Use of Matrion® for Treatment of Complex and Chronic Wounds

CASE SERIES

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Chronic wounds, such as diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), can cause pain, increased risk of amputation, social isolation, and loss of employment opportunities.[1] Annually, more than 9 million people worldwide suffer with a DFU, while in the United States, approximately 600,000 people experience a VLU.[2-4] The incidence of diabetes is increasing globally, leading to a marked increase in DFUs and their associated social, economic, and physical burdens.[5] Venous leg ulcers are the most common type of lower extremity ulceration. Up to 2% of the world population will develop a VLU, increasing to 5% for patients 65 years or older.[6,7] The annual cost of care for VLUs in the U.S. is estimated to be as high as $16 billion.[7] As such, it is imperative to have efficacious treatments for these pernicious wounds.

Over the last two decades, allografts derived from the placental membrane obtained with donor consent have emerged as an important treatment option for chronic wounds.[8] The placenta consists of the amnion and chorion, which includes the trophoblast layer. For ease of cleaning and processing, these layers are often separated. They then may or may not 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 native growth factors and make the allograft difficult to handle and use due to the thinness of the graft, depending on the placental layers retained.[9]

To retain growth factors and make 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. Unlike other placental allografts, the placental membrane layers in Matrion are never separated during processing. Matrion also goes through LifeNet Health's validated and patented Matracell® technology, resulting in at least 90% donor DNA removal, an indicator of decellularization. This advance in placental processing results in a placental allograft that minimizes the potential for patient inflammatory reaction; is 4-times thicker than other placental allografts resulting in superior handling; is a better barrier to bacterial ingress; and provides a porous biohospitable scaffold for cellular migration, attachment, and neovascularization. Additionally, the trophoblast layer contained more than 50% of 4 out of 5 biological factors tested.[10]

This case series follows five patients treated with Matrion for recalcitrant DFUs and VLUs.

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Patient 1

- 51-year-old male
- Diabetes (HbA1c 7.7%)
- Obese (BMI 34%)
- Non-smoker
- DFU, right plantar midfoot
- Wound duration: 11 months
- Previous treatment included debridement, offloading and application of amnion-chorion placental allograft
- Baseline wound area: 1.6 cm^2 (Figure 1A)
- Five applications of Matrion
- Reduction in wound area at 16 weeks: 96.9% (Figure 1B)

Figure 1. Challenging DFU improved with five applications of Matrion after failing to progress with use of another placental allograft. A) Wound at baseline (January 13, 2021– 2 cm x 0.8 cm x 0.2cm) B) 96.9% reduction in wound area at 16 week (May 5, 2021 – 0.5 cm x 0.1 cm x 0.2). Note: Measurements were made in cm despite ruler with inches being shown.

Patient 2

- 72-year-old male
- Diabetes (HbA1c 7.0%)
- Obese (BMI 34%)
- Non-smoker
- DFU, right plantar midfoot
- Wound duration: 7 months
- Previous treatment included off-loading and debridement
- Baseline wound area: 2.5 cm^2 (Figure 2A)
- Eight applications of Matrion
- Reduction in wound area at 16 weeks: 43.5%. An increase in granulation tissue at the base from 85% to 90% was also observed. (Figure 2B)

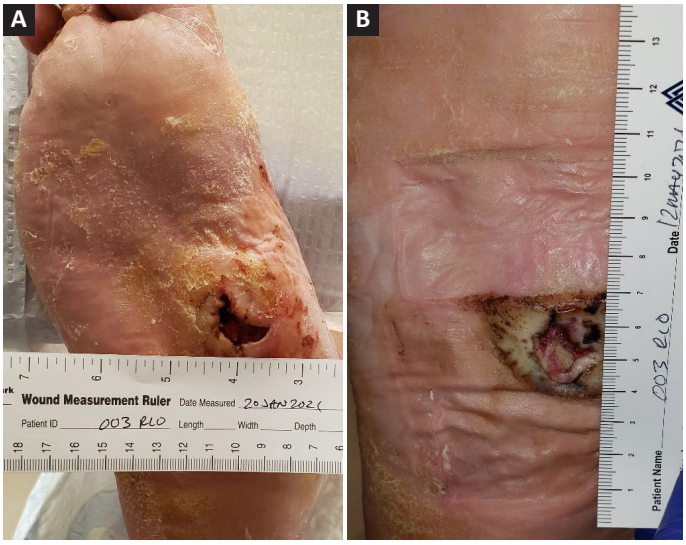

Figure 2. Challenging DFU improved with seven applications of Matrion. A) Wound at baseline (January 20, 2021– 2.3 cm x 1.1 cm x 0.2cm) B) 43.5% reduction in wound size at 16 week (May 12, 2021 – 1.1 cm x 1.3 cm x 0.2). Note: Measurements were made in cm despite ruler with inches being shown.

