International Wound Journal

WILEY | IWJ

ORIGINAL ARTICLE OPEN ACCESS

Multi-Centre, Single-Arm, Prospective Evaluation of Ovine Forestomach Matrix for the Treatment of Complex Wounds in the South Asian Population

Salesh K. Soni[1,2] | Ritesh Panda[3] | Mohan G. Kakola[4] | Jasleen Kaur[5] | Brandon A. Bosque[6] | Barnaby C. H. May[6]

[1]Sir Sayajirao General Hospital, Department of Plastic Surgery, Vadodara, India | [2]Baroda Medical College, Vadodara, India | [3]Department of Trauma & Emergency, Division of Burns and Plastic Surgery, All India Institute of Medical Sciences, Bhubaneshwar, Odisha, India | [4]KR Hospital Medical College and Research Institute, Mysuru, Karnataka, India | [5]Department of Dermatology, Sri Guru Ram Das Institute of Medical Science & Research, Amritsar, Punjab, India | [6]Aroa Biosurgery Limited, Auckland, New Zealand

Correspondence: Barnaby C. H. May (barnaby.may@aroa.com)

Received: 21 February 2026 | **Revised:** 4 May 2026 | **Accepted:** 6 May 2026

Keywords: chronic wounds | complex wounds | diabetic foot ulcer | ovine forestomach matrix | wound healing | wound reconstruction

ABSTRACT

Acute and chronic wounds are a significant clinical and economic challenge worldwide. In India, adoption of advanced bioscaffolds remains constrained by cost, limited healthcare access and cultural/religious beliefs. Ovine forestomach matrix (OFM)-based devices have demonstrated utility in wound bed preparation and soft tissue reconstruction for complex wounds. This prospective multi-centre study evaluated a structured treatment algorithm incorporating OFM-based dressings for wound bed preparation, and grafts for reconstruction. Participants with acute or chronic wounds were assessed weekly for adverse events, granulation tissue coverage, volumetric defect fill and wound closure. Enrolled participants ($n = 100$) presented with common complicating comorbidities and included mainly traumatic wounds (41%) and diabetic foot ulcers (17%). Most lesions were chronic (60%), large (median area: 40.1 cm^2) and contaminated (77.0%, CDC Grade II or CDC Grade III). Participants who completed the study ($n = 83$) achieved granulation tissue coverage in a median of 4.0 (3.7, 5.0) weeks. Full closure was reached at a median of 9.0 (IQR: 8.0, 11.0) weeks. No device-related adverse events or complications were observed. Sequential use of OFM dressings and grafts with a defined treatment algorithm safely facilitated wound bed preparation and reconstruction whilst supporting streamlined clinical decision-making and workflow.

1 | Introduction

Worldwide, acute and chronic wounds place a significant burden on healthcare systems, morbidity and overall quality of life. Whilst acute wounds can be difficult to manage, chronic wounds are considered particularly problematic and are a growing concern [1]. Every country globally has been impacted by the prevalence of chronic wounds, including India, where it is estimated that chronic wounds affect 1.57 per 1000, with an even greater proportion in rural communities (2.64 per 1000) [2]. On the Indian subcontinent, chronic wounds most often result from untreated traumatic wounds, partly due to social stigma and lack of healthcare access [3, 4]. Rural communities are particularly affected by limited healthcare access, limited treatment options, lower health literacy, fewer skilled wound care practitioners, poor economic resources and lack of financial assistance programmes [5]. Restricted access to advanced wound care products remains a limitation throughout India [1], and in this void, many individuals may rely on home-based, traditional remedies, which can result in worsening wounds and misdiagnosis [5]. Where access is available, standard of care (SOC) dressings (e.g., cotton gauze, bandages, lint, plasters) are utilised; however, access to advanced bioscaffolds for wound healing and soft tissue regeneration (e.g., skin substitutes or cellular/acellular matrix-like products, CAMPs) is limited [6, 7]. In

Key Points

- Acute and chronic wounds are challenging to treat and place a significant socio-economic burden on developing nations, such as India.
- Ovine forestomach matrix (OFM) is an extracellular matrix bioscaffold available both as a dressing and as a surgical graft.
- The aim of this prospective study was to evaluate the safety and performance of a treatment algorithm using OFM-based devices for wound bed preparation and surgical reconstruction.
- The study demonstrated the safety of OFM-based devices with no device-related post-operative complications and a median time to close of 9.0 weeks in a complex patient cohort.

a developing country like India, the often elevated cost of these products, stringent storage requirements, religious considerations and lack of awareness are all factors that contribute to their limited use [7].

All modern wound medicine starts with the principles of wound bed preparation (WBP), a systematic, evidence-based approach intended to optimise local wound conditions and promote progression towards healing [8–10]. Central to the concept of WBP are techniques and technologies to transition a chronic wound to an acute state. For example, WBP places an emphasis on debridement to remove devitalized tissue and biofilm, thereby reducing physical barriers to healing and restoring a more acute wound environment [11, 12]. Debridement is a powerful tool, along with disinfectants and antimicrobial dressings to reduce bacterial load and associated biofilm present in chronic wounds. Bacterial contamination impairs wound healing through both direct tissue damage (e.g., via secretion of bacterial collagenases), and indirectly through dysregulation of the wound microenvironment [13]. These effects are markedly amplified when bacteria exist within a biofilm [14]. The chronic wound environment is further characterised by persistent inflammation and elevated tissue protease concentrations, most notably, the matrix metalloproteinases (MMPs) and neutrophil elastase (NE) [15, 16]. Elevated tissue proteases in turn impair tissue extracellular matrix (ECM) deposition via enzymatic hydrolysis of the provisional ECM, neutralise ECM-associated growth factors and inhibit cellular migration [17, 18].

Advanced bioscaffolds complement WBP by addressing persistent deficiencies in the chronic wound microenvironment that may not be fully corrected by debridement, infection control and moisture management alone [19, 20]. Decellularized ECM bioscaffolds provide a provisional tissue matrix that replaces lost structural and biochemical cues, facilitating fibroblast and keratinocyte attachment, migration, angiogenesis and granulation tissue formation [21]. In addition, ECM bioscaffolds can counter the hostile inflammatory environment of the wound bed by inhibiting tissue proteases [22], thereby protecting the endogenous tissue ECM and associated growth factors from proteolysis. These bioscaffolds also retain and present matrix-bound growth factors and matricellular proteins in a physiologic context, enhancing cellular responsiveness and promoting wound progression from inflammation to proliferation [21, 23].

Not all acute and chronic wounds will heal with WBP and SOC dressings alone. Depending on wound characteristics—such as the area, depth, volume and presence of exposed vital structures—as well as patient factors, more aggressive surgical intervention to achieve definitive closure may be required. Advanced bioscaffolds are now considered part of the modern reconstructive ladder [24]. Positioned between conventional wound care and definitive surgical reconstruction, advanced bioscaffolds function as intermediate reconstructive options, facilitating wound closure when healing by secondary intention and SOC is insufficient, yet before escalation to more invasive procedures, such as local or free tissue transfer [25]. Bioscaffolds do not replace interventions described in the reconstructive ladder but rather complement these approaches by offering another tool in the armamentarium of the reconstructive surgeon. For example, for complex defects with exposed structures, bioscaffolds provide temporary coverage, promote granulation tissue formation and prepare the wound bed for delayed primary closure or split-thickness skin grafting (STSG) [26]. In this way, bioscaffolds can effectively bridge gaps within the reconstructive ladder and expand options for the reconstructive approach and ultimately closure [21, 26].

