GUNZE

Use of PELNAC® (TheraGenesis®) to Support Treatment of Transmetatarsal Amputations and Deep Wounds: A Limb Salvage Case Series

CASE STUDY

Case(s) performed by: Dr. Brian Lepow, DPM, FFPM RCPS(Glasg)
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INTRODUCTION

Diabetes mellitus (DM) affects approximately a half-billion people worldwide and is a major risk factor leading to peripheral arterial disease (PAD), which is a "partial or complete occlusion of the peripheral vessels of the upper and lower limbs."[1,2] Both DM and PAD can equally contribute to the occurrence of chronic wounds, such as diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs).[1] These chronic wounds impose substantial treatment and cost burdens on global healthcare systems, representing an estimated 1 to 4% of total healthcare spending in developed countries.[1,3,4] A global increase in the prevalence of diabetes in recent years has led to a marked increase in chronic wounds and their associated social, economic, and physical burdens.[5] Annually, more than 9 million people worldwide are believed to suffer from DFUs, while in the United States alone, approximately 600,000 people experience VLUs.[4,6,7] Patients with such chronic wounds endure pain, disability, and loss of productivity, and are at increased risk for depression, social isolation, amputation, and death.[4,6,8] Current treatments for diabetic ulcers include wound dressing, hyperbaric oxygen, negative pressure wound therapy (NPWT), and, in advanced cases, amputation of the limb.[9-11] However, once amputation occurs, the patient's life expectancy significantly decreases.[12] As such, it is imperative to have efficacious treatments for these pernicious wounds.

One treatment option, guillotine transmetatarsal amputation (gTMA), is a commonly used midfoot surgical procedure that preserves the limb in cases of severe forefoot pathologies such as DFUs.[2,13,14] gTMA has the advantage of maintaining the biomechanics of the foot and ankle and, therefore, can provide high long-term limb salvage rates.[2,13,14] In some cases, arterial optimization is performed in conjunction with gTMA to enable optimal blood circulation at the intended site to facilitate healing.[14] Once the gTMA is completed, wound closure is then facilitated with the application of an autogenous split thickness skin graft (STSG) or another wound matrix.[2,14,15] Although STSG is widely used with the benefits of high survival in cases of poor vascularity, some drawbacks include donor site morbidity, contraction, and appearance.[14,15] An alternative treatment option that avoids the limitations of STSG involves the use of a bilayer wound matrix, which has demonstrated efficacy in various wound care applications.[16-20] One such bilayer wound matrix, PELNAC® (GUNZE), is a collagen-based wound dressing that consists of two layers: a porcine tendon-derived atelocollagen sponge layer and a silicone film layer. It also contains a non-adhesive gauze (TREX™) to reinforce the silicone film, and slits to aid in the drainage of exudate. The biodegradable collagen/silicone matrix provides a flexible scaffold to assist with cellular proliferation for cellular infiltration and capillary growth as demonstrated *in vitro* and *in vivo*.[21,22]

The following case series describes the use of PELNAC to support the treatment of patients with deep wounds for limb salvage. All patients provided consent for inclusion and the use of deidentified images.

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PATIENT 1

A 66-year-old African American female with a medical history of Type 2 DM, PAD venous insufficiency, and ESRD on hemodialysis, presented for gTMA as a result of a severe DFU. Prior to the procedure, she underwent vascular optimization to maintain proper blood supply and circulation. Following gTMA, PELNAC was applied to the wound along with NPWT (Figures 1A and B) and the patient underwent decolonization with daily Vashe® (Urgo Medical®, Fort Worth, TX) wet-to-dry dressing. At approximately 3 weeks postoperative, the silicone layer was removed, and the wound was managed with weekly or biweekly dressing as needed without the need for STSG. Wound closure was achieved at approximately 12 weeks postoperative without complications (Figures 1C and D).

