Novosorb® Biodegradable Temporising Matrix (BTM) and its Applications

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ABSTRACT

The NovoSorb® Biodegradable Temporising Matrix (BTM) (PolyNovo Biomaterials Pty Ltd, Port Melbourne, Victoria, Australia) is a fully synthetic dermal matrix that can be used to reconstruct complex wounds. It consists of a 2mm-thick NovoSorb® biodegradable polyurethane open-cell foam covered by a non-biodegradable scaling member. Application involves a two-stage procedure. In the first stage, BTM is laid onto a clean wound bed, and in the second stage, the sealing membrane is removed and a split skin graft is applied to the neo-dermis. BTM has been used to reconstruct deep dermal and full-thickness burns, necrotising fasciitis, and free flap donor sites in the early phase. This review documents examples from a comprehensive series of cases in which BTM was applied to a wide range of complex wounds, ranging from hand and fingertip injury, to Dupuytren's surgery, chronic ulcers, post excision of cutaneous malignancies, and hidradenitis suppurativa.

BTM can be applied to a wide range of complex wounds which may otherwise require a more challenging reconstruction. It should be considered an important adjunct to the reconstructive ladder.

INTRODUCTION

NovoSorb® Biodegradable Temporising Matrix (BTM) (PolyNovo, Port Melbourne, Victoria, AU) is a bi-layered fully synthetic dermal matrix that has been developed and used for the reconstruction of complex wounds. It consists of a 2mm-thick NovoSorb® biodegradable polyurethane thermoset open-cell foam bonded to a non-biodegradable polyurethane sealing membrane.[1] The open-cell matrix allows for the infiltration of cellular materials and vascular ingrowth to create a neodermis that ultimately supports a split-thickness skin graft (STSG). The sealing membrane acts as a pseudo-epidermis and provides physiological wound closure. It also resists fragmentation, limits tissue in-growth into only the open foam, and contains fenestrations that allow for any fluid that collects within the wound bed to be expressed. The completely synthetic matrix eventually degrades via hydrolysis over a period of roughly 18 months. Prior to application, BTM is stored dry at room temperature (≤ 25°C) and has a shelf life of three years.[2]

Initially developed for use in the management of major burns, the NovoSorb® biodegradable polymer was first tested in vitro to assess its safety and potential toxicity.[3] Several prototypes were developed and tested. The main attributes required of the polymer

were to be non-toxic to cells, to support the invasion and growth of fibroblasts and keratinocytes, and to support blood vessel in-growth. The scaffold would also need to be structured in such a way that it discouraged the formation of long stretches of linear collagen, which might lead to wound contracture, and could also resist infection. Macroscopically, the polymer should be flexible and pliable enough to mold to a wound and resist any shear forces to which it may be subject.

Subsequently, BTM was tested in vivo. Initially, it was tested on rats to confirm that there were no adverse outcomes. Next, tests were conducted in sheep and pigs.[4] Multiple different methods of application were tested against the control of a skin graft, and histological examination of the BTM specimens after allowing an appropriate time for wound healing allowed for refinement of the technology and application techniques. Alternative scaffold designs and thicknesses were tested, the timing to skin graft was studied, the degree of contracture was assessed, and the sealing membrane was added. Optimal seal variants, seal thicknesses and bonding methods were also tested.

Similar to other dermal matrices, BTM can temporize wounds, allow for the integration of vascular tissue to sustain a STSG, and reduce wound contracture. However, unlike other dermal matrices that are of biological origin, BTM is entirely synthetic. This eliminates any risk of inter-species immune-related rejection or disease transmission, as well as any ethical or cultural objections by patients or practitioners.[5]

BTM was first used in humans as a foam interface for negative pressure wound therapy. This was done to test for local adverse reactions, tissue hypersensitivity and anaphylaxis.[6]. In comparison to the control foam, the NovoSorb® foam had no adverse effects in humans.

With short-term biocompatibility confirmed, testing moved to long-term applications. A pilot study was conducted on the use of BTM in free flap donor wounds,[7] which are a more controllable surgical wound compared to major burns. The main lessons from the first long-term applications in humans were that the seal was difficult to remove without tearing and fluid collected underneath the seal. Thereafter, a more robust seal with perforations was used.