Ovine forestomach matrix (OFM) is a decellularized ECM bioscaffold technology that has been commercialised as a range of products engineered for wound healing and soft tissue reconstruction that span the various sites of care. OFM is manufactured from sheep forestomach tissue taken from grass-fed, pasture-raised animals and is a tissue that would otherwise be discarded from New Zealand's agricultural industry, making it a sustainable and cost-efficient technology [27]. Because of its ovine origin, many cultural and religious concerns may be alleviated in communities where porcine or bovine-derived technologies may compromise patients' religious or cultural requirements [27]. An OFM-based 'dressing' was developed for outpatient wound care where it can be used to complement WBP. In this setting, the OFM dressing is typically applied weekly, along with debridement, infection management, appropriate offloading and compression. Additionally, a separate OFM-based 'graft' is available for inpatient reconstruction procedures where the grafts are typically applied once, even in instances of exposed structures, to aid granulation tissue formation prior to closure via tissue transfer or secondary intention. Given the availability of OFM-based devices as both dressings and surgical grafts, we hypothesised that a treatment algorithm could be developed making use of OFM-based devices to complement both WBP and surgical reconstruction. We present the findings of a clinical study evaluating the safety and efficacy of this OFM-based treatment algorithm in the Indian population, where complex acute and chronic wounds were prospectively enrolled.

2 | Materials and Methods

2.1 | General

This prospective, multi-centre, single-arm, post-market study (CTRI registration number: CTRI/2022/01/039714) enrolled participants from July 2022 to January 2025. All patients provided written informed consent for their images and data to be used for

TABLE 1 | Inclusion and exclusion criteria.

Inclusion
• Willing and able to provide written informed consent and to comply with the requirements of the protocol
• Male or female patients aged 18 years or above
• Patients with acute or chronic full thickness wounds, including deep partial burns
Exclusion
• Patients with known sensitivity to ovine (sheep) derived material
• Patients with known sensitivity to ionic silver
• Patients with third degree burns
• Patients with wounds with uncontrolled clinical infection (CDC Contamination Grade = 4), acute inflammation, excessive exudate or bleeding
• Any medical condition or serious intercurrent illness that, in the opinion of the investigator, may make it undesirable for the patient to participate in the study
• Patient is currently participating or has participated in another clinical study within past 30 days prior to enrolment
• Pregnant or lactating women
• Patients with suspected signs and symptoms of COVID-19 or confirmed COVID-19 infection

Abbreviations: CDC = Centres for Disease Control and Prevention; COVID-19 = coronavirus disease of 2019.

research and publication purposes. The study was conducted in accordance with the World Medical Association Declaration of Helsinki ethical guidelines. Ethics approval was granted at each of the four investigational sites (MMC&RI, ref.#: EC138/21; SSG, date: 24/2/22; AIIMS, ref.#: EMF/16/22–23; SGRD, ref.#: SGRD/Ethics/22–28). The primary endpoint was the incidence of treatment emergent adverse events. Secondary endpoints included: proportion (%) of participants with complete wound closure, time (weeks) to complete wound closure, time (weeks) to 100% granulation tissue formation and percent split-thickness skin graft (STSG) take 1 week post-OFM graft application. Normality of the data was assessed via Shapiro–Wilk tests, and descriptive statistics presented as either the mean or median for normal and non-normal data, respectively. Median time to complete healing was estimated from a Kaplan–Meier analysis. All statistics were computed with GraphPad Prism, version 10.6.1.

2.2 | Intervention

Patients with acute or chronic wounds were identified and enrolled according to the inclusion and exclusion criteria outlined in Table 1. If a patient presented with two or more wounds, a single wound was enrolled in the study. Following enrolment, vital signs were recorded, as well as past medical history, clinical laboratory diagnostics, demographics and baseline wound characteristics. Abnormal laboratory test results were identified for patients, where normal ranges were defined as: bacteriuria, 0 CFU/μL; total white blood cell (WBC) count, 4000–10 000/μL; neutrophils, 40% to 70%; plasma glucose, 70 to 160 mg/dL; blood urea nitrogen (BUN), 6 to 20 mg/dL; creatine, 0.55 to 1.02 mg/dL; creatine clearance, > 90 mL/min. As shown in Figure 1, qualifying wounds were treated with a sequential algorithm using three OFM-based products: antimicrobial OFM dressing ('OFM-Ag') (Endoform Antimicrobial, Aroa Biosurgery Limited, Auckland, New Zealand), OFM dressing (Endoform Natural, Aroa Biosurgery Limited, Auckland, New Zealand) and an OFM graft (Myriad Matrix, 3-layer, Aroa Biosurgery Limited, Auckland, New Zealand). Per the treatment algorithm, product selection was guided by the phase of treatment, namely, an initial 'WBP phase' with OFM-Ag and OFM dressings and a latter 'reconstruction phase' with an OFM graft. The sequential treatment algorithm afforded some flexibility to the attending surgeon to make product selection based on the response of the wound at each weekly visit. OFM products were used according to their respective instructions for use. Devices were rehydrated (sterile saline or Ringer's), trimmed to size and placed in the wound bed. The OFM graft was surgically placed with suturing or stapling, according to surgeon preference. Wounds were dressed using a non-adherent contact layer, and secondary dressing (foam or negative pressure wound therapy (NPWT, 125 mmHg)) depending on wound aetiology and institutional protocols. As appropriate, patients received compression or offloading. Throughout the study, wounds were examined weekly and debrided at each visit according to surgeon preference and/or institutional protocols (e.g., sharp, autolytic etc.) to ensure the wound bed was free of slough or necrotic tissue. At each weekly visit, wound dimensions were recorded, photographed and the extent of granulation tissue coverage and fill assessed. Any adverse events (AE), device-related or otherwise, were recorded on a weekly basis or as they presented. All AEs were assessed for severity and causality.

At the initial visit of the WBP phase (TV1, Figure 1), the wound was meticulously debrided, then OFM-Ag applied once per week for 1–2 weeks. Wounds then transitioned to treatment with OFM, applied weekly for 1–2 weeks. After the four-week WBP phase and stabilisation of the wound, the surgeon could opt to apply an OFM graft (GP1, Figure 1) at the start of the reconstruction phase. The OFM graft was allowed to integrate and regenerate granulation tissue within the wound bed. When 100% granulation tissue coverage and/or fill was achieved (GT1, Figure 1), the surgeon could opt for definitive closure using either a STSG (ST1, Figure 1) or via secondary intention, whereby the non-antimicrobial OFM dressing was applied weekly to accelerate epithelialization. If applicable, STSG take (as percentage of the wound area) was assessed 1 week following placement (ST2, Figure 1). All wounds were followed on a weekly basis. Wound closure (WC, Figure 1), defined as 100% re-epithelialization without drainage, was confirmed at a healing confirmation visit (HCV, Figure 1) 2 weeks following closure. A

