Use of Matrion® for Treatment of Chronic and Recalcitrant Wounds

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CASE STUDY

Chronic wounds, such as diabetic foot ulcers (DFUs) and pressure injuries, can cause pain, social isolation, loss of employment opportunities, and increased risk for amputation and death.[1] Annually, more than 9 million people worldwide suffer with a DFU. While in the United States, nearly 2.5 million people experience a pressure injury.[2-4] Further adding to this health crisis is the increasing incidence of diabetes globally, leading to more DFUs and their associated social, economic, and physical burdens.[5] Pressure injuries have been reported to occur in 8-10% of adult hospitalized patients, the heel being within the top three anatomic sites reported.[6,7] These pressure injuries can result in increased length of hospitalization and associated costs, which may not be covered by the Centers for Medicare and Medicaid if the pressure injury developed during hospitilization.[8] As such, it is imperative to have efficacious treatments for these pernicious wounds.

Over the last two decades, allografts derived from the placental membrane of consented donors have emerged as an important treatment option for chronic wounds. These allografts contain endogenous growth factors thought to assist in wound healing by restoring balance to cellular signaling in the chronic wound environment.[9] Initial methods of processing placental membranes for allograft preparation involved separating the placental layers, which can adversely affect the amount of growth factors retained; however, recent advancements in placental membrane processing techniques negate the need for separation.[10,11] Additionally, advanced processing has allowed for inclusion of the trophoblast layer, which is rich in endogenous biological factors but also contains maternal cells that may elicit an inflammatory response if not removed.[11-13]

To garner the benefits of a fully intact placental allograft while minimizing the potential for an inflammatory response, LifeNet Health developed Matrion, the first fully intact and decellularized placental membrane allograft. During processing, the placental membrane layers are never separated, leaving the naturally occurring biological factors intact. Decellularization is achieved using LifeNet Health's patented and validated Matracell® technology, resulting in removal of at least 90% of donor DNA, an indicator of cellular removal. Due to the inclusion of trophoblast layer, Matrion is thicker than other placenta-derived allografts, giving it superior handling.[10] Additionally, its thickness provides a better barrier to bacterial ingress, while decellularization provides a porous, biohospitable scaffold for cellular migration, attachment, and neovascularization.[14]

This case series follows four patients with recalcitrant wounds treated with Matrion.

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Patient 1

- 80-year-old male
- Diabetes
- Healthy weight (BMI 21.3%)
- Former smoker
- DFU, right lateral heel
- Wound duration: 12 months
- Previous treatments included debridement, use of an acellular dermal matrix, pressure dressing, and off-loading
- Baseline wound area: 3.75 cm^2 (Figure 1A): Wagner Grade 2
- Applications of Matrion: 6
- Wound resolution: 7 weeks (Figure 1B)

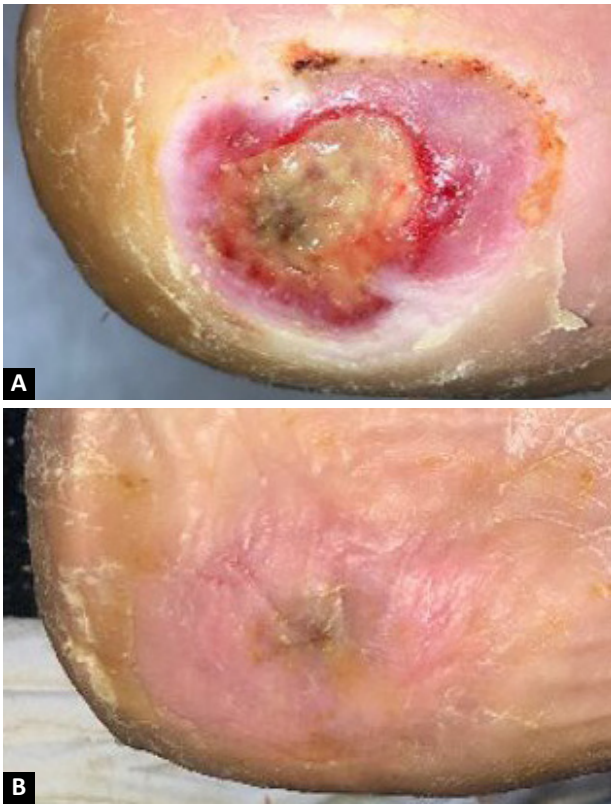

Figure 1. DFU healed with six applications of Matrion after failure to progress with an acellular dermal matrix. A) Baseline: 2.5 cm x 1.5 cm x 0.2 cm (March 3, 2021). B) Wound resolution at seven weeks (April 23, 2021)