A subsequent study was then performed, in which BTM was applied in burn patients as the original indication. This study yielded positive results.[8] These wounds were successfully reconstructed with BTM and subsequent STSG, and several essential points were learned. First, BTM could resist infection, since one patient with culture-proven infection could be treated by expressing the infective collection through the perforations in combination with antibiotics without losing the matrix or leading to graft failure. Second, it worked over bare bone, since one patient with a partially exposed rib achieved a successful reconstruction. Third, BTM could resist pressure, since several patients in this trial were in the intensive care unit and, despite having BTM applied to wounds overlying pressure areas, went on to experience effective integration and grafting.

These results were very promising, and BTM has since been adopted by surgeons around the world who continue to expanded its indications.

INDICATIONS

In our clinical practice, BTM has been used for a variety of complex wound reconstructions on different parts of the body. Initially developed for use in major burn injury, BTM has also been used in cases involving free flap donor wounds, necrotizing soft tissue infections, osteomyelitis, upper- and lower-limb trauma, failed skin grafts, skin resurfacing following oncological resection, hidradenitis suppurativa, and hand surgery.

CONTRAINDICATIONS

BTM application is contraindicated in wounds where necrotic/devitalized tissue is present; such wounds must be surgically debrided to viable tissue pre-application. BTM should not be applied to overtly infected wounds; such wounds should be debrided of non-vital tissue and topically treated with antimicrobial dressings and/or systemic antibiotics before application is considered. BTM should only be applied to surgically debrided chronic wounds where any underlying pathology capable of potentiating the wound has been addressed (e.g., meticulous blood sugar control in diabetic ulceration, compression hosiery/dressings in venous ulceration to combat sustained venous hypertension, etc.). BTM should be applied to wounds only after effective haemostasis has been achieved.

These precautions ensure that BTM has the best possible opportunity to successfully adhere and integrate by avoiding any fluid collection or necrotic tissue between the BTM and the underlying wound bed and enabling the creation of a vascularised soft-tissue structure within the foam matrix scaffold.

1. Free Flap Donor Site

The first application of BTM in humans was for free flap donor wounds.[7] In our experience, we have applied BTM primarily to free flap donor wounds, as well as in cases where donor wounds have either dehisced or failed to take the skin grafts. The ability of BTM to integrate over tendon, bone or neurovascular structures has made it an excellent option, especially in free fibula and radial forearm donor sites. The superior contour and aesthetic outcomes have also allowed us to achieve excellent outcomes with the rare dehisced abdominal donor site following deep inferior epigastric perforator (DIEP) flap. Figure 1 shows one of our cases where we applied BTM to the donor site of a medial sural artery perforator (MSAP) flap in the posterior calf of a 37-year-old male of African ethnic background. Traditionally, this donor site defect would be reconstructed with a split-thickness skin graft. To minimise the risk of hypertrophic scarring, we applied the BTM and followed it with a second-stage split skin graft to reduce the likeli-

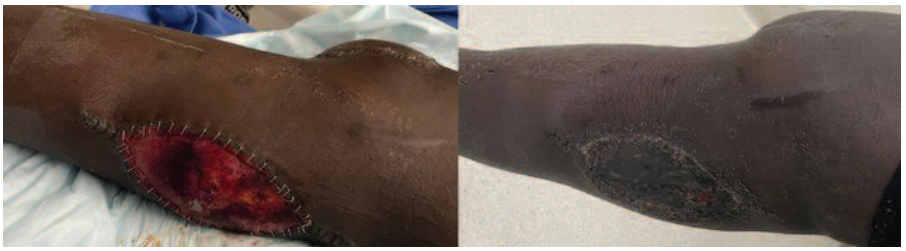

Figure 1. BTM to donor site of medial sural artery perforator (MSAP) on a posterior calf. Left - one week post BTM application; Right - three weeks post STSG.

hood of wound contracture. At three-months follow-up, there was no hypertrophic or keloid scarring.