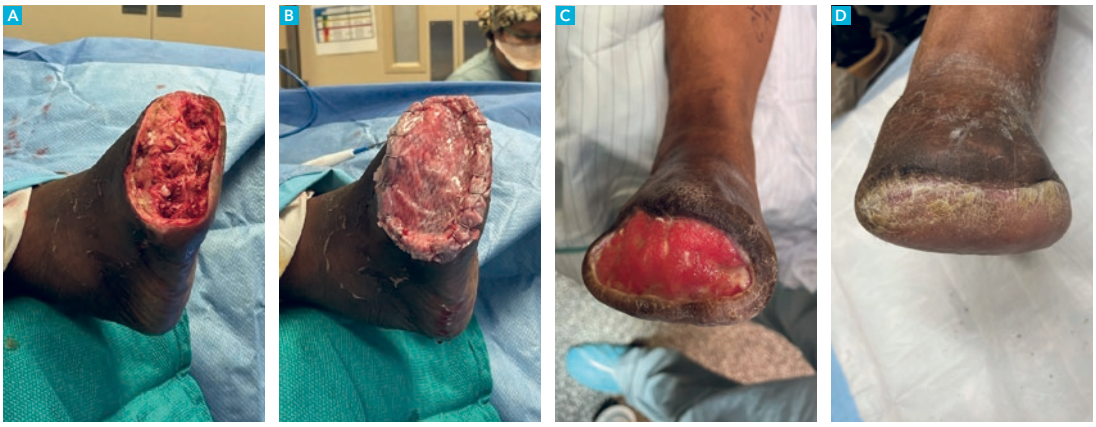

Figure 1. Representative case images of Patient 1 showing (A) intraoperative view of the gTMA and (B) application of PELNAC following gTMA. (C) Continuation of wound closure until (D) full wound closure was observed at 12 weeks postoperative. STSG was not required.

PATIENT 2

A 17-year-old Caucasian female with an elevated BMI otherwise no additional significant comorbidities presented with tissue necrosis on the dorsal side of her foot. The ulcer appeared thrombolytic with no definitive diagnosis (Figure 2A). To treat the wound, the full-thickness lesion was debrided, and PELNAC was applied along with NPWT (Figure 2B). At 2 weeks postoperative, the silicone layer was removed (Figure 2C), and the wound was treated with a weekly or biweekly dressing as needed until full wound closure was achieved at 10 weeks postoperative (Figure 2D). There were no reported complications and STSG was not required.

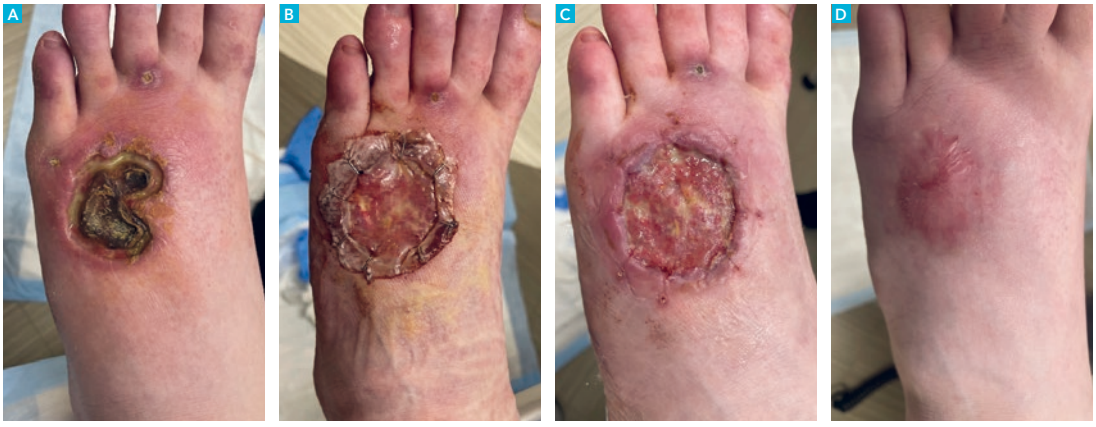

Figure 2. Representative case images of Patient 2 showing (A) wound presentation and (B) intraoperative placement of PELNAC. (C) Silicone layer removal took place at 2 weeks postoperative. (D) Full wound closure was observed at 10 weeks postoperative with standard treatment.

PATIENT 3

A 65-year-old Hispanic male presented with a gangrenous forefoot. Medical history included Type 2 DM, PAD, end stage renal disease (ESRD) on hemodialysis, and hyperlipidemia (HLD). With limb preservation as the ultimate goal, the patient underwent a gTMA, followed by decolonization with daily Vashe® wet to dry dressing (Figure 3A). Following gTMA, the patient underwent arterial optimization to allow for proper blood circulation and PELNAC was applied to the wound along with NPWT (Figure 3B). After 3 weeks postoperative, the silicone layer was removed (Figure 3C), and the patient underwent standard treatment of weekly or biweekly dressing as needed until wound closure occurred at 12 weeks postoperative (Figure 3D; at 8 weeks postoperative. Final images not taken). Of note, the patient did not require a STSG to achieve closure and there were no reported complications.

