

The use of dermal regeneration template for treatment of complex wound with bone/tendon exposed at the forearm and hand, a prospective cohort study

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Abstract

The purpose of this study was to assess the efficacy and safety of Pelnac and split-thickness skin graft for management of complex wound with underlying bone/tendon exposure at forearm and hand.

This is a prospective study, beginning from March 2013 up to May 2017. There were 13 patients, with age of 31.2 years. All of them underwent the staged Pelnac and split-thickness skin graft to manage the complex wound with bone/tendon. Postoperatively, scheduled follow-up was conducted.

The average follow-up was 15 months. There were no infections, wound necrosis, hematoma, or seroma during the phase when Pelnac was applied. There was 100% “take” of the Pelnac in 12/13 patients. In 11 patients, there was complete skin graft “take”. Patients’ satisfaction for the esthetic appearance of the grafted area was $75.0 \pm 8.5/100$. The VSS value was 2.9 ± 2.5 . Regarding the sensory recovery, the response of “normal or near normal” could be obtained in 7/13 patients, “slight loss” in 5 patients and “significant loss” in 1 case. The average DASH score was 27.2 ± 18.5 , and most patients (12/13) could obtain an acceptable ability to perform the daily activities.

Pelnac dermal template is a favorable alternative to flap reconstruction in the treatment of complex wound with underlying tissues exposure.

Abbreviations: DASH = disabilities of the arm, shoulder and hand, VSS = Vancouver Scar Scale.

Keywords: artificial dermis, bone/tendon exposure, Pelnac, soft-tissue defect

1. Introduction

In various surgery fields, management of the complex wound with underlying bone/tendon exposure remains a difficult clinical problem,

requiring multiple advanced soft-tissue management techniques. At forearm and hand sites, especially the dorsum of the hand, there is a greater possibility of bone and tendon exposure secondary to the high-energy traumatic injuries. Due to the functional and social role of forearm and hand, successful management of these complex wounds is especially necessary in the overall functional rehabilitation of the patient; otherwise, joint stiffness, scar contracture, and even severe disability would possibly be left.

A classic teaching is that, complex wound with exposed underlying tissues (bone, joint surface, cartilage, or tendon) must be closed by the surrounding tissues or covered with a vascularized flap to facilitate the ultimate healing. This is why skin grafts or flaps of various types (local, regional, and distal flaps) have been always the predominant treatment options for repairing complex wounds.^[1,2] Although each technique has its own advantage in management of complex wounds, some drawbacks must be taken into account before a decision on treatment option is made or when the cost-effectiveness is evaluated. These main drawbacks include bulkiness, donor site morbidity, patients’ discomfort for a long time, and unfavorable cosmetic and functional results.^[2,3] In addition, the use of the above techniques is frequently hindered by the magnitude of tissue defect and/or limited donor site, especially in those severe polytrauma or medically unstable patients.

Efforts have been always made in the last decades to develop skin substitutes to minimize donor site morbidity while optimizing a functional and aesthetic outcome. Integra was invented by Burke and Yannas^[4] in 1980 and since then, various artificial dermis products such as Alloderm,^[5] Dermagraft,

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Terudermis,^[6] Matriderm,^[7] and Pelnac^[8] have been applied in clinical practices and reported to be useful tools to reconstruct complex full-thickness wounds. The Pelnac (Gunze Co., Ltd., Kyoto, Japan) is a bilayer dermal substitute, which consists of the underlying atelocollagen matrix layer acting as a scaffold for dermal regeneration, and the overlying semipermeable silicone layer acting as a temporary epidermis.^[8,9] Since its availability on the market in 1996, Pelnac has been used for treatment of complex full-thickness skin defects in various causes and exhibited the superior performance.^[9–12]

The application of Pelnac for treatment of traumatic forearm and hand injuries involving exposed bone/ tendon has not been extensively studied. In this prospective study, we described the use of Pelnac in 13 consecutive patients to treat traumatic forearm and hand injuries. The aim of this study was to assess the efficacy and safety of staged Pelnac and thin split-thickness skin graft to cover the large skin and soft-tissue defects with bone/ tendon exposed at forearm and hand.

2. Materials and methods

2.1. Study design

This is a prospective study, beginning from March 2013, up to May 2017. This work has been reported in line with the STROCSS criteria.^[13] The inclusion criteria were traumatic forearm and hand injuries involving exposed bone, and/or tendon. In these injuries, the loss of surrounding tissue precluded definitive treatment by simple wound care, primary closure and skin graft, or some more elaborate reconstructive techniques were unacceptable by patients. The exclusion criteria included advanced age (≥ 70 years), diabetes, heavy smoking, and long-term use of glucocorticoid, which might compromise wound healing.