2. Soft Tissue Infection and Osteomyelitis

One particularly useful attribute of BTM is its resistance to infection. Compared to other dermal matrices, BTM appears to be more resistant to infection and shows integration even in the setting of infection. Initial source control with adequate debridement of non-viable tissue is vital in wound management. Ideally, a culture-negative wound bed is preferred prior to application of BTM. However, in some instances where the wound is colonized, BTM has been shown to have a higher chance of integration compared to other dermal matrices. This led to its use in necrotizing fasciitis.[9] Wagstaff et al. also demonstrated excellent functional and aesthetic outcomes with the use of BTM to reconstruct defects secondary to necrotizing soft tissue infection. Figures 2 and 3 demonstrate the use of BTM in necrotising fasciitis. The patient was a 78-year-old male who developed necrotising fasciitis of the forearm. BTM was applied after three debridement procedures. Unfortunately, the patient contracted COVID and, due to his immunosuppressed status, has had a prolonged recovery from his COVID infection. The second-stage split skin graft was performed three months after the initial application of BTM. Despite the delayed second-stage surgery, the patient has had an excellent aesthetic outcome. This also highlights another advantage of BTM; the ability to provide robust wound coverage for a prolonged period. While the patient was recovering from COVID, he did not develop any infection and only required a twice-weekly dressing change over BTM.

We have observed similar promising outcomes using BTM over colonized bare bone. Figure 4 highlights how BTM is able to integrate over bare bone in the setting of calcaneal osteomyelitis in an 83-year-old diabetic patient with single-vessel run-off in his lower limb. The use of BTM and split-thickness skin graft provided a robust reconstruction, which allowed the patient to walk and bear weight again, and avoided an amputation.

3. Upper- and lower-limb trauma

The ability of BTM to integrate over bare structures is useful in trauma cases, especially in the extremities. Not only is it effective at achieving a healed wound in cases of exposed bare tendon, bone or neurovascular structures, its resistance to contracture helps to maintain function in the upper and lower limbs. We have successfully applied BTM over open joints

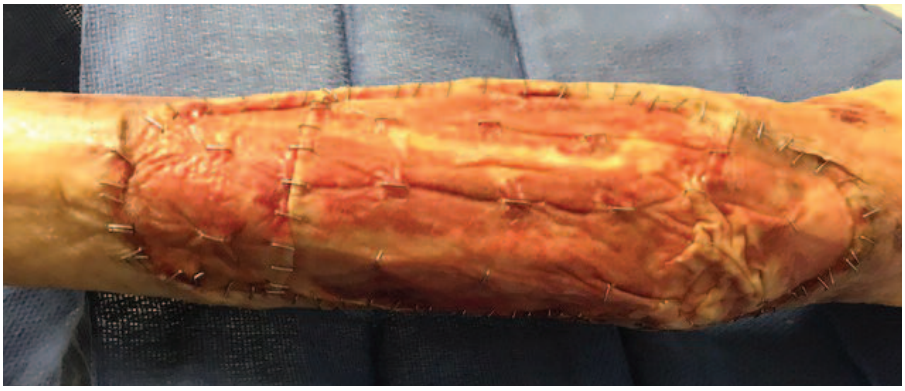

Figure 2. BTM to forearm following necrotizing fasciitis (one week post BTM application).

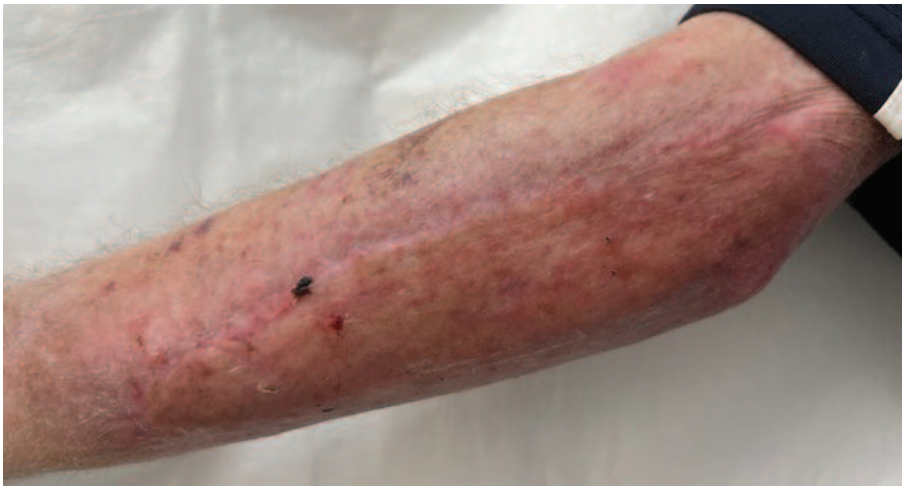

Figure 3. BTM to forearm following necrotizing fasciitis (four weeks post STSG).

