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Multifunctional Polyethylene Glycol Triethoxysilane… Dressing Study – A Clinician-Scientist's Insights and Perspective

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Abstract

Chen et al. [1], compared two modified polyurethane-based wound dressings (PUE and PUESi), both intended for use in chronic wounds, with a negative control (gauze) and a positive control (PolyMem) via a series of preliminary in vitro and rodent model tests. Future studies may find that one or both of these two new dressings are beneficial. However, the results of this first study cannot be relied upon. Although they exhibited in-depth knowledge of manufacturing techniques, the study designers seem far less familiar with the science of wound healing and with PolyMem wound dressings. This helps explain the flaws in the methods that led to many of their tests not being translatable to real-world settings. In addition, the interpretation of some of the test results is questionable.

Visual Abstract or Table 1:

IN VITRO TESTS	ISSUES
1.Transmittance	None. Toxic substances in the test dressings remain in the substrate
2.Thermal stability	Completely irrelevant temperature range; boiling water – oxidizing diamonds (100 – 800° C)!?
3. Pore structure	Unique structure was inappropriately interpreted as inferior; no ingrowth with PolyMem
4. Strength & Stretch	Strength & flexibility are desirable, but more than what is ever needed in real life is not better
5a. Swell	Dressings were completely submersed in saline; does not translate to real-world setting
5b. Absorption speed	Tested only by submersion and checked only at 2 minutes, when all had absorbed equally
5c. Vertical absorption	If test was performed, the results were not published
5d. Evaporation (MVTR)	PolyMem was superior; interpreted as inferior (authors contend that drier is always better)
5e. Suction/conforming	PolyMem conformed better than PEUSi; suction test conducted on overly-saturated PolyMem
6. Adhesion	Tested ability to absorb & retain proteinaceous fluid, not adhesion; PolyMem cleans wounds
7. Surface dryness	PUESi and PolyMem are unlikely to cause maceration, but PUE dressing did poorly on this test
8. Cell viability	PolyMem outperformed PEUSi, but only fibroblasts & dressings not in direct contact with cells
RAT WOUND STUDY	ISSUES
Study Design	PolyMem was not changed appropriately, leading to acknowledged oversaturation (*2.8*).
	Later, PolyMem was not held in place well, leading to air entering under it & forming scab
	Corner sutures to prevent wound healing via contraction differed markedly in depth/effect
1. Adherence	Periwound skin lifted up by Tegaderm affixing PolyMem & PUE was interpreted as adherence
2a. Initial healing	Despite not being changed when indicated, PolyMem outperformed all during the first week
2b. Healing stalled	Air infiltration led to scab formed under PolyMem (~day 14). This is known to slow healing
3a. Histology at day 7	Focused inflammation is positive, needed for closing wounds; PolyMem provides this (see 2a)
3b. Histology at day 7	Collagen tests inconsistent with healing results; do PUE & PUESi promote hypertrophic scar?
3c. Histology at day 21	Claim of "no epithelialization" with gauze and PolyMem is refuted by the authors' Figure 5
CONCLUSIONS	Authors restate goal of dry wound healing, state that moist healing (e.g., PolyMem) is inferior

Keywords: Polyurethane; Negative pressure; Non-adherent; Diabetic foot ulcer; PolyMem; Wound cleansing; Moisture balancing; APTES; Wound healing; Chronic wounds; Interactive dressing; Multifunctional; Inflammation; Polymeric membrane dressing

Introduction

A novel wound dressing technology was featured in a 2023 article by Chen, et al. [1] It is admirable that these investigators/manufacturers were bold enough to compare their new dressing technology (PUE and PUESi)

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to PolyMem, which is increasingly being seen as the gold standard for wound care, rather than only comparing it to gauze [1-5]. However, the authors seem not to have researched this comparator product (PolyMem) and instead, they stated that they "speculated" about its attributes. Consequently, they used PolyMem inappropriately, which led to results that will not translate into real-world applications [1,6].

In addition, Chen et al. [1], applied an overly simplified model of diabetic wound healing. Based upon a correlational study in which inflammation and bacterial infection were associated with increased exudate, they created a dressing with high absorption activity and very high evaporation rates (MVTR) in order to control inflammation and infection in wounds [1]. Although they at one point acknowledge that exudate is often beneficial, the new dressings are designed to remove as much exudate as possible [1]. In fact, exudate is necessary for wound healing, and excess exudate is a symptom, rather than a cause, of inflammation and infection [7-11].

