



# Biodegradable Temporising Matrix (BTM) for the reconstruction of defects following serial debridement for necrotising fasciitis: A case series

Marcus J.D. Wagstaff<sup>a,b</sup>, Ingrid M. Salna<sup>a</sup>, Yugesh Caplash<sup>a</sup>, John E. Greenwood<sup>b,\*</sup>

<sup>a</sup> Department of Plastic and Reconstructive Surgery, Royal Adelaide Hospital, Adelaide, South Australia, Australia

<sup>b</sup> Adult Burn Centre, Royal Adelaide Hospital, Adelaide, South Australia, Australia



## ARTICLE INFO

### Article history:

Received 3 September 2018

Accepted 4 October 2018

Available online 6 October 2018

## ABSTRACT

Serial debridement of tissue affected by necrotising fasciitis results in extensive and deep wounds, sometimes complicated by the exposure of major vessels, tendons, bone or other tissue incapable of supporting healing by skin grafts alone. When skin grafts are used, their contraction can result in contracture of joints, or the neck. On the other hand, reconstruction using tissue flaps can be bulky, with poor contour definition and healing of both reconstruction, and donor site, may be compromised by patient comorbidity and instability. In our institution, concerns regarding infection and loss of dermal substitutes of biological origin in these scenarios (e.g. collagen/glycosaminoglycan) have precluded their use. We present a series of seven consecutive cases of such challenging wounds; temporised and reconstructed with a totally synthetic polyurethane dermal substitute and secondary skin grafting, resulting in durable cover with minimal contracture. The cohort includes anterior neck defects exposing major vessels (2/7), multiple exposed ribs on the chest wall (2/7), lower limbs crossing knee or ankle joints (3/7) and a lower limb amputation by hip disarticulation (1/7). This is the first published series of the use of a completely synthetic dermal substitute in necrotising fasciitis wounds, and the joint largest using any dermal substitute. © 2018 The Authors. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## 1. Introduction

Necrotising fasciitis is a synergistic gangrene which is increasing in prevalence [1], with 628 cases presenting to Australian hospitals in 2016/17. It is associated with significant mortality; causing 290 deaths between January 2009 and February 2018 (unpublished data).

The development of NovoSorb™ Biodegradable Temporising Matrix (BTM™) began at the Royal Adelaide Hospital in South Australia at the end of 2004. Beginning with human in vitro cellular studies, early wound experience was confined to small and large animal models [2–7]. Experience of short-term human exposure to the novel biodegradable polyurethane foam (NovoSorb™) began in 2012, when the foam was used as a Vacuum-Assisted Closure (VAC) interface in debrided pressure sores, compared against Granufoam [8]. The intended role of BTM as a dermal substitute,

*Abbreviations:* BTM, Biodegradable Temporising Matrix; TBSA, Total Body Surface Area; NPWT, negative pressure wound therapy; VAC, Vacuum Assisted Closure; TGA, Therapeutic Goods Administration.

\* Corresponding author at: Adult Burn Service, Level 7, G Wing, Royal Adelaide Hospital, 1 Port Road, Adelaide 5000, South Australia, Australia.

E-mail address: [john.greenwood@sa.gov.au](mailto:john.greenwood@sa.gov.au) (J.E. Greenwood).

<https://doi.org/10.1016/j.burnso.2018.10.002>

2468-9122/© 2018 The Authors. Published by Elsevier Ltd.

This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

was first investigated in humans in the reconstruction of free flap donor sites as a small, complex, surgical (iatrogenic) model later that same year [9], with further experience gained after minor optimization [10,11]. After that time, the focus of the clinical investigation shifted to major and complex burn injuries, the indication for which the BTM was originally designed [12,13]. More comprehensive accounts of the development of BTM and related products have also been published [14–16].

The success of BTM in these varying indications, and its apparent resistance to infection, led to its first use in necrotising fasciitis in 2017 [17]. Following radical debridement, necrotising fasciitis wounds are often extensive with a bed varying in contour, tissue vascularity and composition. Biological dermal substitutes have been reported as successful aides to reconstruction in these scenarios [18–24]. They offer a potentially favourable alternative to split skin graft alone, by replacing lost dermis with thicker, uniform contour and reduced wound contraction. Despite these reports, concerns of a biological substitute becoming digested during its use in infective scenarios (even after successful eradication), left us reluctant to adopt this technology after necrotising fasciitis. Our experience using a synthetic dermal substitute for moderate and severe acute burn wound repair demonstrates that the polyur-

**Table 1**  
Patient Demographics.

No.	Age	Sex	Co-morbidities
1	55	F	Hypothyroidism, alcoholism, osteoporosis
2	32	F	Hypothyroidism, diabetes mellitus, anaemia, depression
3	49	M	Osteoarthritis
4	76	M	Diabetes mellitus, secondary hyperparathyroidism, hypogonadism, hypertension, hypercholesterolaemia, gout, right nephrectomy & chronic renal failure requiring haemodialysis
5	46	M	Nil
6	55	M	Chronic lymphoedema, asthma, depression, Grave's disease, obesity
7	48	F	Nil

ethane structure does not appear to be affected by underlying wound infection, and will continue to integrate into the wound bed following drainage of infected collections through perforations in the seal [12]. In addition, we have used this successfully to reconstruct wounds with complex beds, such as exposed calvarium [13]. This 7 patient consecutive case series details the use of BTM in complex defect reconstructions following debridement for necrotising fasciitis, and constitutes the first reported series of cases of necrotising fasciitis wounds reconstructed with a completely synthetic dermal substitute and the joint largest series using any dermal substitute for this indication [24]. It is also the first series of patients reported where a synthetic dermal substitute has been used to reconstruct acute debrided non-burn wounds.

**Table 2**  
Wound description & use of BTM.

No.	Soft tissue defect	Size of defect (% TBSA)	Indication for BTM	Alternatives considered
1	Loss of all soft tissues of the anterior neck	1.5	Exposed sternocleidomastoids, carotid sheaths & submandibular gland; temporisation	Integra or free anterolateral thigh flap
2	Right forequarter amputation, loss of right chest, flank and abdomen soft tissue	8	3 exposed ribs denuded of periosteum	Integra or repeated NPWT after rib cortex drilling
3	Loss of left lower limb soft tissues	4	Improved contour, prevention of major joint contracture	Primary split skin graft
4	Loss of right chest soft tissues, extensive wounds right axilla	9	2 exposed ribs denuded of periosteum	Integra or repeated NPWT after rib cortex drilling. Regional muscle flap with split skin graft
5	Loss of soft tissues of anterior neck and upper chest	5	Exposed sternocleidomastoids, carotid sheaths & submandibular glands	Integra or free anterolateral thigh flap with split skin graft
6	Extensive loss of bilateral lower limb soft tissues	24	Temporisation; improved contour and prevention of major joint contracture	Primary split skin graft
7	Right lower limb amputation with hip disarticulation including large abdominal soft tissue defect	8.5	Temporisation; more durable weight-bearing surface	Primary split skin graft

**Table 3**  
Operative details & outcomes.

No.	Total stay in hospital (days)	Time to BTM implantation from first debridement (days)	Time to BTM Integration (days)	Time to discharge post-graft (days)	Follow-up since BTM (months)	No. of OR procedures from BTM application	% TBSA BTM loss	% TBSA graft loss over integrated BTM
1	81	10	34	6	4	2	0	0
2	62	19	33	10	20	4	0	0
3	40	8	36	18	18	2	0	0
4	62	29	42	19	17	7	0.5	0
5	32	6	32	8	9	4	0	0
6	93	30	26	37	5	9	0.5	0
7	Still in-patient	41	35	–	1	5	0	0

## 2. Methods

All cases in which BTM has been employed in necrotising fasciitis wound reconstruction have been included. Medical records and operations notes were reviewed retrospectively, including clinical photographs. Photographs were taken of all wounds at each surgery and dressing change. The data collected included demographics, length of stay in hospital, description of defect following serial debridement, indication for BTM, time from implantation to split skin grafting and complications (Tables 1–3).

