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Clinical Impact of Biodegradable Temporizing Matrix Implant in Accelerating Wound Healing and Minimizing Complications: A Retrospective Observational Study

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ABSTRACT

Background: Lower-limb soft-tissue defects with exposed bone or tendon remain difficult to reconstruct, and synthetic dermal matrices such as BTM may offer improved early wound stability and functional outcomes compared with conventional care.

Objectives: To determine the outcomes among BTM implant management techniques in terms of wound healing rate, complication rates, graft or implant survival, restoration of tissue integrity, and patient satisfaction.

Methods: We conducted a single-centre, hospital-based retrospective comparative study at the Department of General Surgery, Chettinad Hospital and Research Institute, Chettinad Academy ofResearch and Education, Kelambakkam - 603103, Tamil Nadu, India. (January 2024–June 2025; IHEC approved reference number-II/0937/25 dated 05.09.2025) including 30 patients ≤65 years with perfused lower-limb soft-tissue defects managed with either BTM (n=15) or conventional care (STSG/NPWT/dressings; n=15)

Results: Baseline parameters including age, BMI, defect duration, wound size, comorbidities, etiologies, and location (foot 43%, ankle 30%). Distal perfusion was adequate in all, and laboratory indices – including haemoglobin (12.5 g/dL), creatinine (0.9 mg/dL), liver enzymes, albumin (3.5–3.6 g/dL), coagulation, and glucose – did not differ. Intraoperatively, BTM showed numerically shorter operative time (72.4 vs 78.6 min; p=0.388) and lower blood loss (95 vs 120 mL; p=0.248). Early postoperative events trended lower with BTM, and the composite 'any complication' was significantly reduced (33.3% vs 60.0%; p=0.039). At two weeks, BTM outperformed conventional care; complete wound healing (60.0% vs 26.7%; p=0.021), graft/implant integration (86.7% vs 66.7%; p=0.042), and independent ambulation (66.7% vs 40.0%; p=0.032) were higher. Patient-reported outcomes favoured BTM (good/very good cosmetic results 80.0% vs 53.3%, p=0.025; satisfaction 86.7% vs 60.0%, p=0.020). Range of motion was numerically higher but not significant. Length of stay (6.4 vs 7.8 days; p=0.012) and return to work (23.1 vs 28.4 days; p=0.027).

Conclusion: BTM achieved superior early wound healing and integration with fewer complications, better functional and patient-reported outcomes, and shorter hospital stay than conventional management in perfused lower-limb defects.

Keywords: *Biodegradable Temporizing Matrix, lower-limb soft-tissue defects, wound healing, complications, functional recovery, patient satisfaction*

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1. INTRODUCTION

Lower-limb soft-tissue defects with exposed bone, tendon, or hardware remain difficult to manage because infection control, durable coverage, and early mobilization must be achieved simultaneously. Contemporary reconstructive pathways range from dressings and split-thickness skin grafts (STSG) to local/regional or free flaps, with negative-pressure wound therapy (NPWT) commonly used as an adjunct, particularly around the ankle and foot where soft-tissue options are limited.(1, 2) Dermal templates have expanded this 'reconstructive ladder' by creating a vascularized neodermis over poorly vascularized structures, potentially improving graft take, contour, and tolerance of motion.(3)

Biodegradable Temporizing Matrix (BTM) is a fully synthetic, bilayer polyurethane scaffold with a sealing membrane designed to permit fibrovascular ingrowth and subsequent delamination for definitive resurfacing. Its synthetic composition avoids xenogenic collagen and has shown favourable resistance to infection in complex wounds.(4, 5) Evidence in extremity reconstruction has grown rapidly; a 2024 multi-center series in hands and extremities reported reliable integration and favourable complication profiles across diverse etiologies, and an upper-extremity case series demonstrated effective coverage over exposed tendon/bone with acceptable early function.(6, 7) Recent syntheses – including a 2024 systematic review/meta-analysis in upper-limb reconstruction and a 2025 broader systematic review – conclude that BTM achieves high integration and wound-healing rates with low adverse-event rates, while calling for comparative studies to define indications versus conventional care.(8, 9)

Nevertheless, data directly comparing BTM with standard modalities (STSG, NPWT-assisted grafting, or dressings) in lower-limb defects remain limited, and randomized evidence for some adjuncts (e.g., NPWT to improve graft take) is still evolving.(10) Against this background, the objective of the present study was to determine the outcomes among BTM implant management techniques in terms of wound healing rate, complication rates, graft or implant survival, restoration of tissue integrity, and patient satisfaction. This study is significant due to the challenges persistent wounds provide for healthcare systems, necessitating prolonged maintenance and causing complications (23) A coming of age treatment that speeds up healing may decrease hospital stays, lower the need for advanced wound healing products, and promotes patients' lives (23)

