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Hand

Outcomes of Biodegradable Temporizing Matrix for Soft Tissue Reconstruction of the Hand and Extremities

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Background: NovoSorb biodegradable temporizing matrix (BTM) is a novel, bilayer, synthetic skin substitute made of biodegradable polyurethane foam covered with a sealing membrane. BTM has demonstrated excellent outcomes in burn literature; however, few studies have been published for hand and extremity soft tissue reconstruction.

Methods: All patients who underwent extremity reconstruction with BTM from 2018 to 2023 were reviewed. Demographics, presentations, and clinical outcomes were recorded.

Results: A total of 86 cases from 54 patients (53.7% pediatric; age range: 0–81 years) were included. Common indications included trauma (36%), infection (18.6%), and malignancy (11.6%). BTM was placed over exposed tendon (38.4%), bone (19%), joints (12.8%), nerves (8.1%), and/or blood vessels (7%). BTM served as temporary wound coverage in 26 cases. Complications included hematoma (8.1%), infection (4.7%), and spontaneous delamination (4.7%). Wound closure was successfully obtained without flap use in 93.3%. Poor BTM take was associated with peripheral vascular disease, hypertension, immunosuppression, and BTM hematoma and infection (<0.05).

Conclusion: This study contributes to the growing body of evidence favoring BTM use in challenging reconstructive cases. Although prospective comparative studies are forthcoming, BTM likely has broad applications in reconstructive surgery.
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INTRODUCTION

The management of complex extremity wounds presents a significant reconstructive challenge, especially when involving full-thickness skin loss with exposure of tendons, bone, or joints. Traditional approaches such as skin grafting have important limitations, including donor site morbidity, potential for contour irregularities and contracture, and limited application over avascular structures.[1–7] Bioengineered dermal scaffolds were developed in part to overcome these limitations.[8–12] Among these, NovoSorb biodegradable temporizing matrix (BTM) has emerged as a promising option. BTM is a completely synthetic bilayer skin substitute made of a biodegradable polyurethane matrix foam covered with a nonbiodegradable polyurethane sealing membrane to mimic the dermis and epidermis, respectively.[13–15] When placed over a wound, it promotes vascularization and dermal regeneration.[13–17] Polyurethane was selected for its low manufacture cost and ability to withstand infection, combating two important limitations of biologic dermal scaffolds such as Integra.[18–21] Since its Food & Drug Administration approval in 2015, BTM has shown promising results in

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preliminary case reports and case series, particularly in the treatment of burns.[22–26] However, continued effort is needed to validate this product in broader reconstructive applications and improve knowledge surrounding its use.[27–33]

The primary aim of this study was to expand surgeon knowledge regarding the application and outcomes of BTM reconstruction in the extremities in both pediatric and adult populations. Using a large patient cohort with mixed presentation characteristics and pathologies, we hypothesize that (1) patients reconstructed with BTM and subsequent full-thickness skin graft (FTSG)/split-thickness skin graft (STSG) would achieve successful wound closure without the need for local or distant flap reconstruction; (2) patients reconstructed with BTM would have lower infection rates compared with published rates of infection by Integra and other bioactive dermal scaffolds; and (3) patients with numerous comorbidities would have poorer outcomes compared with patients without underlying comorbidities.

Takeaways

Question: How effective is biodegradable temporizing matrix (BTM) in extremity reconstruction, considering its outcomes, complications, and predictors of success in various patient demographics and wound presentations?

Findings: This retrospective review found that BTM is highly effective in extremity reconstruction. Complications are rare and may be associated with comorbidities like peripheral vascular disease, hypertension, and immunosuppression.

Meaning: BTM is a promising option for reconstructive surgery of the hands and extremities, offering successful outcomes in a variety of wound presentations.

METHODS

After obtaining approval from the institutional review board, cases were identified from case logs of three surgeons, from 2018 to 2023. BTM reconstruction was performed according to the manufacturer's instructions. In cases where BTM was used as a temporary coverage, the initial surgical steps were the same, but instead of removing the sealing membrane after 4 weeks, the entire BTM template was removed before integration completion. The selection of dressings and the decision to use negative pressure wound therapy (NPWT) were at the discretion of the surgeon at the time of the initial application. All patients reconstructed with BTM, for upper and lower extremity wounds, regardless of insult, were included. Patient demographics and comorbidities were not used as exclusion criteria.

