ORIGINAL ARTICLE

One-stage limb Pelnac[®] reconstruction after removal of skin cancer: safety, efficacy, and aesthetic outcomes

Jia Shi¹, Min Gao¹, Haijun Zhu¹, Weiwei Lu² (🖂)

- ¹ Department of Plastic Surgery, The Central Hospital of Wuhan, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430014, China
- ² Department of Orthopaedics, Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430030, China

Abstract	Objective To assesse the outcomes of one-stage limb reconstruction after removal of skin cancers defect.		
Abstract	Methods This prospective study was conducted from September 2017 to January 2020 and included		
	15 patients. All patients underwent extensive tumor resection and one-stage Pelnac [®] reconstruction of large skin defects, and regular postoperative follow-up was scheduled. At the 6-month follow-up, tumor recurrence and scar quality was assessed using the Vancouver Scar Scale (VSS). None of the patients		
	exhibited infection, wound necrosis, hematoma, seroma, or recurrence.		
	Results All the skin grafts were well accepted by the patients. Nine patients reported normal or near- normal sensory function, while six reported slight sensory loss. No cases of significant functional loss were observed. We enrolled 10 men and 5 women with a mean age of 63.9 years (range: 46–78 years).		
	The mean follow-up duration was 20.6 months (range: 12–36 months). The skin tumors were located on the feet ($n = 4$), forearms ($n = 3$), and legs ($n = 8$). The malignant tumors included malignant melanomas		
	(13.3%), basal cell carcinomas (33.3%), and squamous cell carcinomas (53.3%). The mean operative time		
	was 40.7 min. Two patients underwent radiotherapy. The average length of hospital stay was 2.6 days. The		
	mean skin defect area was 33.2 cm ² (range: 16.6–51.6 cm ²). The patient satisfaction score (regarding the aesthetic appearance of the grafted area) was 79.7/100, and the VSS score was 3.8.		
Received: 10 May 2022	Conclusion Pelnac [®] dermal templates facilitate efficient and reliable reconstruction of skin defects after		
Revised: 5 July 2022	skin cancer resection.		
Accepted: 21 July 2022	Key words: skin cancer; Pelnac [®] ; large-scale skin reconstruction		

Large-scale skin reconstruction after major tumor resection is challenging for both orthopedic and plastic surgeons ^[1–3]. Unlike traumatic tissue loss, the defect area may be large, and the muscle, tendon, and periosteal tissues may have to be removed. In addition, the risk of tumor recurrence and likely subsequent therapy (adjuvant or neoadjuvant radiation) must be considered prior to surgery ^[3]. Treating cancer-related tissue defects is critically important for functional and aesthetic rehabilitation, elimination of scar contractures, and prevention of severe disability. The surgeon must consider the patient's age and general status, skin defect area, planned adjuvant treatment, comorbidities (such as

diabetes or infection), and cosmesis^[4]. This is especially important in older patients with locally advanced cancers, systemic diseases, or a history of skin tumor recurrence. Skin grafts or free flaps have traditionally been used to cover large soft tissue defects after oncological demolition ^[5–6]. Conventional flaps include muscular, myofascial, myocutaneous, and fasciocutaneous flaps ^[7–10]. However, these are associated with donor site morbidity, unreliability, and extended operating times ^[11]. Flap surgery is frequently difficult in older patients, those with systemic diseases and/or limited donor sites, and those undergoing adjuvant or neoadjuvant radiation therapy ^[12, 13]. Short operating time, brief hospitalization, and low

Correspondence to: Weiwei Lu. Email: 215285906@qq.com

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complication rates are important. Artificial dermis is an effective and reliable alternative with few complications when the use of traditional skin grafts or free flaps are restricted. The artificial dermis has been used for various surgical reconstructions for over two decades ^[14]. However, few reports on the use of the dermis for the one-stage reconstruction of complex cancer-related soft tissue defects have been reported.

This prospective study enrolled 15 patients with fullthickness defects and exposed bones or tendons (i.e., wide and deep wounds) who underwent one-stage fullskin reconstruction using an artificial dermis (Pelnac[®]; Gunze, Kyoto, Japan). We evaluated the efficacy, safety, and aesthetic outcomes.

