Use of Dermacell AWM® and Matrion® to Support Treatment of a Non-Healing Bilateral Heel Wound: A Case Report

CASE STUDY

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INTRODUCTION

Chronic wounds, such as diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), impose substantial treatment and cost burdens on global healthcare systems, representing an estimated 1 to 4% of total healthcare spending in developed countries.[1,2] A global increase in the prevalence of diabetes in recent years has led to a marked increase in chronic wounds and their associated social, economic, and physical burdens.[3] Annually, more than 9 million people worldwide are believed to suffer from DFUs, while in the United States alone, approximately 600,000 people experience VLUs.[2,4,5] Patients with such chronic wounds endure pain, disability, and loss of productivity, and are at increased risk for depression, social isolation, amputation, and death.[2,4,6] Current treatments for diabetic ulcers include wound dressing, hyperbaric oxygen, negative pressure therapy, and, in advanced cases, amputation of the limb.[7-9] However, once amputation occurs, the patient's life expectancy significantly decreases.[10] As such, it is imperative to have efficacious treatments for these pernicious wounds.

More recent advanced treatment options for DFUs and VLUs involve the use of an acellular dermal matrix (ADM), which has demonstrated efficacy in a variety of medical applications, including wound care.[11-14] These dermal matrices support cellular and vascular in-growth *in vitro* and *in vivo*.[15,16] One particular human ADM, Dermacell AWM, is decellularized using Matracell® technology, resulting in 97% or greater DNA removal.[17] Moreover, Dermacell AWM is provided at medical device-grade sterility (Sterility Assurance Level [SAL] 10^{-6}), is stored at room temperature, and is ready to use directly from its packaging.[17]

In addition to ADMs, over the last two decades, allografts derived from the placental membrane, obtained from live births with donor consent, have emerged as an important treatment option for chronic wounds.[18,19] The placenta consists of the amnion and chorion, the latter of which includes the trophoblast layer. For ease of cleaning and processing, these layers are often separated. They may or may not then be relaminated to produce an allograft that is amnion-only, amnion-chorion or other amnion-chorion combinations, such as amnion-chorion-amnion. This method of processing can adversely impact the abundance of native growth factors and make the allograft difficult to handle due to the thinness of the graft, depending on the placental layers retained.[18,19]

To retain growth factors and create a thick, easy-to-handle placental allograft, LifeNet Health® developed Matrion, the first minimally-manipulated, fully-intact placental membrane to include a decellularized trophoblast layer. Matrion is decellularized with Matracell technology, resulting in 90% or greater DNA removal.[20,21] Moreover, Matrion is provided sterile, at room temperature, and with no need to rehydrate, thaw, or otherwise prepare prior to application.[20,21]

The following case presentation describes the use of a combination of Dermacell AWM and Matrion to support the treatment of a non-healing bilateral heel wound. The patient provided consent for inclusion and the use of deidentified images.

CASE PRESENTATION

A 79-year-old male patient (BMI = 22.5) with a history of multiple sclerosis, immobility, and Atrial Fibrillation (AFib) presented with Stage 4 non-healing bilateral pressure ulcers on the left and right heels that had persisted for approximately one month. The wounds were initially treated with conservative care including debridement, pressure dressing, and off-loading, without evidence of improvement. At the baseline visit, the patient had signs of infection which were addressed

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using debridement and a course of intravenous antibiotics. The ulcers' baseline measurements (length x width x depth) for the left and right heels were 6.0 cm x 2.5 cm x 0.4 cm and 5.0 cm x 6.0 cm x 0.4 cm, respectively (Figure 1A and B; September 2022). To prevent amputation and utilize all resources possible for this limb salvage case, the surgeon decided to use both Matrion and Dermacell AWM. Following debridement, an application of Matrion (Figure 1C and D) and Dermacell AWM (Figure 1E and F) were applied to the wound on each heel with a non-adherent oil-emulsion dressing and sutured in place (Figure 1G and H). The patient was also provided with off-loading instructions. As early as Week 4, the wounds showed improvement and evidence of wound closure with measurements of 4.5 cm x 1.5 cm x 0.3 cm and 4.5 cm x 5.5 cm x 0.3 cm for the left and right heels, respectively (Figure 2A and B). Matrion and Dermacell AWM were reapplied to each wound at this follow-up (Figure 2C and D). At Week 12, the left heel had a measurement of 1.0 cm x 0.5 cm x 0.3 cm (Figure 3A). Due to the wound being reopened on the right heel, Dermacell AWM was reapplied at this visit (wound measurement of 3.0 cm x 5.0 cm x 0.3 cm; Figure 3B). By Week 18, the wounds were fully healed with 100% granulation and reepithelization (January 2023;
Note: There are no final images for this patient. Unfortunately, the patient passed away prior to the images being taken). There were no reported complications.

