

Experience with NovoSorb[®] Biodegradable Temporising Matrix in reconstruction of complex wounds

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Introduction

The NovoSorb[®] Biodegradable Temporising Matrix (BTM) (PolyNovo Biomaterials Pty Ltd., Port Melbourne, VIC, Australia) is a fully synthetic dermal matrix that can be used to reconstruct complex wounds. It consists of a 2-mm thick NovoSorb biodegradable polyurethane open cell foam covered by a non-biodegradable sealing membrane. The open cell matrix allows for infiltration of cellular materials and acts as a scaffold for the neo-dermis. The sealing membrane provides physiological wound closure but also contains small fenestrations to prevent the accumulation underneath the material.¹

The application of BTM involves a two-stage procedure.¹ In the first stage, the BTM is laid onto a clean wound bed. Cells and blood

Abstract

Background: The NovoSorb[®] Biodegradable Temporising Matrix (BTM) is a synthetic polyurethane dermal matrix used to reconstruct complex wounds including deep dermal and full-thickness burns, necrotising fasciitis and free flap donor site. We hope to further explore its potential applications in this series.

Methods: Patients who received BTM application across four centres over an 18-month period were included. Patients were followed up to assess BTM and graft take, the aesthetic, the return of sensation and complications.

Results: A total of 27 patients with 35 wounds were identified with a range of aetiologies. Thirty-three wounds had 100% integration of BTM at the time of sealing membrane removal. Seven wounds had partial graft loss that later healed by secondary intention. In two cases, re-epithelialisation occurred with BTM alone without split-skin graft.

Conclusion: BTM offers a safe and reliable reconstructive option in challenging wounds that would otherwise require more complex operations.

vessels migrate into the BTM during the integration phase and a vascularised neo-dermis is formed. Capillary refill can be seen from as early as 2 weeks. The polyurethane matrix is biodegradable and breaks down via hydrolysis.² In the second stage, the sealing membrane is removed and a split-skin graft (SSG) is applied to the neo-dermis.¹

BTM differs from the traditional SSG in that it helps to replace the natural thickness of the dermis, minimises contracture, prevents tethering to the underlying structures and allows for the rapid temporising of large total body surface area wounds.³ Unlike other artificial dermal templates that are comprised of allogenic or xenogenic materials, the fully synthetic BTM eliminates the possibility of inter-species immune rejection or disease transmission and avoids ethical or cultural obstacles.⁴ Early in vitro studies confirmed the biocompatibility of BTM.^{2,5} In vivo studies utilising rats and porcine models demonstrated adequate reconstruction of full-thickness wounds with a high resistance to wound contracture and an absence of systemic toxic effects.^{6,7} Comparisons between BTM and Integra[®] (Life Sciences Corp., Plainsboro, NJ, USA) in animal models highlighted the effectiveness of the BTM in providing a stable and flexible wound reconstruction.^{4,8}

The first use in humans was trialled as a polyurethane foam (NovoPore[™], Polynovo) in negative-pressure wound therapy (NPWT) for pressure ulcers.⁹ This showed that short-term implantation in patients did not cause adverse reactions. Following this, the use of a prototype bilayer device consisting of NovoSorb foam with a non-biodegradable sealing matrix in free flap donor wounds showed promising results.¹⁰ Further modification of the sealing membrane including the thickness, bonding layer and the introduction of fenestrations produced superior results in subsequent studies.¹¹

The use of BTM in burns demonstrated that it could successfully treat large total body surface area burns with excellent cosmetic and functional results.^{3,12} This success led to its use in necrotising soft tissue infections to provide pliable wound coverage.^{13,14}

Here, we report a consecutive case series of 35 wounds describing the use of BTM in a range of challenging wounds which would otherwise require more complex reconstructions.

Methods

The study was a multicentred, prospective case series involving 27 patients with 35 complex wounds from January 2019 to December 2020. This study was approved by the ethics committee of Austin Health (Melbourne) with consents obtained from all patients. Patient demographics, indications for BTM, surgical details and outpatient follow-up were recorded. Inclusion criteria included complex wounds with (1) exposure of a critical structure such as tendon and bone, (2) failure of previous skin graft and (3) wound bed where the surgeon did not expect a traditional SSG to take. Exclusion criteria included active infection or residual malignancy.