### 2.1. Initial surgical management

In the acute phase, all cases of necrotising fasciitis are individually managed according to standard of care. This consists of appropriate resuscitation, urgent radical debridement of all clinically infected or and/or necrotic tissue under general anaesthetic and administration of antimicrobials. Specimens of wound tissue were sent for microscopy, culture and sensitivity. In Subjects 2 and 7, the extent of infection necessitated forequarter amputation and lower limb amputation with hip disarticulation, respectively.

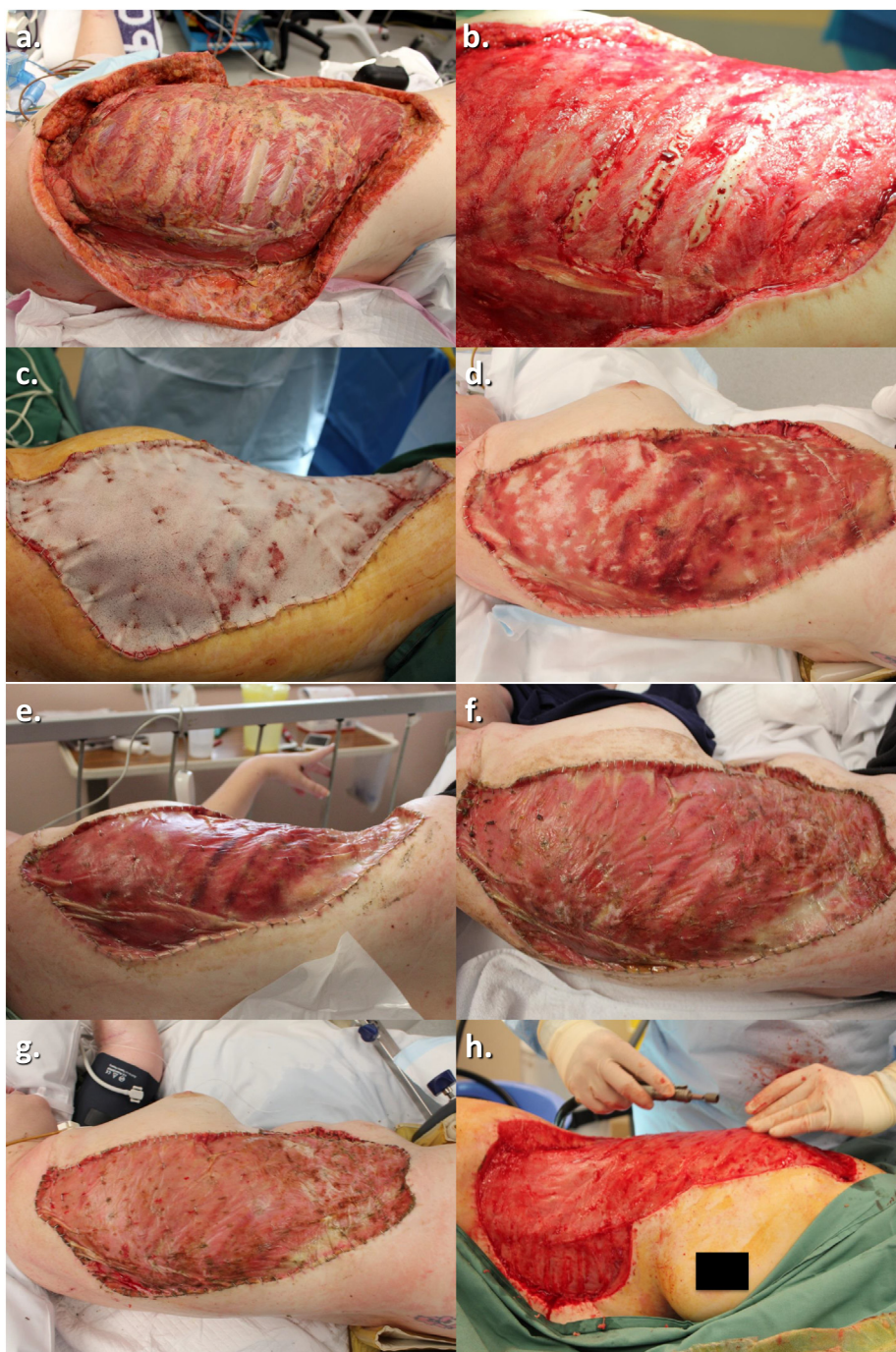
The subjects were returned to theatre often daily, or every second day, for further wound toilet and dressing changes until wound control was achieved. Dressing choices were made according to individual surgeon standard of care, and initially included paraffin tulle gras (Jelonet, Smith and Nephew, Hull, UK) and cotton packs soaked in aqueous povidine-iodine solution (Betadine®, Sanofi, France). Later, negative pressure wound therapy (NPWT) was employed, excluding Subjects 1 and 5 who had exposed



**Fig. 1.** Series of images from Subject 1: a. Initial presentation, b. After 1st debridement, c. Ready for BTM application, d. BTM applied, e. Day 10, post-BTM application, f. Day 34, post-BTM application, g. Day 34, BTM delaminated, h. Day 34, split skin graft applied, i. Day 4 post-graft application, j. Day 6 post-graft application, k. Day 14 post-graft application, left lateral neck rotation, l. Day 14 post-graft application, right lateral neck rotation, m. Day 86 post-graft application, front on view, n. Day 86 post-graft application, right lateral neck rotation, o. Day 86 post-graft application, left lateral neck rotation, p. Day 86 post-graft application, neck extension, q. Day 86 post-graft application, right lateral neck flexion, r. Day 86 post-graft application, left lateral neck flexion, s. Day 86 post-graft application, neck extension seen from right, t. Day 86 post-graft application, neck extension seen from left.



**Fig. 1** (continued)



**Fig. 2.** Series of images from Subject 2: a. Initial debridement, 15 days before BTM application, b. Wound on day of BTM application with exposed rib cortical drill holes visible, c. BTM applied, d. Day 5 post-BTM application, e. Day 15 post-BTM application, f. Day 22 post-BTM application, g. Day 34 post-BTM application, h. Day 34, BTM delaminated and dermabraded, i. Day 34, graft applied, j. Day 37 (3 days post-graft), k. Day 66 (32 days post-graft), l. Day 192 (158 days post-graft), m. Day 396 (362 days post-graft), n. Day 513 (479 days post-graft, lateral view), o. Day 513 (479 days post-graft, front on view).

internal jugular veins. All subjects were initially managed in an intensive care setting with inotropic support. Subject 3 was transferred from a neighbouring unit following achievement of wound control and stabilisation of the patient, to be in the proximity of a dialysis unit.

