per patient treated with a TPE instead of black foam NPWT in this LTAC facility.

Nursing staff reported that the TPE dressing was generally better tolerated (less pain) by patients at the time of dressing changes, and that malodor associated with TPE NPWT treatment was noticeably reduced compared to traditional foam. These observations were informal and were not systematically captured.

Several limitations should be noted. This was a retrospective, non-randomized comparison, and the two patient populations may not have been equivalent with respect to wound etiology, size, or comorbid conditions. While measures using a ruler, are the standard of care in clinical practice, they are subject to inter- and intra-rater reliability variance. The TPE group had an insignificantly smaller average initial wound volume than the foam group (240.7cm^3 vs. 298.4cm^3; p=0.60), which may have contributed to difference in outcomes independent of dressing type or pressure setting. However, this same fact also limited the amount of possible healing that could be obtained, which highlights the insignificantly greater total healing obtained by TPE (% Volume Redux 59% vs. 55%) despite slightly smaller initial size. Additionally, two patients in the TPE group received adjunctive acetic acid irrigations not administered in the foam group, representing an uncontrolled variable, but another 2 patients in the black foam cohort, received Veraflo® instillation.

These findings are preliminary, and prospective, randomized controlled trials will be required to confirm these results. Nonetheless, this initial data indicates the potential clinical and economic benefits of a foamless, low-resistance, non-compressible, non-absorptive NPWT dressing capable of clearing exudate at low negative pressure. The use of lower pressures likely improves perfusion at the wound surface, facilitating more rapid and cost-effective healing.

Conclusion

This study represents the first published clinical data examining outcomes with a novel TPE NPWT dressing compared to traditional ROCF. While numerous high impact case reports have been written and submitted for publication, detailing successful complex wound healing in wounds of various type (acute/traumatic, dysvascular, pressure, post-sternotomy, irradiated and burn), the vast majority of which had previously failed to heal or progress despite weeks to months of ROCF NPWT, this is the first clinical series to actual compare relevant outcomes of the TPE dressing to the current standard of care for NPWT. The TPE dressing's design permits the use of low negative pressure (-50mmHg). Prior studies have demonstrated that traditional black foam at -125mmHg can produce hypoperfusion beneath the dressing, with downward pressures exceeding +187mmHg at the wound surface--a mechanism that may delay healing, particularly over bony prominences or in dysvascular wounds.

Across all outcome measures, the TPE dressing demonstrated meaningful advantages. But due to the small sample size of this trial, the only statistically significant difference was in terms of total duration of care (2.3x lower with TPE, saves 19.3 in-patient treatment days) and 2x fewer dressings (2.0 vs. 7.9). However, in a cost analysis approach, these 2 significant differences reduced total cost of care for patients admitted to this LTAC for wound care by a factor of 2.1x, resulting in an average absolute estimated costs savings per patients of $22,761.

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