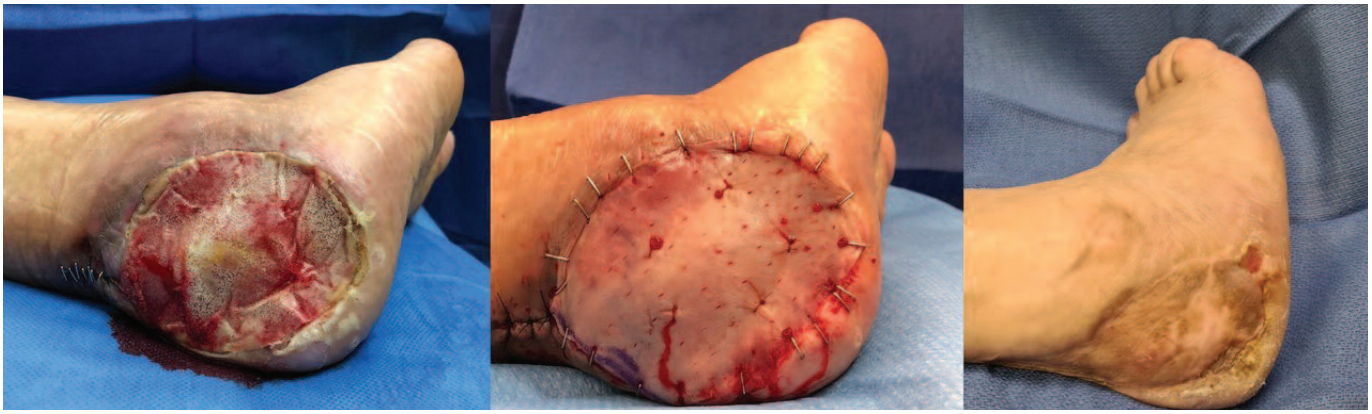

Figure 4. BTM to calcaneum in the setting of calcaneal osteomyelitis.

