Clinical use of DermaBind TL/FM as a wound covering for hard-to-heal wounds of various aetiologies: a case series

Objective: The purpose of this retrospective case series is to describe real-world clinical experience with DermaBind TL or FM, (HealthTech Wound Care, US), a dehydrated full-thickness placental membrane intended for homologous use as a protective wound covering in wounds of various aetiologies that failed to heal with standard of care (SoC).

Method: This retrospective observational, uncontrolled case series collected data from healthcare providers in the US. Eligible cases were patients, ≥18 years of age, with hard-to-heal wounds who received DermaBind TL or FM after having completed a minimum of four weeks of SoC without evidence of wound improvement. Data collected included patient demographics, wound characteristics and wound size.

Results: The cases of 27 patients encompassing 36 wounds were included. The average age of patients included was 72.4 years (range: 37–101 years). The majority of wounds were pressure ulcers (63.9%), followed by diabetic foot ulcers (19.4%) and venous leg ulcers (8.3%). Wound onset was, on average, 29 weeks prior to the first graft application with the placental membrane, and the average wound size was 34cm^2. Graft applications occurred weekly, with an average duration of treatment of 6.7 weeks. The observed average percentage surface area reduction across the 36 wounds was 69.1% (range: –17.6–100%). No adverse events were reported by the provider across all patient cases.

Conclusion: These observations describe the clinical use of DermaBind as a wound covering material consistent with its homologous natural protective role. Larger, prospective studies are warranted to further investigate its clinical use. The authors would like to stress that this non-randomised, retrospective uncontrolled case series was used to describe findings, such as number of grafts applied, observed percentage of surface area reduction and graft wasted, and not to demonstrate efficacy.

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chronic wounds • diabetic foot ulcer • full-thickness placental wound covering • hard-to-heal • venous leg ulcer • wound • wound care • wound dressing • wound healing

The wound healing process involves four phases: haemostasis, inflammation, proliferation and remodelling.[1] In the haemostasis phase, blood vessels constrict to decrease blood flow to the injury, the platelet plug forms and reinforces, and the coagulation cascade is activated.[1,2] The inflammation phase has a significant role in the wound healing process, and involves a complex and dynamic interplay of immune cells.[2,3] The proliferative phase includes the formation of granulation tissue and re-epithelialisation.[2,4] In the final stages of wound healing, collagen synthesis, turnover and organisation, as well as extracellular matrix remodelling take place.[1] When this process is interrupted, wound healing is impaired and can lead to wounds that persist past the typical healing time (around four weeks), leading to a hard-to-heal (chronic) wound.[3] Hard-to-heal wounds that do not demonstrate a percentage area reduction (PAR) of >50% by week four are a strong predictive factor for a wound becoming hard-to-heal.[5] Many individuals with hard-to-heal wounds have underlying medical conditions, such as diabetes, obesity or malnutrition, which complicate the wound healing process.[4] Factors that impair wound healing include oxygenation, infection, venous insufficiency, older age, restricted ambulation, medications, comorbidities, oncological treatments, or lifestyle habits, such as smoking or alcohol use.[4]

Hard-to-heal wound aetiologies include pressure ulcers (PUs), diabetic foot ulcers (DFUs), venous leg ulcers (VLUs) and arterial ulcers.[2,3] These hard-to-heal wounds

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Jason Mendivil,[1] DPM; **Abby E McMahon**,[2] NP; **Oludayo Toby Ojelade**,[2] NP; **Kelly Hobson**,[3] NP; **Melissa Marballie**,[4] DNP, FNP-BC, WCC; **Sandry Alvarez**,[5] NP; **Vivian Adu-Aboagye**,[6] APRN, FNP-C, WCS-C; **Georgia Chiamba**,[7] NP; **Donovan Gowdie**,[8] DPM; **Willie E Landrum II**,[9] MD, WCC; **Ahlam Alzindani**,[10] NP; **Habeeb Yazdani**,[10] MD; **Gabriel Petty**,[11] PA; **Marie-Chantale Simard**,[12] PhD; **Douglas Schmid**,[13] PhD; **Jessica Meadors**,[13] APRN, FNP-C, WCC*

***Corresponding author email:** jessica@healthtechwc.com

1 PULSE Amputation Prevention Centers, US. **2** EvoHealth, US. **3** Reliable Visiting Services, US. **4** The Family Wound Care, US. **5** Maxcure Medical Center, US. **6** BWell Medical and Wellness Center, US. **7** Aptitude Health, US. **8** The Foot and Ankle Treatment Center, US. **9** Willie E Landrum II, MD, PC Internal Medicine, US. **10** Visiting Doctors Solutions, US. **11** Synova Health, US. **12** Silver Raven Advisory LLC, US. **13** HealthTech Wound Care, US.