Although it is true that bacteria thrive in moisture, human immune cells, fibroblasts, endothelial cells, and granulocytes require a moist environment as well [2-8]. In 1962, Winter sparked a "dressings revolution" by demonstrating that wounds healed twice as fast when they were kept sufficiently moist [2,9-11]. Hinman and Maibach [12] confirmed these results in human volunteers in 1963. In a 1990 review of 115 studies, Hutchinson and McGucken [2] found that, regardless of wound type, infection rates were dramatically reduced when occlusive rather than non-occlusive dressings were used, eliminating this concern about moist wound management. A rigorously designed survey found that although the general public continues to believe that wounds should be kept dry, wound experts consistently support the principle of moist wound management [7]. In the 60 years following Winter's study, the evidence that moist wound management leads to superior outcomes has become overwhelming [3,5,11,13-18].

Chen et al. [1] reject this principle, asserting that drying wounds will decrease infection and inflammation and improve healing. Their test found that dry gauze decreases inflammation, rather than increasing it, as is usually the case [1,19]. A detailed exploration of how this could have happened is published elsewhere. However, simply reading the methods section and examining the illustrations in Chen, et al. [1], carefully will reveal that the differences between groups may have had more to do with the study design than with any inherent advantages of the test dressings.

Because desiccation is a cause of increased inflammation and infection, optimal wound healing relies on an environment that is moist – not too wet, and not too dry [8,10,12-16]. PolyMem interacts with the body to balance wound moisture, control inflammation, and continuously cleanse wounds (which addresses infection), all while concentrating nutrients, proteins, and growth factors at the wound site [5,7,17,18].

The authors state that PolyMem is a "commercial PU foam product," implying that it is a conventional foam dressing, which is how they treated it throughout the study [1]. In fact, PolyMem dressings are so different from conventional foam dressings that they are consistently referred to by the generic name, "polymeric membrane dressings" [3,5,6,12-18]. In the Discussion, Chen, et al. [1], refer to "some" wound dressings containing glycerin, apparently unaware that glycerin is one of the components of PolyMem [1,2,5,19,20]. PolyMem's multiple components work synergistically with each other and with the body [5,7,12,21,22]. When used appropriately, PolyMem delivers all of the benefits mentioned in the article, including extra absorption, non-adherence to the wound bed, conforming to the wound, controlling inflammation, and promoting brisk wound healing, even when used on challenging wounds, such as chronic diabetic foot ulcers [5,7,12,22,23].

Specific Issues

This lack of understanding of the complex multifunctional interactive nature of PolyMem dressings, and the need for wound moisture to be balanced rather than eliminated, may help to explain the errors in the investigators' study design and interpretation of their findings. The results of eight in-vitro tests: (1. Fourier transform-infrared spectroscopy, 2. thermomechanical analyses, 3. scanning electron microscopy, 4. tensile strength, 5. water absorption, 6. anti-protein absorption, 7. surface dryness, and 8. biocompatibility), and three tests in diabetic and non-diabetic rodent models: (1. dressing adhesion, 2. wound closure rate, and 3. histology for inflammation and collagen formation), were reported [1]. Although a few of these tests provided useful information, most were of dubious value or do not mimic real-world settings. In addition, some test results were misinterpreted.

How the in vitro test results translate to real-world clinical settings

1. PolyMem and the two study dressings performed similarly on the transmittance (spectroscopy) test, which is interesting, but relevant only because the new dressings contain triethoxysilane (APTES). APTES is potentially fatal if inhaled, and even mild skin exposures can lead to systemic effects [24]. In contrast, PolyMem's components are gentle on skin and completely nontoxic [3,6,25,26].
2. Thermal stability was tested at temperatures ranging from 100°C (the boiling point of water) to 800°C, which is hot enough to oxidize diamonds. PolyMem is designed for use on humans and animals, who cannot withstand such temperature extremes. PolyMem performs well when stored and used in a tropical environment [22,27,28].

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3. The authors noted that PolyMem has a very unique pore structure, as if this were an inherent problem. Independent researchers have found that this unique pore structure allows PolyMem to absorb fluids almost instantly while completely avoiding ingrowth of tissue into the dressing, features not tested in this study [12,21,29,30].

4. Both test dressings outperformed PolyMem on strength and stretch tests. Although it is true that an ideal dressing should possess excellent flexibility and mechanical strength, it is not true that the best dressing is the one that is the strongest and the most flexible. Other criteria are important as well. PolyMem is renowned for how comfortable and conformable it is [3,5,31]. Its flexibility and strength are more than adequate for real-world applications [12,26,29,32,33].