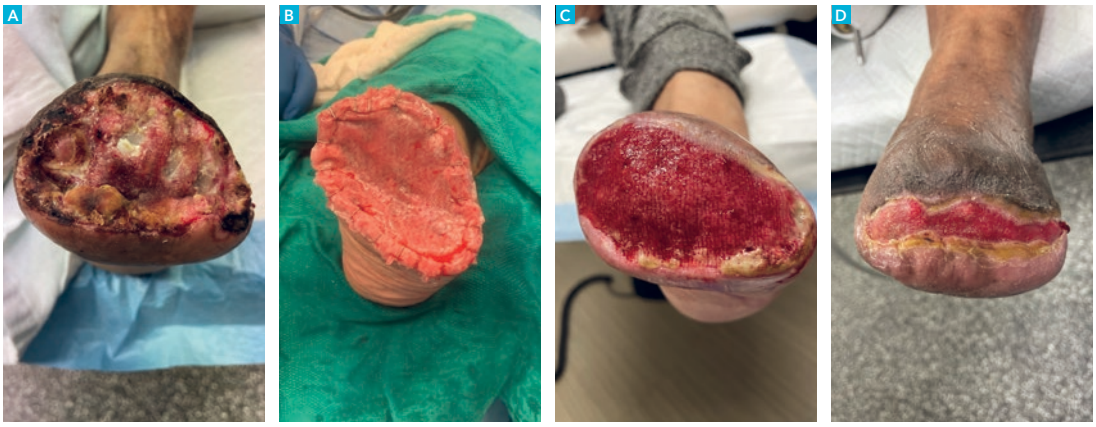

Figure 3. Patient 3 representative case images showing (A) intraoperative view of gTMA and (B) PELNAC placement. (C) Silicone layer removal occurred at 3 weeks postoperative, with (D) evidence of wound closure at 8 weeks postoperative. The wound was reported fully closed at 12 weeks (image not taken) and the patient did not require STSG.

PATIENT 4

A 58-year-old Hispanic male presented with a failed necrotic gTMA from another institution (Figure 4A). His medical history included Type 2 DM, PAD, and ESRD on hemodialysis. First, the wound was debrided, and arterial optimization was performed to allow for proper blood circulation. The patient then underwent revision of the gTMA followed by decolonization of the wound bed with a Vashe® wet-to-dry dressing. At this time, PELNAC was also applied along with NPWT (Figure 4B). At 10 days postoperative, the silicone layer was removed, and 100% granulation was observed (Figure 4C). Full wound closure occurred at 16 weeks postoperative without the need for STSG and without complications (Figure 4D at 14 weeks postoperative. Final images not taken).

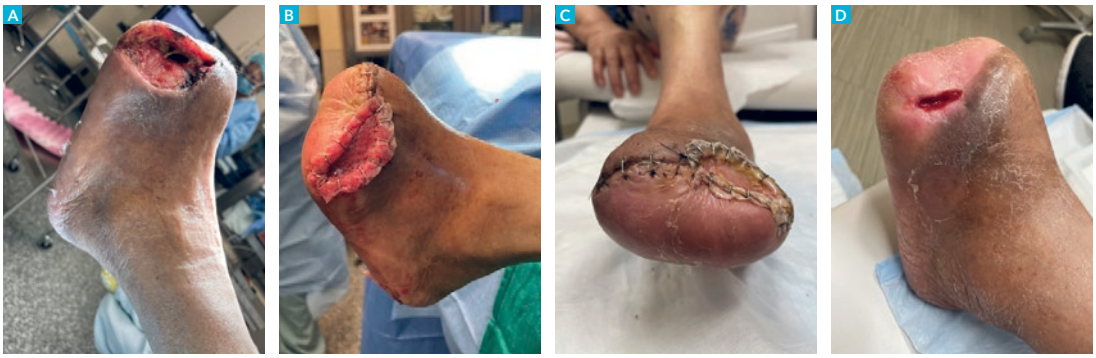

Figure 4. Representative case images of Patient 4: (A) baseline intraoperative view of a gTMA performed at another institution that required revision. (B) Following debridement, PELNAC was placed on the wound and then the patient underwent gTMA revision. (C) Silicone layer removal took place at 10 days postoperative with 100% granulation. (D) Evidence of wound closure at 14 weeks postoperative. Full wound closure reported at 16 weeks and STSG was not required (image not taken).

GUNZE

PATIENT 5

A 60-year-old African American male underwent an open gTMA at another institution that required revision. Since limb preservation was the goal, decolonization and arterial optimization were performed to allow for proper blood circulation prior to the gTMA revision. At the time of the revision, an application of PELNAC was placed on the wound along with NPWT (Figure 5A). Silicone layer removal occurred at 2 weeks postoperative and within 12 weeks, the wound epithelialized and achieved full closure with standard dressings (Figure 5B at 8 weeks postoperative. Final images not taken). There were no reported complications and STSG was not required.