All patients were followed up in the outpatient departments of their respective institutions with a maximum follow-up of 18 months. Outcomes measured included percentage of BTM take at the time of grafting, percentage of SSG take, sensation and aesthetics as measured by the Patient and Observer Scar Assessment Scale (POSAS).¹⁵

Surgical management included initial debridement to remove all devitalised and infected tissue prior to reconstruction with BTM. In cases of malignancies, oncological clearance was obtained prior to BTM reconstruction.

First stage of reconstruction involved the inset of BTM with either staples or sutures. Quilting staples or sutures were utilised to maximise contact between the BTM and the wound bed. The wound edges were also saucerised in some instances to improve dermal contact. After the application of BTM, ActicoatTM (Smith and Nephew) was applied over the BTM and either secured with NPWT between 50 and 75 mmHg or dressed with gauze, crepe bandage and Mefix[®] (Mölnlycke Health Care AB, Gothenburg, Sweden) to provide compression. In wounds that involved the limbs or joints, a plaster or orthotic splint was applied for the first post-operative week. The external dressing was changed once or twice weekly. The BTM was evaluated weekly for integration by assessing for capillary refill. Excess fluid was expressed through the fenestrations before re-dressing. This continued until the BTM was deemed ready for the second stage, which varied from 2 to 10 weeks.

Second stage of reconstruction involved delamination of the sealing membrane and coverage with SSG. Grafts of less than 0.01 in. were harvested with a dermatome and applied as a sheet or meshed graft depending on the size and location of the wound. Inset was achieved with either glue, sutures or staples. Dressings included a combination of JelonetTM, Bactigras or Xeroform[®] (Kendall) followed by gauze or foam with crepe bandage or tape. NPWT dressings were used in selected cases. If the wound involved a limb or joint, immobilisation was applied until graft check at 5–7 days post-operation.

Results

The age of patients ranged from 47 to 95 years, with 19 males and 8 females. The total number of wounds was 35 and included 14 lower limb wounds, 7 upper limb wounds, 12 head and neck wounds, one abdominal wound and one breast wound post-autologous reconstruction. Follow-up ranged from 3 to 18 months. The results are summarised in Table 1.

Thirty-three wounds had 100% integration of BTM at the time of second-stage reconstruction. In one of the cases, the BTM failed to integrate over exposed calvarium despite an absence of haematoma or infection. This patient subsequently had a transposition flap. The other case had an incomplete integration of the BTM with 10% loss. The SSG was taken over the 90% BTM, with the rest of the wound healed by secondary intention. Seven patients had partial graft loss after the second-stage reconstruction, which all healed by secondary intention.

The POSAS scale was used to evaluate the scars of each patient. A mean \pm standard deviation overall patient score of 5.67 \pm 2.82 out of 10 was observed, with one representing normal skin and 10 being very different to normal skin. A mean overall observer score from an independent plastic surgery is of 3.63 \pm 2.04.

Light touch sensation was measured in all patients with an average score of 5.86 ± 2.72 out of 10, with 10 being full sensation. However, one patient had BTM applied over an insensate deep inferior epigastric perforator flap and was excluded.

The following is a further discussion of four example cases.

Case 1

A 72-year-old gentleman presented with right calcaneal osteomyelitis secondary to a pressure injury after a complicated valvular heart surgery. The calcaneal pressure wound was treated with multiple debridement including partial calcanectomy and NPWT dressings. Vascular supply of the foot was optimised with angiography and stenting. Intraoperative bone samples grew Proteus and *Staphylococcus aureus* and were treated with prolonged intravenous antibiotics. The patient requested limb preservation. BTM was applied over the residual calcaneum and a separate posterior calf pressure ulcer. There was full integration of the BTM, and the wound was