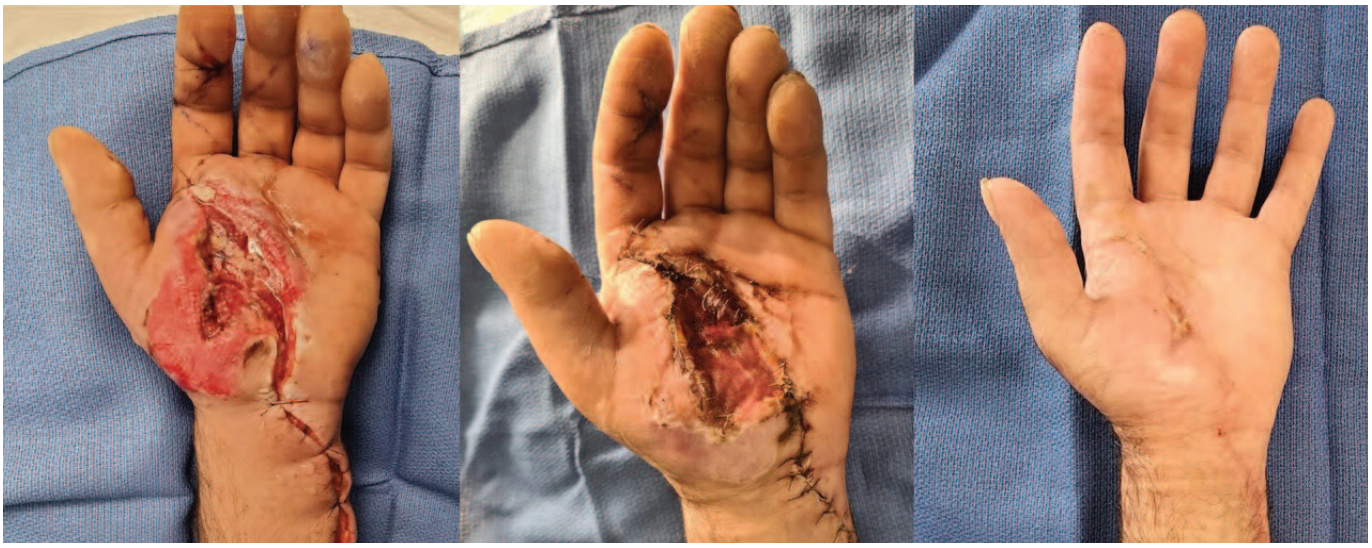

Figure 5. BTM to volar hand and forearm in the setting of flexor tenosynovitis.

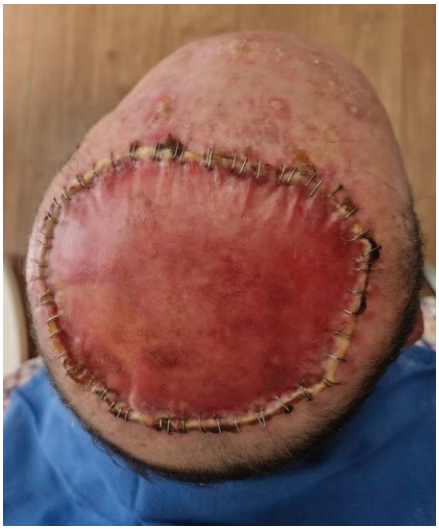

Figure 6. BTM to resurface scalp - two weeks post BTM application

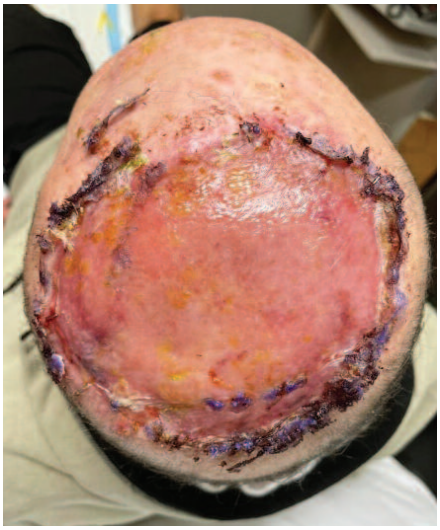

Figure 7. BTM to resurface scalp - two weeks post STSG

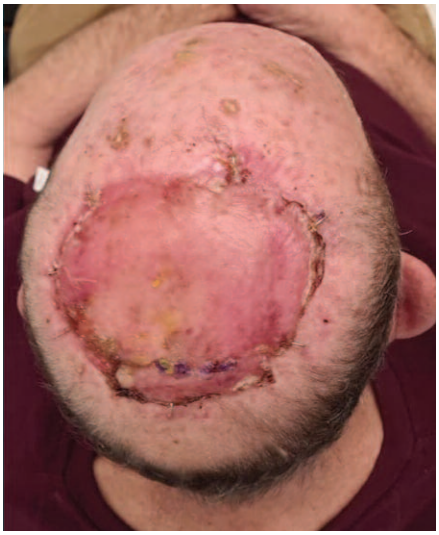

Figure 8. BTM to resurface scalp - three weeks post STSG

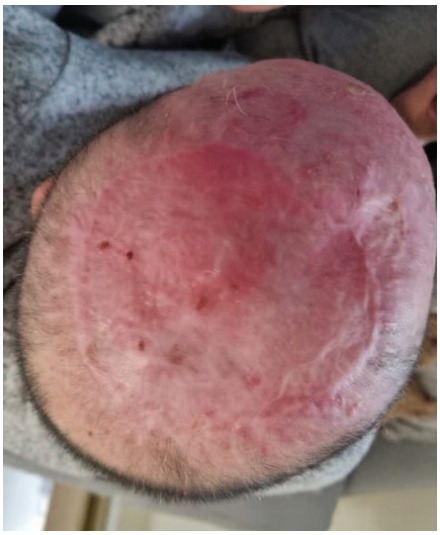

Figure 9. BTM to resurface scalp - six weeks post STSG.

and bare extensor tendon grafts. BTM is also helpful in the co-morbid and elderly population, who would otherwise not be ideal candidates for free tissue reconstruction of complex wounds. BTM allows for a much simpler reconstruction with good outcomes and minimal donor morbidity.