Figure 1A (Pre-BTM): Granulating wound bed over the anterior aspect of the leg following debridement, prepared for dermal substitute placement. (SOURCE- DEPARTMENT OF GENERAL SURGERY CHRI)

Figure 1B (Post-BTM): Biodegradable Temporizing Matrix (BTM) secured with sutures over the anterior aspect of the leg, providing a scaffold for neodermis formation. (SOURCE- DEPARTMENT OF GENERAL SURGERY CHRI)

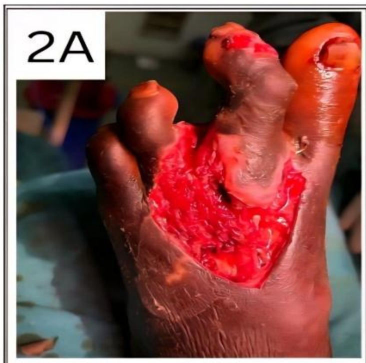

Figure 2A: Pre-BTM implant image of a left foot with a large, open wound on the dorsal aspect. Shows Healthy bed of granulation well prepared for BTM implant. (SOURCE- DEPARTMENT OF GENERAL SURGERY CHRI)

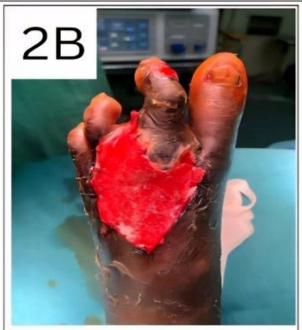

Figure 2B: Post-BTM implant image of the left foot demonstrating a wound over the dorsal aspect. BTM secured in place, and the wound edges have been approximated with sutures to ensure stability of the implant and facilitate neo dermis formation. (SOURCE- DEPARTMENT OF GENERAL SURGERY CHRI)

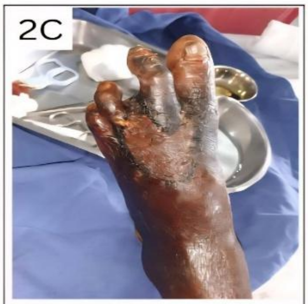

Figure 2C: Postoperative image showing the dorsal aspect of the left foot on postoperative day 12, following BTM integration and split-thickness skin graft (SSG) application. The graft is well-taken over the neo dermis formed by the BTM, indicating successful wound coverage and early healing. (SOURCE- DEPARTMENT OF GENERAL SURGERY CHRI)

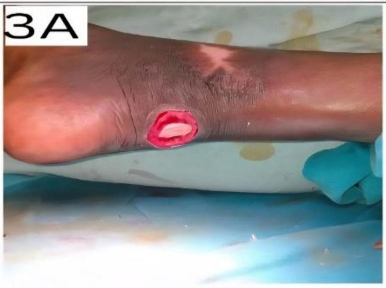

Figure 3A: Pre-BTM implant image of a wound at the posterior aspect of the ankle with full-thickness skin loss and exposed tendon. The wound bed is clean, non-granulating, indicating the need for a biodegradable temporizing matrix (BTM) to facilitate neo dermis formation. (SOURCE-DEPARTMENT OF GENERAL SURGERY CHRI)

Figure 3B: Post-BTM implant image on POD 5, showing the wound covered with the BTM sheet, which has integrated well with the underlying tissue. Early signs of neo dermis formation are visible, and the tendon is adequately protected. (SOURCE- DEPARTMENT OF GENERAL SURGERY CHRI)

2. MATERIALS AND METHODS

This was a single centre, hospital-based, retrospective, observational comparative study conducted in the Department of General Surgery, Chettinad Hospital and Research Institute (CHRI), Chennai, Tamil Nadu, India over a period of 18 months between January 2024 and June 2025. The study was approved by the Institutional Human Ethics Committee (IHEC) with reference number-II/0937/25 dated 05.09.2025. Patients less than 65 years of age; of both gender; with soft tissue defects in the lower limb including exposed bone, tendon, or implants; post-traumatic or post-surgical wounds suitable for management with either BTM implant or conventional methods were included in the study. However, patients with peripheral vascular disease; severe cardiovascular or respiratory compromise precluding surgery; active systemic infection or uncontrolled diabetes affecting wound healing were excluded.