Fig 1. DermaBind TL/FM (HealthTech Wound Care, US) undergoes a proprietary preservation method, which retains all native layers of the placental membrane, including the amnion and chorion with the spongy layer intact

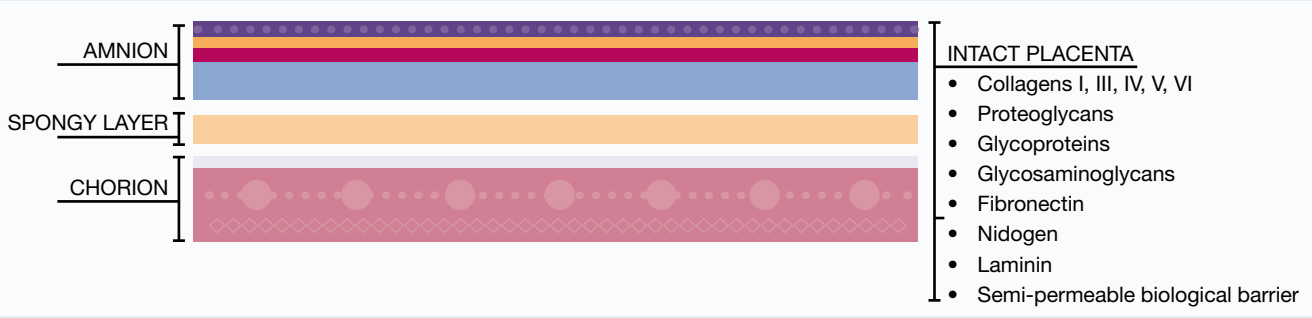
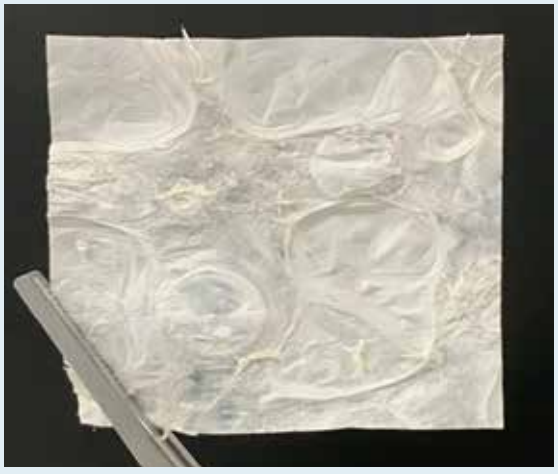


Fig 2. DermaBind TL is a dehydrated placental membrane covering that preserves the comprehensive collagen matrix, glycoconjugates, and glycosaminoglycans. DermaBind TL/FM contains 400+ proteins, including collagens, fibrins, elastins, glycosaminoglycans, and glycoconjugates (image supplied by HealthTech Wound Care, US)



can lead to significant morbidity and mortality.[6] DFUs preceded 84% of diabetes-related lower limb amputations, annually worldwide.[7] More recent reports show that the five-year mortality rate for individuals with diabetes and foot ulceration is approximately 40%, increasing to 63% in individuals who have undergone an amputation.[8] Hard-to-heal wounds can also have negative effects on patients' social and mental wellbeing, causing emotional distress and social isolation.[9]

In the US, it is estimated that the quality of life of almost 2.5% of the total population is affected by hard-to-heal wounds.[9] Since older age is a factor that can affect wound healing, the older population has a higher prevalence of hard-to-heal wounds. In 2019, 16.4% of Medicare beneficiaries were impacted by hard-to-heal wounds. For this same year, expenditure for their care was $2.5 billion USD in the outpatient setting, $1.1 billion USD for home health, and $4.1 billion USD for physician offices.[10]

The primary principles of wound management include: tissue debridement; infection prevention and control; moisture balance; and assessment of the wound edges.[4,11] There are a number of additional clinical management strategies for hard-to-heal wounds. These include autologous platelet-rich plasma, hyperbaric oxygen therapy, negative pressure wound therapy (NPWT), growth factors, cell therapy and skin grafts.[4] With all types of wound classes and therapies, a wound covering must be used.[12]

Wound dressings, including gauze, bandage and cotton wool, can lead to dehydration and reinjury when removed, whereas allograft wound dressings, such as placental-derived coverings, can maintain a moist environment, manage exudate and protect against infections.[13,14] In the published literature, placental membranes have been reported to offer advantages in the management of exudative wounds. The fibrous extracellular matrix provides inherent absorptive properties while maintaining intimate contact with the wound bed.[14] Upon application, the dehydrated graft gradually rehydrates, which has been described as allowing modulation of wound fluid rather than oversaturation, thereby supporting moisture balance and helping to prevent periwound maceration.[15,16] These demonstrated advantages have made them a treatment option in more complicated wounds.[13] Clinical studies have demonstrated the value of placental-derived wound coverings in hard-to-heal wounds, including DFUs and VLUs.[4,17–19]

DermaBind TL and DermaBind FM (HealthTech Wound Care, US) are dehydrated, full-thickness, placental membranes intended for homologous use as a protective wound covering and contain 400+ proteins, including collagens, fibrins, elastins, glycosaminoglycans and glycoconjugates. A proprietary preservation method retains all native layers of the placental membrane, including the amnion and chorion with the spongy layer intact (Figs 1 and 2). The membrane grafts can be used as a protective wound covering on partial- or full-thickness acute or hard-to-heal wounds. The key differentiating factor between these two products is the unique notch on DermaBind FM that allows healthcare providers

using the graft to distinguish between the top chorion layer and bottom amnion layer of the graft that comes into direct contact with the wound. DermaBind TL, on the other hand, has an orientation label on the graft packaging indicating appropriate application with amnion side down.

