A Novel Approach to Understanding the Role of Fenestrated Placental Membrane Allografts in Wound Moisture Balance

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INTRODUCTION

- Maintaining a moisture balance with a sufficient level of moisture without over-saturation is a key element in optimal wound healing[1]. The moisture management capabilities of skin substitutes such as placental membrane allografts have never been published, and adequate methods to evaluate these properties could assist in product development as well as improve clinical decisions in wound treatment.
- Cellular, Acellular, Matrix-like Products (CAMPs), also known as skin substitutes and cellular and/or tissue-based products (CTPs), have gained commercial success in the wound care field in the last 30 years[2].
- The success of placental-based CAMPs or skin substitutes in wound care is well documented[3]. Never delaminated, complete placental membrane products have an extracellular matrix scaffold which is rich in collagen and glycosaminoglycans such as hyaluronic acid[4]. Herein, a modified moisture transference test evaluated the moisture management properties of a fenestrated dehydrated complete human placental membrane (f-dCHPM).
- The f-dCHPMs (Figure 6) used in this study were manufactured with fenestrations, providing channels to allow exudate to move away from the wound. A model wound system (Figures 1 and 2) was utilized to measure the transference of simulated exudate as an indicator of the f-dCHPM's moisture management capabilities. This is the first documented evaluation of the moisture management properties of placental-derived materials.

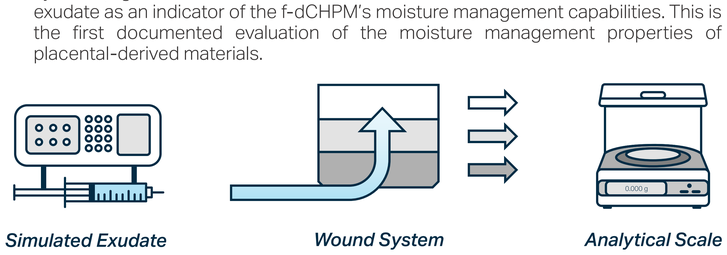

Figure 1: Experimental Diagram.

METHODS

A moisture transference test and simulated exudate formulation were adapted from methods described by Lustig et al[5]. to evaluate the moisture management capabilities of an f-dCHPM compared to a standard of care (SOC) primary dressing, gauze. Donated human placental membranes were recovered under full consent of donors. Tissue was dissected, cleaned utilizing a patented method, which never delaminates the membrane, and lyophilized. The simulated exudate was formulated to obtain a fluid viscosity of 5.99 x 10^{-3} Pa·s, similar to that of whole blood. The system included an artificial wound bed, a primary covering, and a secondary dressing (Figure 2). Simulated exudate was continuously pumped into the system at the rate of a moderately exudating wound. The weight of exudate in the artificial wound bed, the primary covering, and the secondary dressing was measured separately every 30 minutes for 2 hours. The percent of simulated exudate in each portion of the wound model at each timepoint was calculated (Figures 3-5).

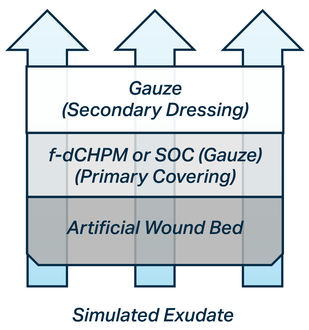

Figure 2: Experimental wound system. Simulated exudate was pumped into a model consisting of an artificial wound bed (bottom), a primary covering (middle, f-dCHPM or SOC [Gauze]), and a secondary dressing (top, Gauze).

RESULTS

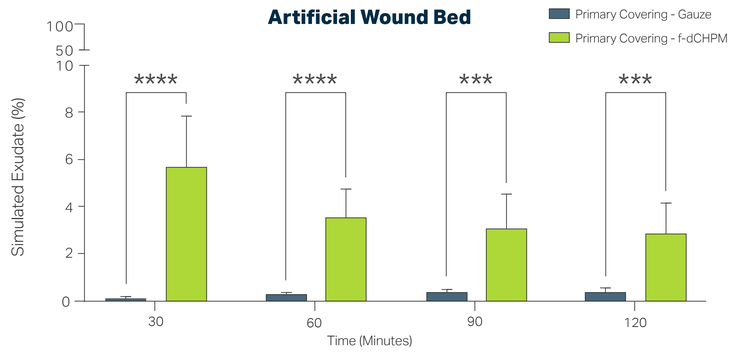

*Figure 3: The percent of simulated exudate (%) in the artificial wound bed. n = 10 replicates per primary covering. ***p<0.005, ****p<0.001.*

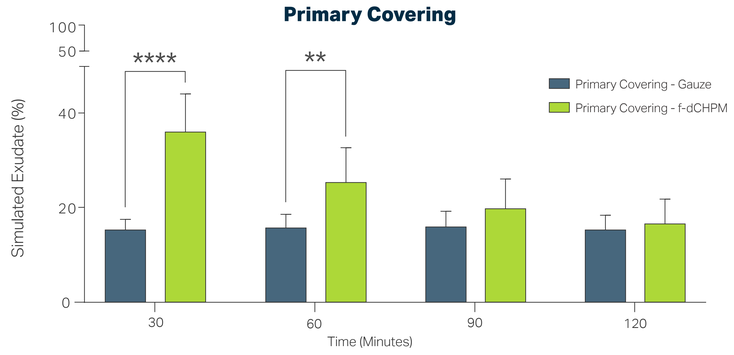

*Figure 4: The percent of simulated exudate (%) in the primary covering. n = 10 replicates per primary covering. **p<0.01, ****p<0.001.*

