Treating wounds with AmnioRederm™: Case series

FA Bruwer
Corresponding author, email: febe@woundclinic.co.za

A case series was performed to demonstrate the application of AmnioRederm™, an amniotic membrane product, on wounds with different aetiologies within the South African context. In the first case, AmnioRederm™ was used to treat a non-healing diabetic foot ulcer. The wound, which was non-responsive to treatment with standard management, began to heal shortly after AmnioRederm™ was applied and within four weeks of treatment the wound size had reduced by over 50%. In the second case AmnioRederm™ was applied to exposed bone following a forefoot amputation which was non-granulating. Granulation of the bone tissue was observed after two applications of AmnioRederm™. This case series demonstrates the application of AmnioRederm™ as an adjunctive treatment of non-healing wounds.

Wound Healing Southern Africa 2020;13(2):55-58

Introduction

Chronic, non-healing or stagnant wounds represent a huge socio-economic burden not only to the patient, but the community as well. In the United States and the UK, the cost of treating these ulcers amounts to 1–2% of the total annual expenditure on health care.[1] These wounds have extended healing trajectories and could take up to six months to heal.[2] Chronic wounds often require advanced interdisciplinary management for a successful outcome and even then, there will be about 2% of wounds that will never heal.[3]

AmnioRederm™ (specifications: Placelta, Midrand, 2020) is a specialised biological dressing, produced from human amniotic membrane to naturally stimulate recovery of non-healing tissues. AmnioRederm™ contains a combination of growth factors, collagen-rich extracellular matrix that stimulate the wound healing process.[4]

The objective of this case series report is to illustrate the application and use of AmnioRederm™ on wounds with different aetiologies within the South African context.

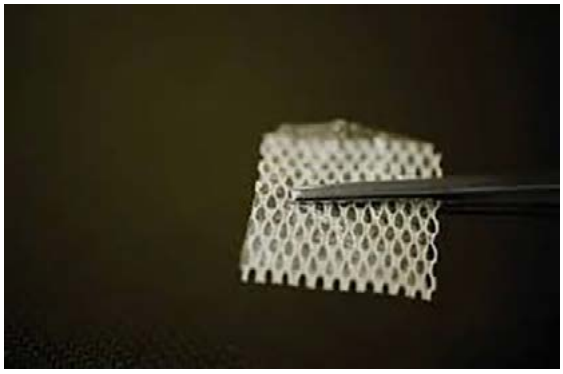


Figure 1: Photo of AmnioRederm™ prior to application

Patients and method

Convenient sampling was used to identify patients suitable for the administration of the product in this clinical prospective study. All patients signed consent for the application of the product as well as publication of the outcome.

Inclusion criteria

- Chronic wound present for more than two months.
- Wound bed optimised, i.e. absence of devitalised tissue and no clinical signs of infection.

Technique

AmnioRederm™ is made from human amniotic membrane, which is a collagen-rich structure comprising the innermost layer of the foetal membrane of the placenta. The wound should be cleansed, and wound bed preparation done to ensure a viable wound bed before the application of AmnioRederm™. Care should be taken to ensure that the product covers and adheres to the wound surface; a non-adherent dressing is then applied as well as a moisture retentive dressing to ensure exudate management is achieved. At weekly or twice weekly examination, wounds should be cleansed with sterile normal saline solution and debrided if required, a new AmnioRederm™ graft should be applied and then covered as described above. The product size currently available is 20 x 30 mm. It can be stored at room temperature and has a five-year shelf life. Figure 1 is a photo of the product.

Standard wound management protocols were adhered to prior to administration of the dressing which included addressing underlying issues and wound bed preparation.