## 2.2. Patient selection

All patients presenting with necrotising fasciitis, including these 7, are considered for all appropriate modes of reconstruction

once wound control has been established, and the patient no longer requires inotropic support. A dermal substitute was offered when it was anticipated that it would improve the clinical course or outcome for the patient against the alternatives of primary split skin grafting or vascularised flap transfer. The indications thus included:

1. Temporising a wound in a patient not initially fit for a lengthy reconstructive procedure or creation of donor sites (Subjects 1 and 7)

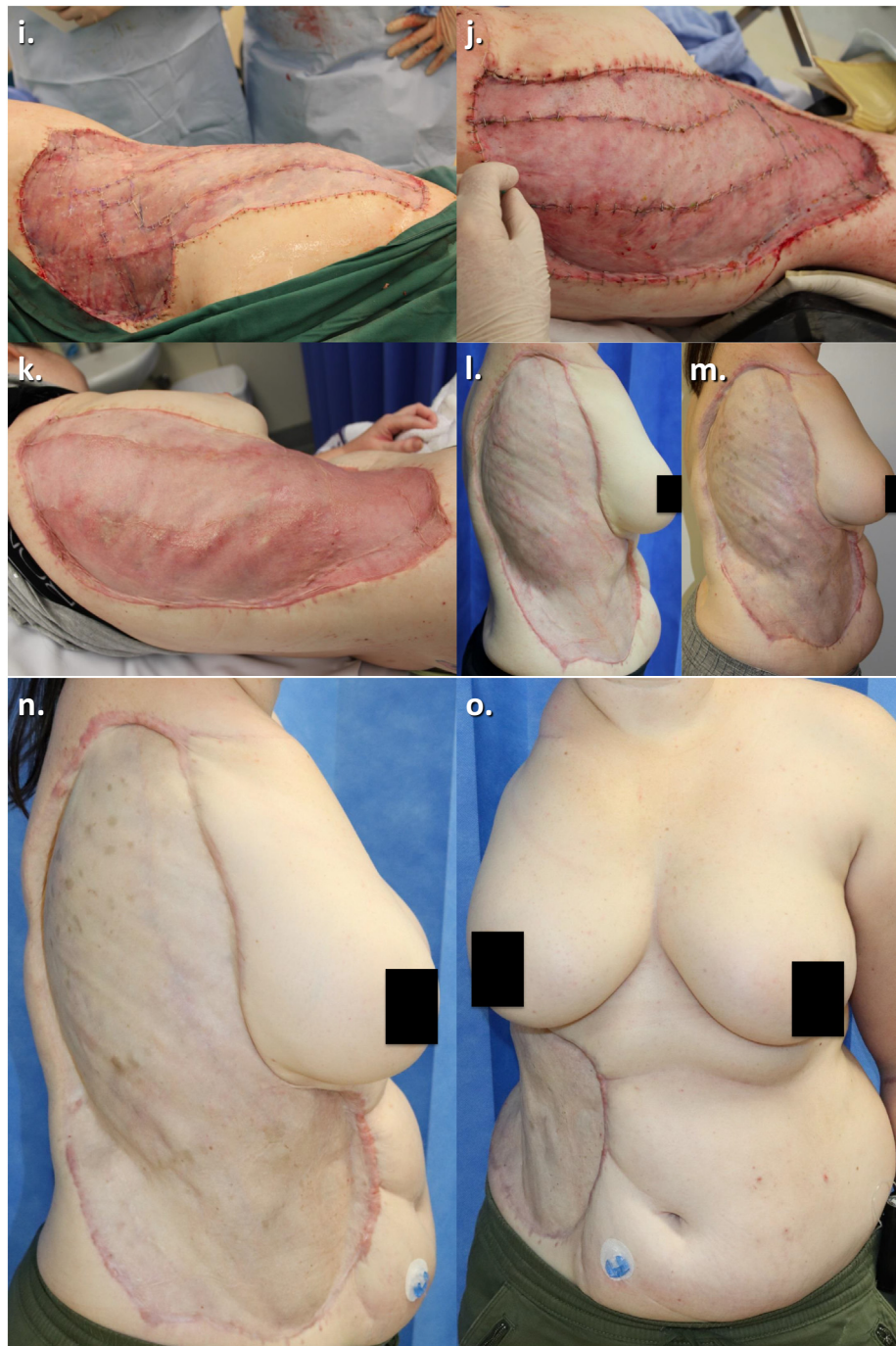


Fig. 2 (continued)

2. Coverage of exposed bone (Subjects 2 and 4)
3. Coverage of complex deep structures of the neck, such as the internal jugular vein and submandibular glands (Subjects 1 and 5)
4. Decreased wound contracture cf. primary skin grafting (Subjects 1–7)
5. Improved contour cf. free vascularised flap cover (Subjects 1 and 5)
6. Improved uniformity of texture cf. primary split skin graft reconstruction (Subjects 1–7)

These options, indications and the expected clinical course were discussed with the subject and/or next of kin and consent was

obtained under the Therapeutic Goods Administration of Australia (TGA) Special Access Scheme (Subjects 1 and 2), or Authorised Prescriber Scheme (Subjects 3 to 7), since BTM was an unapproved product in Australia at the time of these cases.

### 2.3. BTM application and dressing

Under general anaesthetic and after preparation with povidone-iodine solution, the wound edges were excised, and the early granulations on the wound bed were scraped away with a metal ruler. Wounds were thoroughly toiletied with normal saline and haemostasis achieved with bipolar cautery and 1:10,000 adrenaline/saline-soaked packs. The anterior cortex of exposed ribs



**Fig. 3.** Series of images from Subject 3: a. Post-initial debridement, b. BTM applied, c. Day 6 post-BTM application, d. Day 13 post-BTM application, e. Day 33 post-BTM application, f. Day 33, BTM delaminated, g. Day 33, Graft applied, h. Day 162 (129 days post-grafting), i. Day 162, knee flexed, j. Day 358 (325 days post-grafting, lateral view, knee extended), k. Day 358 (325 days post-grafting, lateral view, knee partly flexed).

stripped of periosteum (Subjects 2 and 4) were repeatedly drilled through to the medulla, and the deep fascia over the muscles in Subjects 3 and 6 was pierced with stab incisions, to create a source of angiogenesis and fibrovascular proliferation into the overlying BTM.

In all cases, the factory-fenestrated BTM seal was further fenestrated with a scalpel blade to assist with egress of wound exudate into the dressings. The BTM was cut to size and inset with the seal uppermost, under slight tension, using stainless steel staples to appose it, without overlap, to the skin edges. Staples were also applied to quilt and secure and contour the BTM to the wound bed. The BTM was dressed with a water-activated nanocrystalline

silver dressing (Acticoat, Smith and Nephew, Hull, UK) overlaid with adhesive dressing (Hypafix®, BSN Medical, Hamburg, Germany).