We have also observed spontaneous re-epithelialisation with BTM. BTM was applied over a palm defect of 2 x 6 cm with exposed flexor tendons following a severe flexor tenosynovitis (Fig. 5). The patient was a 37-year-old male with a background of intravenous drug use and multiple discharges against medical advice. He was initially planned for a split-thickness skin graft at around 4 weeks after the application of BTM. However, he missed several medical appointments and when he finally presented to our outpatient department at 9 weeks post application of BTM, the defect had spontaneously re-epithelised without the need for a split-thickness skin graft. Again, this highlights the robust nature of BTM, which can provide an alternate treatment option in particularly challenging patients

4. Skin resurfacing following excision of cutaneous malignancies

Reconstruction following the treatment of skin malignancies is another scenario where we have used BTM due to its advantages over STSG alone. BTM has been useful in skin resurfacing, especially of the scalp, where patients have large areas of sun-damaged skin. With smaller defects, a full-

thickness skin graft (FTSG) is ideal. A local flap is also an option with larger defects, although it leaves a more significant scar. BTM is an excellent alternative for larger defects, as it provides a more robust bed for the application of STSG. Thus, BTM allows an improved contour and aesthetic.

We present a case where we used BTM to resurface a large area of the scalp in the setting of multiple squamous cell carcinoma in situ in an immunocompromised patient. Figures 6-9 show excellent contouring following the application of BTM and STSG.

5. Hidradenitis suppurativa

A more recent application for BTM has been in cases of hidradenitis suppurativa, which present reconstructive challenges of a chronically infected and scarred wound bed, often in very mobile areas such as the axilla. Our experience with BTM in hidradenitis suppurativa is positive, though it is still early and a longer follow-up is required. Figure 10 shows a 28 year-old male with Hurley Stage III hidradenitis suppurativa in the bilateral axillae. He underwent wide excision and resurfacing with BTM followed by split-thickness skin graft 8 weeks later. The result at 12 months post STSG shows great aesthetic results and full range of motion in the axilla.

DISCUSSION

Having achieved successful reconstruction in a multitude of complex wounds, we have found the following technical aspects of BTM application to be helpful. When insetting the BTM, particular attention should be paid to insetting at the seams, as for a FTSG, with either sutures or staples. The dressings of choice that have provided us with the most success are either a tie-over dressing with silver or a silver vacuum-assisted closure (VAC) dressing. Both of these allow for even application of an antimicrobial dressing to the wound bed. The dressing of choice is one that provides an antimicrobial interface such as Acticoat (Smith and Nephew, London, UK). A VAC dressing is then applied to provide compression and maximize the chance of integration. If a VAC dressing is not available, foam and staples provide a reasonable alternative.

The initial dressing is left on for up to one week, after which the dressing regime is changed to Mepilex ® Ag (Mölnlycke, Gothenburg, Sweden) twice weekly in the clinic, with any fluid underneath the BTM gently expressed at each wound review. During the second stage, delamination is performed with gentle teasing so as to not traumatically lift the BTM from the wound bed, and minimal abrasion is performed to refresh the surface prior to grafting. The optimal time to STSG varies between patients and wound factors, but should be from three to six weeks following BTM application. The earliest we have performed STSG following BTM has been two weeks and the latest has been four months. As for STSG, optimal results were achieved by avoiding meshing for better aesthetic purposes and by ensuring careful inset of the graft with sutures and tissue glue. As mentioned previously, we have also observed spontaneous re-epithelialization over delaminated BTM, if it is left long enough.

The performance of BTM in comparison to other dermal matrices is of interest. A retrospective study examined patients treated using BTM or a collagen-chrondroitin sulphate dermal matrix.[10] Reduced skin graft failure rates and a reduced need for secondary procedures associated with the use of BTM were reported. These authors also reported that BTM offered advantages in terms of comparative costs, although this may vary by institution and the choice of dermal matrices available.