2.2. Patients and materials

Before the study began, it was approved by the Institutional Review Board of the No.252 Hospital of People's Liberation Army of China. Written informed consent was obtained from each patient before the reconstruction operation began. During the study period, a total of 17 patients were treated with 18 applications of Pelnac dermal regeneration template (manufactured by Gunze Co. Ltd., Kyoto, Japan; supplied by Guangzhou Jiyuan biotechnology co. LTD; certification number: 3641815). During the follow-up period, 4 patients were lost due to contact information change or personal affairs, leaving 13 patients for final data analysis. There were 11 men and 2 women, with a mean age of 31.2 years (range, 14–54 years). The mechanism of injury was traffic accident in 7 cases, crush injury in 4 cases and bruise injury by heavy object in 2 cases. The site of skin and soft-tissue loss was forearm in 9 cases and hand in 4 cases. The underlying tissue exposed was bone in 3 cases, tendons in 7 cases, and combined bone and tendons in 3 cases. The mean size of skin loss was 32.5 cm², and the range was 12 to 140 cm².

2.3. Operative technique

For every patient, 2 separate operations were performed. The first procedure involved thorough debridement of necrotic tissues, meticulous hemostasis to prevent hematoma formation, and the following Pelnac coverage. For bone exposure, a rongeur forcep was used to remove the necrotic tissues and a kirschner wire was used to slightly drill into the exposed bone surface to induce

punctate bleeding. For tendon exposure, the contaminated tissues around were cleared and desiccated tendon was removed, with healthy tendon left intact. After adequate haemostasis was obtained, Pelnac was trimmed to the appropriate size and shape to achieve a tension-free closure and was sutured to the surrounding skin by interrupted 3–0 or 4–0 absorbable stitch. The overlying silicone layer was stabbed with No.11 scalpel blade to facilitate drainage of effusion. A saline-soaked gauze dressing was used over the Pelnac, followed by a compressive dressing and elastic bandage. Based on our experience, for cases with larger size defect of soft-tissue and severely contaminated wound, negative pressure dressings (vacuum sealing drainage, VSD, Wuhan VSD medical science & technology co., ltd) dressing was covered and fixed to enhance the anti-infection and the “take” ability of Pelnac, which acts as a splintage for the Pelnac and allows a protective barrier layer to be formed. Pelnac was inspected every 3 days or as needed to assess adherence of the silicone layer, vascularization status (coloration of tissues underneath the transparent silicone layer), and to monitor for development of potential complications (infection, hematoma, or seroma).

The second procedure involved the split-thickness skin graft. At 2 to 3 weeks after the Pelnac placement, the color of tissues beneath the silicone layer changed as pink to reddish, indicating the adequate vascularization and formation of dermis-like tissues. Then, silicone layer was removed and if necessary, a moderate debridement of the granulation tissue was performed. Autologous split-thickness skin graft (0.2–0.4 mm) harvested from the anteromedial thigh was applied over the Pelnac dermis, and tie-over fixation was performed. At 10 to 12 days later, the dressings and tie-over were removed and the graft survival was evaluated.

2.4. Follow-up

After discharge, every patient was routinely followed-up at 2 weeks, 1, 3, 6, and 12 months on an outpatient basis, according to our strict protocol. At each follow-up, epithelialization, scar quality, and potential complications (infection, hematoma, seroma, or skin graft loss) were traced documented. At the final follow-up (minimum, 12 months), the scar quality, patients' satisfaction with the esthetic appearance (hundred-mark system), functional recovery of the injured limb, sensibility of the grafted skin, and need of reoperation were evaluated.

Scar quality was evaluated by Vancouver Scar Scale (VSS)^[13] which included 4 variables (pigmentation, vascularity, pliability, and height), each with higher scores indicating more severe scarring (Table 1). Disabilities of the arm, shoulder and hand (DASH) questionnaire^[14] was used to evaluate patients' ability to perform injured upper extremity daily activities. This questionnaire includes 30 self-reported items, with the total score ranging from 0 points (no disability) to 100 points (maximum disability). Patients' subjective feeling was used to describe the level of sensory recovery and the potential response could be “normal or near normal”, “slight loss”, “significant loss,” and “complete loss”, with the same area of the contralateral uninjured side set as a control.