Dressings were changed twice weekly under aseptic conditions, either on the ward or in the operating theatre (depending on requirements for general anaesthetic, sedation, or neither), cleaning the surface of the BTM with 1% chlorhexidine-impregnated sponges (Medisponges). Subject 6, with an underlying comorbidity of bilateral lower limb lymphoedema, exuded heavily from her wounds, through the BTM fenestrations, necessitating frequent cotton pack dressing changes. A negative pressure wound therapy (NPWT) dressing (GranuFoam® Vacuum Assisted Closure – VAC®,



**Fig. 3** (continued)

Acelity, San Antonio, Texas) was applied to successfully draw out the exudate through the fenestrations, reducing the frequency of dressing changes back to twice weekly.

#### 2.4. Integration phase

Integration of the BTM into the wound bed was assessed by subjective clinical appearance at each dressing change. Given our experience we use the following parameters to assess integration.

- 1) Blanching and capillary refill on digital pressure
- 2) Obliteration of the visible foam cells through the transparent seal

#### 3) Uniformity of the salmon-pink colour

The BTM adheres within 7 days, and some areas were integrated against the above criteria by 14 days, however delamination and split skin graft application was only scheduled following evidence of integration of the area slowest areas (often those over areas of least vascularity, e.g. bone).

#### 2.5. Delamination and split skin graft application

Under general anaesthetic, the staples were removed and BTM was delaminated using controlled traction with forceps. The surface of the vascularised matrix was refreshed with light



**Fig. 4.** Series of images from Subject 4: a. Final debridement, 4th and 5th ribs exposed, b. BTM applied, c. Day 4 post-BTM application, d. Day 16 post-BTM application, e. Day 22 post-BTM application, f. Day 34 post-BTM application, g. Day 43 post-BTM application, h. Day 43 post-BTM delamination, i. Day 43 post-graft application, j. Day 43 graft held with VAC, k. Day 50 post-BTM application (7 days post-graft), l. Day 72 post-BTM application (29 days post-graft), m. Day 90 post-BTM application (47 days post-graft and anterior part of axillary wound closed), n. Day 155 post-BTM application (112 days post graft and axillary wound totally closed), o. Day 167 post-BTM application, p. Day 197 post-BTM application, q. Day 244 post-BTM application, r. Day 328 post-BTM application and good shoulder abduction.



**Fig. 4** (continued)

dermabrasion with a diamond-tipped burr mounted on a Hall's drill to clear any surface biofilm and granulations, encourage light capillary bleeding and smooth any seams according to our standard of care with other dermal substitutes [11]. Split skin graft

was harvested at 0.010" – 0.012" thickness using a Zimmer dermatome and either hand fenestrated and applied as sheet grafts (Subjects 1–5), or meshed at 1:1.5 (Subject 7) or 1:2 (Subject 6) ratios. Skin grafts were applied with stainless steel staples and



**Fig. 5.** Series of images from Subject 5: a. Initial presentation, b. After first debridement, c. \$ days later and ready for BTM application, d. BTM application, e. Day 3 post-BTM application, f. Day 10 post-BTM application, g. Day 17 post-BTM application, h. Day 24 post-BTM application, i. Day 31 post-BTM application, BTM delaminated and dermabraded, j. Day 31 post-BTM application, graft applied, k. Graft at 3 days post-application (Day 37 post-BTM), l. Graft at 12 days, m, n. and o. Graft at 84 days (Day 115 post-BTM), p. Graft at 140 days, neck extension, q. Graft at 140 days, neck left lateral rotation, r. Graft at 140 days, neck right lateral rotation, s. Graft at 140 days, neck extension lateral view, t. Graft at 235 days, neck extension, u. Graft at 235 days, neck left lateral rotation, v. Graft at 235 days, neck right lateral rotation, w. Graft at 235 days, neck neutral lateral view.

dressed according to standard of care with either Mepitel (Mölnlycke, Gothenburg, Sweden) and Acticoat, or paraffin tulle-gras and Betadine-soaked gauze, or Mepitel and VAC.

The first dressing changes were performed around Day 3–5, and were according to standard of care of split skin grafts. Staples were removed and physical therapy was commenced at either the first or second dressing change, depending on stability of the graft against shear. Scar therapy, with moisturising cream and massage, commenced once the wound was closed and subsequent compres-

sion and silicone therapy according to the standard of care of our Allied Health therapists.

### 3. Results

Seven cases have been reconstructed in the last two years, in two-stages, where BTM represented the first stage and split skin autografting the second (Table 1). The mean age was 58 years