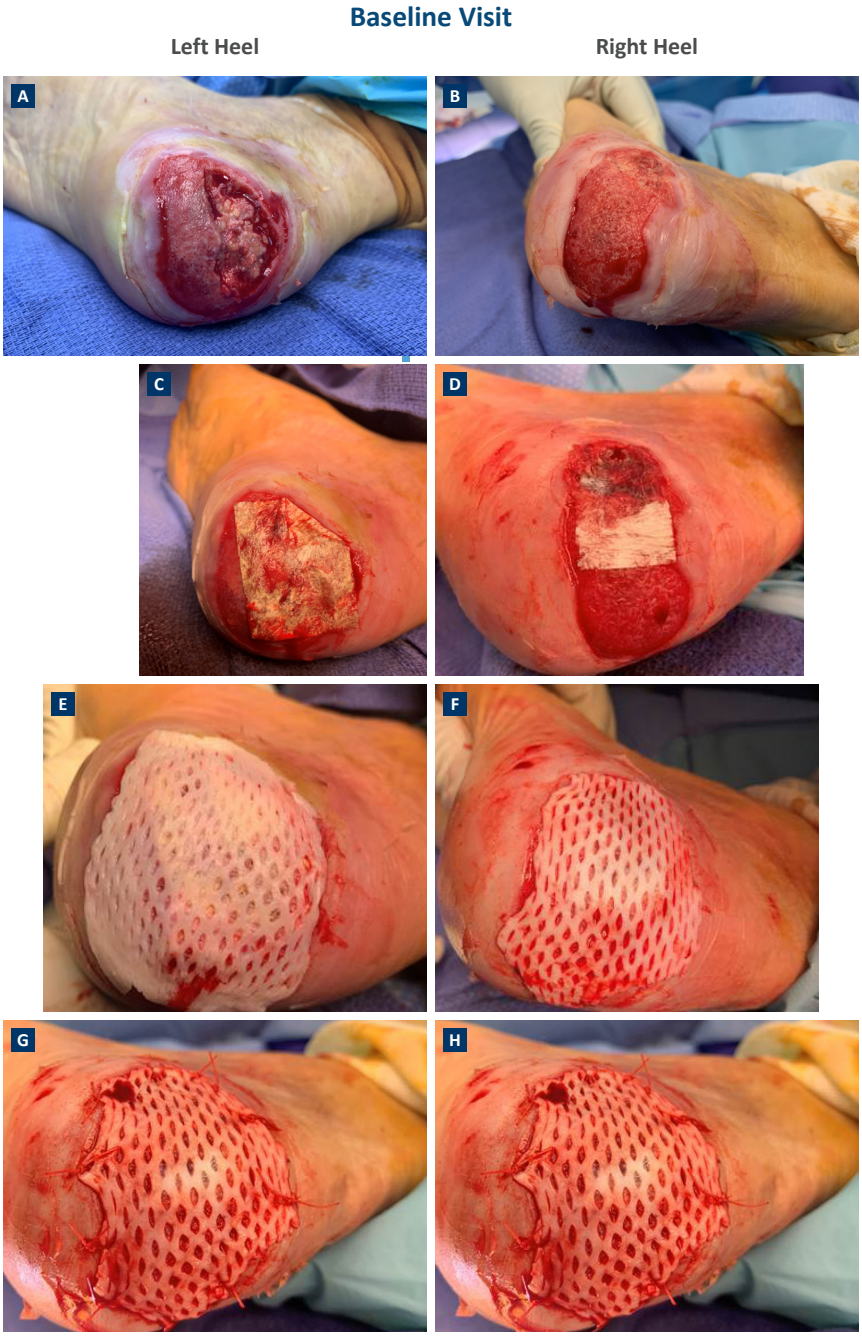

Figure 1. The baseline visit (Sept 2022) showing the initial patient presentation for the left (a; wound measurement: 6.0 cm x 2.5 cm x 0.4 cm) and right heels (b; wound measurement: 5.0 cm x 6.0 cm x 0.4 cm). Following debridement, application of Matrion to the left (c) and right (d) heels and application of Dermacell AWM to the left (e) and right (f) heels. Finally, the previously mentioned application of Matrion and Dermacell AWM in combination with oil-emulsion dressing were sutured in place for both the left (g) and right (h) heels.