Sensation (out of 10)	Calf 8	D L G G G G G G G G G G G G G G G G G G	Q	Left breast 0 (insensate DIEP)	Abdomen 3	Vertex 3	Anterior scalp 4	10	10	വ	വ	7	00	Q	L	N/A (0)	10	8
POSAS score (overall, out of 10)	Patient calf 7 Observer calf 3	Patient neel / Observer heel 3	Patient 9 Observer 3	Patient breast 9 Observer breast 3	Patient abdomen 9 Observer abdomen 4	Patient vertex 10 Observer vertex 4	Patient anterior scalp 9 A Observer anterior scalp 5	Patient 4 Observer 2	Patient 5 Observer 1	Patient 8 Observer 2	Patient 7 Observer 5	Patient 9 Observer 5	Patient 2 Observer 2	Patient 4 Observer 1	Patient 3 Observer 2	N/A (10)	Patient 1 Observer 2	Patient 7
% SSG take at 1 month	Calf 100%	0% C/ 199U	Calf 100%	Left breast 100%	Abdomen 90%	Vertex 50%	Anterior scalp 70%	N/A (sealing membrane removed on day 52)	100%	100%	100%	80%	100% (second SSG)	N/A	100%	Trans-position flap used	100%	100%
% BTM integration at the time of SSG	Calf 100%		Calf 100%	Left breast 100%	Abdomen 90%	Vertex 100%	Anterior scalp 100%	100%	100%	100%	100%	100%	100%	100%	100%	%0	100%	100%
Wound base	Muscle	bone (with history of osteomyelitis)	Muscle and tendon	Fat	Fat	Bone (irradiated)	Bone (irradiated)	Muscle and tendon	Muscle and tendon	Muscle and tendon (significant scarring)	Fat and paratenon	Bone (irradiated)	Fat	Fat	Tendon	Bone	Tendon	Muscle
Time from BTM inset to SSG	27 days		34 days	36 days		52 days		Never grafted— healed by secondary intention	24 days	81 days	28 days	28 days	46 days	Never grafted— healed by secondary intention	29 days	N/A	49 days	15 days
Complications	Ē		īz	Sinus tract in the abdominal wound		Nil		īz	Ĩ	īz	Ē	Partial wound breakdown with some exposed bone	Failed initial skin graft	Ē	Ē	BTM failed to integrate, no infection	Z	Nil
Indication	Grade IV pressure sores on right calf and right heel with calcaneal	osteornyeints	Failed SSG with exposed Achilles tendon in the setting of necrotising fasciitis of the right leg	Left mastectomy skin flap necrosis and abdominal wound dehiscence in the setting of a	DIEP flap	Delayed reconstruction of vertex and anteiror scalp following	excision of SCC and prior radiotherapy	Left radial forearm free flap donor site after failed SSG	Left fibula free flap donor site after failed SSG with exposed tendon	Left knee wound breakdown with polymicrobial prosthetic knee joint infection and exposed patella tendon	Same patient as above but 1 year later. Second-stage left knee reconstruction	Delayed reconstruction following scalp SCC excision and prior radiation	Right leg BCC with signficiant ulceration	Grade III right heel pressure sore	Right hand dorsum traumatic degloving with exposed extensor tendon	Scalp SCC excision with burring of the outer table	Left hand dorsum wound post excision of SCC with failed SSG and exposed tendon	Left pre-auricular SCC re-excision
Age	72/M		61/F	47/F		84/M		63/M	64/M	65/F	66/F	87/M	75/F	95/M	73/M	68/M	69/F	95/M