Patient demographic data and indication for BTM were recorded. Details of the wound (eg, location, exposed structures), indication (temporization versus reconstruction), and treatment were abstracted from medical records and operative notes. Outcomes of interest included percentage take of BTM and skin graft, complications, and overall reconstructive success. Success was defined as achieving wound closure with BTM and skin grafting or BTM alone without the need for alternative reconstructive routes such as local tissue transfer or free flap coverage. BTM take rate was not recorded in cases where BTM was used as a temporary wound coverage, as the BTM was usually removed before integration occurred. Temporizer cases were also excluded when reporting methods of wound closure (eg, skin graft, secondary intention, flap coverage) and overall reconstructive success. Complications were recorded for all cases, regardless of indication. Data collection and analysis was performed independent of the senior author.

Statistical analyses were performed with IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, N.Y.). Demographic, operative, and outcomes data were recorded in a binary format. After assessing for normalcy, group comparisons were analyzed with Fisher exact tests. A multiple regression was run to determine independent predictors of BTM take rate. Results for all analyses were interpreted with an alpha of 0.05.

RESULTS

Case Demographic and Presentation Characteristics

A total of 86 cases from 54 patients were included. Patient ages ranged from 0 to 81 years with the majority of patients being non-Hispanic White (72.2%). Hypertension, peripheral vascular disease (PVD), and immunosuppression were the most common comorbidities, and 22% of patients actively used tobacco or had a significant history of tobacco use (Table 1). Trauma was the primary indication for reconstructing with BTM (36%), followed by infection (18.6%) (Fig. 1), malignancy excision reconstruction (11.6%; Fig. 2), and burns and burn scar contracture releases (10.5%). [**See Video 1 (online),** which displays cases that highlight a variety of indications of BTM as well as examples of BTM complications.] [**See Video 2 (online),** which displays continued case examples of BTM reconstruction, including examples of case failures and complications.]

In 26 cases (30.2%), BTM was used as a temporizer while the patient awaited further debridement of wounds or another form of definitive closure. BTM was placed over exposed tendon in 33 (38.4%) cases (Fig. 3), bone in 19 (22.1%) cases, and/or joints in 11 (12.8%) cases (Fig. 4). BTM was placed over nerves in seven (8.1%) cases and major blood vessels as a temporizer in six (7%) cases (Table 2). Staples were used more commonly than suture to secure the edges (58% versus 42%, respectively). The average BTM template size was 125.5 cm^2, with a minimum surface area of 2 cm^2 and a maximum of 2880 cm^2 (Table 3). NPWT was used in 54.7% of cases, and most cases were immobilized after placement of BTM (70.9%; Table 3). Skin grafting usually occurred within 30 days of BTM placement, with a median interval of 27 days (Table 4). Length of follow-up ranged from 1 month to over 2 years, with a median interval of 6 months from the time of BTM placement to last follow-up.

Reconstructive Outcomes

Overall reconstructive success was 93.3%, with only four cases requiring additional intervention beyond BTM and skin grafting, such as flap coverage (n = 2) or ongoing wound care (n = 2). Two cases required flap coverage due to failure of BTM integration over vital structures [**see Video 2 (online)**]. The remaining two failures were chronic wounds that never achieved closure. After BTM integration and delamination, 10 cases went on to heal through secondary intention by re-epithelialization without the need for skin graft. Of note, these wounds were smaller on average, with a mean surface area of 15.8 cm^2 (range: 2–39 cm^2). The average BTM and skin grafting take rates were 88.6% and 92.1%, respectively (Tables 3 and 4).

