Abstract

An 84-year-old female presented with a sacral pressure ulcer measuring 16.2 cm^2 in circumference. Patient's wound was treated using DermaBind TL™ (formerly AmnioBind), a terminally sterilized, dehydrated, full-thickness placental membrane allograft consisting of amnion, chorion, and the associated intermediate (spongy) layer. Treatment consisted of wound debridement, covering the wound with DermaBind TL, and covering the wound with gauze. Every 6-7 days the gauze was removed, the wound debrided, and new DermaBind TL™ allograft applied. Treatment proceeded for 14 weeks in which time the wound was reduced to 0.01 cm^2 in circumference.

Introduction

As the largest organ of the human body, the skin has a significant impact on various human activities and functions, including protection from pathogens, sensing of the external environment, and thermoregulation [1]. However, as the outermost part of the human body, the skin, due to its elastic and soft nature, is prone to develop wounds [2, 3]. Although human skin is able to repair itself spontaneously to restore its structural and functional integrity, wound care is still paramount to prevent infection and dehydration, relieve pain, protect the open site, accelerate the healing process and prevent scarring, especially in large and open wounds or burns [4-6]. In 2014, there were 17.2 million hospital visits for acute wounds in the United States [7]. Currently, approximately 1-2% of the population in developed countries suffer from chronic wounds [8]. Meanwhile, chronic wounds such as diabetic ulcers, vascular ulcers and pressure ulcers, which have a long and cruel healing time due to disease, aging or inappropriate treatment, not only affect patients' daily lives, but are also associated with high morbidity and mortality [9, 10].

The physiology of wound healing is well understood [11]. The healing process involves four overlapping phases: hemostasis, inflammation, proliferation, and remodeling [5, 12-14]. There are many types of wounds: acute incisional and excisional wounds can undergo a normal healing process, while chronic wounds have aberrant healing conditions [10]. In the clinic, wound healing management varies according to tissue characteristics, intrinsic regenerative capacity, wound classification, and other environmental variables [6, 10, 15-17]. Therapeutic strategies for wounds are diverse and include hyperbaric oxygen therapy [18-20], negative pressure therapy [21], vacuum-assisted closure [22], ultrasound [23], electrotherapy [24, 25], autografts/allografts and xenografts [4, 26, 27], cell-based therapy and engineered skin grafts [4, 28, 29], and topical drug and growth factor delivery [30-32]. Regardless of the wound class and the chosen wound management strategy, a wound dressing is required [33]. Traditional passive wound dressings such as gauze, bandage, and cotton wool would adhere to the skin tissue, causing dehydration and re-injury when removed. In contrast, allograft wound dressings integrate the multifunction of maintaining a moist

environment, managing exudate and protection from pathogens, adhesiveness, and suitable mechanical properties have recently surged and demonstrated extraordinary advantages in more complicated situations [4, 34, 35].

Case

The patient is an 84-year-old Caucasian female with a past medical history (PMH) of type 2 diabetes mellitus (DM2), anxiety, atrial fibrillation (A-Fib), cerebrovascular accident (CVA), generalized weakness, high cholesterol, hypertension, and mild depression. At enrollment, she presented with a Stage 3 sacral pressure ulcer, which had an onset of 61 weeks prior. She has never smoked.

Case data was submitted after the completion of DermaBind™ treatment. Addendums are available in the portal to clarify the submitted documents. The type of conservative treatment the patient used prior to DermaBind™ and her A1C level are still pending. The patient has passed all inclusion criteria per the provider with the noted addendum.

The patient did not use an allograft or skin substitute before using DermaBind. Data was received with the first application of DermaBind™ on November 5, 2024, with weekly applications up to February 4, 2025. The wound measurement table is provided below.