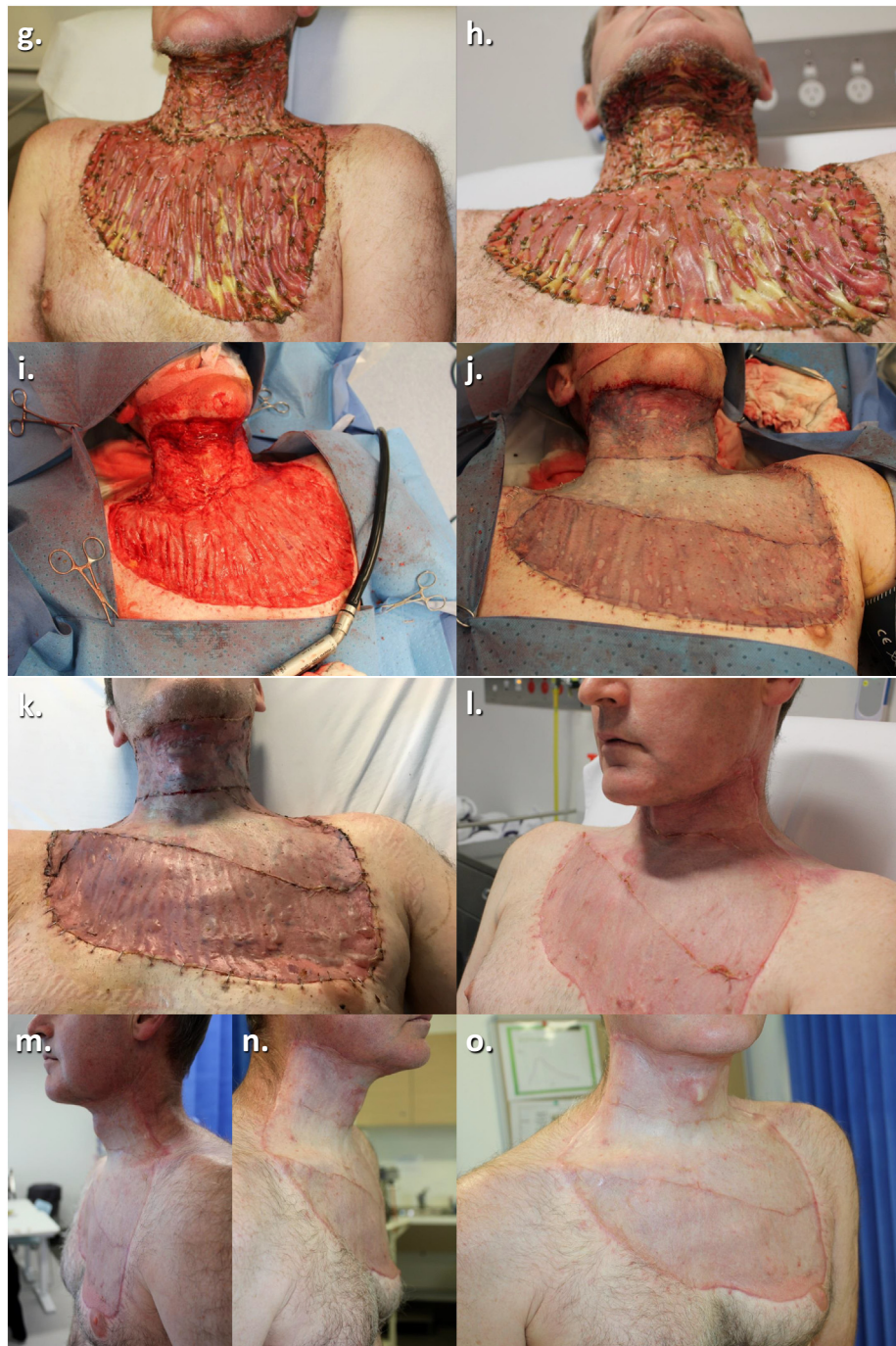


Fig. 5 (continued)

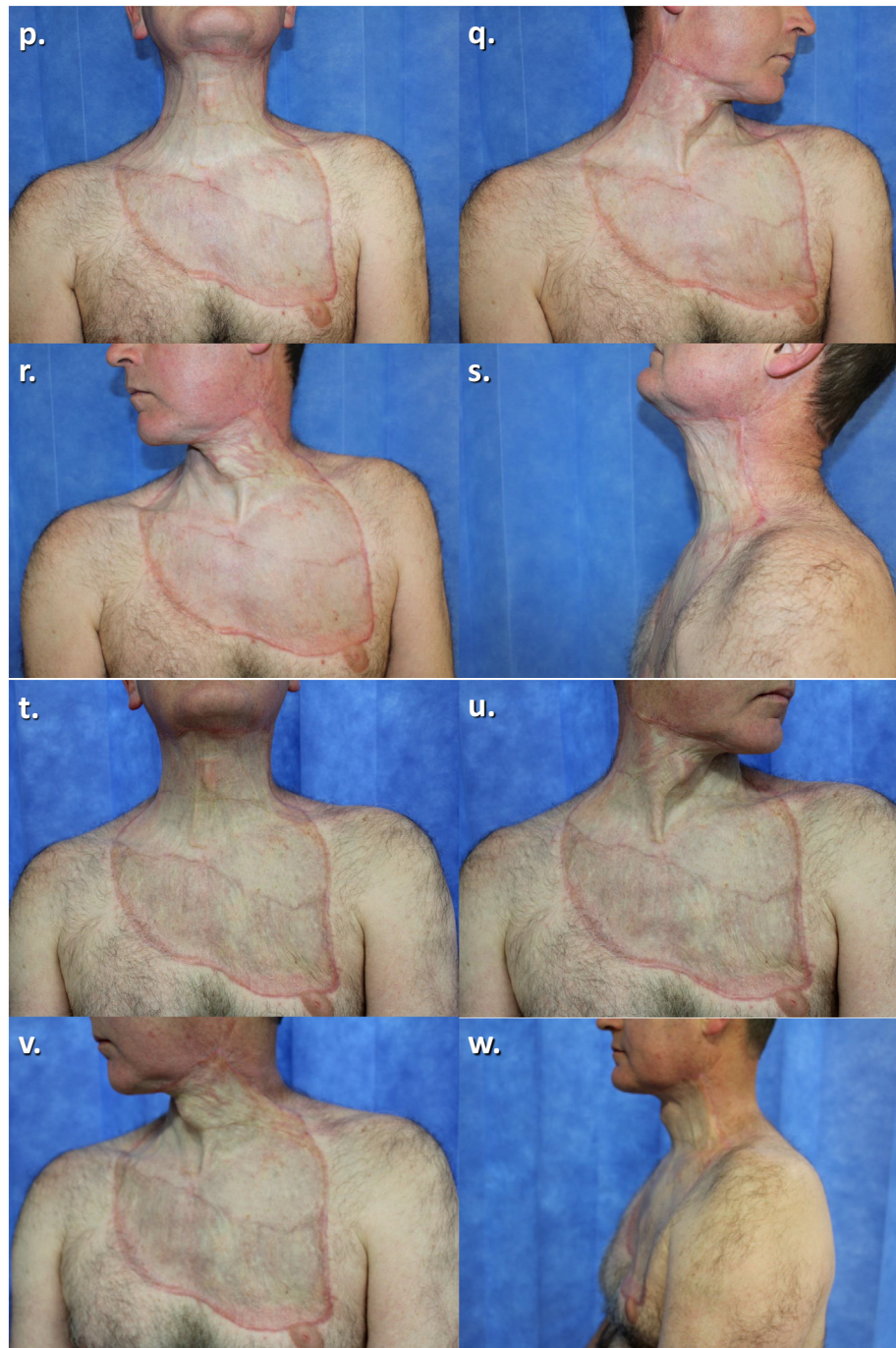
(31 to 88 years), and the male to female ratio = 3:4. The median inpatient bed days from first debridement to discharge following split skin graft take was 62 days. Subjects 3 and 5 were discharged for outpatient dressing management during the integration phase. Subject 7 remains an inpatient post-skin grafting for rehabilitation management following through-hip amputation, along with 5th ray amputation of the contralateral foot.

A few general result statements can be made. Firstly, no BTM was lost in any patient except where BTM had been placed over 'mobile cavities' (the axilla and the thigh/hip in Subjects 4 and 6, respectively). In retrospect, placement in these sites was futile, as grafting these sites primarily would have been. These areas were all less than 0.5% TBSA, and were subsequently closed with further

management using cavity excision, skin edge mobilisation and closure (Subject 4) or NPWT alone (Subject 6). Secondly, no graft was lost over integrated BTM.

### 3.1. Individual subject results

**Subject 1** – necrotising fasciitis began in the right parotid and spread into the neck (Fig. 1a), necessitating radical debridement (Fig. 1b). BTM was applied to abraded granulations over the strap muscles of the neck centrally and the sternocleidomastoid muscles laterally, with the major vessels of the neck in between and the left submandibular gland superiorly (Fig. 1c & d). The BTM integrated steadily and was slowest centrally over the strap muscles (Fig. 1e



**Fig. 5** (continued)

& f). Delamination occurred at Day 34 (Fig. 1g) and was sheet-autografted after dermabrasion (Fig. 1h). Massage and moisturising of the graft was possible 4 days later (Fig. 1i). The graft rapidly became robust and mobile (Fig. 1j–l). At her last appointment (Day 86), the neck range of motion was excellent (Fig. 1m–t). She, unfortunately, died four months following graft application. Post-mortem examination concluded that her death was unrelated to the device.