On 5 January 2023, the US Food and Drug Administration's (FDA) Tissue Reference Group (TRG) determined that DermaBind TL appeared to meet all four criteria under 21 (Code of Federal Regulations) CFR § 1271.10(a) based on the product's described processing[20] and intended homologous use as a wound covering for acute and hard-to-heal wounds. DermaBind TL qualifies for regulation solely under Section 361 of the [US] Public Health Service (PHS) Act and the regulations in 21 CFR Part 1271. On 3 November 2023, the FDA's TRG determined that DermaBind FM, when intended for use as a wound covering and to protect the wound from the external environment also appeared to meet the criteria for regulation solely under section 361 of the PHS Act and the regulation in 21 CFR Part 1271.

The purpose of this case series is to describe retrospective, uncontrolled, real-world clinical experience with DermaBind TL or FM as a protective wound covering in hard-to-heal wounds of various aetiologies that failed to heal with SoC.

Methods

Study design

Deidentified data were collected from included patients whose wounds had failed to heal after four weeks. Data collection took place in the US between 2023–2025. The providers were given one of three options:

- Completing a deidentified seven-page questionnaire
- Completing a deidentified Excel (Microsoft Corp., US) worksheet
- Uploading deidentified data for extraction by HealthTech Wound Care personnel.

Each provider was extensively trained on the case submissions, required documents, inclusion criteria and secure portal upload. Data were entered and reviewed independent of the providers and of HealthTech Wound Care.

Participants and eligibility

Healthcare professionals who focus on wound care management or who specialised in wound care were able to submit cases to be included in this retrospective study. Eligible participants were adults ≥18 years of age with hard-to-heal wounds treated in the US, and who had completed a minimum of four weeks of SoC without evidence of wound improvement.

Demographics and clinical data

Baseline demographic and clinical data collected, if available, included: age; sex; race; ethnicity; medical history; surgical history; social history (such as lifestyle habits, social circumstances); allergies; medications; and wound aetiology. For patients with diabetes, haemoglobin A1c (HbA1c) values were collected, if available. When applicable, ankle–brachial pressure index (ABPI) and/or toe–brachial pressure index (TBPI) were also recorded, in addition to other advanced imaging, such as non-invasive arterial Doppler.

Wound-specific data included wound location, duration, and confirmation of non-healing wounds following failed SoC. Product names and dates of use for failed treatment were also requested. Wound assessments were collected pre- and post-allograft application and included: date of visit; wound length; width; depth; surface area; wound bed tissue type; deepest exposed structure; exudate amount and type; periwound description; pain; signs of infection; presence of oedema and treatment; offloading modalities used; wound cleansing method; and dressing type.

Documentation of debridement used and wound images were recorded at each visit along with any adverse events, if applicable. Wound size was captured via planimetry, photographic analysis, and using the linear measurement method, depending on the providers' standard clinical practice. Measurements obtained were non-blinded and completed by the provider or a trained clinician. The numeric rating scale (NRS 0–10; where 0=no pain and 10=worst possible pain) was used to capture pain severity; some cases did not report pain values.

Due to the nature of this retrospective case study, wound assessment tools were not captured and these were not standardised across providers. However, providers used similar templates and/or questionnaires to the Bates-Jensen Wound Assessment tool for wound assessment[21] and the TIMERS (tissue; infection/inflammation; moisture; edge of wound; regeneration/repair of tissue; social factors) framework model for wound assessment and management,[22] proprietary developed tools, the digital wound management platform (eKare, US) or electronic health record (WoundExpert, US). Pre-graft wound assessments (tissue type, deepest exposed structure, exudate type and severity, periwound description and pain measures) were missing for wounds 1, 2, 9–12, 16 and 17). Pre-graft wound measurements were missing for wounds 6,9–12 and 16–19. Pre-graft wound images were missing for wounds 2, 9–12 and 16–19. The number of grafts applied, and wound onset were not documented for wound 2. Pain severity was not consistently reported at each visit by some providers. Results are presented descriptively, and no statistical analysis was performed.

Ethical approval and patient consent

Institutional Review Board approval was not required for this retrospective case study as patients had already been treated by their provider with DermaBind TL or FM based on medical necessity and failed conservative treatment. Patient consent was obtained by their provider for the use and release of deidentified data, and publication of photographs/images.

Wound management and DermaBind TL or FM application

After failing SoC for ≥4 weeks, wound bed preparation was completed and approved for full-thickness placental membrane application by the provider. The wounds were cleansed with either normal saline or a wound cleanser. The allograft was applied to the wound surface area and the graft was trimmed, if necessary. Rehydration was completed with normal saline or passive hydration. A non-adherent dressing was used with Adaptic (Solventum Corp., US), Xeroform (Covidien, US), Versatel (Medline, US) or other silicone contact layer, or with non-stick Telfa (Cardinal Health, US). Some providers secured the allograft with Steri-Strips (3M, US) while others secured the non-adherent dressings with Steri-Strips for additional securement; other providers chose not to use Steri-Strips. Skin preparation was used on the periwound in various cases. The next steps were use of a dry dressing, such as gauze, bordered gauze or foam. If the wound was on the lower extremity, roll gauze or Kerlix (Covidien, US) wrap was used. Compression therapy proceeded, if warranted, to the lower extremity. Visits were conducted weekly for new graft application and wound assessment. Providers completed sharp or mechanical debridement, if warranted, prior to the graft application; most completed serial sharp debridement weekly. In addition, a properly maintained wound bed, tissue quality, infection prevention, exudate management, compression therapy, aggressive offloading, elevation, management of underlying comorbidities, appropriate nutrition and optimisation of nutrition, and blood glucose control were documented.