Table 1. Patient Demographics (n = 54)

Total no. patients (%)	54 (100)
Median age at surgery (y) (range)	16.9 (0.3–81.4)
Total no. pediatric cases (%)	29 (53.7)
Gender (%)	
Male	28 (51.9)
Female	23 (42.6)
Transgender (FtM)	3 (5.6)
Race (%)	
White	39 (72.2)
Black	8 (14.8)
Hispanic	3 (5.6)
American Indian	1 (1.9)
Asian	1 (1.9)
Other/undisclosed	2 (3.7)
Comorbidities (%)	
Hypertension	10 (18.5)
Immunosuppression	9 (16.7)
PVD	7 (13)
Substance abuse	5 (9.3)
DVT	3 (5.6)
Diabetes	1 (1.9)
Smoking status (%)	
Current smoker	8 (14.8)
Former smoker	4 (7.4)
Never smoker	42 (77.8)

FtM, female-to-male.

Minor complications were observed in both BTM (17.4%) and skin grafting (13%). However, these complications did not preclude overall reconstructive success. Among the minor complications noted after BTM application, four cases (4.7%) developed postoperative cellulitis or superficial infections. Infections were confirmed with wound cultures, with results indicating bacterial (n = 3) and fungal (n = 1) etiologies [**see Videos 1 and 2 (online)**]. All infections resolved without long-lasting complications and were effectively managed with antibiotic therapy, twice-daily wet-to-dry dressing changes or NPWT with quarter strength Dakin's solution, and skin grafting at approximately 4 weeks post-BTM placement (Table 3). Other complications related to BTM included premature delamination (n = 4) and hematoma (n = 7). Furthermore, there were two cases in which there was 0% take of BTM after 4 weeks. Both patients had multiple comorbidities and poor wound care compliance. One patient developed an infection at the wound site, and the other patient had a chronic wound that had failed