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Patient 3

- 64-year-old male
- Diabetes (HbA1c 7.0%)
- Obese (BMI 34%)
- Non-smoker
- DFU, right plantar forefoot
- Wound duration: 6 weeks
- Previous treatment included debridement and off-loading
- Baseline wound area: 1.3 cm^2 (Figure 3A)
- One application of Matrion
- Complete wound resolution at 3 weeks (Figure 3B)

Figure 3. Challenging DFU resolved with one application of Matrion. A) Wound at baseline (February 3, 2021– 1.0 cm x 1.3 cm x 0.2cm) B) Wound resolution at three weeks (February 24, 2021). Note: Measurements were made in cm despite ruler with inches being shown.

Patient 4

- 60-year-old male
- Chronic venous insufficiency
- Overweight (BMI 28 %)
- Non-smoker
- VLU, left ankle
- Wound duration: 7 months
- Previous treatment included debridement
- Baseline wound area: 2.1 cm^2 (Figure 4A)
- Two applications of Matrion
- Complete wound resolution at 3 weeks (Figure 4B)

Figure 4. Challenging VLU resolved with two applications of Matrion. A) Wound at baseline (January 27, 2021– 3.0 cm x 0.7 cm x 0.2 cm) B) Wound resolution at three weeks (February 3, 2021)

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Patient 5

- 84-year-old female
- Chronic venous insufficiency
- Non-smoker
- VLU, left lateral leg
- Wound duration: 4 months
- Previous treatment including debridement
- Baseline wound area: 1.3 cm^2 (Figure 5A)
- Four applications of Matrion.
- Complete wound resolution at 4.5 weeks (Figure 5B)

Figure 5. Challenging VLU healed with four applications of Matrion.
A) Wound at baseline (January 27, 2021– 1.1 cm x 1.2 cm x 0.2cm)
B) Wound resolution at 4.5 weeks (March 31, 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 a viable treatment option for challenging chronic wounds. The clinician author commented that these patients were some of his most challenging patients and representative of real-world patients he sees at his clinic. He further commented that he was impressed with how well Matrion helped these difficult wounds resolve or move towards resolution. Overall average baseline wound duration was 6.1 ± 2.1 months (range: 1.5 to 11) Patients received an average of 4.0 applications of Matrion (range: 1 – 8), resulting in effective wound area reduction or closure. Three of the five wounds (60.0%) healed at an average of 3.5 ± 0.9 weeks with an average of 2.3 ± 1.5 (range: 1 – 4) Matrion applications. The baseline wound duration of these wounds was 4.2 ± 2.8 months. The remaining two wounds had average reduction in wound area of 70.2 ± 37.8% with an average of 6.5 ± 2.1 (range: 5 – 8) Matrion applications. Baseline wound duration of these wound was 9.0 ± 2.8 months. One of these patients progressed towards wound resolution despite having failed to progress with use of a different placental allograft, suggesting that all placental-derived allografts may not have the same clinical efficacy.

Challenging ulcerations in this case series included chronic VLUs, midfoot DFUs, and one DFU that failed to progress with use of a different placental allograft. Chronic VLUs near the ankle, like the two presented in this series, are more difficult to heal than ones located more proximal on the leg. A 3% reduction in the likelihood to heal also occurs with every one-month increase in VLU duration.[11] Ulcer duration greater than 6 months has been demonstrated to result in delayed healing.[12] Likewise, midfoot DFUs are notoriously difficult to heal and result in up to 40% of lower extremity amputations.[13-15]

Matrion is the first minimally manipulated, decellularized, fully intact, placenta membrane allograft to include the trophoblast layer. This minimizes the potential for patient immune response and results in a graft that is easier to handle and retains more of the biological factors and extracellular matrix components endogenous to the placental membrane than those products that are not decellularized or are without the trophoblast layer.[10] The results of this case series suggest that Matrion may be a viable treatment option for challenging chronic lower extremity wounds.

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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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