Failed SoC included sharp and surgical debridement, Hydrogel (Cardinal Health, US), Medi-honey (Derma Sciences, New Zealand), Santyl (Smith+Nephew, US), silver nitrate, silver dressings and creams, povidone-iodine, alginates, collagen, non-adherent dressings, dry dressings, foams, or Unna's boot. Additional measures included: exudate management; maintaining a moist wound environment; compression therapy; elevation of lower extremities; frequent repositioning; aggressive offloading (low air loss mattress, wheelchair cushions, wedges, Charcot restraint orthotic walker (CROW) boot, postoperative shoe, total contact casting); optimising nutrition; blood glucose control; prevention of infection; or surgery, if warranted. Supplementation with Ensure (Abbott Laboratories, US), Pro-Stat (Nutricia, US), multivitamins, vitamin C, or zinc was used to ensure optimal nutrition. NPWT or vascular management were also used. Comorbidities were managed by the patient's primary care provider and required close observation in some patient cases at greater risk for limb loss.

Table 1. Baseline characteristics

Demographics	Patients (n=27)
Age, years, mean	72.4
Female, n (%)	16 (59.3)
Past medical history, n (%)	
Diabetes	13 (48.1)
Hypertension	9 (33.3)
Peripheral artery disease	5 (18.5)
Venous insufficiency	2 (7.4)
Heart failure	4 (14.8)
End-stage renal disease	2 (7.4)
Bedbound	3 (11.1)
Paraplegia	2 (7.4)

Results

A total of 27 patient cases were collected encompassing 36 wounds. Healthcare providers that submitted cases included: two doctors of podiatric medicine; two doctors of medicine; eight nurse practitioners; and one physician assistant across the US. The average age of patients included was 72.4 years (range: 37–101 years), and 59.3% of the patients were female. On average, patients had >5 documented comorbidities. Additional baseline demographics can be found in Table 1.

The majority of wounds were PUs (63.9%), followed by DFUs (19.4%) and VLUs (8.3%). PUs were stages 2–4. DFUs were Wagner grade 2 and 3. VLUs were partial- and full-thickness. Additional wounds included full-thickness trauma injury and full-thickness post-necrotising fasciitis. The average wound size was 34cm^2. Wound onset was, on average, 29 weeks prior to first graft, with dates ranging from 2017 to 2025. Additional baseline wound characteristics can be found in Table 2. The locations of wounds included bilateral lower extremities, including foot and ankle, arm, sacrum, buttocks, coccyx, midback and hips.

Graft applications occurred weekly, for an average duration of treatment of 6.7 weeks (range: 2–15 weeks). Grafts were continued as deemed clinically appropriate by the provider. Visits were conducted in both the clinic and mobile wound care setting. In one patient, only two grafts were applied, separated by 32 days (wound 7); the patient was seen weekly for wound assessment, and wound care was provided with Adaptic dressing and rolled gauze applied to lower extremity wound. Additional treatment was received by two patients in conjunction with the allograft. In wounds 24 and 25, NPWT was applied, and in another patient with two wounds used plain packing strip packed into a tunnel while the allograft was used on the surface of the wound (wounds 13, 14).

Average percentage surface area reduction across the 36 wounds was 69.1% (range: –17.6–100%). Of the wounds, nine (25%) healed completely and, in total, 28 (77.8%) wounds had a ≥50% percentage reduction in surface area (Table 3). Of the remaining wounds, three

Table 2. Baseline wound characteristics

Characteristics	Wounds (n=36)
Surface area, cm^2, mean	34
Time since onset, weeks, mean	29
Wound aetiology, n (%)	
Pressure ulcer	23 (63.9)
Diabetic foot ulcer	7 (19.4)
Venous leg ulcer	3 (8.3)
Non-pressure hard-to-heal ulcer	1 (2.8)
Necrotising fasciitis	1 (2.8)
Traumatic injury	1 (2.8)

had between 40–49% reduction; two worsened (wound 9: –2.6% reduction; wound 17: –17.6% reduction), and three wounds remained at a similar surface area (wound 16: 12.2% reduction; wound 19: 12.1% reduction; wound 31: 4.8% reduction) (Fig 3). Figs 4–7 represent different wound aetiologies with various percentages of observed wound closure in patients included in the study.

Necrotic tissue, slough, granulation and re-epithelialisation were reported. Across all clinical cases, slough and necrotic tissue were able to be debrided before application of the full-thickness placental membrane. Exudate type and severity ranged from none to serous, serosanguineous or sanguineous with a severity of scant/mild or moderate. The deepest exposed structure in most wounds included subcutaneous tissue and fascia. In two patients (Patients S (wound 23) and T (wounds 24, 25 and 26)), muscle exposure was noted.