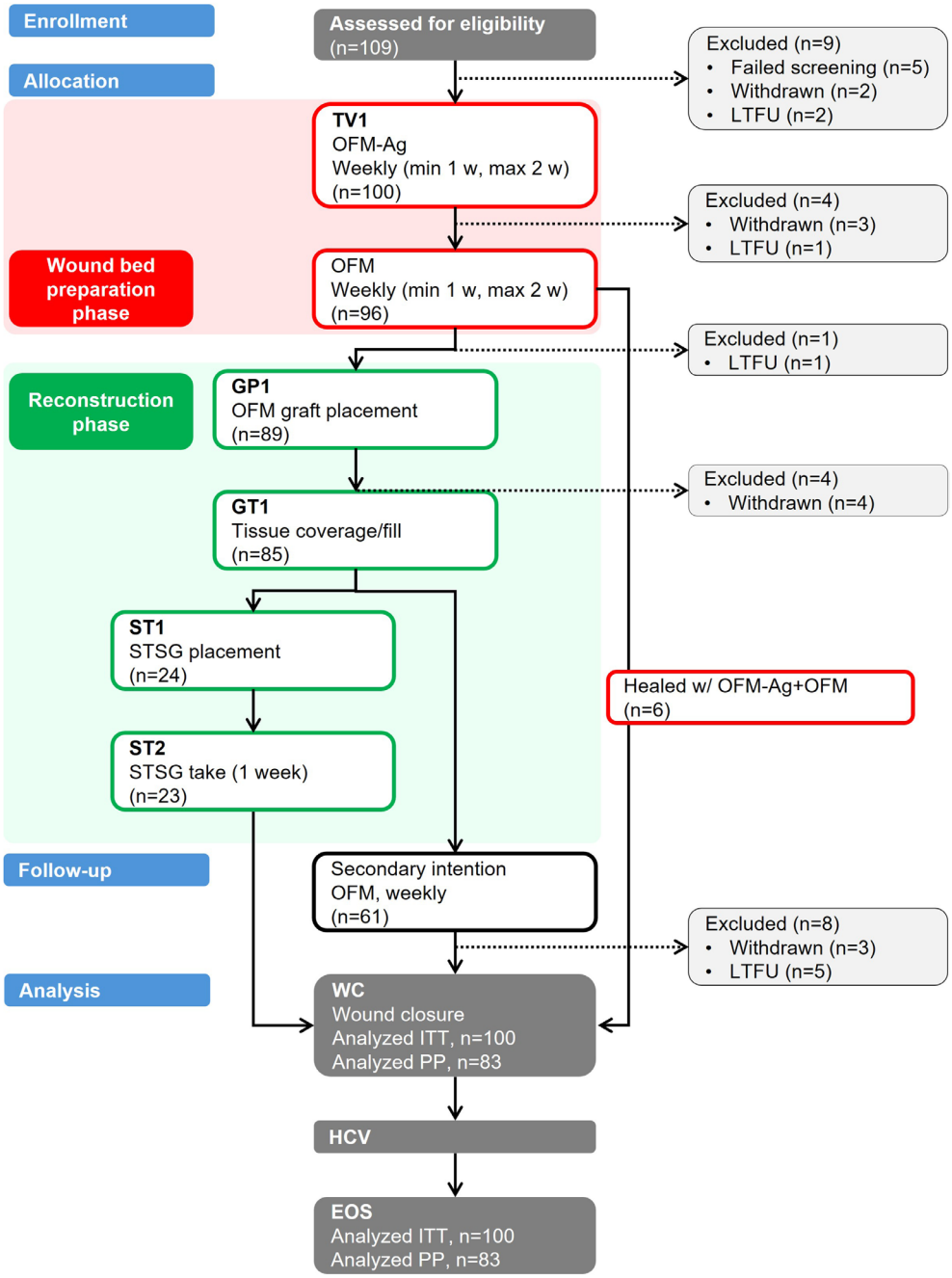

FIGURE 1 | Modified CONSORT diagram. EOS = end of study; GP1 = OFM graft placement; GT1 = 100% granulation tissue formation; HCV = healing confirmation visit; ITT = intention-to-treat; LTFU = lost to follow-up; PP = per-protocol; ST1 = STSG placement; ST2 = 1-week STSG take recording; STSG = split-thickness skin graft; TV1 = first treatment visit; WC = wound closure.

final safety assessment was undertaken for each patient 3 months after the initial treatment (EOS, Figure 1).

3 | Results

3.1 | General

A total of 109 patients were initially screened and 100 participants enrolled in the intention-to-treat (ITT) population (Figure 1). All participants were South Asian in the ITT population, with 74% males and 26% females (Table 2). The median body mass index (BMI) was 23.3 kg/m^2 (IQR: 21.3, 25.5) and the mean age was 42.4 ± 15.5 years old (Table 2). Relevant comorbidities and complicating factors in the ITT population included Type II diabetes (21.0%), hypertension (13.0%), sclerotherapy (3.0%) and prior surgical interventions (42.0%). The median ankle-brachial index (ABI) was 1.1 (1.0, 2.0). Laboratory diagnostics results identified the following proportion of participants with results outside normal range for: bacteriuria (20.0%), total WBC count (19.0%), neutrophils (36.0%), plasma glucose (12.0%), BUN (39.0%), creatinine (33.0%) and creatinine clearance (38.0%).

TABLE 2 | Patient demographics.

Parameter	ITT	PP
Participants, *n*	100	83
Race, *n* (%)		
South Asian	100 (100.0%)	83 (100.0%)
Gender, *n* (%)		
Male	74 (74.0%)	61 (73.5%)
Female	26 (26.0%)	22 (26.5%)
Age, median (IQR), [mean ± SD] (years)	[42.4 ± 15.5], 45.0 (32.5, 57.8)	[45.5 ± 15.8], 45.0 (32.0, 58.0)
BMI, median (IQR), [mean ± SD] (kg/m^2)	23.3 (21.3, 25.5), [23.9 ± 3.6]	23.3 (21.3, 25.3), [23.9 ± 3.5]
Type II diabetes, *n* (%)	21 (21.0%)	19 (22.9%)
Hypertension, *n* (%)	13 (13.0%)	12 (14.5%)
Sclerotherapy, *n* (%)	3 (3.0%)	2 (2.4%)
Cancer history, *n* (%)	3 (3.0%)	3 (3.6%)
Prior surgical intervention, *n* (%)	42 (42.0%)	35 (42.2%)
ABI, median (IQR), [mean ± SD]	1.1 (1.0, 1.2), [1.1 ± 0.1]	1.1 (1.0, 1.1), [1.1 ± 0.1]
Bacteriuria, *n* (% patients outside normal range)	20 (20.0%)	19 (22.9%)
Total WBC count, *n* (% patients outside normal range)	19 (19.0%)	17 (20.5%)
Neutrophils, *n* (% patients outside normal range)	36 (36.0%)	28 (33.7%)
Plasma glucose, *n* (% patients outside normal range)	12 (12.0%)	10 (12.0%)
BUN, *n* (% patients outside normal range)	39 (39.0%)	30 (36.1%)
Creatinine, *n* (% patients outside normal range)	33 (33.0%)	30 (36.1%)
Creatinine clearance, *n* (% patients outside normal range)	38 (38.0%)	32 (38.6%)

Abbreviations: ABI = ankle-brachial index; BMI = body mass index; BUN = blood urea nitrogen; IQR = interquartile range; ITT = intention-to-treat population; *n* = sample size; PP = per-protocol population; SD = standard deviation; WBC = white blood cell.

At the time of enrollment, in the ITT population, 60.0% of wounds were considered chronic (> 4 weeks and unresponsive to standard of care) and 40.0% of wounds were acute, with a median wound age of 4 weeks (IQR: 3, 8) (Table 3). Treated wounds had a median starting area of 40.1 cm^2 (IQR: 18.0, 97.5) (Table 3). The defects had variable etiologies, and included: traumatic (41.0%), diabetic foot ulcers (DFU) (17.0%) and soft tissue infections (15.0%). Of the DFUs, the majority (82.3%) were Wagner 3 or 4. The majority of wounds affected the lower extremity (82.0%), with 18.0% presenting with exposed structures and 26.0% with tunnelling or undermining (median depth: 10 mm (IQR: 10, 20)). The majority of wounds (77.0%) were contaminated (CDC Grade II or III) (Table 3). Amongst the PP population, 36.1% of patients received compression, whilst 31.3% received offloading and 4.8% were concomitantly with NPWT (Table 3).

After the initial treatment visit (TV1), several participants failed to complete the study, either being lost to follow-up (LTFU) ($n = 7$) or withdrawn ($n = 10$), leaving $n = 83$ in the per-protocol (PP) population (Figure 1). Amongst the PP population, $n = 6$ wounds (7.2%) received only OFM-Ag + OFM dressings ('WBP Group', Table 4) and closed without the need for reconstruction with an OFM graft. The remaining $n = 77$ wounds in the PP cohort received an OFM graft ('Reconstruction Group', Table 4). The OFM graft was surgically placed in the wound bed and allowed to integrate and regenerate granulation tissue. Once complete granulation tissue coverage and fill had been achieved in these wounds, $n = 59$ (71.1%) were closed via secondary intention using weekly application of OFM dressing and the remaining $n = 24$ (28.9%) were closed via application of a STSG.