Patients and methods

This prospective study was conducted between September 2017 and January 2020. The inclusion criterion was wound defects after enlarged skin resection. Early tumors (stages I and II) are the best candidates for a one-stage procedure. Advanced cases requiring more extensive surgery and a more complicated tumor-related treatment schedule, which will significantly delay the healing process, are not suitable for this treatment. The exclusion criteria were diabetes, heavy smoking, infected wound, and poor compliance, all of which affect wound healing. This study was approved by the ethics committee of Tongji Medical College, Huazhong University of Science and Technology, China. Informed consent was obtained from all the patients. The China Food and Drug Administration has approved the artificial dermis, Pelnac[®], for clinical use.

Data were collected for 15 patients who underwent skin cancer enlarged resection and one-stage large skin reconstruction using an artificial dermal matrix,

Table 1 Postoperative data collected

197

including their age, sex, and wound area (Table 1). None of the patients were lost to follow-up. There were 10 men and 5 women, with a mean age of 63.9 (range: 46–78, std: 10.4) years. The malignant tumors included malignant melanoma (13.3%), basal cell carcinoma (53.3%), and squamous cell carcinoma (33.3%). The mean area of skin loss was 33.2 (range: 16.6–51.6, std: 9.9) cm².

All operations were performed in a standard sterile environment. The first stage involved extensive tumor resection according to recognized guidelines. If the bone was exposed, Kirschner wires were used to create small holes on the bony surface to induce punctate bleeding. If the skin cancer had infiltrated the bone, osteotomy was performed to access the bleeding points. The second stage involved the application of an artificial dermis (Pelnac[®]), which was used to cover the wounds following the manufacturer's protocol. After immersion in saline for 15 s, the Pelnac[®] template was trimmed to the shape and size of the wound to achieve tension-free closure. Next, the Pelnac[®] template was sutured to the surrounding skin using 4/0 Prolene sutures. Small drainage holes were created in the outer layer to facilitate exudation. The Pelnac® template was inspected every 2-3 days. At approximately 3-4 weeks, based on the wound area and depth, new vascularized skin usually formed, so the outer layer of the Pelnac® template could be peeled off. The type of tumor, size of the wound defect, length of hospitalization, operative time, healing time, and surgical complications were recorded (Table 2).

During the follow-up (minimum 12 months), patient satisfaction with appearance was rated on a 100-point scale, with normal skin as the reference. Scar quality was evaluated using the Vancouver Scar Scale (VSS), which includes four items (pigmentation, pliability, vascularity, and height)^[15]. Higher scores indicate more severe scarring. Sensory recovery was evaluated based

ID	Age (years)	Sex	Wound side	Subjective satisfaction with the aesthetic appearance	Sensation (A: near normal;B: slight loss;C: significant loss)	The vancouver Scar Scale value
1	46	F	Foot	90	Α	2
2	49	М	Leg	85	A	3
3	56	М	Forearm	85	A	3
4	65	М	Leg	80	В	4
5	78	F	Foot	80	A	4
6	67	М	Forearm	85	В	4
7	69	F	Leg	75	A	3
8	51	М	Leg	80	A	3
9	55	М	Foot	90	A	4
10	76	М	Forearm	75	В	3
11	68	F	Leg	80	A	4
12	76	М	Leg	75	В	5
13	74	М	Foot	70	В	5
14	67	F	Leg	65	В	6
15	61	М	Leg	80	A	4

on patient responses as "normal or near-normal," "slight loss," "significant loss," or "complete loss" compared with the contralateral uninjured area or the normal tissue next to the wound (Table 2).

Results

The average follow-up period was 20.6 (range: 12–36, std: 7.9) months. The average time from placing the Pelnac[®] template to recovery was 37.5 (range: 28–56, std: 7.8) days. No infections, hematomas, or seromas were observed in any patient during the Pelnac® phase. Only one patient who received adjuvant radiation therapy experienced mild neodermal ulceration that healed spontaneously without any residual deficit. All the skin grafts were obtained. No tumor recurrence was observed. Patient satisfaction and VSS scores were assessed by a surgeon who was not involved in the treatment. The average patient satisfaction score for the aesthetic appearance of the grafted area was 79.7 (range: 65–90, std: 7.2), while the average VSS score was 3.8 (range: 2-6, std: 1.0). Nine patients reported normal or near-normal sensory function, six reported slight sensory loss, and none reported significant loss (Table 2). The clinical case is shown in Fig. 1.