**Subject 2** – necrotising fasciitis affected the right upper limb, axilla, right lateral chest and flank necessitating forequarter amputation. Three ribs were denuded of periosteum as a result and required multiple cortical drill holes to facilitate granulation from

the bony medulla (Fig. 2b), on the day of, and prior to, BTM application (Fig. 2c). BTM integration was uneventful (Fig. 2d–g) and delamination/dermabrasion occurred on Day 34 (Fig. 2h). Fenestrated sheet graft was applied (Fig. 2i). Graft take was complete and rapidly robust (Fig. 2j & k). The progress of her graft maturation was recorded (Fig. 2l–o), leaving an acceptable result at Day 513 to consider prosthesis manufacture.

**Subject 3** – the defect resulting from serial debridement was predominantly anterior and extended across the left knee from mid-thigh to distal leg (Fig. 3a). BTM was applied and allowed to integrate (Fig. 3b–d). Complete integration at Day 33 (Fig. 3e) was followed by delamination/dermabrasion (Fig. 3f) and sheet



**Fig. 6.** Series of images from Subject 6: a, b & c. Post final debridement, d & e. Post-BTM application, f. Two days post BTM application, g. Day 8 post-BTM application, h. Close-up of the failed BTM bridge between hip and thigh at Day 8, i. BTM at Day 26, j. Day 26 post-BTM delamination, k. Day 26 post-graft application, l. Day 41 post-BTM (day 15 post-grafting), m. Day 23 post-grafting, n. Day 136 post-grafting.

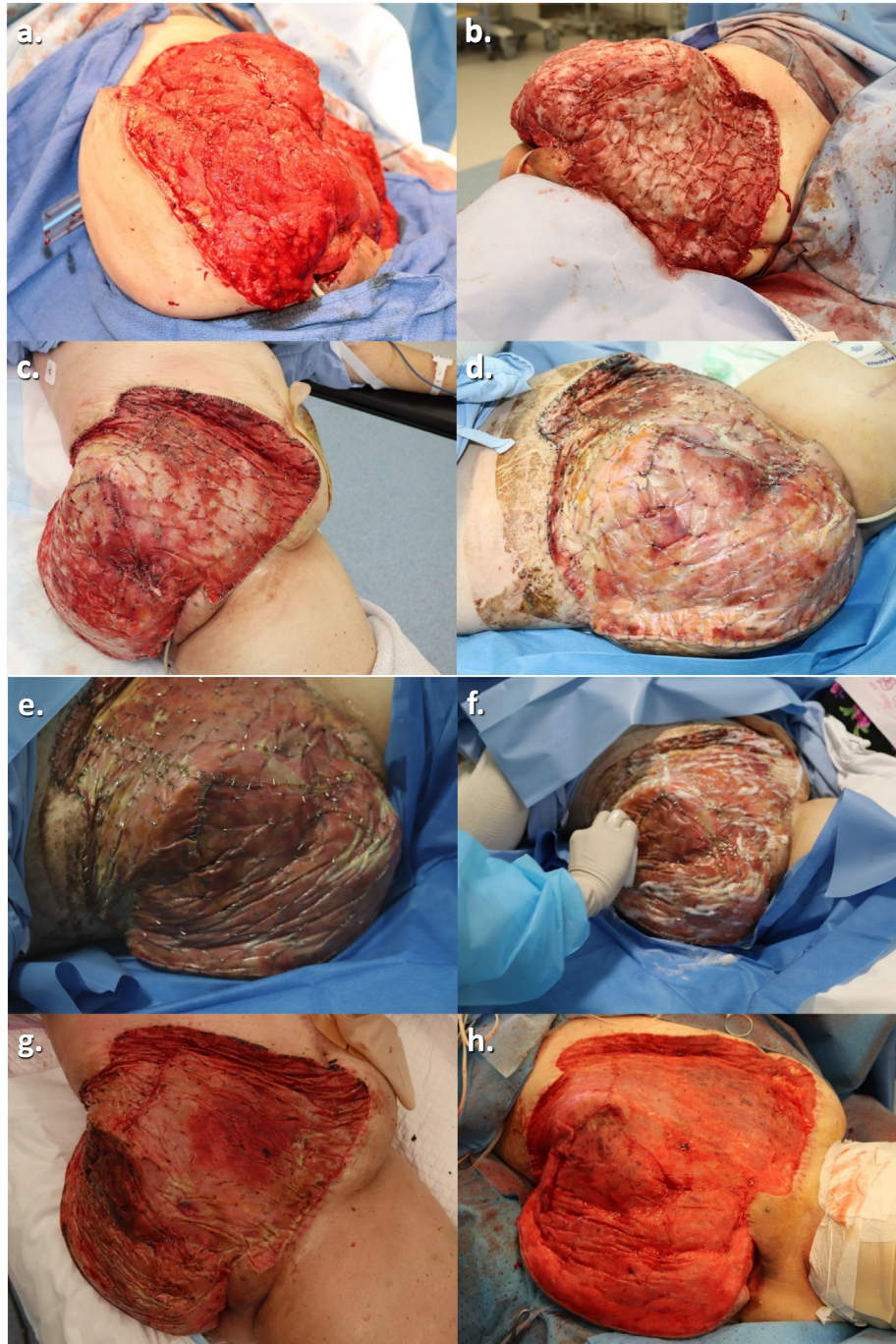


Fig. 6 (continued)

graft application (Fig. 3g). Graft take was complete and a good cosmetic and functional result achieved early (Fig. 3h & i). The result at 1 year is also shown (Fig. 3j & k).

**Subject 4** – an elderly gentleman in end-stage renal disease requiring dialysis developed necrotising fasciitis in the right flank, right axilla and with a deep tissue cavitation extending deep to the scapula posteriorly and under the pectoralis minor anteriorly. After debridement, the fourth and fifth ribs were exposed and denuded of periosteum (Fig. 4a), the cortices of which were drilled before BTM was applied (Fig. 4b). Initially the BTM coloured as expected

(Fig. 4c), but the bridging portion over the cavity eventually failed (Fig. 4d–f). The remaining BTM integrated and was delaminated (Fig. 4g) and grafted (Fig. 4h) at Day 43. The grafts were held in place and the cavity closed by VAC application (Fig. 4i). The graft took well except over the remaining cavity (Fig. 4j) and was allowed to become robust (Day 72), at which point the anterior axillary (pectoral) tissue was raised, advanced and fixed to the graft edge with staples (Fig. 4k). By Day 90, this was firmly healed (Fig. 4l). On Day 155, the posterior aspect of the cavity was closed by raising and advancing the tissue over the latissimus dorsi



**Fig. 7.** Series of images from Subject 7: a. Wound resulting from the final debridement after hip disarticulation and right lower limb amputation, b. BTM application, c. Day 2 post-BTM application, d. Day 9 post-BTM application, e. Day 12, f. Day 15, g & h. Day 34 pre- and post-BTM delamination on the day of grafting, i. 3 days post-graft application, j. 16 days post-graft application and Day 50 post-BTM application.