The median time from first treatment visit (TV1) to complete granulation tissue coverage (GT1) for all wounds that received an OFM graft was 4.0 (IQR: 3.7, 5.0) weeks, including time spent during the WBP phase (Table 4). The median time from graft placement (GP1) to complete granulation tissue coverage (GT1) was 1.1 (IQR: 1.1, 2.1) weeks. Overall, 24 (28.9%) wounds received a STSG, with a median STSG take of 95% (IQR: 90, 100).

The median time to wound closure (TV1 to WC) for the ITT population was 10.1 (95% confidence interval, CI: 8.4, 11.4) weeks and 9.0 (95% CI: 8.0, 11.0) weeks for the PP population, as

TABLE 3 | Wound characteristics.

Parameter	ITT	PP
Participants, *n*	100	83
Wound age, median (IQR), [mean ± SD] (weeks)	4 (3, 8), [17.6 ± 45.0]	4 (3, 8), [11.8 ± 27.5]
< 4 weeks, *n* (%)	40 (40.0%)	36 (43.4%)
> 4 weeks, *n* (%)	60 (60.0%)	47 (56.6%)
Wound area, median (IQR), [mean ± SD] (cm^2)	40.1 (18.0, 97.5), [84.9 ± 142.0]	39.0 (15.0, 81.0), [73.4 ± 104.9]
Wound type, *n* (%)		
Trauma	41 (41.0%)	37 (44.6%)
DFU	17 (17.0%)	16 (19.3%)
Wagner 2	2 (11.8%)	2 (12.5%)
Wagner 3	9 (52.9%)	9 (56.3%)
Wagner 4	5 (29.4%)	5 (31.3%)
Soft tissue infections	15 (15.0%)	13 (15.7%)
VLU (CEAP6)	9 (9.0%)	5 (6.0%)
Surgical	7 (7.0%)	6 (7.2%)
Burns (DPT)	5 (5.0%)	4 (4.8%)
Donor site	5 (5.0%)	2 (2.4%)
PI (Grade IV)	1 (1.0%)	—
Wound location, *n* (%)		
Lower extremity	82 (82.0%)	66 (79.5%)
Upper extremity	16 (16.0%)	15 (18.1%)
Trunk	2 (2.0%)	2 (2.4%)
Exposed structures, *n* (%)	18 (18.0%)	16 (19.3%)
Tunnelling or undermining present, *n* (%)	26 (26.0%)	21 (25.3%)
Tunnel depth, median (IQR), [mean ± SD] (mm) (*n*)	10 (10, 20), [13 ± 8] (26)	13 (10, 20), [13 ± 9] (21)
CDC contamination score, *n* (%)		
Grade I—clean	23 (23.0%)	18 (21.7%)
Grade II—clean-contaminated	74 (74.0%)	62 (74.7%)
Grade III—contaminated	3 (3.0%)	3 (3.6%)
Compression, *n* (%)		30 (36.1%)
Offloading, *n* (%)		26 (31.3%)
NPWT, *n* (%)		4 (4.8%)

Abbreviations: CDC = Centers for Disease Control and Prevention; CEAP6 = Clinical, Aetiology, Anatomic and Pathophysiologic 6 classification, 'active leg ulcer'; DFU = diabetic foot ulcer; DPT = deep partial thickness burn; IQR = interquartile range; ITT = intention-to-treat population; *n* = sample size; NPWT = negative pressure wound therapy; PI = pressure injury; PP = per-protocol population; SD = standard deviation; VLU = venous leg ulcer.

determined from Kaplan–Meier survival analysis (Figure 2). For the wounds that received only OFM-Ag + OFM ($n = 6$), the median time to closure was 3.2 (IQR: 2.9, 4.6) weeks. In the reconstruction group, which only included wounds that received an OFM graft, the median time from OFM graft placement (GP1) to closure was 6.0 (IQR: 4.0, 11.0) weeks. Of the $n = 59$ (71.1%) wounds in the reconstructive group that closed via secondary intention, the median time to closure was 10.0 (IQR: 7.1, 14.0) weeks. The remaining wounds ($n = 24$) that received a STSG had a median time to closure of 9.5 (IQR: 6.0, 14.5) weeks. The incidences of wound closure in the ITT and PP populations at 12 weeks were 57% and 68.7%, respectively, and were 83% and 100% over the entire time of the study, respectively.

For the PP population, the median number of product applications per patient was 8 (IQR: 5, 12), inclusive of all OFM devices used (Table 5). Across the PP population, the median application of OFM-Ag + OFM dressings was 6 (IQR: 4, 10), and for the OFM graft, the median product application was 1 (IQR: 1, 2).

No device-related AEs were observed, and no moderate or serious AEs were reported (Table 6). A total of 6 (6%) mild AEs occurred, of which 4 (4%) were related to changes to the peri-wound skin. Two (2%) participants reported ulcerations at 3 and 9 weeks after wound closure, but these were not a recurrence of the index wound.

3.2 | Case Example 1

A 59-year-old female with a BMI of 26, and medical history of hypertension, type II diabetes with several abnormal laboratory results, including: 73.80% neutrophils, 5.56 mg/dL BUN, 95.89 mL/min creatinine clearance and 32934 CFU/μL of urine. The participant presented with a clean-contaminated (CDC Grade II) chronic diabetic ulcer of 9 weeks on the left foot (6 × 6 cm) with serous drainage (Figure 3A, pre-debridement). Treatment commenced (TV1, Figure 3B) with two weekly applications of OFM-Ag. On Day 13 (Figure 3C), the wound received a single application of OFM dressing (Figure 3D), then on Day 19 (Figure 3E) a single OFM graft was placed with surgical staples (Figure 3F). Granular tissue coverage and fill were achieved at Day 26 (not shown), and due to patient considerations closure via secondary intention was elected using weekly applications of OFM dressing to aid epithelialization.

TABLE 4 | Healing outcomes.

Parameter	ITT	PP
Participants, *n*	100	83
Treatment		
WBP Group (OFM-Ag + OFM only), *n* (%)	11 (11.0%)	6 (7.2%)
Reconstruction Group (OFM-Ag + OFM + OFM graft), *n* (%)	89 (89.0%)	77 (92.8%)
Closure method		
Secondary intention, *n* (%)	59 (59.0%)	59 (71.1%)
STSG, *n* (%)	24 (24.0%)	24 (28.9%)
Time to granulation tissue coverage		
TV1 to GT1, median (IQR), [mean ± SD] (weeks) (*n*)	—	4.0 (3.7, 5.0), [4.5 ± 1.5] (77)
GP1 to GT1, median (IQR), [mean ± SD] (weeks) (*n*)	—	1.1 (1.1, 2.1), [1.5 ± 1.1] (77)
Time to STSG		
GP1 to ST1, median (IQR), [mean ± SD] (weeks) (*n*)	—	2.1 (1.1, 6.1), [4.2 ± 5] (24)
STSG Take		
ST1 take, median (IQR), [mean ± SD] (%) (*n*)	—	95 (90, 100), [90.2 ± 14.7] (23)
Time to Close—all wounds		
TV1 to WC, median (95% CI) (weeks)[a]	10.1 (8.4, 11.4) (100)	9.0 (8.0, 11.0) (83)
Time to close—WBP group		
TV1 to WC, median (IQR), [mean ± SD] (weeks) (*n*)	—	3.2 (2.9, 4.6), [3.6 ± 1.1] (6)
Time to close—reconstruction group		
GP1 to WC, median (IQR), [mean ± SD] (weeks)	—	6.0 (4.0, 11.0), [7.9 ± 5.4] (77)
Secondary intention group, TV1 to WC, median (IQR), [mean ± SD] (weeks) (*n*)	—	10.0 (7.1, 14.0), [10.7 ± 5.5] (59)
STSG group, TV1 to WC, median (IQR), [mean ± SD] (weeks) (*n*)	—	9.5 (6.0, 14.5), [10.6 ± 5.6] (24)
12-Week closure		
Closure incidence (%) at 12 weeks	57 (57.0%)	57 (68.7%)
Incidence of closure		
Closure incidence (%), TV1 to WC	83 (83.0%)	83 (100.0%)

Abbreviations: CI = confidence interval; GP1 = OFM graft placement; GT1 = 100% granulation tissue formation; ITT = intention-to-treat; IQR = interquartile range; LTFU = lost to follow-up; *n* = sample size; PP = per-protocol; SD = standard deviation; ST1 = STSG placement; ST2 = 1-week STSG take recording; STSG = split-thickness skin graft; TV1 = first treatment visit; WC = wound closure; WBP = wound bed preparation.
[a]Determined from Kaplan–Meier survival analysis.