5. Although the authors used Simulated Body Fluid for the swelling test, inexplicably, absorption was tested with buffered saline [1]. To prevent maceration, dressings should absorb fluid both vertically and quickly [14]. No test results of these aspects of absorption were reported. Absorption was tested by completely immersing the dressings, which would not happen in real-life settings. PolyMem and both of the test dressings absorbed large quantities of saline and were fully saturated at 2 minutes, which was the first time interval assessed [1]. The authors speculated about reasons for PolyMem's excellent absorption performance, again indicating a lack of knowledge of the complex moisture-balancing system PolyMem provides wound patients [30,33-35].

   The evaporation (MVTR) test was interpreted through the lens that drier is always better, when in fact, wound closure is fastest when the dressing MVTR is less than 720g/m^2 in 24hrs [1,36]. PolyMem is specifically designed to prevent desiccation in dry wounds, which is a common problem for diabetic wounds in patients with arterial insufficiency, while absorbing and allowing the evaporation of excess fluid from overly wet wound areas [12,22,23,37,38]. In real-world settings, PolyMem's "intelligent" backing adjusts the MVTR based upon the moisture in the dressing to promote an ideally moist wound healing environment [12,20,34,35].

   PolyMem gently swells to conform to the contours of the wound bed, performing as well as the PEUSi dressing in this regard [1]. The micro-negative pressure tests were conducted after saturating the dressings fully by turning a simulated body fluid filled test tube over onto the pad for 10 seconds. This rendered the results meaningless. Although PolyMem provides mild negative-pressure as it works with the body to optimize the wound healing environment [12,32,37,39-41], this "water flux" is disabled if the dressings become overly saturated (e.g., if they are left in place far longer than indicated) [34].

6. The "anti-adhesion test" in this study did not assess for adherence to the wound bed directly, but rather, the ability of the dressing to absorb and retain proteinaceous fluid was used as a surrogate [1]. Equating absorption of cellular debris with adherence has already been repudiated [42]. This test is invalid for testing adhesion because PolyMem is designed to break the chemical bonds between the slough and other wound contaminants in the wound bed and pull these contaminants up into the dressing, and many of these substances contain protein [26,33,42-45]. PolyMem dramatically outperformed the PUE and PUESi dressings in its ability to absorb proteinaceous fluid (like debris-containing chronic wound fluid) [1]. PolyMem's ability to continuously atraumatically cleanse and debride wounds is a beneficial feature, and is completely unrelated to adherence to the wound bed [42]. Independent clinicians and researchers consistently find that PolyMem does not adhere to the wound bed [2,12,19,20,25,29,31,33,39-41,44,46-48].

7. Both the PUESi dressing and PolyMem performed well on the surface dryness test, indicating that these two dressings are less likely leak fluid back into the wound bed than the PUE dressing. This is important for preventing maceration, particularly under compression bandages [2,12,44].

8. PolyMem outperformed the PUESi dressing (as well as gauze) on the "cell viability" at 24 hours test, but this does not appear to be a meaningful test [1]. Keratinocytes and, importantly, white blood cells, were excluded from the test, which was conducted by "treating" fibroblasts with fluid extracted from dressings soaked for an unstated period of time with an unstated fluid. Why were the dressings not placed in direct contact with any living cells?

How the test results in rats translate to real-world clinical settings

PolyMem was not used according to the Instructions for Use in the tests on rodent models, rendering the results irrelevant in real-world situations [6]. The continuous wound cleansing system is expected to cause an increase in exudate when PolyMem is first applied; the dressing draws fresh nutrient-filled fluid from the body to replace the chronic wound fluid and cellular debris that is absorbed by the dressing [5,6,12,22]. Changing a PolyMem interactive dressing on a rigid schedule is as nonsensical as changing a baby's diaper on a rigid schedule; instead, change when the absorbed wound fluid, visible through the dressing backing, reaches any of the wound edges, as per the Instructions for Use [6]. Dressing change intervals can vary from twice a day to every 7 days as the PolyMem facilitates wound debridement, cleansing, and healing [6].

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Using Tegaderm across the entire surface of the dressing, as was done in this study, limits the PolyMem backing's ability to adjust the MVTR to keep the wound ideally moist, shortening the effective lifespan of the dressings. As the authors themselves noted, the PolyMem dressings shown in Figure 4 are clearly so overly-saturated that fluid is leaking out from under the dressings, indicating that they were not changed at the appropriate intervals [1].

1. In contrast to the gauze dressing, the PolyMem pad did not adhere to the wound beds at all [1]. However, because the Tegaderm affixing the dressings was inconsistently loosened from the skin prior to the photos being taken, the periwound skin was lifted up by the Tegaderm in the photos of PolyMem on the Non-DM rat (upper left), PolyMem on the DM rat (lower right), and PUE on the DM rat (lower right). See Figure 4 [1].