**Fig. 7** (continued)

(Fig. 4m). This similarly healed well (Fig. 4n & o). The images at Day 244 (Fig. 4p) and Day 328 (Fig. 4q) show increasing shoulder range of motion with time. His necrotising fasciitis involved *Clostridium septicum* and, as predicted by this combination, colonoscopy revealed a bowel malignancy, which was treated.

**Subject 5** – the synergistic neck infection required a more radical debridement than Subject 1 (Fig. 5a–c). BTM was applied (Fig. 5d) and allowed to integrate, again showing delay over the strap muscles centrally (Fig. 5e–h). Delamination and dermabrasion on Day 31 (Fig. 5i) were followed by sheet autograft (Fig. 5j). Graft take was complete and rapid (Fig. 5k). Robustness

was associated with good contour early (Fig. 5l) and at 4 (Fig. 5m–o) and 6 (Fig. 5p–s) months. His last review at 266 days (8 months) post-BTM application (Fig. 5t–w), bodes well for his long term result.

**Subject 6** – extensive lower limb wounds generated by serial debridement (Fig. 6a–c), received BTM (Fig. 6d & e). Integration progressed as expected (Fig. 6f & g) marred only by that stretched over a cavity between the left lateral hip and thigh (Fig. 6h). Due to high volume exudate, NPWT was applied with the GranuFoam directly over the BTM seal, set to run continuously at 50 mmHg and changed twice weekly. The BTM was integrated by Day 26

(Fig. 6i), when it was delaminated/dermabraded (Fig. 6j), and grafted with 1:2 mesh graft (Fig. 6k). All the graft took (Fig. 6l) and became robust very quickly (Fig. 6m).

**Subject 7** – very significant infection resulted in right lower limb hip disarticulation. Although muscle was available to cover the pelvic acetabulum, a significant defect was left (Fig. 7a) onto which BTM was applied and extensively quilted with staples (Fig. 7b). The BTM integrated over the next 34 days (Fig. 7c–g). Delamination was followed by dermabrasion (Fig. 7h). The graft took completely by 3 days (Fig. 7i).

#### 4. Discussion

The aim of wound closure after any injury is a functional result, which is cosmetically acceptable. Radical debridement for soft tissue infections, following trauma, or to achieve an adequate surgical margin after cancer excision, often leaves a wound indicating reconstruction by free tissue transfer for coverage of ungraftable structures. Where grafts can be used, the thin coverage of the resulting contour defect is often distressing to patients, as well as being less robust, and prone to contracture.

The 7 subjects in this series all presented with life-threatening, necrotising soft tissue infection. They also came, however, with diverse patient and wound demands that required an individualised approach to their timing and strategy of reconstruction.

Dermal substitutes temporise a wound by affording physiological closure through reduction of trans-epidermal water loss. Granulation and associated myofibroblast-mediated wound contraction is reduced during the integration phase. Temporising provides a window of delay prior to reconstruction, which can be used to allow a patient to physiologically recover. In addition, the dermal substitute is integrated into the wound, creating a thicker, more uniform and robust foundation layer, the approximate thickness of dermis, onto which split-thickness skin graft can be applied. We have previously observed that BTM, like other dermal substitutes, can bridge areas of non-viable tissue such as bone and tendon denuded of periosteum and paratenon, respectively. We have also subjectively experienced that wounds reconstructed using BTM result in a soft and pliable resurfacing that glides over the underlying bed, reducing the appearance of tethering of underlying mobile structures such as muscle and tendon.

**Subject 1** (previously reported [17]) was unstable on the intensive care unit, with systemic sepsis and pneumonia. At this time she was not physically fit enough for a long, involved reconstruction, such as a free anterolateral thigh flap. Her debridement of infected skin, platysma and investing fascia exposed the deep structures of the neck, which were being repeatedly dressed once wound control had been achieved. We were concerned that the exposed vessels were at risk of blow-out. We considered a free anterolateral thigh flap as the best flap option to cover the neck structures, however in our hands this has previously resulted in a bulky reconstruction obliterating the cervicomentale angle, which may have been later improved with liposuction procedures.

She was offered a dermal substitute reconstruction to temporise both wound and patient, offer improved contour against a free flap reconstruction, cover vital structures and reduce post-skin graft contracture that may indicate later releases. Free flap reconstruction remained an option as contingency if these outcomes were not achieved. She remained inpatient until skin grafting, given our caution regarding her exposed neck vessels, and because this was the first time we had embarked on such a case. At Day 4 post-skin grafting, her grafts were adherent enough to sanction removal of staples and she was discharged for rehabilitation two days later. Her outcome at four months was the desired pliable, uniform reconstruction with good range of movement and a pleas-

ing contour prior to her unrelated death at four months post-implantation. **Subject 5** was debrided nine months ago to a similar plane on the neck, and further extended to the chest and prepectoral areas to the level of his areolae. BTM was applied in a similar manner and dressing changes were performed on the ward until two weeks post-implantation, before discharge for further dressing changes as an outpatient. He resumed full-time work within three months of debridement and continues to maintain work, family and social activities 9 months following his debridement.

**Subjects 2 and 4** were examples of BTM being applied over exposed ribs, denuded of periosteum. The bones were drilled to provide a source of neovascularization over the bridging matrix. This manoeuvre had been successfully employed previously with BTM under 4th degree burn injury involving the chest wall and the successful use of Integra has also been reported over exposed bone in necrotizing fasciitis [12,23]. In these cases, BTM successfully integrated over the exposed bones and then sustained split skin graft to stable healing. **Patient 2** is an insulin-dependent diabetic whose infection spread up her arm and onto the trunk, including the muscles of the shoulder girdle, necessitating a right forequarter amputation. **Subject 4** was a 72 year old gentleman with pre-existing end-stage renal failure necessitating regular dialysis. Both their reconstructions are now over 18 months old, they still exhibit contour depression, compared to the thickness of the surrounding trunk tissue, however the reconstructions appear and feel robust, and both patients are able to stand up straight without contracture-attributable resistance and **Subject 4** has a full range of abduction of the right shoulder.

**Subject 3** had fenestrated sheet grafts applied over the BTM that had been implanted into his wound over the thigh, knee and leg. He has maintained a full range of movement across his knee and ankle throughout his post-treatment rehabilitation to date (18 months post-implantation).

**Subject 6** is a patient who presented with bilateral lower limb necrotising fasciitis, indicating extensive debridements on both legs. She also had pre-existing lymphoedema. Once the BTM had been applied, the exceptionally high degree of exudate indicated use of NPWT set at 50 mmHg continuous to draw the fluid off. Prior to this case we had been concerned that NPWT over BTM might collapse the foam pores and inhibit integration, despite it being readily used with other dermal substitutes such as Integra [21,22]. Much of her BTM was integrated within 14 days, however we waited for all areas to integrate prior to delamination at day 26, the earliest of the cohort, suggesting a possible role for NPWT in shortening the integration phase.