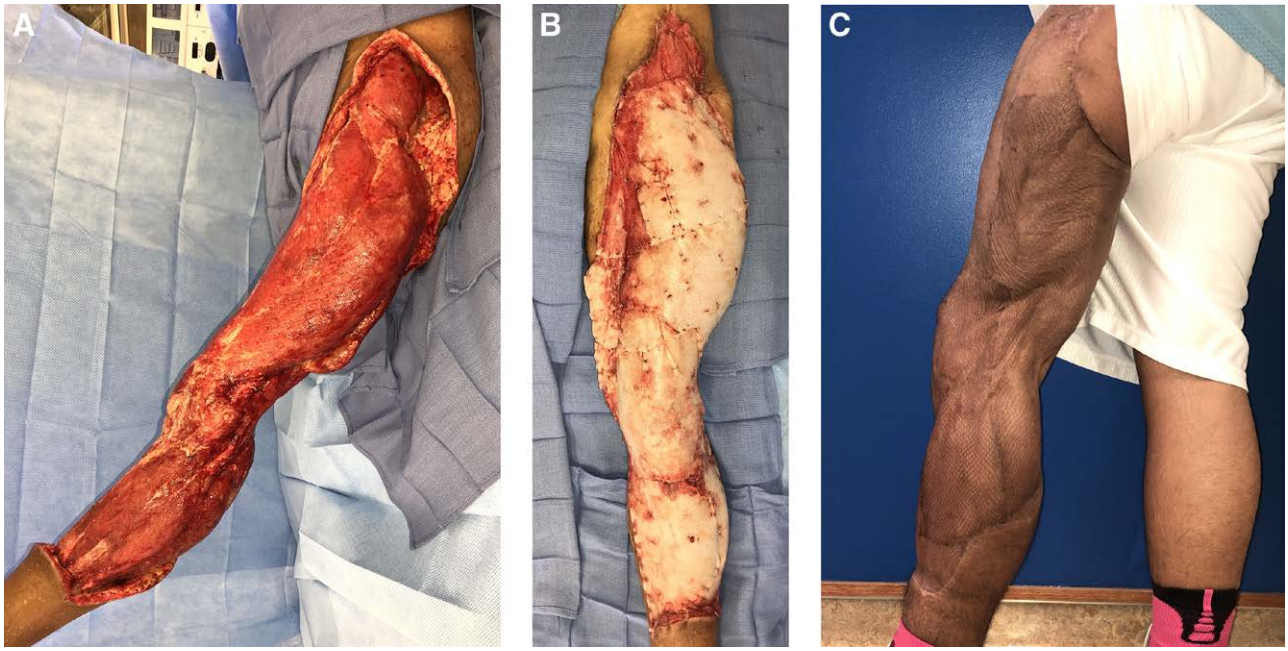

Fig. 1. This figure corresponds to a case of lower extremity necrotizing fasciitis in a 16-year-old male patient. A, The patient's soft tissue deficit over the left leg. The defect area was too large for flap coverage, and skin grafting may have limited range of motion over the knee. B, The patient immediately after BTM placement. C, The patient 10 months after reconstructing with BTM and STSGs. The patient has full range of motion and resumed sporting activities without any functional deficits. See supplemental videos for more details. Printed with permission from and copyrights retained by Shaun D. Mendenhall, MD.

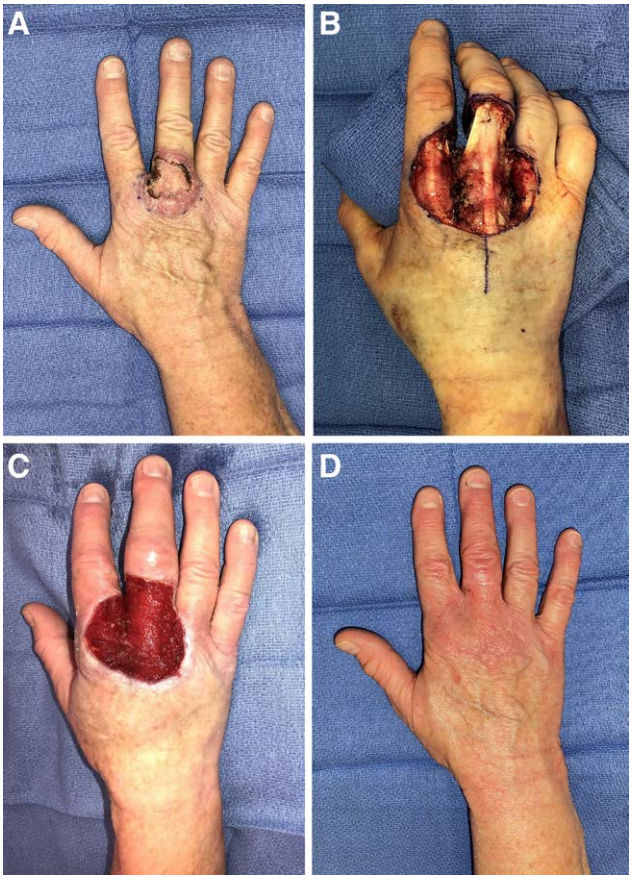

Fig. 2. Photograph showing an 81-year-old patient who had invasive squamous cell carcinoma of the dorsal hand. A, The squamous cell carcinoma before resection. B, The defect after malignancy excision. C, BTM after 4 weeks, immediately after delamination. Note the vascularization of the wound bed. D, Seven months (33 wk) after skin graft. Printed with permission from and copyrights retained by Shaun D. Mendenhall, MD.