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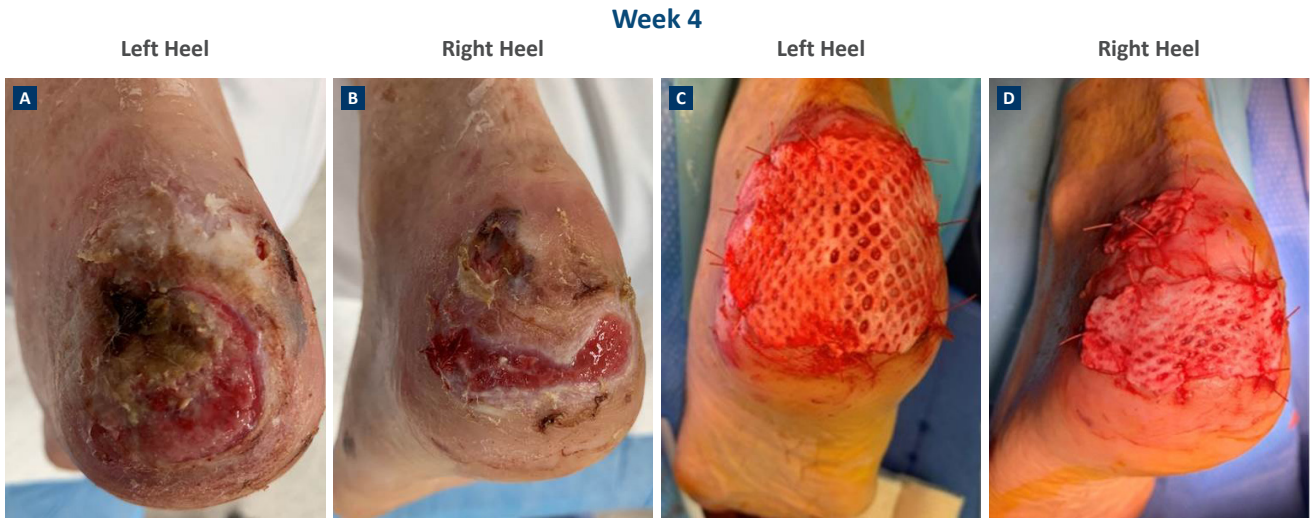

Figure 2. Week 4 follow-up (Oct 2022) showing improvement and evidence of wound closure for the left (a; wound measurement: 4.5 cm x 1.5 cm x 0.3 cm) and right heels (b; wound measurement: 4.5 cm x 5.5 cm x 0.3 cm). At this follow-up, there was a reapplication of Matrion and Dermacell AWM for the left (c) and right (d) heels.

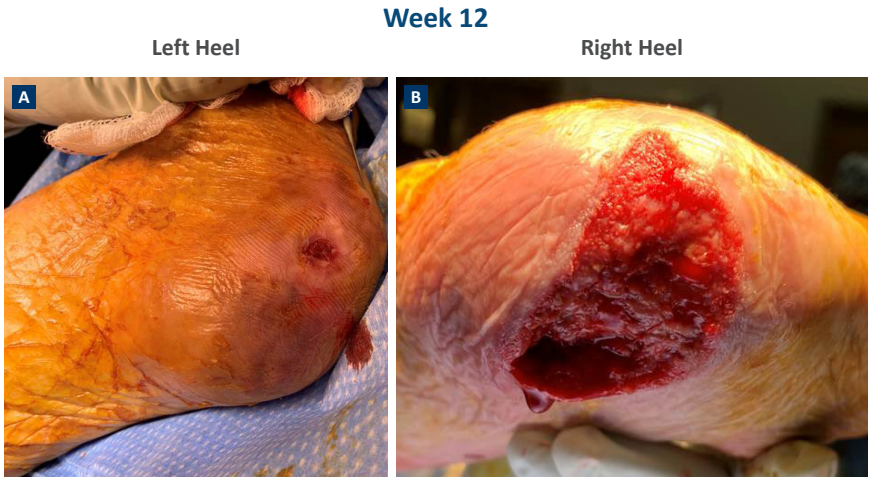

Figure 3. Presentation at Week 12 showing significant wound reduction for the left (a; wound measurement: 1.0 cm x 0.5 cm x 0.3 cm) and right heels (b; wound measurement: 3.0 cm x 5.0 cm x 0.3 cm). Dermacell AWM was reapplied to the right heel only at this visit due to wound reopening (image not taken). The wounds were reported fully closed at Week 18. *Note: There are no final images for this patient. Unfortunately, the patient passed away prior to the images being taken.*

SUMMARY

This case presentation demonstrates a novel and successful use of Dermacell AWM and Matrion to support full wound closure for this patient with challenging comorbidities that can impede healing when other treatments had failed. Therefore, these results support the clinical advantages of Dermacell AWM and Matrion, both processed to minimize the risk of inflammatory reactions in patients. Although a case study cannot be used to predict how Dermacell AWM and Matrion will behave in other patients, these results demonstrate a versatile and successful use of these grafts to support wound closure.