We powered the study to detect a clinically important difference in complete wound healing between BTM and conventional management. Assuming healing proportions of 90% (BTM) versus 65% (conventional), with two-sided α = 0.05, power = 80%, and equal allocation, the required sample size was 15 participants per group (total = 30). The calculation used the two-sample test for independent proportions (Fleiss method with continuity correction).(6, 11) A detailed review of the hospital records (retrieved using nonprobability sampling technique – convenience sampling) and follow-up charts was done to extract relevant data. Patient history including age, sex, BMI, comorbidities (diabetes, peripheral vascular disease, smoking, nutritional status), etiology and duration of defect (trauma, infection, postoperative, ulcer, or malignancy), wound size and location was recorded. Distal limb perfusion was assessed with handheld Doppler. Baseline evaluation included complete blood count, renal and liver function tests, coagulation profile, blood glucose, chest X-ray, ECG, and echocardiography when indicated.

During preoperative counselling, the range of management options – including BTM implantation and conventional methods (STSG, NPWT, or dressings) – was presented. The potential benefits, expected outcomes, and complications of each approach (e.g., infection, graft/implant failure, donor-site morbidity, functional and cosmetic results, recurrence, and need for re-operation) were discussed. Patients were optimised for comorbidities, kept nil per oral for eight hours, and given prophylactic antibiotics (one dose before incision and another six hours later). All wounds were thoroughly debrided, and margins refreshed to ensure a well-vascularised bed before treatment. In the BTM group, in a haemostatic, well-vascularised bed; scaffold oriented with the sealing membrane outward; trimmed to fit with 2–3 mm peripheral overlap; secured using interrupted 3-0 nylon sutures or skin staples at 1–2 cm intervals with optional quilting to minimise dead space; sealing membrane fenestrated to permit egress of seroma/haematoma; closed-suction drain placed for larger cavities; bolster dressing applied as a splinting layer at −75 to −125 mmHg; limb immobilised and elevated. In the comparison group, wounds were managed with STSG, NPWT, or conventional dressings based on wound characteristics and the surgeon's judgement; all patients were monitored similarly. Postoperative care included hourly wound assessments for 24 hours and then every six hours until day 5. Evaluations covered wound colour, temperature, capillary refill, exudate, and early signs of infection or failure. Limbs were elevated with splints or plaster slabs to mitigate oedema. Daily wound care, analgesia, antibiotics, and early mobilisation were provided. Operative time and intraoperative blood loss were documented. Early surgical outcomes—including infection, graft/implant loss, seroma, haematoma, and other complications—were recorded until discharge. At the two-week follow-up, wound healing, graft/implant integration, functional recovery (range of motion, weight-bearing, ambulation, and return to work), cosmetic results, and patient satisfaction were assessed. Length of hospital stay was also recorded.

Statistical analysis: All analyses were two-sided (α=0.05). Continuous variables were summarized as mean (SD) and categorical variables as n (%), with between-group comparisons performed using Welch's t-test for continuous data and Fisher's exact or χ^2 tests for categorical data. Reporting followed STROBE guidelines, and analyses were performed in Stata 16 and R 4.3.

3. RESULTS

The mean age was 48.6 ± 10.1 years in the BTM group and 49.9 ± 9.8 years in the conventional group (p=0.723), while the mean BMI was similar at 24.9 ± 3.2 vs 24.5 ± 3.0 kg/m² (p=0.727) (Table 1). The average duration of the defect before intervention was 17.3 ± 12.8 days in the BTM arm and 19.1 ± 14.0 days in the conventional arm (p=0.716), and mean wound size was 68.5 ± 31.4 cm² vs 64.2 ± 29.7 cm² (p=0.703). Males predominated in both groups (66.7% vs 60.0%), and diabetes (33.3% vs 40.0%), smoking (40.0% vs 33.3%), and undernutrition (20.0% vs 13.3%) were distributed without significant difference. Trauma was the most common etiology (50.0% overall), followed by infection (20.0%) and postoperative wounds (16.7%), with a single case of malignancy in the conventional arm. Wound location was similar, most frequently at the foot (43.3%) and ankle (30.0%).