Patient 2

- 70-year-old female
- Obese (BMI 48.6%)
- No tobacco use
- Unhealed wound from prior excision of squamous cell carcinoma, lateral aspect of left foot
- Wound duration: 9 months
- Previous treatments included debridement, use of an acellular dermal matrix, pressure dressing, and off-loading
- Baseline wound area: 2.25 cm^2 (Figure 2A): Wagner Grade 1
- Applications of Matrion: 3
- Wound resolution: 4 weeks (Figure 2B)

Figure 2. Excision site from squamous cell carcinoma healed with three applications of Matrion. A) Baseline: 1.5 cm x 1.5 cm x 0.1 cm (March 3, 2021). B) Wound resolution at four weeks (April 23, 2021)

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Patient 3

- 28-year-old female
- Wheelchair-bound with spina bifida
- Pressure Injury, right plantar heel
- Wound duration: Unknown
- Previous treatment included debridement, negative pressure wound therapy, silver- impregnated dressings and cadexomer iodine Baseline wound area: 10.5 cm^2 (Figure 3A): Wagner Grade 2
- Applications of Matrion: 8
- Wound resolution: 9 weeks (Figure 3B)

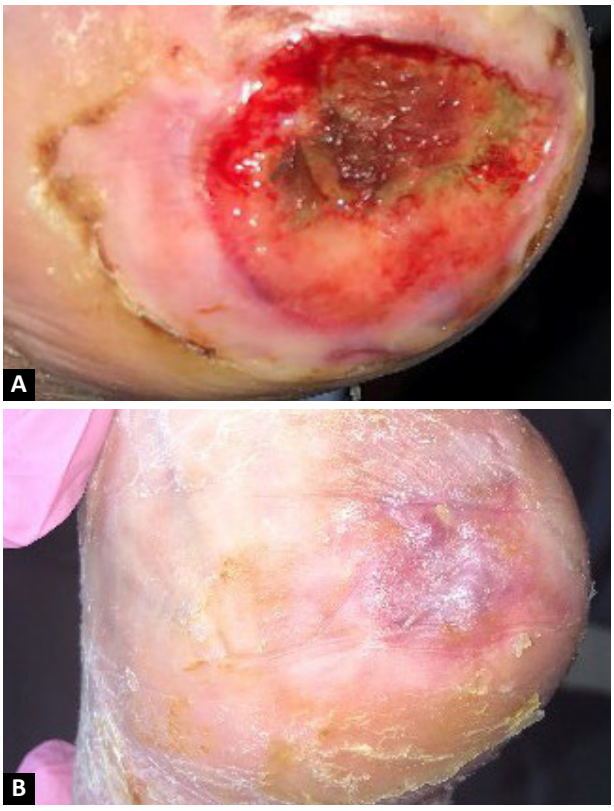

Figure 3. Pressure injury healed with three applications of Matrion. A) Baseline: 3.0 cm x 3.5 cm x 0.3 cm (April 30, 2021). B) Wound resolution at nine weeks (June 24, 2021).

Patient 4

- 76-year-old male
- Diabetes
- Overweight (BMI 29%)
- Active use of chewing tobacco
- DFU, medial aspect of left hallux
- Wound duration: 1 month
- Previous treatment included debridement and off-loading
- Baseline wound area: 0.04 cm^2 (Figure 4A): Wagner Grade 1
- Applications of Matrion: 3
- Wound resolution: 3 weeks (Figure 4B)

Figure 4. DFU healed with three Applications of Matrion. A) Baseline: 0.2 cm x 0.2 cm x 0.1 cm (May 5, 2021). B) Wound resolution at three weeks (May 27, 2021).

Conclusions

While a case series cannot be considered predictive of graft behavior in other patients, these results provide support for the use of Matrion as an efficacious treatment in challenging chronic wounds. Patients received an average of 5 applications of Matrion (range: 3-8) resulting in complete resolution at an average of 5.75 weeks (range: 3-9). Challenging ulcerations in this series included wounds present for greater than six months, a heel pressure injury, and wounds that failed to progress despite use of an acellular dermal matrix.[15] Pressure injuries of the heel are challenging to heal due to the minimal soft tissue covering, proximity to bone, and potential for localized ischemia due to the single angiosomal supply from the posterior tibial artery.[16] Even with vascular intervention and wound care, median time to healing is three months.[16] In this case series, previous failure to reach resolution of both the heel wound and the wound to the lateral aspect of the foot using an acellular dermal matrix may have been due to reduced microvascular supply to the area. The biological factors and porous structure found in Matrion may have facilitated neovascularization, helping these wounds to heal. This case series suggests that the use of Matrion can assist in achieving resolution in challenging chronic wounds.[14]

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Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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