The ulcer was deemed closed at 145 days (Figure 3G). Healing was confirmed 2 weeks after, and a safety follow-up was performed at Day 236 (Figure 3H). The patient had a positive treatment course with no complications or adverse events. Over the course of treatment, the ulcer received 3 OFM-Ag + OFM during the WBP phase, a single OFM graft, then 11 OFM dressings to aid closure via secondary intention.

3.3 | Case Example 2

A 42-year-old male with a BMI of 25, an ABI of 0.92 and a BUN level of 5.10 mg/dL with Type II diabetes presented with a chronic, post-surgical wound on the dorsum of the left foot with exposed bone. At screening, the wound had been present for 8 weeks and was classified as clean-contaminated and with serous drainage. The defect measured 15 × 9 cm, with a depth of 2 mm. The day of the start of treatment (TV1, Figure 4A), the wound was treated with OFM-Ag, followed by a second application on Day 5 and a single application of OFM dressing on Day 12. On Day 20, an OFM graft was applied and secured with staples. On Day 35 (15 days after OFM graft placement), the wound was deemed ready for STSG transplantation. On Day 42, the 1-week STSG take was 90% (Figure 4B), and full re-epithelialization was achieved on Day 75, corresponding to 40 days post-STSG (Figure 4C). No complications or recurrences

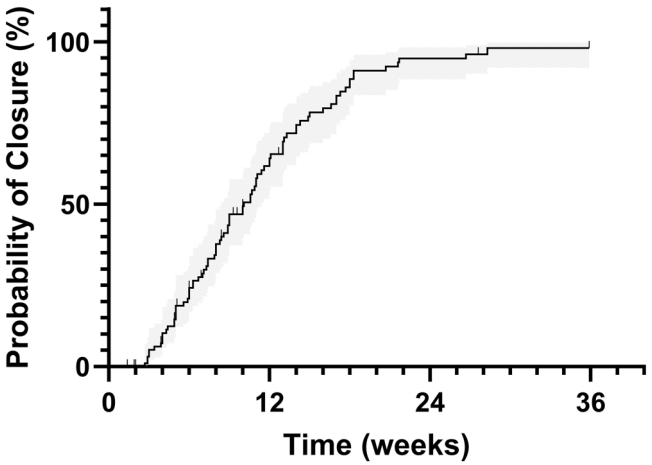

FIGURE 2 | Kaplan–Meier survival analysis for the ITT population ($n = 100$). Tick marks represent censored wounds. 95% Confidence intervals are indicated in grey.

TABLE 5 | Product applications.

Parameter	PP
Total OFM-Ag + OFM applications, median (IQR), [mean ± SD]	6 (4, 10), [8 ± 5]
Total OFM graft applications, median (IQR), [mean ± SD]	1 (1, 2), [1 ± 1]
Total product applications, median (IQR), [mean ± SD]	8 (5, 12), [9 ± 5]

Abbreviations: IQR = interquartile range; OFM = ovine forestomach matrix; PP = per-protocol; SD = standard deviation.

TABLE 6 | Safety assessment.

Parameter	Value
Total AEs, *n* (%)	6 (6.0%)
AEs related to device, *n* (%)	—
Mild AEs, *n* (%)	6 (6.0%)
Moderate AEs, *n* (%)	—
Severe AEs, *n* (%)	—
AE type and incidence, *n* (%)	
Ulceration (not recurrence of index wound), *n* (%)	2 (2.0%)
Pain, *n* (%)	1 (1.0%)
Dry skin, *n* (%)	1 (1.0%)
Pruritus, *n* (%)	1 (1.0%)
Skin exfoliation, *n* (%)	1 (1.0%)

Abbreviations: AE = adverse event; *n* = sample size.

were noted through the safety follow-up period on Day 175 (Figure 4D). Over the course of the treatment, the defect received 3 OFM-Ag + OFM during the WBP preparation phase, followed by a single OFM graft and STSG.

4 | Discussion

In this multi-centre study, wounds were managed with a treatment algorithm where WBP and surgical reconstruction were complemented with OFM-based devices. The primary endpoint of the study was the incidence of treatment-emergent adverse events, made more challenging by the complexity of the patient population and the index wounds enrolled. Many participants presented with complicating comorbidities that would otherwise predispose these individuals to poor healing outcomes and pose an increased risk of adverse events, including amputation and infection. For example, many participants in the study presented with Type II diabetes, hypertension, abnormal kidney function (as evidenced by abnormal laboratory values for creatinine concentrations, creatine clearance rates and BUN concentrations) and altered inflammatory/infection markers (e.g., total WBC count, neutrophils, bacteriuria). Additionally, many of the index wounds were complicated by wound age, exposed vital structures, tunnelling or undermining and gross contamination. Even in the face of these challenges, no device-related AEs were recorded during the study, which is consistent with the low complication rates previously observed with OFM-based devices. Further, no infections were reported across the cohort, a finding that is consistent with prior retrospective and prospective studies evaluating OFM-based devices in complex wound and reconstruction applications. For example, previous retrospective and prospective studies of OFM in limb salvage have reported zero infections [28, 29]. Similarly, in the reconstruction of traumatic soft tissue defects, reported complication rates ranged from zero [30] to 6.6% superficial infections [31].

The treatment algorithm presented in Figure 1 was developed to complement the principles of WBP and surgical reconstruction with OFM-based devices. Whilst advanced bioscaffolds are commonly used for outpatient wound care and inpatient surgical reconstruction, to our knowledge, this is the first attempt to structure a treatment algorithm making use of advanced bioscaffolds from day one of SOC wound management through to surgical reconstruction and ultimately wound closure. Much has been written about the use of OFM dressings as part of WBP [10, 32–34] to provide a provisional ECM scaffold, correct the pro-inflammatory phenotype and address bacterial colonisation. Early research demonstrated that soluble components of OFM inhibit tissue proteases, including many of the MMPs (e.g., MMP-1, −2, −3, −9 and −13) and NE [35]. Additionally, OFM is known to include many naturally occurring ECM-associated anti-inflammatory proteins (e.g., TIMP-4, serpin H1, B10, B12, alpha-2 macroglobulin and annexin A1) [36]. More recently, OFM-Ag containing ionic silver was introduced to provide another tool for early wound management and WBP. OFM-Ag has been shown to have broad-spectrum antimicrobial activity against a range of gramme-positive, gramme-negative bacteria, as well as yeast and mould, including some drug-resistant strains [37]. In vitro efficacy testing demonstrated that OFM-Ag has antimicrobial activity that lasts up to 7 days; additionally, the dressing has been shown to inhibit biofilm formation in vitro [37]. When used early and in combination with standard WBP, including debridement, moisture balance and bacterial control, OFM dressings may help set the stage for healing. In this study, all wounds responded well to management with OFM dressings during the WBP phase, with six of the wounds ('WBP