Table 1: Baseline patient and wound characteristics by treatment group

Characteristic		BTM (n=15)	Conventional (n=15)	Total (N=30)	p value
Age (years), Mean (SD)		48.6 (10.1)	49.9 (9.8)	49.2 (10.0)	0.723
BMI (kg/m²), Mean (SD)		24.9 (3.2)	24.5 (3.0)	24.7 (3.1)	0.727
Defect duration (days), Mean (SD)		17.3 (12.8)	19.1 (14.0)	18.2 (13.4)	0.716
Wound size (cm²), Mean (SD)		68.5 (31.4)	64.2 (29.7)	66.3 (30.6)	0.703
Male sex, n (%)		10 (66.7)	9 (60.0)	19 (63.3)	1.000
Diabetes, n (%)		5 (33.3)	6 (40.0)	11 (36.7)	1.000
Peripheral vascular disease, n (%)		0 (0.0)	0 (0.0)	0 (0.0)	_
Smoking (current/former), n (%)		6 (40.0)	5 (33.3)	11 (36.7)	1.000
Undernutrition, n (%)		3 (20.0)	2 (13.3)	5 (16.7)	1.000
Etiology, n (%)	Trauma	8 (53.3)	7 (46.7)	15 (50.0)	0.809
	Infection	3 (20.0)	3 (20.0)	6 (20.0)	
	Postoperative	2 (13.3)	3 (20.0)	5 (16.7)	
	Ulcer	2 (13.3)	1 (6.7)	3 (10.0)	
	Malignancy	0 (0.0)	1 (6.7)	1 (3.3)	
Wound location, n (%)	Foot	7 (46.7)	6 (40.0)	13 (43.3)	0.979
	Ankle	4 (26.7)	5 (33.3)	9 (30.0)	
	Leg (shin)	3 (20.0)	3 (20.0)	6 (20.0)	
	Knee/Thigh	1 (6.7)	1 (6.7)	2 (6.7)	
*Statistically significant at p<0.05					

At baseline, distal limb perfusion assessed by handheld Doppler was adequate in all participants across both groups (Table 2). Mean haemoglobin was 12.6 ± 1.5 g/dL in the BTM arm and 12.4 ± 1.6 g/dL in the conventional arm, while leukocyte counts averaged 9.7 ± 2.4 and 10.0 ± 2.6 ×10⁹/L, respectively. Platelet counts were also comparable (270.0 ± 70.0 vs 280.0 ± 68.0 ×10⁹/L). Renal function remained preserved with a mean creatinine of 0.9 ± 0.2 mg/dL in both groups. Liver function tests showed mean AST of 28.0 ± 10.0 vs 29.0 ± 11.0 U/L and ALT of 30.0 ± 12.0 vs 31.0 ± 12.0 U/L, with bilirubin consistently 0.8 ± 0.3 mg/dL. Albumin levels were similar (3.6 ± 0.4 vs 3.5 ± 0.4 g/dL). Coagulation profiles (INR 1.06 ± 0.08 vs 1.05 ± 0.08; aPTT 31.1 ± 4.1 vs 31.5 ± 4.0 s) and random blood glucose (118.0 ± 32.0 vs 121.0 ± 34.0 mg/dL) also showed no significant differences. None of the baseline laboratory parameters differed significantly between the groups.

Table 2: Distal perfusion and baseline laboratory evaluation by treatment group

Characteristic	BTM (n=15)	Conventional (n=15)	Total (N=30)	p value
Distal limb perfusion by handheld Doppler – adequate signal, n (%)	15 (100.0)	15 (100.0)	30 (100.0)	_
Haemoglobin (g/dL), Mean (SD)	12.6 (1.5)	12.4 (1.6)	12.5 ()1.6	0.727
Total leukocyte count (×10^9/L), Mean (SD)	9.7 (2.4)	10.0 (2.6)	9.8 (2.5)	0.745
Platelet count (×10^9/L), Mean (SD)	270.0 (70.0)	280.0 (68.0)	275.0 (69.0)	0.694
Serum creatinine (mg/dL), Mean (SD)	0.9 (0.2)	0.9 (0.2)	0.9 (0.2)	1.000
AST (U/L), Mean (SD)	28.0 (10.0)	29.0 (11.0)	28.5 (10.5)	0.796
ALT (U/L), Mean (SD)	30.0 (12.0)	31.0 (12.0)	30.5 (12.0)	0.821
Total bilirubin (mg/dL), Mean (SD)	0.8 (0.3)	0.8 (0.3)	0.8 (0.3)	1.000
Albumin (g/dL), Mean (SD)	3.6 (0.4)	3.5 (0.4)	3.5 (0.4)	0.499
INR, Mean (SD)	1.06 (0.08)	1.05 (0.08)	1.05 (0.08)	0.735
aPTT (s), Mean (SD)	31.1 (4.1)	31.5 (4.0)	31.3 (4.1)	0.789
Blood glucose (mg/dL), Mean (SD)	118.0 (32.0)	121.0 (34.0)	119.5 (33.0)	0.805
*Statistically significant at p<0.05				

The mean operative time was slightly shorter with BTM (72.4 ± 18.5 min) compared to conventional management (78.6 ± 20.2 min, p=0.388) and mean intraoperative blood loss was lower (95.0 ± 50.0 vs 120.0 ± 65.0 mL, p=0.248) (Table 3). Early postoperative complications to discharge included infection in 13.3% of BTM versus 26.7% of conventional patients, graft/implant loss in 6.7% versus 20.0%, and smaller proportions with seroma, haematoma, or other events. Notably, the composite measure of 'any early complication' occurred in one-third of BTM patients versus 60.0% in the conventional group, a difference that reached statistical significance (p=0.039), highlighting a lower overall complication burden with BTM use.