Clinical cases

Patient 1

A 74-year-old male with noninsulin-dependent diabetes mellitus (NIDDM) and a University of Texas grade A3 diabetic foot ulcer

Figure 2A: Before start of treatment

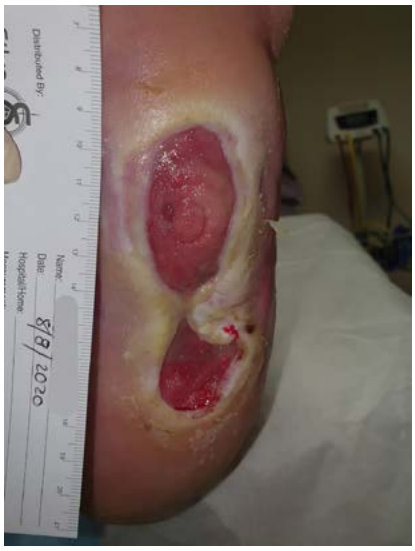


Figure 2B: With first application Day 0

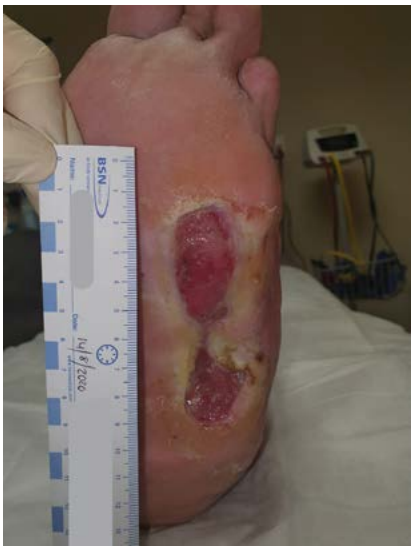


Figure 2C: First week of application

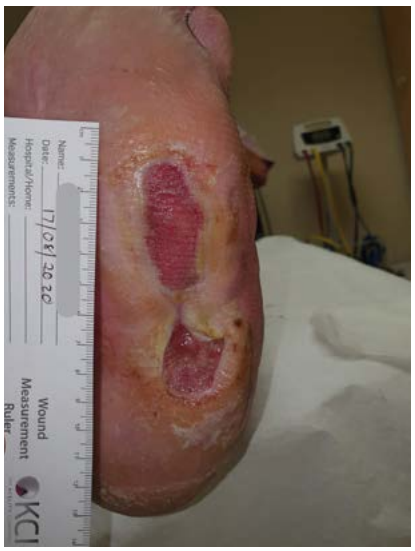


Figure 2D: Second week

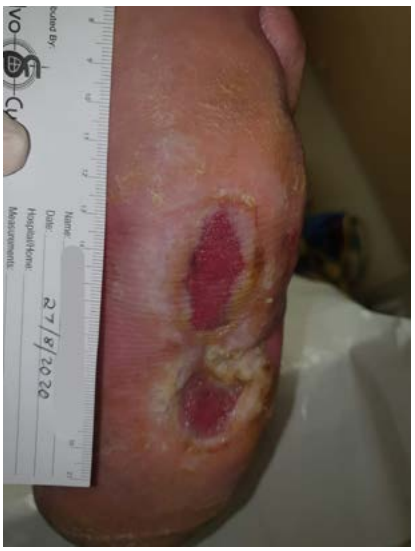


Figure 2E: Third week

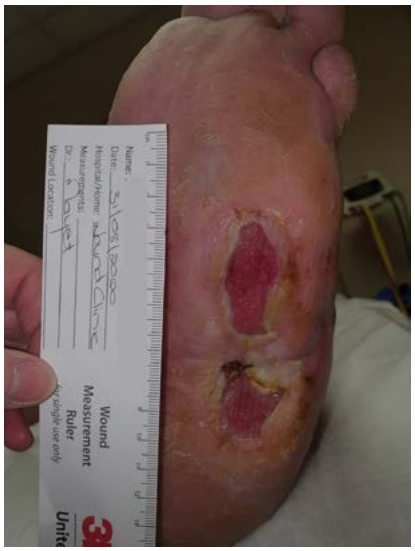
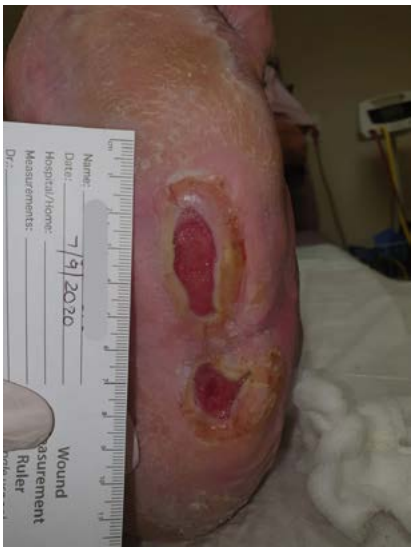


Figure 2F: Fourth week



measuring 9 x 3 cm (27 cm^2) on the plantar aspect of his left foot[5] had had a previous amputation of the fifth toe and was showing signs of Charcot foot arthropathy. The wound developed in January of 2020 and deteriorated despite standard management which included offloading, exudate management, maintenance debridement and a reduction in bioload which was initiated in May of 2020 when the patient was referred.

Figures 2A to 2E depict photos of weeks one, two and three of application of AmnioRederm™. The patient was seen twice a week and after the first week, the exudate level had decreased from being a highly exuding wound requiring the application of a superabsorber and frequent dressing changes (every second day), to a low level of exudate requiring only a polyurethane foam dressing together with the AmnioRederm™ application, reducing the cost of dressing changes. In four weeks (Figure 2F) the wound size had decreased by more than 50% from