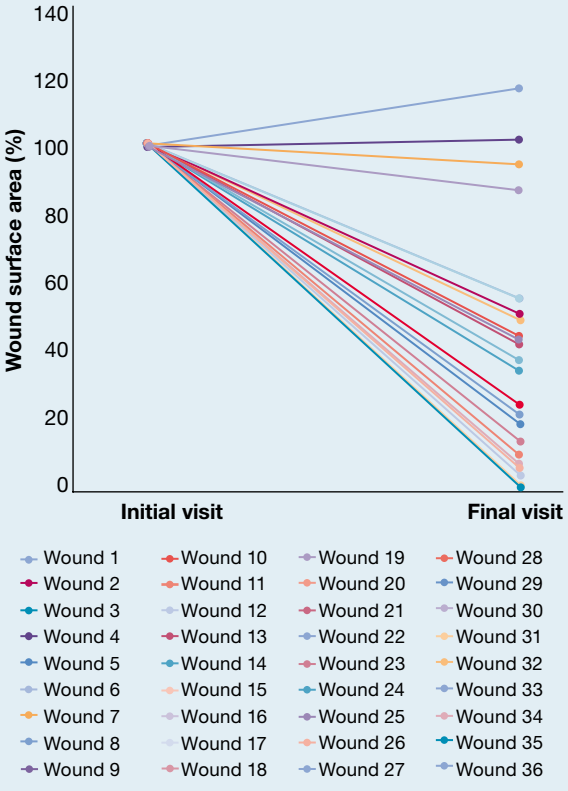
Methods for reporting pain varied across cases. In general, pain remained mild and consistent across therapy. No adverse events were documented in any of the patients.

Discussion

In this observational experience—the application of the grafts as wound coverings—nine (25%) wounds were observed as completely healed. In total, 28 (77.8%) wounds had ≥50% reduction in surface area (including nine healed wounds). After thorough assessment and where SoC has failed, providing a placental graft, if deemed appropriate by the treating provider, may play a role in the wound healing process as a protective wound covering.

An area of interest for this study was the placement of appropriately sized grafts to serve as a covering layer over an open wound bed. Selecting a graft close to the wound size permitted minimal wastage. This approach was carried out in a manner consistent with placental homologous use, where the covering function of the grafts over the wound paralleled the placenta's natural role as a protective barrier to potentially support an environment that can promote the healing cascade.

Fig 3. Change in wound surface area (%) from first measurement to final follow-up. Change in wound surface area was normalised to percentage change, resulting in overlapping lines due to similar % changes in wounds 5 and 6; in wounds 4, 12 and 20; in wounds 7, 8, 15, 18, 27–30 and 35; in wounds 10, 22 and 25; in wounds 16 and 19; and in wounds 33 and 36



When wounds fail to progress through the healing phases in an orderly fashion, hard-to-heal wounds persist. Each wound is unique, given the wound aetiology and the comorbidities of the patient. Hard-to-heal wounds are complex and require a multidisciplinary approach in addition to using advanced modalities. Not every patient will require or be an acceptable candidate for this protective wound covering. If underlying comorbidities and wound bed preparation are not managed appropriately, progression to wound healing will not be observed, and this can result in delayed wound healing. These considerations emphasise the importance of looking at the patient as a whole and not disregarding other patient-related factors when treating these complex wounds.

The patients included in this retrospective case series had many comorbidities requiring clinical management, with, on average, ≥5 comorbidities per patient. This is likely an underestimation, as some patients had no or few documented medical histories. Despite this likely under-reporting, the number of comorbidities emphasises the complexity of these clinical cases. Many of the comorbidities, such as diabetes, can negatively impact

Table 3. Wound characteristics and clinical course

Patient	Wound	Age, years	Sex	Wound aetiology	Stage/Wagner grade/ partial- or full thickness	Wound location	Time from wound onset to graft application, weeks	Duration of graft application, weeks	Initial surface area, cm^2	Surface area at final follow-up provided, cm^2	Surface area reduction	
											cm^2	%
A	1	64	M	DFU	WG 2	Right foot	32	5	1.2	0.04	1.16	96.7
B	2	70	F	PU	NR	Sacral	NR	4	38	16	22	57.9
C	3	84	F	PU	Stage 3	Sacral	61	14	16.2	0.01	16.19	99.9
D	4	99	F	PU	Stage 3	Right leg	9	15	20.72	1.2	19.52	94.2
E	5	74	F	VLU	FT	Right lower leg	365	10	460	256.5	203.5	44.2
F	6	53	F	PU	Stage 3	Left hip/thigh area	47	2	25.37	14.1	11.27	44.4
G	7	72	M	DFU	WG 3	Left distal plantar 4th toe	10	2	1	0	1	100
H	8	68	M	PU	Stage 3	Lateral right heel	8	6	33	0	33	100
I	9	74	F	DFU	WG 2	Right ankle, medial aspect	24	10	16.32	16.75	–0.43	–2.63
J	10	77	F	DFU	WG 2	Right foot	24	6	1.5	0.66	0.84	56
K	11	76	M	DFU	WG 2	Left foot plantar to the 1st metatarsal head	8	10	0.88	0.08	0.78	88.6
L	12	50	M	DFU	WG 2	Left plantar heel	16	4	3.5	0.2	3.3	94.3
M	13	38	M	PU	Stage 4	Sacrum/buttock, coccyx-left buttock	9	10	80.5	10.8	69.7	86.6
M	14	38	M	PU	Stage 4	Sacrum/buttock, gluteus, right-right buttock	9	10	70.4	24.18	46.22	65.76
M	15	38	M	PU	Stage 2	Sacrum/buttock, gluteus, left-left lower	4	4	4.95	0.04	4.95	100
N	16	65	F	PU	Stage 3	Right gluteus	33	3	45.6	40.04	5.56	12.2
N	17	65	F	PU	Stage 3	Sacrum	33	3	28.8	33.88	–5.08	–17.6