Table 3: Intraoperative metrics and early surgical outcomes (to discharge) by treatment group

Characteristic/Outcome		BTM (n=15)	Conventional (n=15)	Total (N=30)	p value
Operative time (min), Mean (SD)		72.4 (18.5)	78.6 (20.2)	75.5 (19.3)	0.388
Intraoperative blood loss (mL), Mean (SD)		95.0 (50.0)	120.0 (65.0)	107.5 (62.5)	0.248
Early surgical outcomes to discharge, n (%)	Infection	2 (13.3)	4 (26.7)	6 (20.0)	0.651
	Graft/implant loss	1 (6.7)	3 (20.0)	4 (13.3)	0.598
	Seroma	2 (13.3)	1 (6.7)	3 (10.0)	1.000
	Haematoma	1 (6.7)	2 (13.3)	3 (10.0)	1.000
	Other complications	1 (6.7)	2 (13.3)	3 (10.0)	1.000
Any early complication (composite), n (%)		5 (33.3)	9 (60.0)	14 (46.7)	0.039*
*Statistically significant at p<0.05					

At two-week follow-up, outcomes were consistently better in the BTM group compared to conventional management (Table 4). Complete wound healing was achieved in 60.0% of BTM patients versus 26.7% in the conventional limb (p=0.021), and graft/implant integration was higher with BTM (86.7% vs 66.7%, p=0.042). Functional recovery was superior, with 66.7% achieving independent ambulation compared to 40.0% (p=0.032). Patient-reported outcomes also favoured BTM, with good/very good cosmetic results in 80.0% vs 53.3% (p=0.025), higher mean cosmetic scores (4.2 vs 3.6, p=0.018), and greater satisfaction (86.7% vs 60.0%, p=0.020; mean score 4.3 vs 3.7, p=0.018). Although ROM was numerically better with BTM (78.0% vs 70.0%), this was not statistically significant (p=0.119). Efficiency outcomes also showed benefit: length of stay was shorter (6.4 vs 7.8 days, p=0.012) and return to work earlier (23.1 vs 28.4 days, p=0.027).

Table 4: Two-week follow-up outcomes by treatment group

Two-week outcome	BTM (n=15)	Conventional (n=15)	Total (N=30)	p value
Complete wound healing, n (%)	9 (60.0)	4 (26.7)	13 (43.3)	0.021*
Graft/implant integration, n (%)	13 (86.7)	10 (66.7)	23 (76.7)	0.042*
Need for re-surgery, n (%)	0 (0.0)	2 (13.3)	2 (6.7)	0.623
Independent ambulation, n (%)	10 (66.7)	6 (40.0)	16 (53.3)	0.032*
Cosmetic result good/very good (≥4/5), n (%)	12 (80.0)	8 (53.3)	20 (66.7)	0.025*
Cosmetic score (1–5), Mean (SD)	4.2 (0.6)	3.6 (0.7)	3.9	0.018*
Patient satisfaction satisfied/very satisfied (≥4/5), n (%)	13 (86.7)	9 (60.0)	22 (73.3)	0.020*
Patient satisfaction score (1–5), Mean (SD)	4.3 (0.6)	3.7 (0.7)	4.0	0.018*
Range of motion at affected joint (% of expected) Mean (SD)	78.0 (12.0)	70.0 (15.0)	74.0	0.119
Length of hospital stay (days), Mean (SD)	6.4 (1.1)	7.8 (1.5)	7.1	0.012*
Return to work (days), Mean (SD)	23.1 (7.5)	28.4 (8.2)	25.8	0.027*
*Statistically significant at p<0.05				

4. DISCUSSION

The two groups in this comparative cohort were well balanced at baseline, supporting a fair appraisal of treatment effects. Age, BMI, wound chronicity, and size were closely matched, with no significant differences in comorbidities such as diabetes, smoking, or undernutrition, and with broadly similar etiologies and lower-limb distributions. This comparability is important because outcomes after complex extremity reconstruction are sensitive to case mix – particularly perfusion status, infection burden, and host factors – and imbalance can confound apparent treatment advantages. In this study, distal limb perfusion was uniformly adequate by handheld Doppler, a bedside modality with acceptable interobserver reliability for vascular assessment of the foot and ankle, thereby ensuring that both groups entered care with a viable substrate for tissue integration and healing. (12)