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REFERENCES

1. Kolluri R, Lugli M, Villalba L, et al. An estimate of the economic burden of venous leg ulcers associated with deep venous disease. Vascular Medicine. 2022;27(1):63-72. doi: 10.1177/1358863X211028298
2. Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. *N Engl J Med.* 2017; 376(24):2367-2375. doi: 10.1056/NEJMra1615439
3. World Health Organization. Diabetes Fact Sheet. https://www.who.int/news-room/fact-sheets/detail/diabetes. Published 2022. Accessed August 2022.
4. Hobizal KB, Wukich DK. Diabetic foot infections: current concept review. *Diabet Foot Ankle.* 2012; 3. https://doi.org/10.3402/dfa.v3i0.18409
5. Sen CK, Gordillo GM, Roy S, et al. Human skin wounds: a major and snowballing threat to public health and the economy. *Wound Repair Regen.* 2009; 17(6):763-771. https://doi.org/10.1111/j.1524-475X.2009.00543.x
6. Järbrink K, Ni G, Sönnergren H, et al. The humanistic and economic burden of chronic wounds: a protocol for a systematic review. Systematic reviews. 2017; 6(1):1-7. https://doi.org/10.1186/s13643-016-0400-8
7. Dumville JC, Deshpande S, O'Meara S, et al. Foam dressings for healing diabetic foot ulcers. Cochrane Database Syst Rev. 2011;9:1-46. DOI: 10.1002/14651858.CD009111.pub2
8. Gupta S, Bates-Jensen B, Gabriel A, et al. Differentiating negative pressure wound therapy devices: An illustrative case series. Wounds. 2007;19(1):1-9. https://www.researchgate.net/publication/296614785_Differentiating_Negative_Pressure_Wound_Therapy_Devices_An_Illustrative_Case_Series
9. Zamboni WA, Wong HP, Stephenson LL, et al. Evaluation for hyperbaric oxygen for diabetic wounds: A prospective study. Undersea Hyperb Med. 1997;24(3):175-179 PMID: 9308140
10. Qaarie MY. Life Expectancy and Mortality After Lower Extremity Amputation: Overview and Analysis of Literature. Cureus. 2023 May 12;15(5):e38944. doi: 10.7759/cureus.38944
11. Wong I, Burns J, Snyder S. Arthroscopic graftjacket repair of rotator cuff tears. J Shoulder Elbow Surg. 2010; 19(2):104-109. DOI: 10.1016/j.jse.2009.12.017
12. Wilkins, R. Acellular dermal graft augmentation in quadriceps tendon rupture repair. Curr Orthop Pract. 2010; 21(3):315-19. DOI: 10.1097/BCO.0b013e3181c7ea2e
13. Lee, Daniel. Achilles tendon repair with acellular tissue graft augmentation in neglected ruptures. J Foot Ankle Surg. 2007; 46(6): 451-55. DOI: 10.1053/j.jfas.2007.05.007
14. Wainwright DJ, Bury SB. Acellular dermal matrix in the management of the burn patient. Aesthet Surg J. 2011; 31(7):13S-23S. DOI: 10.1177/1090820X11418202
15. Capito AR, Tholpady SS, Agrawal H, Drake DB, Katz AJ. Evaluation of host tissue integration, revascularization, and cellular infiltration within various dermal substrates. Ann Plast Surg. 2012;68:495-500. DOI: 10.1097/SAP.0b013e31823b6b01
16. Armour AD, Fish JS, Woodhouse KA, Semple JL. A comparison of human and porcine acellularized dermis: Interactions with human fibroblasts in vitro. Plast Reconstr Surg. 2006;117(3):845-56. DOI: 10.1097/01.prs.0000204567.28952.9d
17. LifeNet Health. Dermacell AWM IFU, 63-0050-05
18. Wetzell B, Ork B, Softic D, Morse J, Hutchens W, Meng F, McLean JB, Moore MA, Qin X. Characterization of a full-thickness decellularized and lyophilized human placental membrane for clinical applications. Int Wound J. 2024 May;21(5):e14888. doi: 10.1111/iwj.14888.
19. Banerjee J, Dhall S. Therapeutic benefits of treating chronic diabetic wounds with placental membrane allografts. In: Wound Healing, Tissue Repair, and Regeneration in Diabetes. Elsevier; 2020:323-335. https://doi.org/10.1016/B978-0-12-816413-6.00016-2
20. Qin X, Chen S, Aschenbach L, Chen J, Inventors; LifeNet Health, assignee. WO/2017/112934. Decellularized placental membrane and methods of preparing and use thereof. 2017.
21. LifeNet Health. Matrion IFU, 63-0282.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings, and precautions.

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