Table 3. Wound characteristics and clinical course (continued)

Patient	Wound	Age, years	Sex	Wound aetiology	Stage/Wagner grade/ partial- or full-thickness	Wound location	Time from wound onset to graft application, weeks	Duration of graft application, weeks	Initial surface area, cm^2	Surface area at final follow-up provided, cm^2	Surface area reduction	
											cm^2	%
O	18	65	F	PU	Stage 2	Left buttock	NR	4	12.42	0	12.42	100
O	19	65	F	PU	Stage 4	Sacrum/buttock coccyx	25	10	33.55	29.5	4.05	12.1
P	20	67	M	PU	Stage 4	Sacrum	19	10	35.75	2	33.75	94.4
Q	21	84	F	DFU	WG 3	Right plantar aspect of the great toe on right foot	7	6	2.4	0.5	1.9	79.2
R	22	72	F	NF	FT	Right thigh	25	10	89.28	38.6	50.42	56.5
S	23	78	F	Traumatic injury	FT	Right arm	NR	3	2.94	1.5	1.44	49.0
T	24	91	M	PU	Stage 4	Left hip	23	8	45.6	17.1	28.5	62.5
T	25	91	M	PU	Stage 4	Right hip	24	8	38.4	16.7	21.7	56.5
T	26	91	M	PU	Stage 3	Right ischial	24	8	16	3	13	81.3
U	27	71	F	PU	Stage 4	Mid-back	11	3	6.72	0	6.72	100
V	28	53	M	PU	Stage 4	Right buttocks	9	10	9.8	0	9.8	100
V	29	53	M	PU	Stage 3	Coccyx	11	5	0.88	0	0.88	100
W	30	95	F	VLU	FT	Left anterior lower leg	7	6	2.1	0	2.1	100
X	31	73	F	VLU	FT	Right lateral lower leg	33	9	1.26	1.2	0.06	4.8
Y	32	101	F	PU	Stage 3	Right medial heel	6	5	19.27	4.59	14.68	76.2
Y	33	101	F	PU	Stage 3	Right lateral hip	6	5	11.7	5.8	5.9	50.4
Y	34	101	F	PU	Stage 3	Right medial lower leg	7	4	5	0.36	4.64	92.8
Z	35	59	M	PU	Stage 4	Sacral region	7	7	9.8	0	9.8	100
AA	36	82	F	Non-pressure chronic ulcer	PT	Popliteal crease right leg	18	2	32.33	16.04	16.29	50.4

DFU—diabetic foot ulcer; F—female; FT—full-thickness; M—male; NF—necrotising fasciitis; NR—not reported; PT—partial-thickness; PU—pressure ulcer; VLU—venous leg ulcer; WG—Wagner grade

Fig 4. Patient K, wound #11: a 76-year-old male patient with a diabetic foot ulcer (DFU) Wagner Grade 2 of left plantar foot to the first metatarsal head. Patient had a documented haemoglobin A1c of 8%, with a wound duration of >8 weeks. First graft application and post debridement **(a)**. After 10 applications with DermaBind, a 88.6% surface area reduction was noted **(b)**

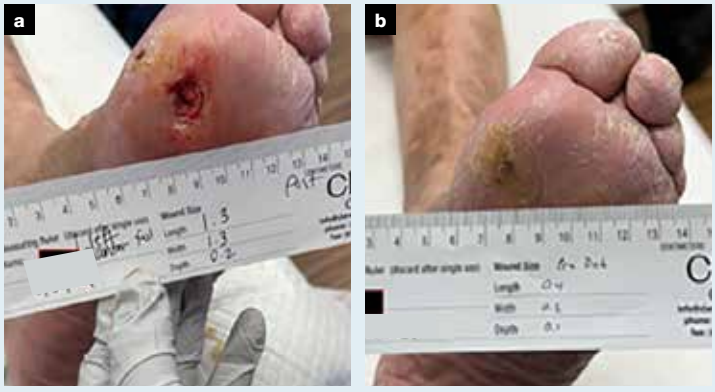


Fig 5. Patient V, wound #28: a 53-year-old male patient with a stage 4 pressure ulcer of the right buttock of nine weeks' duration. Initial visit prior to graft application **(a)**. After 10 applications with DermaBind, a 100% surface area reduction was observed **(b)**