The intraoperative trajectory showed modest efficiency signals with BTM – shorter mean operative time and lower blood loss – consistent with the practical advantage of a single-stage scaffold placement over some conventional strategies that may require more extensive bed preparation, flap elevation, or adjunctive fixation. Although these differences were not individually significant, they align with the rationale for dermal templates as time-efficient means to secure immediate coverage, protect exposed structures, and prepare a vascularized neodermis for subsequent closure if needed.(13, 14) Mechanistically, synthetic bilayer matrices such as BTM comprise a biodegradable polyurethane foam scaffold bonded to a sealing membrane; after application to a haemostatic, well-vascularized bed, fibrovascular ingrowth proceeds, yielding a robust neodermis that can be delaminated and resurfaced – typically with STSG – during the second stage. Early clinical series in extremity reconstruction have documented reliable integration over exposed tendon or bone and high rates of definitive coverage using this staged approach. (6, 7, 15)

The early postoperative profile in our cohort further supports a perioperative advantage with BTM. While individual event rates (infection, graft/implant loss, seroma, hematoma) trended favourably, the composite 'any early complication' was significantly lower with BTM (33.3% vs 60.0%). This pattern mirrors multi-study experience that synthetic dermal templates can moderate early wound instability and reduce reintervention risk by providing a temporizing, mechanically protective cover while the wound bed vascularizes.(6, 15) It is notable that baseline laboratory parameters – including albumin and glucose – were similar between groups; both markers are established correlates of postoperative infection and wound morbidity, so their balance argues that the observed difference in early complications is not simply an artifact of nutritional or glycaemic disparities.(16-18)

At two weeks, BTM was associated with higher rates of complete wound healing and scaffold integration. These findings are consonant with upper- and lower-extremity case series that report dependable BTM integration over complex wounds – often in the context of exposed tendon or bone – and subsequent successful grafting, with low rates of infectious failure when placed on a well-debrided, bleeding bed.(6, 7, 15) Although our follow-up window is short, early integration is clinically meaningful; it reduces the vulnerable interval during which bioburden or mechanical shear can precipitate loss, and it accelerates the transition from 'wound care' to rehabilitation. Even where conventional care employs negative-pressure wound therapy (NPWT) to bolster STSG take – a strategy supported by randomized and observational evidence – BTM may still confer an advantage by creating a vascularized intermediate layer that improves graft contour, durability, and tolerance of motion.(19, 20)

Functional recovery metrics in this study also favoured BTM; more patients achieved independent ambulation by two weeks, ROM percentages trended higher, and time to return to work was shorter. While direct functional comparisons between dermal templates and conventional care are limited, the direction of effect is biologically plausible. By providing immediate, stable coverage that resists shear, BTM can enable earlier protected mobilization, which is known to support joint motion and gait retraining after limb reconstruction; in turn, earlier mobilization reduces edema and stiffness, facilitating quicker return to activities.(14) The synthetic composition of BTM may also contribute; unlike xenogenic collagen templates, it avoids antigen-related inflammation, and its pore architecture is engineered to optimize cellular migration and neovascularization, potentially shortening the integration interval.(13)

Patient-reported outcomes in the present cohort – cosmetic ratings and satisfaction – showed significant advantages with BTM at two weeks. Emerging extremity literature emphasizes that dermal substitutes can improve contour, pliability, and skin quality compared with graft-only reconstruction, translating into better cosmetic appraisal and functional comfort in footwear or during hand use.(7, 21) Although longer-term scar metrics (e.g., Vancouver Scar Scale) were not assessed here, case series and reviews document favourable scar texture and decreased contracture with dermal template-assisted coverage, particularly over mobile surfaces such as the ankle and dorsum of the foot.(15) The efficiency signal – shorter length of stay and earlier return to work – is clinically relevant for both patients and health systems. Synthetic dermal templates can reduce the need for complex flap coverage in selected defects, simplifying perioperative care and allowing earlier discharge. In published series, staged BTM reconstruction often avoids free tissue transfer in patients with limited recipient vessels or high comorbidity burden, while still achieving durable closure; these pathway efficiencies plausibly translate to shorter LOS and improved productivity.(8) Even within conventional pathways, adjuncts like NPWT improve STSG take and may shorten dressing-change frequency, but they do not provide the dermal bulk or shear resistance that can facilitate early ambulation to the same extent, especially over joints.(19)