the initial consultation, and the wound had divided into two smaller wounds measuring 3.5 x 1.8 cm and 2 x 1.6 cm, which calculates to about 9.5 cm^2. The wound edges were advancing and standard care could be resumed. The patient continued to follow up and wound progress was consistent; four weeks after the last application the wound was 95% healed.

Patient 2

A 60-year-old male sustained an injury on duty in July 2020. The crushing injury resulted in a forefoot amputation which was closed with a skin flap, but infection caused tissue breakdown resulting in an open wound extending down to the bone. This was now classified as a chronic wound.

The surgeon referred the patient for wound care to allow granulation tissue to cover the exposed bone previous to skin grafting of the wound. Negative pressure wound therapy (NPWT) was applied, but the granulation tissue required to cover the bone was not growing as expected after five weeks of NPWT (Figure 3A). AmnioRederm™ was applied to the exposed bone and covered with moist "White foam™" (3M/KCI,….); NPWT was applied covering the wound. Granulation tissue formation was noticeable on the edge of the exposed bove after the first application of the product (Figure 3B) and then covering about 50% of the exposed bone after the second application (Figure 3C). The second application was done four days after the first application. After the second treatment with AmnioRederm™ and coverage of the bone, the patient was referred back to the referring surgeon to complete his treatment as planned.