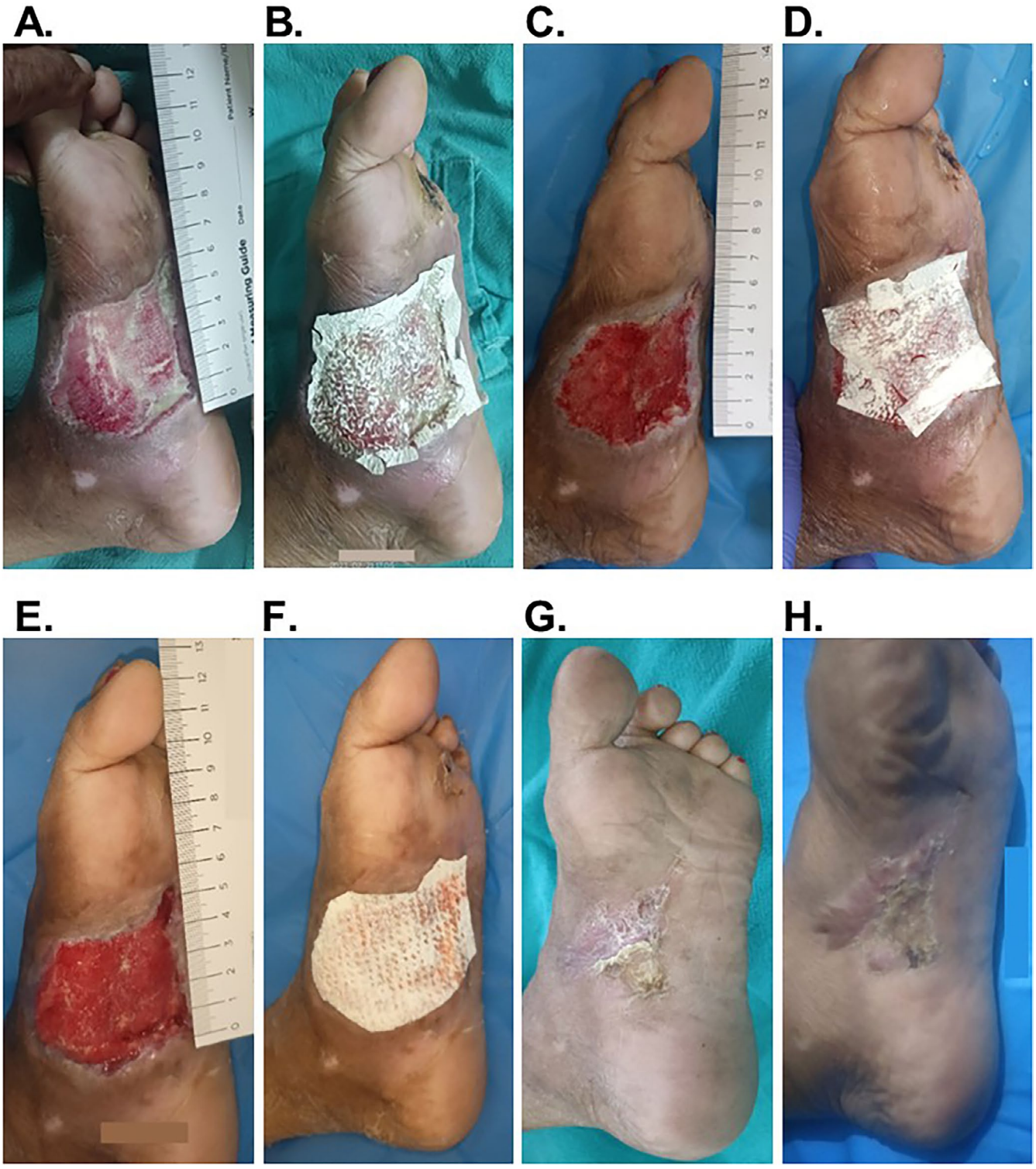

FIGURE 3 | Case example 1. (A) Presentation at TV1 pre-debridement. (B) Post-application of the first OFM-Ag dressing on TV1. (C) Wound appearance on Day 13. (D) Post-application of the OFM dressing on Day 13. (E) Wound appearance on Day 19. (F) Post-application of OFM graft on Day 19. (G) Wound closure on Day 145. (H) Safety follow-up on Day 236.

Group', Table 4) achieving wound closure within ~3 weeks with OFM-Ag + OFM alone and not requiring further reconstructive intervention.

Seventy-seven wounds in the PP population progressed to the reconstructive phase and received at least one OFM graft, with definitive closure achieved either via secondary intention (using weekly OFM dressing applications) or STSG application. The versatility in the reconstruction approach was critical, since not all patients were ideal candidates for staged reconstruction due to donor site limitations and patient history (smoking status, comorbidities, surgery reluctance and risk of nonadherence to wound care) [38–41]. The median time from OFM graft placement to complete granulation tissue coverage and/or fill was

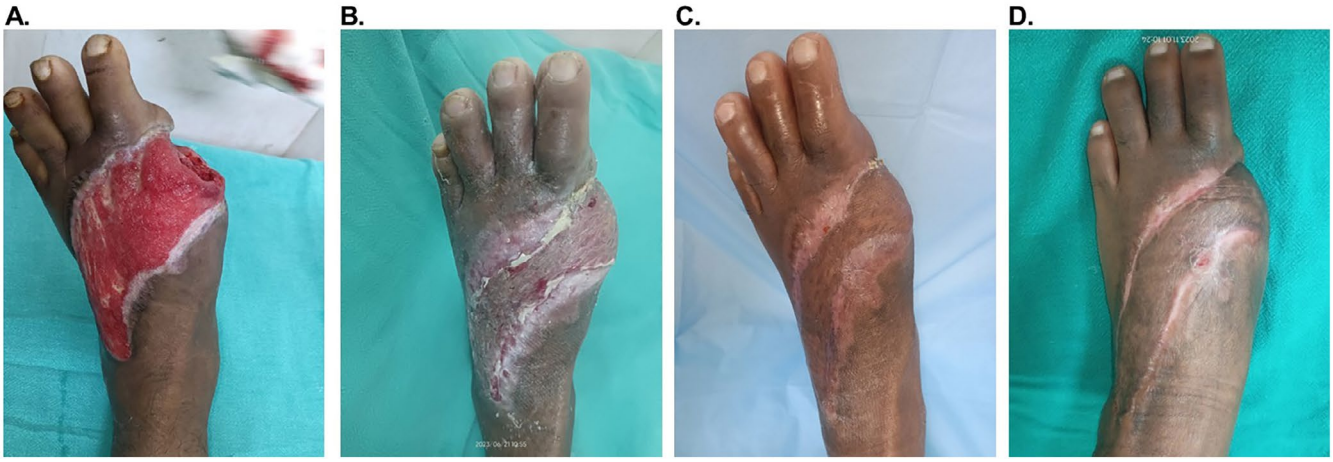

FIGURE 4 | Case example 2. (A) Wound presentation at TV1 pre-debridement. (B) Day 42, 1-week post-STSG. (C) Wound closure on Day 75, 40 days post-STSG. (D) Safety follow-up on Day 175.

1.1 (IQR:1.1, 2.1) weeks. This is slightly shorter than previous reports, where the time to granulation tissue formation using an OFM graft has been reported from 3.3 ± 1.3 weeks [30] to 5.5 ± 0.4 weeks [29]. This may reflect the positive impact of including OFM dressings in the WBP phase on graft repopulation and granulation tissue formation, or differences in the complexity of the treated soft tissue defects. Where the OFM graft was used to stage reconstruction, the median time to STSG grafting was 2.1 (IQR: 1.1, 6.1) weeks and STSG take was ~95% across this cohort, supporting the vitality of the underlying granular bed.

When considering all wounds in the PP population, the overall time to heal was 9.0 (IQR: 8.0, 11.0) weeks. Though direct comparisons to prior published studies are challenging given confounding variables, it is valuable to compare our healing outcomes with prior reports on the use of OFM devices in both outpatient wound care and inpatient surgical reconstruction. For example, a large, real-world study reported a mean time to close of 14.6 ± 0.5 weeks across 1150 DFUs where OFM dressings were used as part of standard of care wound treatment in the outpatient setting [42]. Studies in surgical reconstruction of lower extremity defects using an OFM graft reported mean times to heal of 13.7 ± 6.9 weeks [28] and ~28 weeks [29]. However, the latter studies included significantly challenging soft tissue defects; for example, over 95% of the cohort reported by Lawlor et al. had one or more predictors of amputation and the majority of defects were grossly contaminated (~95%, CDC Grade III) [29].