Importantly, any treatment-related differences in infection risk are unlikely to be explained by baseline host factors in this dataset, because haemoglobin, leukocyte count, creatinine, liver enzymes, albumin, and glycemia were comparable. The literature consistently associates hypoalbuminemia and perioperative hyperglycaemia with surgical site infection and impaired wound healing across surgical domains, including orthopaedics and general surgery.(16, 18, 22) That these risks were evenly distributed here reinforces the likelihood that lower early complication rates in BTM reflect characteristics intrinsic to the reconstructive modality; the sealed, protected environment; the controlled exudate egress through fenestrations; and the rapid establishment of a vascular neodermis ready for definitive resurfacing.(6, 15)

Our findings are directionally consistent with recent prospective and retrospective reports of BTM in complex wounds of the extremities. In a hand and extremity cohort, Struble et al.(6) reported high rates of successful BTM integration with low reconstructive failure and acceptable complication rates, concluding that BTM is a versatile option across diverse wound etiologies. Jou et al.(7) described effective BTM use for upper-extremity defects with exposed bone or tendon, emphasizing early success in creating a vascularized bed that permitted subsequent grafting and functional rehabilitation. A review and case series by Kidd et al.(15) synthesized experiences across trauma, infection, and oncologic wounds, reporting integration in the majority of cases and highlighting BTM's utility when flap options are limited or contraindicated. Finally, a 2025 systematic review concluded that NovoSorb® BTM is effective across complex wounds with low infection rates and few adverse events, adding broader external validity to the favourable signal seen here.(8)

Taken together, the present results suggest that, in carefully prepared, perfused lower-limb wounds, BTM may confer clinically meaningful advantages in early complication burden, early healing and integration, functional recovery, and patient experience, with potential downstream savings in LOS and earlier RTW. However, this study has several limitations. First, its single-centre, retrospective, observational design with clinician-selected treatment introduces selection bias and confounding by indication; despite adjusted analyses, unmeasured confounders (e.g., rehabilitation intensity, wound microbiology, surgeon technique) may persist. Second, the small convenience sample (15 per arm) limits statistical power for secondary endpoints and rare adverse events, increases imprecision of estimates, and risks type II error or unstable subgroup effects. Third, short follow-up focused on in-hospital and two-week outcomes precludes assessment of longer-term endpoints such as durable graft/implant survival, scar quality, contracture, reoperation beyond two weeks, and sustained function. Fourth, outcome assessment was not blinded and relied on chart abstraction, which is vulnerable to measurement and documentation bias; functional and cosmetic results used simple Likert scales rather than fully validated instruments, and Doppler screening without ABI/toe pressures may misclassify marginal perfusion. Fifth, the comparator arm pooled heterogeneous conventional strategies (STSG, NPWT, dressings) without stratified analyses, limiting granularity on which components drive differences.

5. CONCLUSION

In this single-centre comparative cohort of lower-limb soft-tissue defects with adequate distal perfusion, baseline demographics, comorbidities, wound size, and laboratory profiles were well balanced between groups. Compared with conventional management, BTM use was associated with a significantly lower composite rate of early complications to discharge, higher two-week rates of complete wound healing and graft/implant integration, and superior early functional and patient-reported outcomes, including independent ambulation, cosmetic appraisal, and satisfaction. Efficiency metrics also favoured BTM, with shorter length of stay and earlier return to work, while operative time and blood loss were numerically but not significantly reduced. Range of motion trended better with BTM without reaching statistical significance at two weeks. Taken together, these findings support BTM as an effective and patient-centred option for managing complex lower-limb defects in appropriately prepared, well-vascularized wounds.

REFERENCES

[1] Zeiderman MR, Pu LLQ. Contemporary approach to soft-tissue reconstruction of the lower extremity after trauma. Burns Trauma. 2021;9:tkab024.

[2] Mansour AM, Jacobs A, Raj MS, Lee FG, Terrasse W, Wallace SJ, et al. Lower Extremity Soft Tissue Reconstruction Review Article. Orthopedic Clinics of North America. 2022;53(3):287-96.

[3] Jeyaratnam S, Sebastin SJ, Das De S. Revisiting the reconstructive ladder for soft tissue reconstruction in the lower extremity. Ann Transl Med. 2024;12(1):7.

[4] Rajaram R, Zhang M, Premaratne G, Ng S. Novosorb(®) BTM- history, production and application in challenging wounds. Front Bioeng Biotechnol. 2024;12:1450973.

[5] Lo CH, Brown JN, Dantzer EJG, Maitz PKM, Vandervord JG, Wagstaff MJD, et al. Wound healing and dermal regeneration in severe burn patients treated with NovoSorb® Biodegradable Temporising Matrix: A prospective clinical study. Burns. 2022;48(3):529-38.