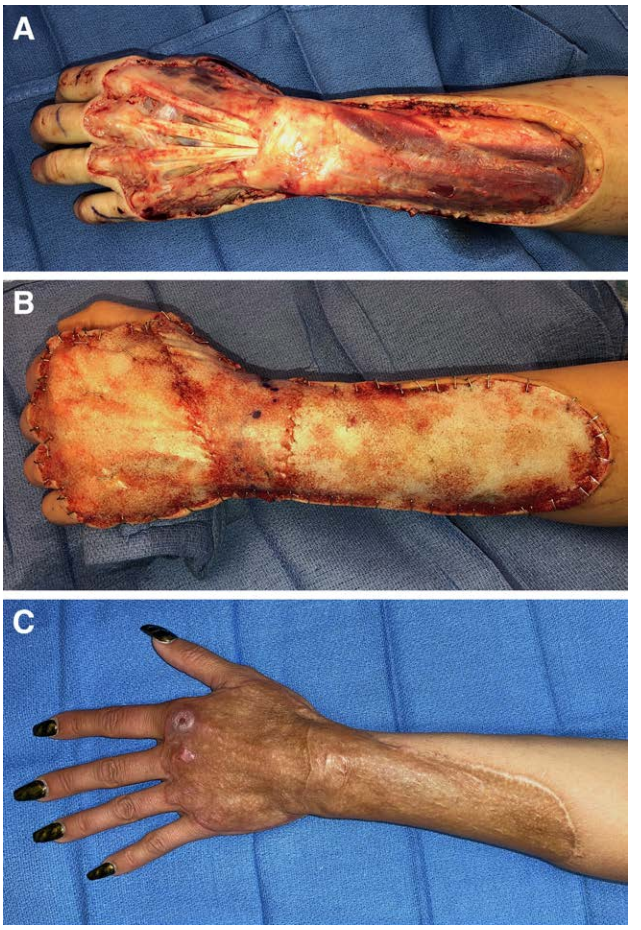

Fig. 3. Photograph of an upper extremity case of a 36-year-old woman who had necrotizing fasciitis with exposed tendons. BTM and STSG mitigated the need for free flap coverage and restored important ROM for this patient. A, The patient's wound after final debridement. The extensor mechanism over the metacarpals was exposed with minimal paratenon. B, The wound immediately after placing BTM. C, The patient's dorsal hand and forearm 16 months after skin grafting. The patient has near full extension and flexion at the metacarpophalangeal joints and wrist. See supplemental videos for more details. Printed with permission from and copyrights retained by Shaun D. Mendenhall, MD.

multiple treatment attempts. The latter patient was on immunosuppressant therapy, and at 6 weeks post-BTM placement, there was minimal incorporation of BTM. Wound closure was still achieved in these patients after granulation promotion through alternate methods (eg, debridement, NPWT) and subsequent skin grafting [**see Video 2 (online)**].

Risk Factors for Poor Take

Differences in comorbidities were observed between patients with good (≥75%) versus poor (<75%) BTM take. Cases that experienced poor BTM take (n = 8) had significantly higher rates of PVD ($P = 0.04$) and hypertension ($P = 0.03$) compared with cases with good BTM take. No significant differences were observed with diabetes, deep vein thrombosis, substance abuse, immunosuppressive therapy, and active tobacco use ($P > 0.05$). Compliance with dressing and/or immobilization care was similar between groups as well ($P = 0.185$; Table 5). Furthermore, number of comorbidities was significantly correlated with percentage take of BTM ($r = -0.387$, $P = 0.002$). Regression analysis revealed that BTM infection, hematoma, and patient immunosuppression were independent predictors of poor BTM take ($P < 0.05$; Table 6). Size, location, and etiology of wounds did not influence BTM take.

DISCUSSION

This is the largest and most diverse cohort study to evaluate the efficacy of BTM in reconstructive surgery of the upper and lower extremities. The inclusion of a wide spectrum of ages (0–81), demographic characteristics, and wound etiologies supports the generalizability of BTM. Despite containing a heterogenous cohort, BTM's overall reconstructive success remained high and comparable to other leading dermal scaffolds.[28,34,35] Thus, this study demonstrated BTM's versatility and reliability as a