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Table 1 Patient details

Age	Indication	Complications	Time from BTM inset to SSG	Wound base	% BTM integration at the time of SSG	% SSG take at 1 month	POSAS score (overall, out of 10)	Sensation (out of 10)
62/F	Left dorsal foot wound breakdown with exposed tendon post arthrodesis	Complete graft failure—left to heal by secondary	40 days	Tendon	100%	%0	Observer 2 Patient 8 Observer 7	۵
75/M	Right hand middle and ring finger traumatic wounds with exposed	Nil	24 days	Tendon	100%	100%	Patient 4 Observer 4	o
93/M	extensor rendons Nasal dorsum wound post BCC excision with failed full-thickness	Z	26 days	Perichondrium	100%	100%	Patient 1 Observer 2	ω
91/M	Scalp SCC excision with burring of	Nil	39 days	Bone	100%	50%	Patient 9	0
42/M	Right wrist traumatic wound with	Nil	36 days	Muscle and	100%	100%	Patient 3	7
74/M	exposed extensor tendons Failed SSG post left heel melanoma	Nil	43 days	tendon Fat	100%	100%	Ubserver 3 Patient 5 Observer 4	9
89/M	Right nasal sidewall infiltrative BCC	Nil	43 days	Perichondrium	100%	100%	Patient 4	Ð
59/M	requiring multiple re-excisions Excision of ulcerative BCC right thigh BCC with musice	Fall with haematoma	41 days	Muscle	100%	100%	Observer 2 Patient 6 Observer 3	o
70/F	Involvement Excision of multiple SCCs in right brown left brown assel dorenum	Nil	31 days	Muscle	Right brow 100%	Right brow 100%	Patient right brow 6 Observer right brow 5	Right brow 4
	and right hand dorsum			Muscle	Left brow 100%	Left brow 100%	Patient left brow 6 Observer left brow 6	Left brow 4
				Perichondrium	Nasal dorsum 100%	Nasal dorsum 100%	Datient nasal dorsum 9 Observer nasal	Nasal dorsum 3
				Tendon	Right hand 100%	Right hand 100%	dorsum 8 Patient right hand 4 Observer right hand 4	Right hand 5
82/M	Excision of left pre-tibial and left medial ankle SCCs with exposed	Nil	30 days	Periosteum	Left pre-tibial 100%	Left pre- tibial 100%	Observer right hand 4 Patient left pre-tibial 1 Observer left pre-	Left pre-tibial 8
				Periosteum	Left medial ankle 100%	Left medial ankle 100%	Patient left medial ankle 1 Observer left medial	Left medial ankle 8
86/F	Soft tissue defect following open left distal fibula fracture and open	Nil	44 days	Fat and muscle	100%	90%	ankie z Patient 6 Observer 4	7
76/M	Right dorsal hand degloving with	Nil	27 days	Paratenon	100%	100%	Patient 4 Observer 3	ы
81/M	Excision of large scalp SCC with exposed calvarium	Nil	25 days	Bone	100%	100%	Patient 3 Observer 2	С
BCC, b.	asal cell carcinoma; BTM, Biodegradable 1 ma: SSG_solit-skin craft	Femporising Matrix; E	JIEP, deep inferior epig	Jastric perforator; ICU,	intensive care unit; POSAS,	Patient and Observer	Scar Assessment Scale; SC	CC, squamous cell

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Fig 1. Right calcaneal pressure sore with osteomyelitis reconstructed— (a) with Biodegradable Temporising Matrix after delamination. (b) Result at 18 months post-operatively.

successfully grafted 4 weeks later. Follow-up at 18 months postgrafting (Fig. 1) showed adequate and durable soft tissue coverage with no recurrent wound breakdown.

Case 2

A 64-year-old lady presented with an infected and dehisced knee wound with underlying prosthesis. She had a previous left total knee replacement with gradually worsening range of motion following an intra-medullary nail fixation of a femur fracture of the ipsilateral side. An arthrotomy and manipulation under anaesthesia was performed to release scar tissue but she presented 1 month later with wound dehiscence and infected prosthesis. She underwent multiple debridement and the prosthesis was replaced with an antibiotic spacer. Intraoperative samples grew Pseudomonas, *Escherichia coli*, Bacteroides and *Staphylococcus epidermidis* which were treated with a prolonged course of intravenous antibiotics. The antibiotic spacer was covered with a heavily scarred patella tendon temporised with NPWT. BTM was applied over the patella tendon. After 10 weeks, an SSG was applied. Follow-up at 12 months demonstrates complete healing of the wound (Fig. 2b).

The spacer was removed at 12 months and replaced with a new prosthesis. The wound was closed primarily but she again developed a wound dehiscence just distal to the previous BTM site at 4 weeks after the operation. The wound was debrided, and a local perforator flap was used to cover the wound and BTM was applied to the donor defect. The donor defect was grafted at 8 weeks. At 6 months follow-up, the wound remained stable (Fig. 2c).