Figure 3A: Before first treatment

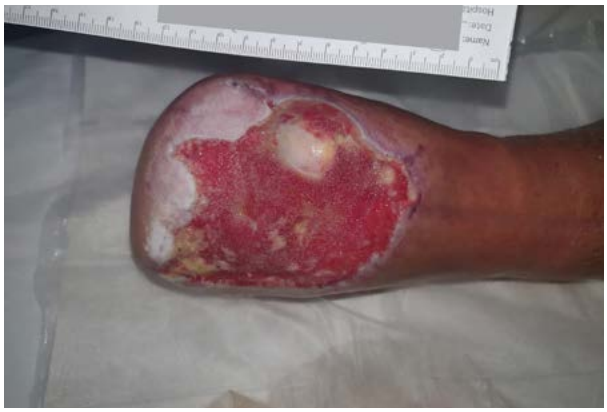


Figure 3B: After first treatment

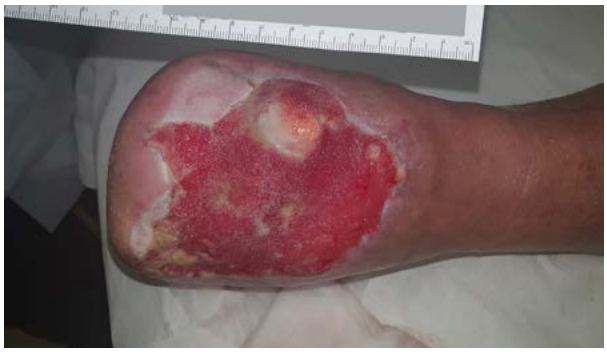
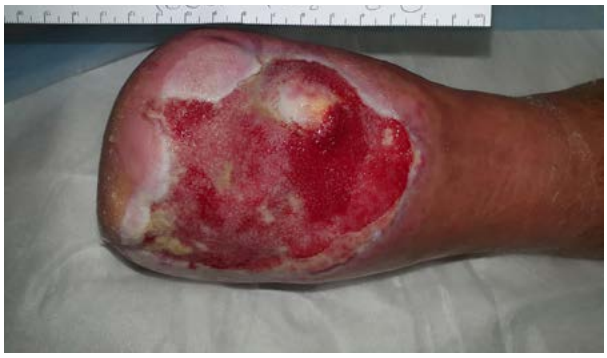


Figure 3C: After second treatment



Discussion

Caring for non-healing, chronic wounds is costly and with an ever-increasing pressure on resources, there is a need for consistent, intuitive clinical practice and solutions that provide structured, measurable outcomes for these patients.

Placental tissues have several clinical uses in areas of wound care, burn treatment, and ocular surface reconstruction.[5] Use of cellular and tissue-based products (CTPs) continues to be reviewed and accepted as an intervention for non-healing or non-advancing wounds. Placental membrane application in wound care has emerged to become an advanced therapy solution for difficult, hard-to-close chronic wounds with a significant reduction in time to healing and overall cost of care when compared to standard care.[6]

AmnioRederm™ was effective in the treatment of the wounds in these two cases by accelerating the wound healing process. In the first case of a non-healing diabetic foot ulcer, AmnioRederm™ treatment led to a reduction in wound size of over 50% in four weeks. In the second case, only two treatments with AmnioRederm™ resulted in granulation tissue covering about 50% of the exposed bone. These cases demonstrate that AmnioRederm™ should be considered as an adjunctive therapy for non-healing wounds where standard of care has not been effective.

References

1. Atkin L, Tickle J. Best practice statement leg ulceration pathway: Revision required to reflect new evidence. Wounds UK. 2018;14(4):58-62.
2. Harding K, Dowsett C, Fias L, et al. Concensus recommendations: Simplifying venous leg ulcer management. Wounds Internetional. 2015;72.
3. Krasner DL, Rodeheaver GT, Sibbald RG, Woo KY. Chronic wound care: a clinical source book for healthcare professionals. Fifth ed. Malvern, PA: HMP Communications; 2012.
4. Lavery LA, Fulmer J, Shebetka KA, et al. The efficacy and safety of Grafix® for the treatment of chronic diabetic foot ulcers: Results of a multi-centre, controlled, randomised, blinded, clinical trial. Int Wound J. 2014;11(5):554-60.
5. Zelen CM, Serena TE, Gould L, et al. Treatment of chronic diabetic lower extremity ulcers with advanced therapies: A prospective, randomised, controlled, multi-centre comparative study examining clinical efficacy and cost. Int Wound J. 2016;13(2):272-82.
6. Serena TE, Carter MJ, Le LT, et al. A multicenter, randomized, controlled clinical trial evaluating the use of dehydrated human amnion/chorion membrane allografts and multilayer compression therapy vs. multilayer compression therapy alone in the treatment of venous leg ulcers. Wound Repair Regen. 2014;22(6):688-93.