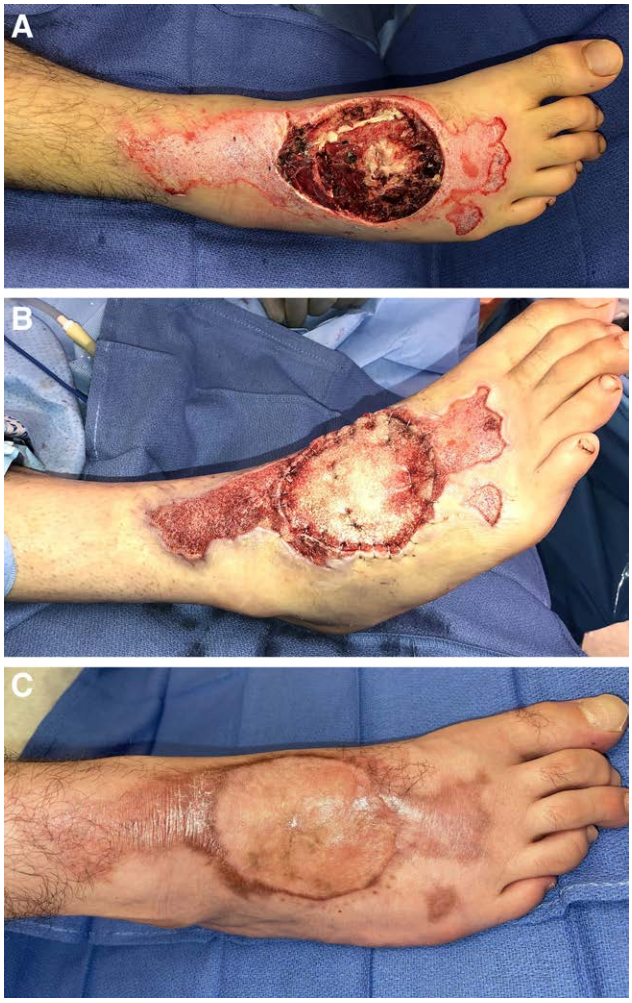

Fig. 4. Photograph of a lower extremity case of a 21-year-old man who had an exposed tarsometatarsal joint after a side-by-side utility-terrain vehicle accident. A, The patient's injury at presentation. B, The wound after placing BTM. C, The wound 5 months after STSG. Printed with permission from and copyrights retained by Shaun D. Mendenhall, MD.

dermal scaffold in temporizing wounds and serving as an adjunct to skin graft reconstruction.

BTM Infection

A salient feature of BTM is its robust performance in the setting of prior or current infection (Fig. 1). This was first illustrated in cases of necrotizing fasciitis by Wagstaff et al,[34,36] who demonstrated successful closure of debrided wounds using BTM followed by skin grafting. Greenwood and colleagues[34,36–39] later supported these observations by demonstrating that infections under BTM could be expressed through fenestration and topically treated without affecting BTM integration. Their findings included the postoperative infection rate of 8.7%, suggesting a more favorable rate when compared with other dermal matrices, such as Integra. For example, Jeschke et al[40] reported an infection rate of 33% using Integra alone and 16% using Integra with NPWT and fibrin glue. A possible

Table 2. BTM Indication and Wound Presentation (n = 86)

Indication (%)	
Temporization	26 (30.2)
Definitive reconstruction	60 (69.8)
Wound etiology (%)	
Trauma	31 (36)
Infection	16 (18.6)
Malignancy excision	10 (11.6)
Burns and burn scar contracture	9 (10.5)
Flap donor site	8 (9.3)
Chronic wounds	6 (7)
Pressor-induced skin necrosis	4 (4.7)
Flap loss	2 (2.3)
Fasciotomy site	1 (1.2)
Wound location (%)	
Upper extremity	45 (52.3)
Lower extremity	41 (47.7)
Exposed structures (%)	
Muscle	41 (47.7)
Tendon	33 (38.4)
Bone	19 (22.1)
Joints	11 (12.8)
Nerve	7 (8.1)
Blood vessels	6 (7)

Table 3. BTM Characteristics and Outcomes (n = 86)

Median template size, cm^2 (IQR)	60 (23–150)
Template reapplication at the same site (%)	10 (11.8)
Concomitant treatments (%)	
NPWT	47 (54.7)
Immobilization	61 (70.9)
Compliance	79 (91.9)
Mean BTM take rate ± SD*	88.6±25
Poor (<75%) take*	8 (13.3)
BTM reapplication (%)*	4 (6.7)
Overall reconstructive success*	56 (93.3)
Method of wound closure*	
Skin graft (STSG/FTSG)	49 (81.7)
Healed by secondary intention (%)	10 (16.7)
Flap coverage (%)	2 (3.3)
Complications	
Hematoma or seroma	7 (8.1)
Cellulitis or infection	4 (4.7)
Early or spontaneous delamination	4 (4.7)

*n = 60.
IQR, interquartile range.