Week	Length (cm)	Width (cm)	Area (cm2)	% Reduction
Enrollment	4.5	3.6	16.2	-
Week 1	4.4	3.6	15.8	2.5
Week 2	4.3	3.3	14.2	12.3
Week 4	2.8	2.4	6.7	58.6
Week 8	1.7	1.0	1.7	89.5
Week 12	0.7	0.5	0.4	97.5
Week 14	0.1	0.1	0.01	Closed

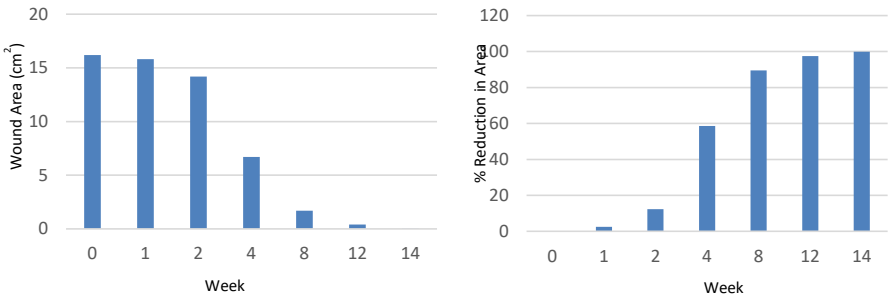

Figure 1. Graphical representation of: A) wound circumference, and B) Percent wound circumference reduction over a 14 week span

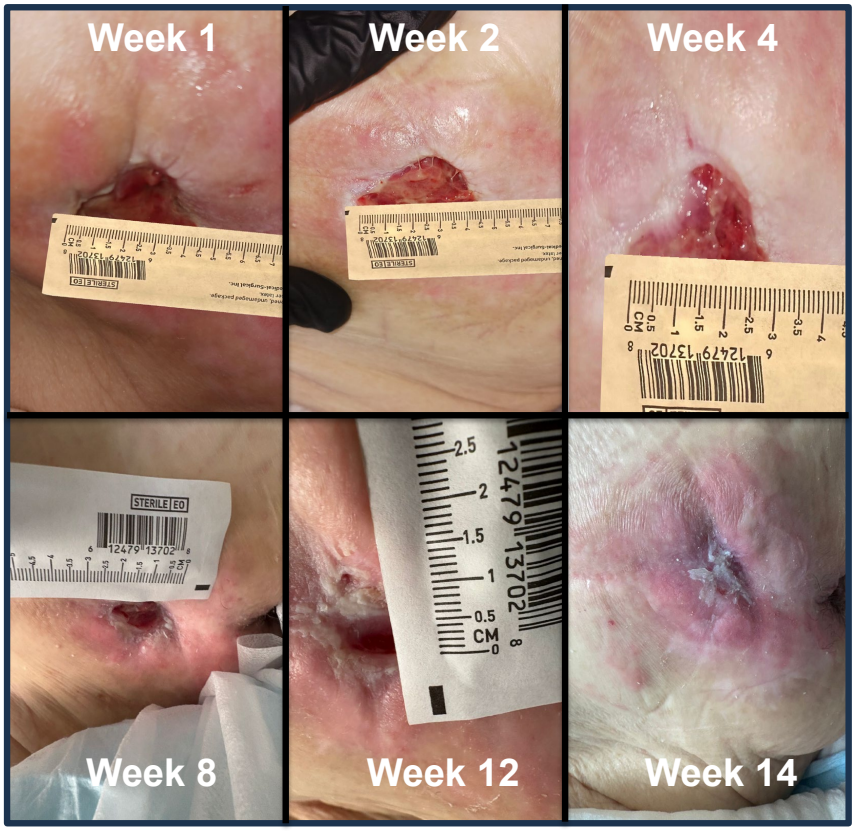

Figure 2. Photos depicting DermaBind TL™ treated sacral wound. Initial wound area was 16.2 cm^2 and, after 4 applications, had decreased over 50%. By week 14, the wound had closed completely.

Discussion

A patient, 84F, with a non-healing sacral pressure ulcer, was treated using DermaBind TL™ for 14 weeks. During this 14-week period, there was a significant reduction in the circumference and the depth of the diabetic foot ulcer. After 4 weeks of treatment, this wound had decreased in circumference by nearly 59%.

The purpose of this case study was to assess the feasibility, ease of use and safety associated with the use of this novel full-thickness placental membrane allograft. The sacral pressure ulcer treated with DermaBind TL™ experienced at least a 50% reduction in wound area within 4 weeks of initial application. The authors believe that this is the only case reported in the literature of the use of this therapy. Considering that this patient had previously failed conventional wound treatments, the results obtained support the hypothesis that full-thickness placental membrane allografts are effective in promoting wound healing. No adverse events were observed in the study.