Case 3

A 65-year-old gentleman underwent a left radial free forearm flap for a maxillary squamous cell carcinoma defect. The initial SSG to his forearm donor site failed. The wound was debrided leaving the flexor carpi radialis and palmaris longus tendons exposed. Intraoperative samples grew mixed skin flora. BTM was applied and, interestingly, the wound almost completely re-epithelialised at 4 weeks. A decision was made to allow it to heal without an SSG with the sealing



Fig 2. Left knee wound dehiscence with underlying metalware. (a) Reconstructed with Biodegradable Temporising Matrix (BTM) over scarred patella tendon (b) at 12 months post-reconstruction, (c) second reconstruction with a local perforator flap and BTM to the donor site and (d) at 6 months post-reconstruction.

membrane removed at day 52 post-operatively. Follow-up at 12 months showed no recurrence of wound breakdown.

Case 4

A 93-year-old gentlemen presented with a failed full-thickness skin graft after the excision of a nasal dorsum squamous cell carcinoma. Biopsy of a lesion on the left nasal alar confirmed a separate basal cell carcinoma (BCC). The nasal dorsum wound and the left nasal alar BCC were excised en bloc and resurfaced with BTM. The BTM was well integrated and delaminated at 4 weeks. An SSG was applied and at 8 weeks follow-up the graft showed excellent aesthetic result (Fig. 3).

Discussion

BTM has demonstrated its reliability and versatility in the reconstruction of complex wounds in patient with multiple comorbidities. Most cases were successfully grafted at 3–4 weeks post-operatively, ranging from 2 to 10 weeks. Furthermore, the dermal matrix was robust enough to heal in the setting of partial graft loss.

Advantages of BTM include the ability to convert a wound bed into a surface suitable for skin graft, such as exposed bone or



Fig 3. (a) Failed full-thickness skin graft on the dorsum of the nose with a separate foci of basal cell carcinoma (BCC) on the left nasal alar. (b) Debridement and excision of left nasal alar BCC en bloc and resurface with Biodegradable Temporising Matrix (c) at 6 months follow-up.

tendon. In the cases of exposed tendons, this also allows preservation of the tendon function. In patients with multiple morbidities, it provides a robust and simple reconstructive option for complex wounds. The operation can be performed under local or regional anaesthesia and has an overall low complication profile and donor site morbidity.

In two of the cases, there was complete re-epithelisation of the wound without the need for a skin graft. To our knowledge, this has yet to be reported in the literature. This offers valuable insight into what BTM is capable of as a dermal matrix and could provide the basis for future research.

The sensory regeneration of the wounds reconstructed with BTM can significantly influence the patients' quality of life after the reconstruction. This is particularly important when BTM is used in the weight-bearing portion of the lower limb. A sensate reconstruction can maintain function and also help in preventing further injury to the area. In our cases, early results are promising, with most patients regaining partial sensation over the majority of their wounds. This may provide further benefits over more complex reconstructions. Further studies with longer follow-up and more in-depth sensory assessment would be beneficial.

The POSAS score also suggest overall good aesthetic result with BTM reconstruction. It matches the thickness of most defects without the need for further revision or debulking.

Disadvantages of BTM include potential failure to integrate especially in cases of borderline vascularity or infection, as well as the staged nature of the reconstruction. These limitations are, however, common to all dermal matrices. Prior radiation, especially in the scalp, poses high risk of failure to integrate in our series. Four patients with scalp malignancies that involved burring of the outer table and radiotherapy had either partial graft failure or, in one case, complete failure of integration of BTM. This may form the basis of future studies.

robust reconstructive options in a wide range of complex wound, especially when local and free tissue transfer are not a suitable option.

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Author contributions

Henry Li: Conceptualization; data curation; formal analysis; investigation; methodology; software; validation; writing-original draft; writing-review & editing. Pelicia Lim: Data curation; investigation; resources. Edward Stanley: Investigation; methodology; resources. Geoffrey Lee: Data curation; investigation; resources. Sandra Lin: Data curation; investigation; resources. Derek Neoh: Resources; supervision. Julian Liew: Resources; supervision. Sally Ng: Conceptualization; investigation; methodology; project administration; resources; supervision; validation; writing-original draft; writing-review & editing.

Conflict of interest

There are no conflicts of interest to disclose except that author Julian Liew holds minor shares in the PolyNovo.

Data availability statement

The data used in this study is kept in the respective hospital's departmental database and medical records.

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BTM has been shown to be effective in burns, necrotising fasciitis and free flap donor wounds. Our series suggest it provides reliable and

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