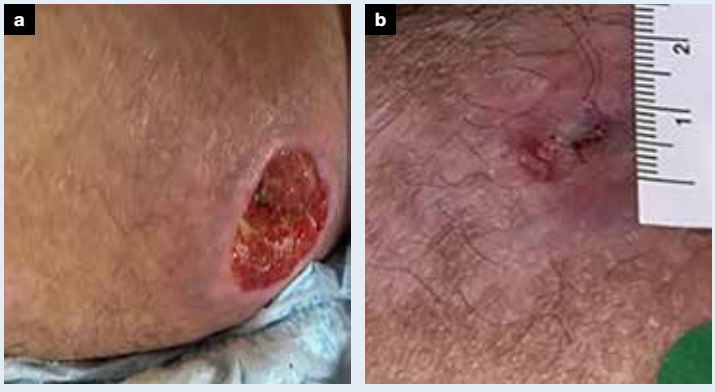
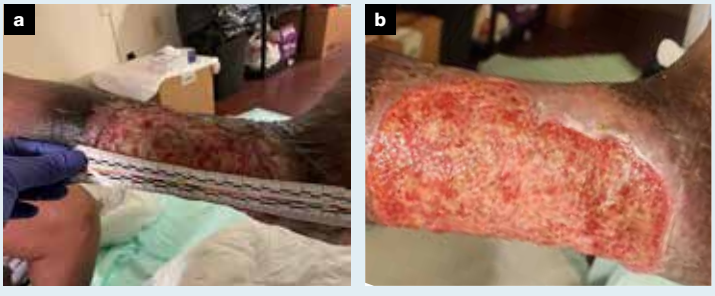


Fig 6. Patient E, wound #5: a 74-year-old female patient with a full-thickness venous leg ulcer to right lower leg of 365 weeks' duration. Initial wound surface area was 460cm^2 **(a)**. After 10 applications with DermaBind, the surface area reduced to 256.5cm^2. This image is used as a reference for part of the wound treated as it could not be captured in one photograph **(b)**



the wound healing process.[4] These complexities are commonly seen in clinical practice and provide valuable perspective in the real-world management of hard-to-heal wounds. Interestingly, despite these important clinical considerations in wound management, there was no distinguishable impact of diabetes control among the patients included in this present case series. For example, Patient AA had an HbA1c of 9.7%; however, their corresponding wound (wound 36) demonstrated a 50.4% reduction in surface area. On the other hand, Patient I had an HbA1c of <8%, but their corresponding wound (wound 9) worsened by 2.63%.

Wound closure observations

Across the cohort, a variety of closure patterns were documented post use of the grafts as wound coverings. Some nine wounds had complete resolution, as reported by the clinician over the observation period, highlighting the complexity of managing hard-to-heal wounds to closure. Several wounds demonstrated progressive reduction in size during the observation, ultimately reaching full closure or a size reduction that no longer warranted the use of a graft as wound covering, as per Local Coverage Determination (LCD) guidelines. These guidelines are a vital resource for providers using skin substitute grafts, and cellular and tissue-based products.[23]

Other wounds remained stable without signs of deterioration and maintained a consistent wound surface without enlargement or breakdown. In certain cases, a striking reduction in wound size was observed. For example, wound 5 was a VLU with a surface area of 460cm^2 that had an onset of seven years prior to first graft application. DermaBind graft was initiated as part of a regimen to prevent lower limb amputation, as reported by the provider. The surface area was reduced to 256.5cm^2 after 10 graft applications, corresponding with a 44.2% surface area reduction.

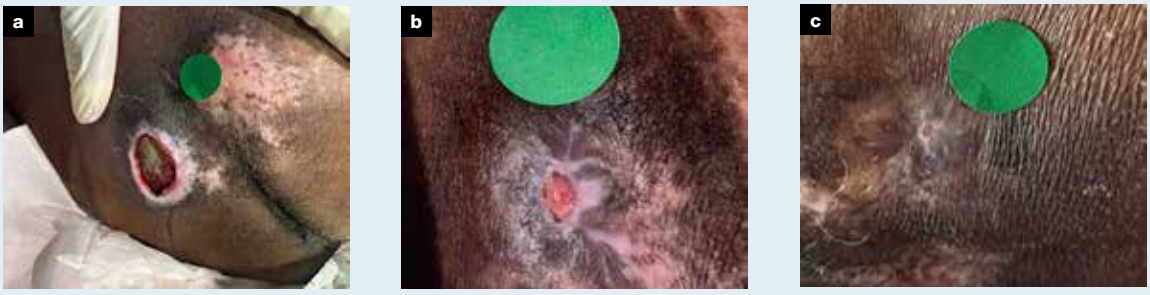
Pain

Pain scores reported by patients varied, with one patient (wound 20) moving from 9 to 0 on the pain scale. While these reports are anecdotal in nature, they illustrate the potential variability of patient experience under similar management strategies. Most cases report the stability of symptoms, with pain neither escalating nor declining significantly over the course of observation. It is important to note that all these observations are reported descriptively. They are not intended to imply a direct causal effect of the grafts but, rather, to provide a full account of clinical outcomes as observed. These accounts also highlight the heterogeneity of patient experience with wound coverings and reinforce the importance of individualised care.