2. Despite PolyMem not being changed at appropriate intervals, during the first week it outperformed all three other dressings in the non-DM model and matched the performance of the PUESi and PUE dressings in the DM model, with clear signs of granulation and measurable brisk healing [1]. However, around day 14, healing under the PolyMem dressings slowed. The authors note (2.11) that the wounds covered with PolyMem developed "eschar" in the wound bed [1]. Eschar (or more likely, scab) is an indication that the wound bed became dry. It seems likely that the PolyMem dressings were not securely affixed to the wound bed at that time. This would explain why the healing under PolyMem, which had been the most rapid of all the groups, suddenly stalled.

   In addition, unlike human wounds, rat wounds close primarily by contraction, rather than epithelialization and granulation [49]. It appears as if the sutures on the corners of the PolyMem-managed wounds were deep enough that they dramatically inhibited contraction, while the wounds managed with PUESi closed almost entirely by contraction (see Figure 5) [1].

3. The histological analyses reported here raise many questions. The biopsies were taken on day 7, at which time, according to Figure 5, the wounds managed with PolyMem had improved more than all the other wounds in the non-DM rats and more than all except the PUE-managed DM rat [1]. Why are the collagen test results in Figure 7 so dramatically inconsistent with these results and the images in Figure 5, especially when compared with the gauze-managed DM rat [1]? Could it be that PolyMem is the only study dressing that is not promoting excess collagen formation (which leads to hypertrophic scarring)? Or is the test simply inaccurate? Would conducting biopsies during the middle of the healing process (on day 7 of 21) affect the results of the healing study? Did the unblinded investigators conduct the biopsies without bias?

Focused inflammation is required for brisk wound healing [9,23]. Substantial elimination of inflammation is one of the main reasons systemic steroids are detrimental to healing [50]. It is well documented that PolyMem controls the diffuse secondary inflammation that causes edema, bruising, and pain without eliminating the focused inflammation required for keeping the wound clean and healing [3,12,22,23]. Chen, et al. [1], failed to differentiate between detrimental and beneficial inflammation. Moreover, gauze increases wound inflammation both as a result of the foreign body reaction and because with gauze, wounds become too dry [9,51]. Why did these tests find so little inflammation under the gauze dressings (significantly less than under the PUE dressing) [1]? The authors suggested that the gauze decreased inflammation by decreasing maceration, which is consistent with their theory, but is inconsistent with the clinical literature and with the photos of the gauze and PUE managed wounds in Figure 4 [1,9].

Discussion

In the discussion section of the paper, the authors asserted that because PolyMem had a lower absorption capability and water vapor permeability than PUE and PUESi, these new dressings can potentially provide a better wound healing environment than PolyMem [1]. However, thirty years of real-world research evidence demonstrates that PolyMem's complex moisture balancing system, which redistributes fluid across the wound bed and adjusts the evaporation rate of the backing, is an integral factor in PolyMem's ability to consistently provide an optimal wound healing environment [12,42,52].

Chen, et al. [1], also speculated that an advantage of their new PUE and PUESi dressings could be that they "may generate a repulsive protein effect and further prevent tissue-wound dressing adhesion." However, by repulsing protein, these dressings would concentrate the biofilm matrix, slough, and other cellular debris in the wound bed, providing a growth medium and habitat for bacteria [53,54]. The authors state that adhesion was observed with the comparator dressings [1], but as stated earlier, protein absorption is not a reliable test for adherence to the wound bed. In the rat models, the PolyMem pad did not adhere to the wound bed: rather, the adhesive Tegaderm adhered to the rodent skin and hair on both PolyMem managed rats and on the PUE managed DM rat [1]. Only the gauze dressing adhered to the wound bed (see Figures 3d and 4) [1].

Finally, a clear conflict of interest exists. Even if the authors and their institutions do not intend to profit financially from producing these novel wound dressings, as the inventors

and manufacturers they certainly had a vested interest in the test dressings appearing to outperform the comparators when they designed and implemented their unblinded tests.

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Conflicts of Interest: As a result of her extensive experience managing wound patients while working for five years in a remote clinic in northern Ghana, West Africa, Linda Benskin became so passionate about the benefits of PolyMem Dressings that she is currently an employee of Ferris Mfg. Corp., the makers of PolyMem. Linda Benskin also works independently creating an evidence base and educational materials for village health worker training programs in remote and conflict areas of impoverished tropical countries. She is the codeveloper of the Available Technology Dressing (ATD) technique, a sustainable system that empowers patients to manage their own wounds using household materials in an intentional, evidence-based, way.

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