3. Results

The average follow-up was 15 months, ranging from 12 to 27 months. The average interval from the placement of Pelnac to the skin graft was 21.2 \pm 4.2 days (range, 14–31 days). The time from the Pelnac placement to complete reepithelialization of the wound was 11.0 \pm 3.5 days (range, 8–19 days). There were no

Table 1**Vancouver Scar Scale.**

Vancouver Scar Scale		
Parameter	Descriptor	Points
Pigmentation	Normal	0
	Hypopigmentation	1
	Mixed	2
	Hyperpigmentation	3
Vascularity	Normal	0
	Pink	1
	Red	2
	Purple	3
Pliability	Normal	0
	Supple (flexible with minimal resistance)	1
	Yielding (gives way to pressure)	2
	Firm (inflexible not easily moved; resistant to manual pressure)	3
	Banding (rope-like tissue that blanches with extension of scar)	4
Height	Contracture (permanent shortening of scar producing deformity or distortion)	5
	Normal (flat) 0	0
	0 mm and <2 mm	1
	≥2 mm and <5 mm	2
	≥5 mm	3

infections, wound necrosis, hematoma, or seroma during the phase when Pelnac was applied. There was 100% “take” of the Pelnac in 12 out of 13 patients until skin graft; and in the remaining 1 case the temporary silicone layer prematurely loosened before the neodermis was deemed not to be ready for a skin graft. For this case, the loose silicone layer was removed and the beneath neodermis continued to develop uneventfully; and in the ensuing week the skin graft was performed. In 11 out of 13 patients, there was complete skin graft “take” (100%), while in the remaining 2 patients there was partial skin graft loss (10%, 14%) but not requiring additional surgery.

At the final follow-up, patients’ satisfaction for the esthetic appearance of the grafted area was in average $75.0 \pm 8.5/100$ (62–95). The VSS value was 2.9 ± 2.5 (range, 0–8), representing a favorable result. Regarding the sensory recovery, the response of “normal or near normal” could be obtained in 7/13 patients, “slight loss” in 5 patients and “significant loss” in 1 case. The average DASH score was 27.2 ± 18.5 (range, 0–62), and most patients (12/13) could obtain an acceptable ability to perform the daily activities without pain or restriction by tissue adhesion. The poor DASH score (62) was observed in a 27-year young man who had open fractures of 2nd and 3rd metacarpal bones and exposed torn tendons, due to mechanical crushing injury. After the definitive fracture reduction and fixation, a large size of skin and soft-tissue defect was left (8 cm × 5.5 cm) and finally reconstructed by Pelnac and staged autogenous skin graft. At the 12-month follow-up, he complained of weak holding and grasping strength of the injured hand and was unable to perform daily activities. He was suggested to continue active exercises and if non-effective, to receive release surgery.

Figures 1 and 2 presented the 2 typical cases.

4. Discussion

High-energy forearm and hand injury with subsequent full-thickness skin defect and underlying tissue exposure is not

uncommon in the department of emergency or orthopaedics. Due to their social and functional role, an optimized functional and esthetic outcome should be targeted as a priority when a reconstructive surgery for the complex wound is decided. Traditionally, debridement followed by skin grafting or flap reconstruction has been always the primary treatment option, but with variable success in regard to flap viability and the donor site morbidity. Furthermore, the application of the flap techniques is frequently hindered by the magnitude of tissue defect and/or limited donor site, especially in patients with significant comorbidities or associated injuries. Pelnac, a dermis substitute that allows dermis-like tissue growth into matrix layer and vascularization over areas of exposed bone or tendons, provides a powerful alternative for the reconstructive surgery. In this study, we used staged Pelnac and autologous split-thickness skin to treat 13 cases of forearm and hand full-thickness skin defect and bone/tendon exposure, and got favorable clinical results at the final follow-up.

In recent decades, Pelnac and other tissue-engineering have become a very popular alternative method for reconstruction and were reported to provide favorable clinical outcomes in full-thickness skin defects in various causes.^[7,11,12,15] Wei et al^[16] applied Pelnac and autologous split-thickness skin graft for treatment of 9 cases of large size and full-thickness skin defects at the hand, and found a 77.8% of excellent and good rate of the functional recovery at the minimum 2-year follow-up. Compared to the traditional autologous skin flap transplantation, Pelnac combined with autologous split-thickness skin grafting more likely resulted in a favorable clinical outcome in treatment of hand complex wounds, in term of scar quality (VSS), aesthetic appearance, functional recovery and donor site morbidity.^[17] Huang et al^[18] used free skin flap combined with VSD technique to treat the large soft-tissue defect in the forearm, and the results showed 2 of the 11 cases had partial necrosis of the distal margin of the flap. Huang et al applied free flap to repair 102 cases of soft-tissue defect in forearm and hand, and obtained the favorable results during the 0.5 to 6-year follow-up in most patients; however, 3 cases developed severe vascular crisis and 1 case had necrosis on the distal tip of the flap.^[19] On the other hand, simplicity, immediate and plentiful availability of this material is also the important considerations when a decision was made to employ Pelnac. Pelnac is readily available in sheets without limitation by magnitude of tissue defects, which is of particular clinical significance in the emergent operations required for coverage of the exposed bone/tendon to prevent infection. Furthermore, compared to flap transplantation Pelnac is less technically demanding and allows the procedure to be performed on an outpatient basis, which provides a more “practical” option for surgeons in primary hospitals.