**Subject 7** required a right lower limb through-hip amputation with extensive soft tissue debridement to the abdominal wall, up to the level of the umbilicus, across the right groin to the right labia majora and natal cleft. She had a diversion colostomy and exploratory laparotomy wound. Her acetabulum was reamed of its articular surface and covered with local muscles from the pelvic girdle. Similar to **Subject 6**, it took considerable time before her wound started to show capacity for healing (fine granulations and epithelialisation from the edges). She was also undernourished and had a long period of disorientation. Temporising her with BTM enabled us to improve her nutrition with supplementary nasoenteric feeds, to hopefully improve her donor site and skin graft healing, and also gave her time to improve her orientation, understanding and assent prior to the creation of further wounds. Her wound size and position dictates a closure that will be extensive and robust enough to facilitate mobility, withstand pressure and remain stable. Although she is still in the maturation phase of her skin graft healing, subjective results thus far are promising.

## 5. Conclusion

BTM already has an established central role in our management of severe and extensive burn injury. We are now satisfied that, where indicated for temporising wound and patient, seeking aesthetic contour and uniformity of wound cover, and coverage of exposed bone and tendon, BTM also has a beneficial role in necrotising fasciitis defects. Although limited, this is also the first data to suggest that NPWT may have a role in shortening the integration phase of BTM in wounds.

## Acknowledgements

The authors would like to thank Sasha Stewart, Manager of the South Australian Audit of Surgical Mortality for the unpublished data that opens this manuscript.

## Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

## Declaration of interest

John Greenwood and Marcus Wagstaff would like to disclose that both hold shares in PolyNovo Biomaterials Pty Ltd (the manufacturer of the NovoSorb™ foam and BTM™ device).

## References

- [1] Hodgins N, Damkat-Thomas L, Shamsian N, Yew P, Lewis H, Khan K. Analysis of the increasing prevalence of necrotising fasciitis referrals to a regional plastic surgery unit: a retrospective case series. *J Plast Reconstr Aesthet Surg* 2015;68(3):304–11.
- [2] Li A, Dearman BL, Crompton KE, Moore TG, Greenwood JE. Evaluation of a novel biodegradable polymer for the generation of a dermal matrix. *J. Burn Care Res* 2009;30(4):717–28.
- [3] Greenwood JE, Li A, Dearman B, Moore TG. Evaluation of NovoSorb™ novel biodegradable polymer for the generation of a dermal matrix. Part 1: In-vitro studies. *Wound Prac Res* 2010;18(1):14–22.
- [4] Greenwood JE, Li A, Dearman B, Moore TG. Evaluation of NovoSorb™ novel biodegradable polymer for the generation of a dermal matrix. Part 2: In-vivo studies. *Wound Prac Res* 2010;18(1):24–34.
- [5] Greenwood JE, Dearman BL. Split-skin graft application over an integrating, biodegradable temporising polymer matrix: immediate and delayed. *J. Burn Care Res* 2012;33(1):7–19.
- [6] Greenwood JE, Dearman BL. Comparison of a sealed, polymer foam biodegradable temporising matrix against Integra™ dermal regeneration template in a porcine wound model. *J Burn Care Res* 2012;33(1):163–73.
- [7] Dearman BL, Stefani K, Li A, Greenwood JE. Take of a polymer-based autologous cultured composite 'skin' on an integrated temporising dermal matrix: proof of concept. *J Burn Care Res* 2013;34(1):151–60.
- [8] Wagstaff MJD, Driver S, Coghlan P, Greenwood JE. A randomised, controlled trial of negative pressure wound therapy of pressure ulcers via a novel polyurethane foam. *Wound Rep Regen* 2014;22:205–11.
- [9] Wagstaff MJD, Schmitt BJ, Coghlan P, Finkemeyer JP, Caplash Y, Greenwood JE. A biodegradable polyurethane dermal matrix in reconstruction of free flap donor sites: a pilot study. *ePlasty* 2015;15:102–18.
- [10] Dearman BL, Li A, Greenwood JE. Optimisation of a polyurethane dermal matrix and experience with a polymer-based cultured composite skin. *J Burn Care Res* 2014;35(5):437–48.
- [11] Wagstaff MJD, Schmitt BJ, Caplash Y, Greenwood JE. Free flap donor site reconstruction: a prospective case series using an optimized polyurethane temporising matrix. *ePlasty* 2015;15:231–48.
- [12] Greenwood JE, Schmitt BJ, Wagstaff MJD. Experience with a synthetic bilayer Biodegradable Temporising Matrix in significant burn injury. *Burns Open* 2018;2:17–34.
- [13] Greenwood JE, Wagstaff MJD, Rooke M, Caplash Y. Reconstruction of extensive calvarial exposure after major burn injury in two stages using a biodegradable polyurethane matrix. *ePlasty* 2016;16:151–60.
- [14] Greenwood JE, Wagstaff MJD. The use of biodegradable polyurethane in the development of dermal scaffolds. Chapter 22. In: Cooper SL, Guan J, editors. *Advances in Polyurethane Biomaterials*. Duxford, UK: Woodhead Publishing Series in Biomaterials, (Elsevier Inc.); 2016. ISBN:978-0-08-100614-6.
- [15] Greenwood JE. Hybrid biomaterials for skin tissue engineering. Chapter 9. In: Albanna MZ, Holmes IV JH, editors. *Skin Tissue Engineering and Regenerative Medicine*. London, UK: Academic Press (Elsevier Inc.); 2016. ISBN:978-0-12-801654-1.
- [16] Greenwood JE. The evolution of acute burn care - retiring the split skin graft (Hunterian Lecture). *Ann R Coll Surg Eng* 2017;99:432–8. <https://doi.org/10.1308/rcsann.2017.0110>.
- [17] Wagstaff MJD, Caplash Y, Greenwood JE. Reconstruction of an anterior cervical necrotizing fasciitis defect using a biodegradable dermal substitute. *ePlasty* 2017;17:29–36.
- [18] Akhtar S, Hasham S, Abela C, Phipps AR. The use of Integra in necrotizing fasciitis. *Burns* 2006;32(2):251–4.
- [19] Bache SE, Watson SB. Bedside application of integra after debridement of necrotizing fasciitis. *J Plast Reconstr Aesthet Surg* 2011;64(4):559–60.
- [20] Rashid OM, Nagahashi M, Takabe K. Management of massive soft tissue defects: The use of INTEGRA® artificial skin after necrotizing soft tissue infection of the chest. *J Thorac Dis* 2012;4(3):331–5.
- [21] Mazzone L, Schiestl C. Management of septic skin necroses. *Eur J Pediatr Surg* 2013;23(5):349–58.
- [22] Danielsson PA, Fredriksson C, Huss FR. A Novel concept for treating large necrotizing fasciitis wounds with bilayer dermal matrix split-thickness skin grafts, and negative pressure wound therapy. *Wounds* 2009;21(8):215–20.
- [23] Pagnini D, Colizzi L, Giacomina A, Gianotti G, Gandini D, Lorenzetti F, et al. A devastating case of heroin-associated necrotizing fasciitis of the upper limb with bone exposure. A useful treatment method. *J Plast Reconstr Aesthet Surg* 2009;62(6):e151–152.
- [24] Abed S, Dantzer E, Souraud JB, Brissy S, Fournier B, Boyé T, et al. The place of skin substitutes in surgical treatment of necrotizing cellulitis: seven cases. *Ann Dermatol Venereol* 2014;141(1):49–52.