Wound care on the Indian subcontinent has some unique challenges. As a developing economy, the Indian population does not have ready access to advanced bioscaffolds for wound repair and reconstruction. Widespread access is in part limited by cost, but the education and training needed to effectively use these types of products must also be considered. Cost of care using bioscaffolds is mainly driven by the costs to operationalise healing with these types of technologies, as well as post-operative complications. For example, many of the advanced bioscaffold grafts require repeat weekly surgical re-application. In contrast, our findings herein showed a median OFM graft application of 1 (IQR: 1, 2), and a median total OFM product application across the entire treatment algorithm was 8 (IQR: 5, 12). This has a direct impact on the cost of care by reducing the need for repeat visits to the operating room. Additionally, and as others have shown with OFM grafts, complications associated with these devices are rare. As such, costs to medically or surgically intervene to address device-related complications (e.g., infection, graft loss) are reduced. Lastly, when considering a treatment algorithm, we were mindful of the level of training and expertise required to implement care using OFM-based devices. Across the four participating sites, both the investigators and the wider wound care teams found OFM-based devices' easy to use, since special storage or handling conditions were not required, and thus complemented existing clinical practise guidelines. Overall, the inclusion of a treatment algorithm enabled partial treatment standardisation, enhanced treatment workflow and reduced uncertainty with respect to product selection.

5 | Limitations

As a single-arm prospective study, the outcomes are limited by the absence of randomisation and comparison to a control cohort. Further studies could seek to include a control arm, though identifying the most appropriate control treatment may be challenging since the algorithm spans from initial wound management through to surgical reconstruction. Lack of rigid treatment standardisation further limits the generalizability of the findings. Additionally, in the current study we did not specifically exclude acute wounds nor limit treatment to a single wound aetiology.

6 | Conclusion

We have developed and implemented an end-to-end treatment algorithm whereby OFM-based devices, including dressings and grafts, were used to complement both WBP and surgical reconstruction leading to wound closure. Across the 100 participants prospectively enrolled in the study, no device-related complications were reported. The study demonstrated that OFM-based devices could be used alongside WBP to heal wounds, and/or as a precursor for staged reconstruction with an OFM graft, achieving overall healing in ~9 weeks across a complex wound cohort.

Acknowledgements

The authors acknowledge Nina Slabkevich, MD (Clinical Research Associate, Aroa Biosurgery Limited) and CBCC Global Research (Ahmedabad, Gujarat, India) for their contribution to the execution of the study. The authors would also like to acknowledge Giulia Crosio, PhD (Medical Writer, Aroa Biosurgery Limited) for the preparation of this manuscript.

Funding

Funding for this study was provided by Aroa Biosurgery Limited.

Ethics Statement

The study was conducted in accordance with the World Medical Association Declaration of Helsinki ethical guidelines. Ethics approval was granted at each of the four investigational sites (KR Hospital Medical College and Research Institute, ref.#: EC138/21; Sir Sayajirao General Hospital, date: 24/2/22; All India Institute of Medical Sciences, ref.#: EMF/16/22–23; Sri Guru Ram Das Institute of Medical Science & Research, ref.#: SGRD/Ethics/22–28).

Consent

All patients provided written informed consent for their images and data to be used for research and publication purposes.

Conflicts of Interest

Brandon A. Bosque and Barnaby C. H. May are employees of Aroa Biosurgery Limited.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

References

1. D. Deshmukh, G. Maheshwari, M. Pruthi, P. Mujawdiya, S. Gupta, and S. Sagar, "Data Driven Evidence-Based Wound Care in Developing Countries: Challenges, Requirements and Significance," *Wounds Asia* 5, no. 1 (2022): 6–10.

2. A. Sharma, V. Srivastava, R. Shankar, A. K. Yadav, M. A. Ansari, and S. K. Gupta, "Epidemiological Profile of Chronic Wounds in an Indian Population: A Community-Based Cross-Sectional Observational Study," *Cureus* 16, no. 9 (2024): e68684, https://doi.org/10.7759/cureus.68684.

3. N. Gupta, S. K. Gupta, V. K. Shukla, and S. P. Singh, "An Indian Community-Based Epidemiological Study of Wounds," *Journal of Wound Care* 13, no. 8 (2004): 323–325, https://doi.org/10.12968/jowc.2004.13.8.26657.

4. A. Sharma, "Epidemiological Profile of Chronic Wounds in a Rural and Urban Community of an Indian District: A Feasibility Study Trial," *Formosan Journal of Surgery* 56, no. 5 (2023): 167–169, https://doi.org/10.1097/fs9.0000000000000067.

5. E. Haesler, "Local Resource Wound Treatments: Evidence Summaries for Resource Limited Settings," *Wounds International* 14, no. 2 (2023): 16–22.

6. R. K. Chalannavar, M. S. Divakar, A. Kumar, et al., "Wound Healing: Traditional Plant Based and Modern Wound Dressing-An Update," *International Journal of Biological and Pharmaceutical Sciences Archive* 9, no. 02 (2025): 044–066.

7. A. K. Singh and Y. R. Shenoy, "Skin Substitutes: An Indian Perspective," *Indian Journal of Plastic Surgery* 45, no. 2 (2012): 388–395.

8. J. Panuncialman and V. Falanga, "The Science of Wound Bed Preparation," *Surgical Clinics of North America* 89, no. 3 (2009): 611–626, https://doi.org/10.1016/j.suc.2009.03.009.

9. G. S. Schultz, R. G. Sibbald, V. Falanga, et al., "Wound Bed Preparation: A Systematic Approach to Wound Management," *Wound Repair and Regeneration* 11 (2003): S1–S28.

10. R. G. Sibbald, J. A. Elliott, R. Persaud-Jaimangal, et al., "Wound Bed Preparation 2021," *Advances in Skin & Wound Care* 34, no. 4 (2021): 183–195, https://doi.org/10.1097/01.ASW.0000733724.87630.d6.

11. R. G. Sibbald, D. Williamson, H. L. Orsted, et al., "Preparing the Wound Bed—Debridement, Bacterial Balance, and Moisture Balance," *Ostomy/Wound Management* 46, no. 11 (2000): 14–22.

12. R. D. Wolcott, J. P. Kennedy, and S. E. Dowd, "Regular Debridement Is the Main Tool for Maintaining a Healthy Wound Bed in Most Chronic Wounds," *Journal of Wound Care* 18, no. 2 (2009): 54–56, https://doi.org/10.12968/jowc.2009.18.2.38743.

13. W. Costerton, R. Veeh, M. Shirtliff, M. Pasmore, C. Post, and G. Ehrlich, "The Application of Biofilm Science to the Study and Control of Chronic Bacterial Infections," *Journal of Clinical Investigation* 112, no. 10 (2003): 1466–1477, https://doi.org/10.1172/JCI20365.

14. S. L. Percival, S. M. McCarty, and B. Lipsky, "Biofilms and Wounds: An Overview of the Evidence," *Advances in Wound Care* 4, no. 7 (2015): 373–381, https://doi.org/10.1089/wound.2014.0557.

15. N. J. Trengove, S. R. Langton, and M. C. Stacey, "Biochemical Analysis of Wound Fluid From Nonhealing and Healing Chronic Leg Ulcers," *Wound Repair and Regeneration* 4, no. 2 (1996): 234–239.

16. N. J. Trengove, M. C. Stacey, S. MacAuley, et al., "Analysis of the Acute and Chronic Wound Environments: The Role of Proteases and Their Inhibitors," *Wound Repair and Regeneration* 7, no. 6 (1999): 442–452, https://doi.org/10.1046/j.1524-475x.1999.00442.x.

17. G. S. Schultz, G. P. Ladwig, and A. Wysocki, "Extracellular Matrix: Review of Its Roles in Acute and Chronic Wounds," *World Wide Wounds* 2005 (2005): 1–8.