Material utilisation and waste minimisation

An observation of practical importance was the low level of graft wastage documented throughout the series. In most cases, the selection of graft size was closely matched to the dimensions of the wound surface area, resulting in efficient utilisation. Minimal trimming was required and unused remnants were minimal. This careful matching not only reduced waste but also contributed to cost-conscious clinical practice. The

Fig 7. Patient Z, wound #35: a 59-year-old male patient with a Stage 4 pressure ulcer of the sacral region of seven weeks' duration. Initial visit prior to graft application **(a)**. Week 8, seven graft applications completed. Provider ceased graft application and proceeded with standard of care (SoC) **(b)** . Week 11, after three weeks of SoC, 100% re-epithelialisation was reported **(c)**



ability to use grafts efficiently is an important consideration for both providers and healthcare systems, particularly in the management of hard-to-heal wounds where resources are often applied repeatedly over extended periods. There are a variety of strategies that can be used to ensure appropriate use of grafts. It is vital to add that providers paid attention to the number of grafts used, and that they ceased to use placental membrane application as per LCD guidelines (e.g., when a wound size reduced to the point of not warranting further graft application) and continued with the SoC. The providers always chose treatments based on proper use, medical necessity and current LCD guidelines.[23] In this series, some cases (wounds 7, 8, 27, 29, 30 and 35) showed complete wound closure, post graft applications and return to SoC, after only a few visits, and in one case, after only one visit.

Adverse events

Throughout the observation, no adverse events were identified or reported in association with the application of the grafts by the providers. The absence of graft-related complications, such as infections, were consistent across all cases documented. This favourable safety profile is noteworthy given the inherent vulnerability of patients with hard-to-heal wounds, who are often at higher risk of complications due to comorbidities and impaired healing capacities. This reported finding is in line with the lack of significant adverse events reported in the post-marketing period of DermaBind. With >11,000 grafts shipped since June 2022, no adverse events have been reported. The lack of adverse events reporting suggests that, when used as wound coverings and as per manufacturer's instructions for use, the grafts were well-tolerated by patients. While causality cannot be inferred, the uniform absence of untoward outcomes provides reassurance about the acceptability of clinical use in the observed population. Continued vigilance and reporting will remain essential in broader clinical use.

Limitations

This series included a relatively low number of patients with wounds of diverse aetiology. Patients also had numerous comorbidities and were treated in different settings, such as outpatient clinics or at home via mobile care. Another confounding factor was the use of concomitant therapies. These interventions may have positively impacted wound healing and make it impossible to tease out the role played by these or by the graft as a wound covering—albeit this case series replicates what will be observed in real-world evidence and in practice, outside of registered clinical trials. These confounding factors limit comparability, generalisability and causality of the observations. Criteria for healing was not absolutely standardised and relied on the clinical judgement, experience and expertise of the providers in wound care. Complete re-epithelialisation was used to document complete wound closure by the providers. Confirmation of wound recurrence was not captured for this retrospective case series.

Data collection methods were diverse, mirroring real-world evidence capture of data. Cases were submitted using different tools, which introduces a risk of inconsistency, transcription errors and variability in data quality. To diminish these, data were entered then reviewed independently for accuracy as they were collated. Follow-up intervals were different between wounds, even within the same aetiology. Reported outcomes occurred at different timepoints (5, 8 and 11 weeks), without synchronisation across patients, as expected in wounds of varied aetiologies, size and severity, even if all wounds needed to be hard-to-heal in order to be included. This leads to variable exposure to the wound covering and to different numbers of graft applications, with an average of 6.7 weeks of treatment (range: 2–15 weeks).

There were no standardised tools to capture the pain measures across all sites, and the same is true for templates/questionnaires to assess wound tissue type, deepest exposed structure, exudate type and severity, and periwound description. Even though they were not standardised, the questionnaire and templates used by the providers not only shared similarities to validated tools, but they also shared similarities to each other.

Adverse events were collected if documented in the clinical chart; however, since they were not prospectively sought, this could lead to their being under-reported, and an over-estimation of the tolerability of the grafts.

No formal statistical analysis was performed, which is a weakness of the study. Further prospective studies powered to look at efficacy are warranted in the future.

Conclusion

These observations describe the clinical use of DermaBind as a wound covering material consistent with the placental membrane's natural homologous protective role. While complete closure was documented in some cases, stability was maintained in others, and two cases demonstrated worsening. The report of pain going from a level of 9 to 0 over the course of observation was reported in one case, whereas the broader cohort exhibited a more modest pattern of pain control. Minimal waste was observed due to appropriate graft-to-wound matching. The low wastage underscores the feasibility of tailoring graft selection to wound size in real-world practice. Finally, no adverse events were reported.

Importantly, these outcomes are presented descriptively, without inference of causation. The intent is to characterise the experience of a wound covering in practice while maintaining appropriate allograft stewardship to prevent overuse and waste. These findings may inform future protocol development, provide a foundation for future clinical observation, and highlight areas for research, particularly in pain outcomes, wound size progression and resource utilisation. **JWC**

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Reflective questions

- How is DermaBind TL/FM used and tolerated in real-world clinical practice as a wound covering?
- What complexities must clinicians navigate when managing hard-to-heal wounds?
- What characteristics and demographics that impact wound healing are observed in real-world clinical practice?

notes