The prerequisite of successful Pelnac take is a surgically clean wound; otherwise, any residual devitalized tissue or product by host reaction would potentiate failure. In our clinical practices, after Pelnac was sutured to the surrounding skin, small stabs were made into the overlying silicone layer to facilitate drainage of effusion. In addition, for cases with larger size defect of soft-tissue and severely contaminated wound, negative pressure dressing was applied over the silicone layer, which acts as a splintage for the Pelnac and allows a protective barrier layer to be formed to enhance the anti-infection and the “take” ability of Pelnac. In this study there were no infections, hematoma, or seroma observed and there was 100% “take” of Pelnac in 12/13 patients, which can be partially due to the application of VSD. In addition, negative pressure therapy was reported to significantly shorten



Figure 1. A 23-year man sustained a traffic accident injury to the right hand, with combined fractures and soft-tissue defect (9cm × 6cm). Wound lavage and debridement were performed; afterwards, Pelnac artificial dermis was covered (A, B). At the 19th day after the Pelnac placement, epidermalization in great mass from surrounding tissues of the wound bed developed and the size of tissue defect was significantly reduced by 2/3 (C), Autologous split-thickness skin graft harvested the anteromedial thigh was performed (D). At the follow-up, patients obtain a satisfying esthetic appearance (85%) and a satisfying functional recovery with DASH score of 11 (E, F).



Figure 2. A 34-year man sustained an accidental crush injury and steam burns to the right forearm, with skin and soft tissue defects by 15 cm × 11.5 cm and bone/tendon exposure (A). Wound lavage and thorough debridement were performed (B, C) and then Pelnac artificial dermis was covered and fixed (D). At the postoperative 26th day since Pelnac placement, the overlying silicone layer was removed and autologous split-thickness skin graft was performed (F). At 39th day after the initial procedure, the skin graft had a 100% survival (G, H). At the last follow-up, the patient had an acceptable esthetic appearance (67%), and obtained a favorable functional recovery with DASH score of 32 (I-L).

the “waiting time” for artificial dermis incorporation and vascularization by 1 to 2 weeks.^[20,21] In the present study, we did not observe this significant effect of VSD; and the average time was 22.4 days in 5 cases with VSD application and 20.5 days in 8 cases without application (data not shown in the result part). This seemingly reverse discrepancy between both groups might be related to our treatment protocol whereby the more severe and complex wounds were more likely assisted by the use of VSD. Nevertheless, the “waiting time” reported in this study was comparable to that of most previous studies^[22–25] that used combined artificial dermis products and assisted negative pressure therapy for treatment of full-thickness skin defects in various causes.

Despite, some drawbacks associated with Pelnac must be considered. Firstly, the primary drawback of Pelnac is the high cost. A 4 × 6 cm sheet of Pelnac costs approximately RMB 3000 CY at our institution, and generally several sheets are necessitated to cover the wound with large size tissue defects. Secondly, need of at least 2 procedures and the long “waiting” time allowing well-vascularization of neodermis for skin graft are tests for patients’ patience. Thirdly, although no infections were found in this study, the risk of infection could not be neglected. Strict clinical surveillance after Pelnac placement or skin graft is still necessitated to drain hematoma and other products to prevent infections under the silicone layer.

The prospective design, a minimum of 12-month follow-up and focus on a specific site (forearm and hand) are the merits of this study. The absence of a control group for direct comparison of the effects of Pelnac is the primary limitation of this study. In the future, more comparative prospective trials are needed to evaluate the long-term benefits of Pelnac on the complex wound.

In conclusion, in this study most patients could obtain an acceptable esthetic appearance and functional recovery. The successful treatment of the above cases demonstrates Pelnac dermal template is a useful adjunct in the treatment of traumatic injuries with underlying tissues exposure, as an alternative to flap reconstruction.

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