[6] Struble SL, Patel NK, Graham EM, Tipps JA, Vaile JR, Leeflang EJ, et al. Outcomes of Biodegradable Temporizing Matrix for Soft Tissue Reconstruction of the Hand and Extremities. Plastic and Reconstructive Surgery – Global Open. 2024;12(7).

[7] Jou C, Chepla KJ. Novosorb Biodegradable Temporizing Matrix for Reconstruction of Complex Upper-Extremity Wounds. Journal of Hand Surgery Global Online. 2024;6(5):614-8.

[8] Fruergaard O, Ørholt M, Lyngsaa Lang C, Berg Drejøe J, Herly M, Vester-Glowinski P, et al. A systematic review of the Novosorb® Biodegradable Temporizing Matrix in the treatment of complex wounds. Burns Open. 2025;9:100378.

[9] Kostova M, Alexander TD, Monroy MDLC, Murdeshwar H, Duvnjak H, McCance HC, et al. The Efficacy of Biodegradable Temporising Matrix for Upper Limb Reconstruction: A Systematic Review and Meta-Analysis. Cureus. 2024;16(12).

[10] Lindholm VM, Salminen AW, Koskenmies SJ, Salmivuori MK, Hannula-Jouppi KSE, Isoherranen KM. An exploratory randomized clinical trial on negative pressure wound therapy for lower limb full-thickness skin grafts of dermatosurgical patients. Int Wound J. 2024;21(6):e14911.

[11] Abdulmughni LA, Al-Sanabani JA, Gilan WM, Issa MA, Jowah HM. Split-thickness skin graft outcomes and associated risk factors in patients with skin defects at Al-Gumhouri hospital, Sana'a, Yemen: a prospective observational study. BMC Surg. 2025;25(1):292.

[12] Tehan PE, Chuter VH. Use of hand-held Doppler ultrasound examination by podiatrists: a reliability study. Journal of Foot and Ankle Research. 2015;8(1):36.

[13] Taupin P, Gandhi A, Saini S. Integra® Dermal Regeneration Template: From Design to Clinical Use. Cureus. 2023;15(5):e38608.

[14] Chang DK, Louis MR, Gimenez A, Reece EM. The Basics of Integra Dermal Regeneration Template and its Expanding Clinical Applications. Semin Plast Surg. 2019;33(3):185-9.

[15] Kidd T, Kolaityte V, Bajaj K, Wallace D, Izadi D, Bechar J. The use of NovoSorb biodegradable temporising

matrix in wound management: a literature review and case series. J Wound Care. 2023;32(8):470-8.

[16] Yuwen P, Chen W, Lv H, Feng C, Li Y, Zhang T, et al. Albumin and surgical site infection risk in orthopaedics: a meta-analysis. BMC Surg. 2017;17(1):7.

[17] Zhang F, Huang L, Li M, Quan Z, Wang Y, Luo H, et al. Effect of Pre-Operative Low Serum Pre-Albumin on Surgical Site Infection in Post-Surgery Subjects: A Systematic Review and Meta-Analysis. Surg Infect (Larchmt). 2023;24(8):684-91.

[18] Takesue Y, Tsuchida T. Strict glycemic control to prevent surgical site infections in gastroenterological surgery. Ann Gastroenterol Surg. 2017;1(1):52-9.

[19] Yin Y, Zhang R, Li S, Guo J, Hou Z, Zhang Y. Negative-pressure therapy versus conventional therapy on split-thickness skin graft: A systematic review and meta-analysis. Int J Surg. 2018;50:43-8.

[20] Jiang Z-Y, Yu X-T, Liao X-C, Liu M-Z, Fu Z-H, Min D-H, et al. Negative-pressure wound therapy in skin grafts: A systematic review and meta-analysis of randomized controlled trials. Burns. 2021;47(4):747-55.

[21] Struble SL, Patel NK, Graham EM, Tipps JA, Vaile JR, Leeflang EJ, et al. Outcomes of Biodegradable Temporizing Matrix for Soft Tissue Reconstruction of the Hand and Extremities. Plast Reconstr Surg Glob Open. 2024;12(7):e5956.

[22] Bellusse GC, Ribeiro JC, de Freitas ICM, Galvão CM. Effect of perioperative hyperglycemia on surgical site infection in abdominal surgery: A prospective cohort study. American Journal of Infection Control. 2020;48(7):781-5.

[23] Dr. Modiem Ram Vivek, Dr. Ram Prasath Elangovan, Dr. A. Prabakar A Comparative Study Between the Use of Efficacy of Topical Sucralfate vs 5% Povidone Iodine in Chronic Lower Limb Non-Healing Ulcers Journal of Neonatal Surgery 2025; 14 (27s): 1022-1030