Table 4. Skin Graft Characteristics and Outcomes

STSG (%)	38 (44.2)
FTSG (%)	17 (19.8)
Median area STSG (cm^2) (IQR)	80 (35–187)
Median area FTSG (cm^2) (IQR)	18 (8–30)
Median time to SG (d) (IQR)	27 (22–34)
Mean skin graft take rate ± SD	92.1±21.5
Complications (%)	
Cellulitis or infection	0
Hematoma or seroma	2 (3.7)
Dehiscence or shear	3 (5.5)
Failure	2 (3.7)

Table 5. Comorbidity Associations with Poor BTM Take

	Good BTM Take (≥75%)	Poor BTM Take (<75%)	*P*
Comorbidities (%)			
Hypertension	7 (13.5)	4 (50)	0.031*
Diabetes	1 (1.9)	0 (0)	0.867
PVD	4 (7.7)	3 (37.5)	0.043*
History of DVT	5 (9.6)	3 (37.5)	0.065
Substance abuse	4 (7.7)	1 (12.5)	0.592
Immunosuppressive therapy	8 (15.4)	3 (37.5)	0.154
Active tobacco use	7 (13.5)	1 (12.5)	0.087
Noncompliance with dressing care and/or immobilization (%)	4 (7.7)	2 (25)	0.183

P values from Fisher exact test.
*Statistically significant.

Table 6. Regression Results for Percentage BTM Take

Independent Variable	Coefficient	*P*
HTN	-10.427	0.301
PVD	-5.786	0.605
History of DVT	-13.968	0.08
Immunosuppressive therapy	-18.198	0.01*
BTM hematoma	-45.653	<0.001*
BTM infection	-31.927	0.023*

*Statistically significant.
HTN, hypertension.

Table 7. Indications and Relative Contraindications for BTM

Indications
Well-debrided and clean wounds
Deep full-thickness wounds for filling in of depth
Exposed healthy bone
Exposed healthy tendons
Exposed small joints (hands and feet)
Temporary coverage of wounds while awaiting graft or flap
Defects after scar contracture release
Coverage of small vessels and nerves
Flap donor sites
Relative Contraindications
Frankly infected or necrotic bone/wounds
Large joints
Large blood vessels (unless only temporary)
Presence of synthetic material, grafts, hardware, etc
Radiated tissue
Open fracture of large bones
If prolonging definitive would closure by a month is not feasible

explanation for BTM's lower postoperative infection rate may be its synthetic scaffold material, which is not a substrate to most pathogens.[21] Antimicrobial dressings over the BTM, such as Acticoat or Granufoam silver dressing, which were used in many cases in our series, may also play a role in limiting infections.[37] In our cohort, only four cases (4.7%) developed infections at the site of BTM placement. In these cases, we did not use fenestration of BTM in the management of the infections. Instead, we removed the sealing membrane, leaving some of the polyurethane foam still in place. The wounds were treated with quarter strength Dakin's solution dressings or an irrigating wound vac and went on to grafting and healing on the same timeframe as if there was no infection [**see Video 2 (online)**].

Risk Factors for Poor Take and Management of Complications

While our utilization of BTM was highly successful overall, there were four instances of reconstructive failures that required a flap for closure or did not achieve wound closure [see **Video 2 (online)**]. Several lessons were learned through these cases. Firstly, bone preparation is essential when placing BTM over the bone. Inadequate debridement or placement of BTM over the necrotic bone led to less-favorable outcomes, often necessitating subsequent flap coverage. Therefore, BTM is not suitable for coverage over areas of active osteomyelitis or open fractures, both of which require vascularized soft tissue coverage for appropriate healing (Table 7). However, placement over healthy bone (with or without periosteum) was successful in our series (Table 7). Secondly, the management of chronic wounds proved to be another formidable challenge. In our cohort, we encountered two patients whose BTM reconstructions failed to achieve complete wound closure. This outcome highlighted the necessity for more aggressive debridement and wound bed preparation in cases of chronic wounds prior to BTM placement. One limitation of BTM is that, similar to a skin graft, it lives off of vascularity from the underlying tissue and, therefore, cannot reliably be elevated secondarily for revision work such as tenolysis, bone grafting, or nerve repair.