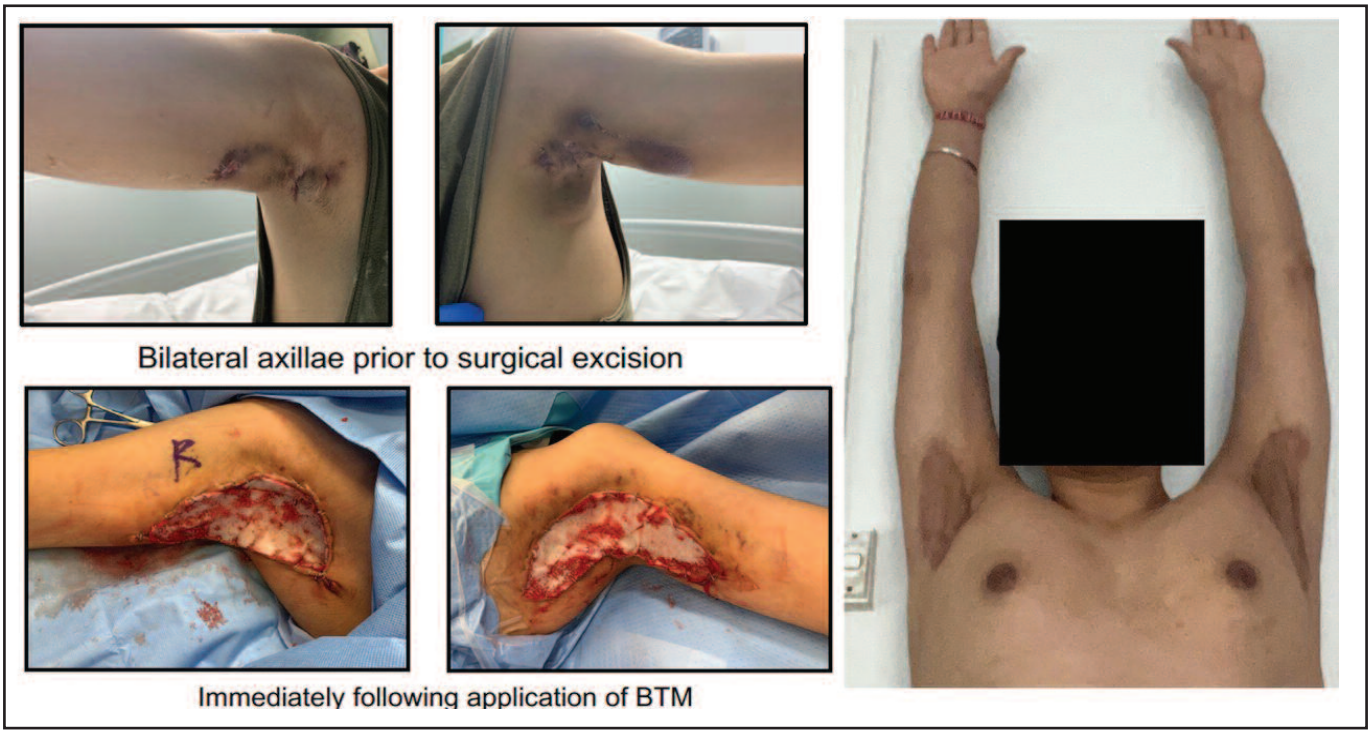

Figure 10. BTM to bilateral axilla in the setting of hidradenitis suppurativa

CONCLUSION

BTM has been demonstrated to be effective in the reconstruction of complex wounds. Our experience has shown that the possible indications for BTM far exceed its original intended use in major burns. Its ability to temporize wounds, integrate over exposed structures, resist infection, show minimal contracture, a natural contour, and excellent aesthetic results, as well as its relative simplicity compared to flap reconstruction make it a versatile reconstructive option for various complex wounds. With time, our understanding of the technology and technical expertise will further expand its potential applications and further refine patient care. **STI**

AUTHORS' DISCLOSURES

The authors declare that there are no conflicts of interest.

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