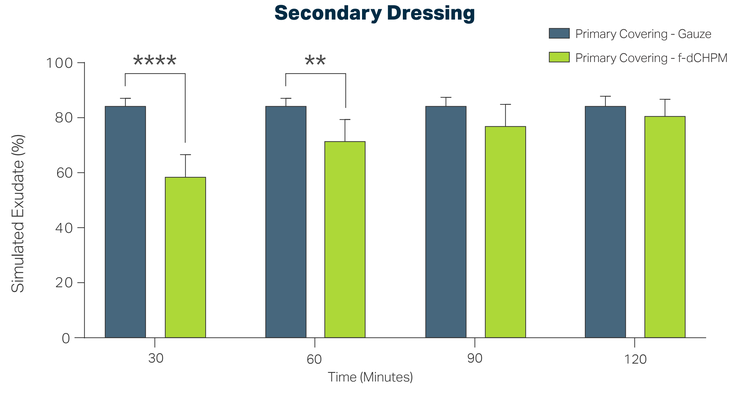

*Figure 5: The percent of simulated exudate (%) in the secondary dressing. n = 10 replicates per primary covering. **p<0.01, ****p<0.001.*

DISCUSSION AND CONCLUSION

- This novel method demonstrated that f-dCHPM provided an improved balance of moisture across a modeled wound system when compared to SOC. This is the first known description of moisture transference capabilities of placental-derived materials.
  - > *Significantly more simulated exudate was retained in f-dCHPM at both 30 and 60 minutes than SOC (Figure 4).*
  - > *Significantly more simulated exudate remained in the artificial wound bed dressed with f-dCHPM than that dressed with SOC (Figure 3); this is similarly demonstrated in Figure 5 which showed that the SOC system resulted in significantly more exudate being transferred into the secondary dressing at 30 and 60 minutes.*
- Essential wound healing processes require a balanced level of moisture in the wound bed; however, oversaturation can cause maceration of healthy tissue. The benefits of a moist wound environment include increased cell performance, collagen synthesis, and autolytic debridement[6]. In this study, SOC immediately transferred greater than 99% of the simulated exudate away from the wound bed, while f-dCHPM better facilitated a moist wound environment.
- The improved wound bed moisture management provided by f-dCHPM can be attributed to the material properties and product configuration, i.e., the porous scaffold provided by dCHPM and its fenestrations. The method herein provides valuable evidence that can aid in the development of new CAMPs, as well as assist clinicians with selecting appropriate wound coverings.
- Initial results of this study show that f-dCHPM demonstrates beneficial material properties that should be further explored. Future studies should include investigating other SOC and secondary dressing options such as collagen dressings and using additional simulated exudate properties, i.e., different viscosities.

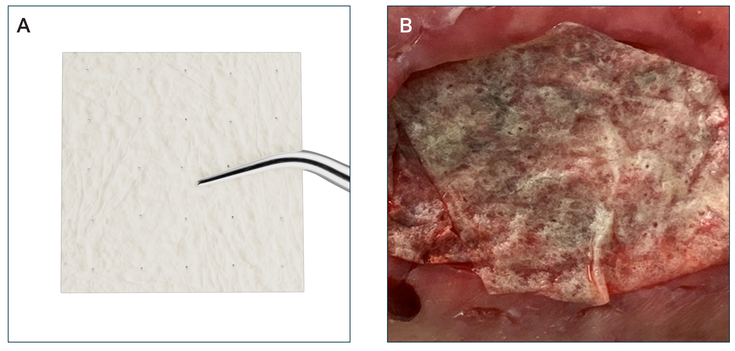

Figure 6: (A) Full thickness f-dCHPM allograft. (B) f-dCHPM on an excision wound. Three weekly applications of f-dCHPM were applied, and the wound resolved between days 78 and 112.

References: 1. Bishop, S. M., Walker, M., Rogers, A. A. & Chen, W. Y. J. Importance of moisture balance at the wound-dressing interface. J Wound Care 12, 125-128 (2003). 2. Wu, S., Carter, M., Cole, W., Crombie, R., Kapp, D. L., Kim, P., Milne, C., Molnar, J., Niezgoda, J., Woo, K., Zabel, D., & Hamm, R. Best practice for wound repair and regeneration use of cellular, acellular and matrix-like products (CAMPs). J. Wound Care 32, S1-S31 (2023). 3. Roy, A., Mantay, M., Brannan, C. & Griffiths, S. Placental Tissues as Biomaterials in Regenerative Medicine. Biomed Res Int 2022 (2022). 4. Roy, A. & Griffiths, S. Intermediate layer contribution in placental membrane allografts. J. Tissue Eng. Regen. Med. 14 1126-1135 (2020). 5. Lustig, A., Alves, P., Call, E., Santamaria, N. & Gefen, A. The sorptivity and durability of gelling fibre dressings tested in a simulated sacral pressure ulcer system. Int Wound J 18, 194-208 (2021). 6. Nuutila, K. & Eriksson, E. Moist Wound Healing with Commonly Available Dressings. Adv. Wound Care 10 685-698 (2021). SCI24-002 Rev 01

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