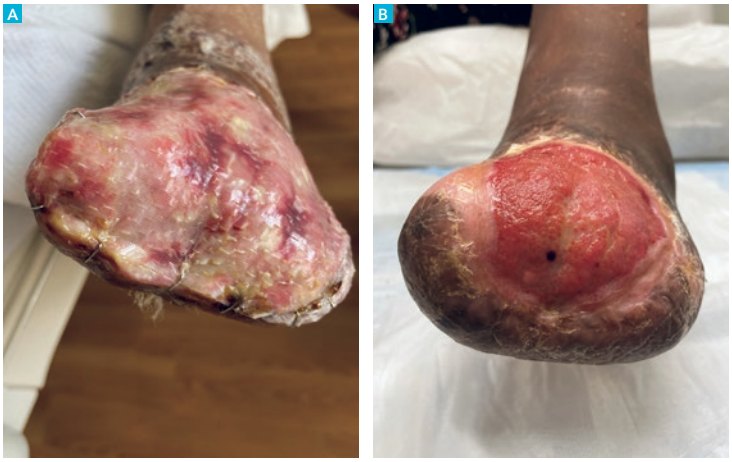

Figure 5. Patient 5 representative case images: (A) intraoperative placement of PELNAC post-gTMA and (B) evidence of wound closure at 8 weeks postoperative. Full wound closure was achieved at 12 weeks postoperative (image not taken).

SUMMARY

This case series demonstrates a novel and successful use of PELNAC for limb salvage for patients with challenging comorbidities that can impede healing. Therefore, these results support the clinical advantages of PELNAC in cases where other treatments had failed. Of note, none of the patients required STSG to achieve closure. Although a case series does not necessarily predict how PELNAC will behave in other patients, these results demonstrate versatile and successful uses of this graft to support wound closure.

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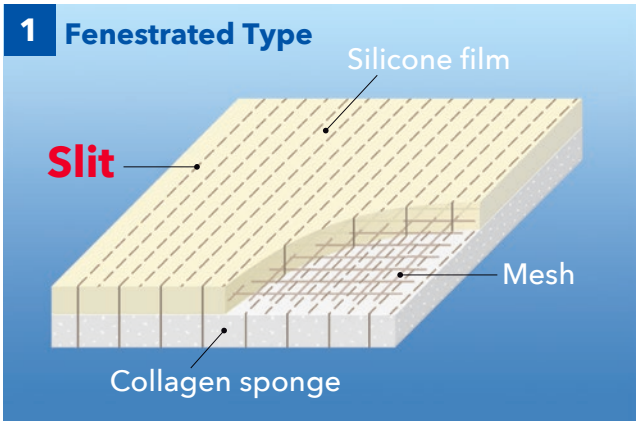
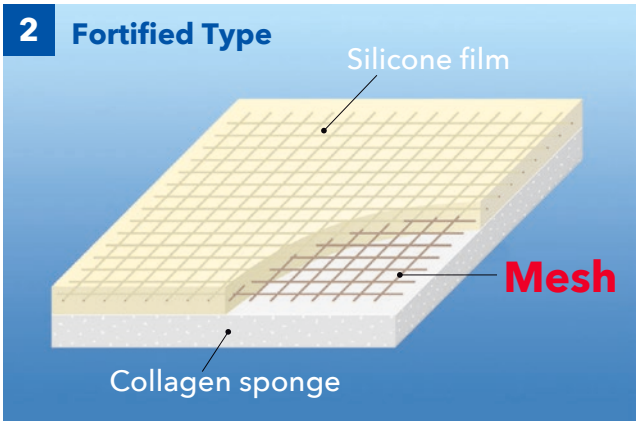
- *Please refer to your region's instructions for use for a complete list of indications, contraindications, warnings, and precautions.*
- *PELNAC®, Marketed as TheraGenesis® in the USA, is a proprietary collagen-matrix technology developed and manufactured by GUNZE LIMITED.*
- *TheraGenesis® is a registered trademark of LifeNet Health, Inc.*

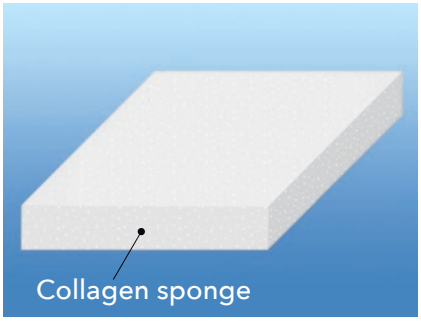
PRODUCT TYPES

Bilayer





Single-Layer (No silicone film)



PRODUCT LINEUP

Size	Dimension*	Sheet/Box	Fenestrated	Fortified	Single Layer
3S	40 x 30(mm)	1	PN-D40030	PN-F40030	PN-S40030
SS	40 x 60(mm)	1	PN-D40060	PN-F40060	PN-S40060
S	82 x 60(mm)	1	PN-D82060	PN-F82060	PN-S82060
M	82 x 90(mm)	1	PN-D82090	PN-F82090	PN-S82090
L	82 x 120(mm)	1	PN-D82120	PN-F82120	PN-S82120
LL	120 x 240(mm)	1	PN-D120240	PN-F120240	PN-S120240
3L	200 x 240(mm)	1	PN-D200240	PN-F200240	PN-S200240

*1mm = 0.03937in

GUNZE

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