BTM failure or cases of poor BTM take may be the result of poor wound care compliance coupled with patient comorbidities, such as hypertension, PVD, immunosuppressive therapy, and active tobacco use. Our study specifically highlighted the significant impact of immunosuppression on BTM take, underscoring the intricate relationship between a patient's immune response and the success of BTM integration. Although other comorbidities were associated with poor BTM take, they did not emerge as independent predictors in our analysis; therefore, BTM may offer a promising reconstructive option for patients who are not suitable candidates for flap procedures due to their medical comorbidities. The affordability of BTM also positions it as an attractive primary option in many cases. However, it is important to acknowledge that our research may have been underpowered to establish guidelines or draw definitive conclusions in this regard. Thoughtful preoperative discussions detailing the risks and benefits of reconstructing with BTM should always take place as part of the informed consent process.

BTM infection and hematoma were also significant predictors of poor BTM take rate. When examining cases involving these complications, our research shed light on effective management strategies. Specifically, the authors observed that addressing BTM hematomas could be accomplished by either creating small incisions in the BTM or gently elevating the BTM to evacuate the hematoma, all while preserving BTM integration. Infections, as discussed previously, could also be effectively managed without completely removing the BTM. These insights were gleaned

from years of BTM utilization; thus, early cases of infection and hematoma, predating the implementation of these strategies, influenced BTM take adversely. Initiating management of complications with these strategies from the outset likely would have minimized their impact on BTM integration.

BTM Cost

Another benefit of BTM in comparison with other dermal substitutes is reduced cost. Direct comparisons by Kozak et al[41] show that using a dermal substitute, such as Integra, significantly reduces total costs relative to free flap repairs. Considering that BTM is roughly one-fourth the cost of Integra, it is likely that BTM may generate additional cost reductions.[28] The low cost of BTM also allows it to be used as a temporary wound coverage, protecting vital structures and keeping the wound hydrated while awaiting definitive reconstruction (30.2% of cases in our practice). Nonetheless, while material price can be readily predicted, additional costs due to complications and advanced wound care cannot. Although the burden of such unforeseen costs will likely be similar for different dermal substitutes, cost analysis studies are needed before more definitive cost comparisons can be made. Future comparisons should thus analyze surgical outcomes and overall costs to elucidate which options promote value-based care.

This study underscores the versatility of BTM and its successful use in many different clinical scenarios. Importantly, BTM was used to reconstruct radial forearm phalloplasty donor sites in three cases. Historically, Integra has been the preferred dermal template for addressing this specific defect.[42] However, our study achieved excellent results using BTM in this cohort, highlighting its potential as a cost-effective alternative for such procedures [**see (Videos 1 and 2 (online)**].

Long-term Outcomes

Although our current study did not specifically gather data on long-term outcomes or scar quality, based on the authors' experience, BTM has been associated with satisfactory long-term scarring results. The average length of follow-up in our cohort was 6 months, with many patients followed for greater than a year after their index procedure. Based on long-term observation of these patients, overall, the tissue quality is softer and more supple after BTM than directly going to an STSG. The pigmentation of scars seems to depend on the donor site of the skin graft and native pigmentation of the patient more than anything else. We have provided photographs and supplemental videos that highlight many of these long-term results [**see Videos 1 and 2 (online)**].

Study Limitations

There are inherent limitations of this study that should be considered before contemplating any adjustments to clinical practices. Information and selection bias likely influence study findings, as data variables were collected and analyzed retrospectively. Furthermore, although this cohort is larger than other BTM studies in the literature, there was a small number of failures and complications, which likely impacted the analyses. Larger, prospective studies would mitigate these limitations.

CONCLUSIONS

Overall, this heterogenous cohort study demonstrates that BTM is a safe, reliable dermal scaffold that can be used across patients of diverse ages, presentation characteristics, and wound types. Reconstruction with BTM consistently produces high skin graft take rates, low rates of postoperative infection, and relatively lower cost compared with competing dermal substitutes. Patients who are noncompliant with wound care with numerous comorbidities will likely experience more complications than their counterparts. Although prospective studies are forthcoming, this study strengthens the evidence in favor of extremity reconstruction with BTM.

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DISCLOSURES

Author Shaun D. Mendenhall is an educational consultant for PolyNovo, the manufacturer of NovoSorb BTM. All the other authors have no financial interest to declare in relation to the content of this article.

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