18. G. S. Schultz and A. Wysocki, "Interactions Between Extracellular Matrix and Growth Factors in Wound Healing," *Wound Repair and Regeneration* 17, no. 2 (2009): 153–162, https://doi.org/10.1111/j.1524-475X.2009.00466.x.

19. R. G. Sibbald, H. L. Orsted, P. M. Coutts, and D. H. Keast, "Best Practice Recommendations for Preparing the Wound Bed: Update 2006," *Advances in Skin & Wound Care* 20, no. 7 (2007): 390–405, https://doi.org/10.1097/01.ASW.0000280200.65883.fd.

20. N. J. Turner and S. F. Badylak, "The Use of Biologic Scaffolds in the Treatment of Chronic Nonhealing Wounds," *Advances in Wound Care* 4, no. 8 (2015): 490–500, https://doi.org/10.1089/wound.2014.0604.

21. S. F. Badylak, D. O. Freytes, and T. W. Gilbert, "Extracellular Matrix as a Biological Scaffold Material: Structure and Function," *Acta Biomaterialia* 5, no. 1 (2009): 1–13, https://doi.org/10.1016/j.actbio.2008.09.013.

22. D. Kolahreez, L. Ghasemi-Mobarakeh, F. Liebner, et al., "Approaches to Control and Monitor Protease Levels in Chronic Wounds," *Advanced Therapeutics* 7, no. 5 (2024): 2300396, https://doi.org/10.1002/adtp.202300396.

23. S. F. Badylak, "Xenogeneic Extracellular Matrix as a Scaffold for Tissue Reconstruction," *Transplant Immunology* 12, no. 3–4 (2004): 367–377, https://doi.org/10.1016/j.trim.2003.12.016.

24. A. Palackic, R. P. Duggan, M. S. Campbell, et al., "The Role of Skin Substitutes in Acute Burn and Reconstructive Burn Surgery: An Updated Comprehensive Review," *Seminars in Plastic Surgery* 36, no. 1 (2022): 33–42, https://doi.org/10.1055/s-0042-1743455.

25. J. E. Janis, R. K. Kwon, and C. E. Attinger, "The New Reconstructive Ladder: Modifications to the Traditional Model," *Plastic and Reconstructive Surgery* 127 (2011): 205S–212S, https://doi.org/10.1097/PRS.0b013e318201271c.

26. J. T. Shores, A. Gabriel, and S. Gupta, "Skin Substitutes and Alternatives: A Review," *Advances in Skin & Wound Care* 20, no. 9 (2007): 493–508, https://doi.org/10.1097/01.ASW.0000288217.83128.f3.

27. S. G. Dempsey, A. D. Young, R. W. F. Veale, and B. C. H. May, "Sustainable Biomaterials: Turning Food Waste Into Advanced Regenerative Technology," in *Regenerative Biomaterials—Emerging Biomaterial Solutions to Aid Tissue Regeneration*, ed. Y. Reinwald (IntechOpen, 2025).

28. B. A. Bosque, S. G. Dowling, M. BCH, et al., "Ovine Forestomach Matrix in the Surgical Management of Complex Lower-Extremity Soft-Tissue Defects: A Retrospective Multi-Center Case Series," *Journal of the American Podiatric Medical Association* 113, no. 3 (2023): 22–81, https://doi.org/10.7547/22-081.

29. J. Lawlor, B. A. Bosque, C. Frampton, D. A. Young, and P. Martyka, "Limb Salvage via Surgical Soft-Tissue Reconstruction With Ovine Forestomach Matrix Grafts: A Prospective Study," *Plastic and Reconstructive Surgery. Global Open* 12, no. 12 (2024): e6406, https://doi.org/10.1097/gox.0000000000006406.

30. M. T. Cormican, N. J. Creel, B. A. Bosque, S. G. Dowling, P. P. Rideout, and W. M. Vassy, "Ovine Forestomach Matrix in the Surgical Management of Complex Volumetric Soft Tissue Defects: A Retrospective Pilot Case Series," *Eplasty* 23 (2023): e66.

31. M. T. Cormican, W. M. Vassy, C. Cook, et al., "Vascularized Tissue Coverage of Trauma and Acute Care Surgery Defects With Ovine Forestomach Matrix: Interim Results of a Prospective Multicenter Study," *Journal of Trauma and Injury* 39, no. 1 (2025): 42–51, https://doi.org/10.20408/jti.2025.0090.

32. G. A. Bohn, B. Liden, G. Schultz, Q. Yang, and D. J. Gibson, "Ovine-Based Collagen Matrix Dressing: Next-Generation Collagen Dressing for Wound Care," *Advances in Wound Care* 5, no. 1 (2016): 1–10, https://doi.org/10.1089/wound.2015.0660.

33. G. A. Bohn, G. S. Schultz, B. A. Liden, et al., "Proactive and Early Aggressive Wound Management: A Shift in Strategy Developed by a Consensus Panel Examining the Current Science, Prevention, and Management of Acute and Chronic Wounds," *Wounds* 29, no. 11 (2017): S37–S42.

34. D. T. Ferreras, S. Craig, and R. Malcomb, "Use of an Ovine Collagen Dressing With Intact Extracellular Matrix to Improve Wound Closure Times and Reduce Expenditures in a US Military Veteran Hospital Outpatient Wound Center," *Surgical Technology International* 30 (2017): 61–69.

35. L. Negron, S. Lun, and M. BCH, "Ovine Forestomach Matrix Biomaterial Is a Broad Spectrum Inhibitor of Matrix Metalloproteinases and Neutrophil Elastase," *International Wound Journal* 11, no. 4 (2012): 392–397, https://doi.org/10.1111/j.1742-481X.2012.01106.x.

36. S. G. Dempsey, C. H. Miller, R. C. Hill, K. C. Hansen, and M. BCH, "Functional Insights From the Proteomic Inventory of Ovine Forestomach Matrix," *Journal of Proteome Research* 18, no. 4 (2019): 1657–1668, https://doi.org/10.1021/acs.jproteome.8b00908.

37. T. Karnik, S. G. Dempsey, M. J. Jerram, et al., "Ionic Silver Functionalized Ovine Forestomach Matrix—a Non-Cytotoxic Antimicrobial Biomaterial for Tissue Regeneration Applications," *Biomaterials Research* 23, no. 6 (2019): 17, https://doi.org/10.1186/s40824-019-0155-0.

38. M. Asuku, T. C. Yu, Q. Yan, et al., "Split-Thickness Skin Graft Donor-Site Morbidity: A Systematic Literature Review," *Burns* 47, no. 7 (2021): 1525–1546, https://doi.org/10.1016/j.burns.2021.02.014.

39. B. Zhang, P. Luo, J. Sun, et al., "The Epidermal Barrier Structure and Function of re-Harvested Skin From Non-Scalp Donor Sites," *Journal of Investigative Surgery* 36, no. 1 (2023): 1–7, https://doi.org/10.1080/08941939.2022.2146318.

40. J. Humeda, D. Jaalouk, and S. M. Leal-Khouri, "Skin Grafting," in *Mohs Micrographic Surgery*, ed. K. Nouri (Springer Nature Switzerland, 2025), 571–600.

41. N. Sobti, I. L. Valerio, and K. R. Eberlin, "Split Thickness Skin Grafts (STSGs) and Contemporary Skin Graft Alternatives," in *Operative Techniques in Orthopedic Trauma: A Practical Guide to Fracture Care*, ed. A. G. von Keudell and M. J. Weaver (Springer Nature Switzerland, 2025), 709–718.

42. B. A. Bosque, C. Frampton, A. E. Chaffin, et al., "Retrospective Real-World Comparative Effectiveness of Ovine Forestomach Matrix and Collagen/ORC in the Treatment of Diabetic Foot Ulcers," *International Wound Journal* 19, no. 4 (2022): 741–753, https://doi.org/10.1111/iwj.13670.