Human amniotic membrane has been used to promote granulation tissue in wounds for over a century. It has been shown to promote new vessel formation in leg ulcers and has bacteriostatic properties [36]. It is sometimes used in developing countries as a low-cost treatment for burns because it has been shown to reduce pain and speed healing [37]. It has been shown to increase the success rate of skin grafting in burn patients [38]. Amniotic membrane tissue is harvested from the placenta from mothers who are seronegative for HIV, sexually transmitted diseases (STDs), hepatitis C (HVC), and hepatitis B (HBS) tests, although it is often not feasible to use or store fresh amniotic membrane. Several amniotic membrane products are available to the clinician for use in wound management. These products may be dehydrated or cryopreserved and may contain amnion alone or amnion and chorion. The full-thickness placental membrane product used in this evaluation is composed of both amnion and chorion layers of amniotic membrane as well as the associated intermediate layer.

In the clinical setting, randomized controlled trials suggest that placental membrane derivatives can be used to effectively treat diabetic neurotrophic ulcers [43]. In the study by Berhane et al, patients were randomized to receive standard care alone or standard care with the addition of dehydrated Amnion (dHAM) every week [39]. After the first application of dHACM 7/10 (70%) of PUs responded to treatment with a reduction in wound size. Within two weeks of dHACM initiation into the plan of care, 4/10 (40%) of PUs had reduced in size by >50%. By week four, 60% of PUs (6/10) had reduced in size by >50%. Overall, during the eight week evaluation period, 9/10 PUs reduced in size, three of which healed completely. In this single case, our DermaBind TL™ observations were similar to the results obtained by other investigators suggesting that research into multiple dHAM applications on wounds of different sources is warranted and will likely yield further positive results in addition to those we observed. In fact, another randomized trial evaluated weekly versus bi-weekly application of dHACM for the treatment of diabetic foot ulcers and found that wounds treated with weekly dHACM application healed faster than those treated bi-weekly [40]. The mean time to healing was only 2-4 ± 1-8 weeks in the weekly dHACM group compared to 4-1 ± 2-9 weeks in the biweekly dHACM group (P = 0-039) [40]. Faster healing with weekly application provides an economic benefit in that these patients require fewer visits and dressing changes to the wound care center and reduce their risk of adverse events.

Chronic wounds are burdensome in terms of both the negative impact on patient quality of life and the financial costs associated with their management. The development of effective, affordable and durable techniques for rapid wound closure is a priority for healthcare systems. Future research comparing the efficacy of skin substitute products and classes is clearly needed, as the current literature can only be used to evaluate product efficacy compared with standard wound dressing techniques. In addition to the efficacy of various skin substitutes, the cost of application must be considered. The investigation of shelf-stable, low-cost allografts could address current clinical concerns by making advanced allografts more widely available to both clinicians and patients by limiting expensive handling practices and production costs. Human amniotic membrane (dHAM) has unique biochemical properties that make it potentially applicable to wound care. dHACM has been developed as a potential vehicle for these properties in a shelf-stable form, limiting product cost and allowing for greater ease of use. The dHACM has been shown to be both clinically and cost effective compared to other advanced wound care products for the treatment of diabetic lower extremity ulcers [41-42]. Considering that DermaBind TL contains the amnion, chorion, and the intermediate (spongy) layer, it

follows that a full-thickness placental membrane would have at least similar, if not better, results.

This non-randomized product study supports the hypothesis that placental membrane allografts can be used in chronic wound therapy. These data are consistent with data obtained in similar studies and build on the established history of placental membrane derivative use for non-healing wounds. Future research would require the performance of multicenter randomized controlled trials to evaluate the efficacy of placental membrane in the treatment of chronic wounds of various causes and whether full-thickness placental membrane is more effective in the treatment of these wounds than other currently available products.

Conclusion

DermaBind TL™ offers an effective and easy-to-use treatment alternative for the management of chronic wounds. Clinical improvement results strongly suggest significant and faster healing when compare to standard of care alone, resulting in complete wound closure, in wounds treated with full-thickness placental membrane-containing products. Chronic wounds that do not respond to other standard treatment options show significant healing and wound coverage with placental membranes. Easy storage and extended shelf life promote clinical acceptance in the wound care environment. Lower complication rates compared to other similar products have been reported in numerous clinical studies. Although DermaBind TL™ has a higher unit (dressing) cost compared to standard wound care, the overall cost is similar or lower considering the faster healing and presumably lower rate of complications and clinical sequelae such as amputations.

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