The patients included 10 (66.7%) men and 5 (33.3%) women. The mean patient age was 63.9 (range: 46–78, std: 10.4) years. The mean follow-up period was 20.6 (range: 12–36, std: 7.9) months. The tumors included malignant melanomas (13.3%), basal cell carcinomas (53.3%), and squamous cell carcinomas (33.3%). The tumor sites were the legs (n = 8), forearms (n = 3), and feet (n = 4).

The mean area of skin loss was 33.2 (range: 16.6–51.6, std: 9.9) cm². The mean operating time was 40.7 (range:

30–59, std: 7.7) min. The average length of hospital stay was 2.6 (range: 2–4, std: 0.6). The mean healing time was 37.5 (range: 28–56, std: 7.8) days. The mean VSS score was 3.8 (range: 2–6, std: 1.0), indicating satisfactory cosmetic results (flat, pliable graft with normal pigmentation and vascularization not fixed to the underlying bone) in all patients.

Discussion

Larger soft tissue defects often require split-thickness skin grafts or local, regional, or fasciocutaneous flaps^[16-17]. Autologous skin flaps remain the major reconstruction option for large, full-thickness soft tissue defects [9, ^{18]}. Pelnac[®] (Gunze, Kyoto, Japan), first described by Suzuki et al.^[19], is an acellular bilayer dermal substitute derived from collagen. The lower layer is a porous, threedimensional atelocollagen matrix that serves as a scaffold supporting epidermal cell growth, and the upper layer is made of semipermeable silicone and serves as a temporary epidermis that protects against infection and mechanical trauma [20-21]. The dermal matrix of porcine type I collagen is nearly identical to that of human collagen; it is not perceived as an antigen, and the rejection rate is low [22]. The dermal collagen matrix is gradually replaced by endogenous collagen during healing, and a new vascularized skin usually forms. Replacement occurs gradually according to wound size, depth, and radiotherapy status. Prolonged and complicated procedures can compromise wound healing. In all of our patients, Pelnac® successfully covered complex wounds with exposed bones or tendons. The cosmetic results were good, and all outcomes were satisfactory.

Pelnac® has been used to treat traumatic wounds

 Table 2
 Preoperative clinical data of the patients

ID	Tumor type	Skin loss (cm ²)	Operation time (min.)	Length of hospitalization (days)	Healing time (days)	Complication	Follow -up (months)
1	BC	16.6	30	1+1	28	No	12
2	BC	24.4	32	1+1	35	No	12
3	BC	28.6	35	1+1	36	No	15
4	SC	36.0	40	1+2	42	No	24
5	MM	32.5	41	1+1	32	No	24
6	SC	40.4	45	1+2	45	No	36
7	SC	28.8	38	1+1	30	No	12
8	BC	30.1	40	1+2	33	No	18
9	BC	19.6	31	1+1	28	No	12
10	BC	37.9	42	1+2	36	No	24
11	BC	27.0	41	1+1	32	No	18
12	SC	42.5	48	1+2	45	No	24
13	MM	48.4	50	1+2	45	No	24
14	SC	51.6	59	1+3	56	Mild neodermal ulceration	n 36
15	BC	34.2	39	1+2	39	No	18

BC, basal cell carcinoma; SC, squamous cell carcinoma; MM, malignant melanoma



Fig. 1 A clinical case of a 69-year-old woman with recidivate SC at the right leg underwent wide excision and reconstruction with Pelnac[®]. (a) Preoperative view; (b, c) Wide and deep excision of tumors with soft-tissue defect (28.8 cm²) and bone and tendon exposure; (d) Pelnac[®] coverage; (e) Wound bed outer layer of the Pelnac[®] template peeled off; (f, g) Wound healing on the 15th and 30th day after the Pelnac[®] template was peeled off; (h) At the follow-up (12 months), the patient achieved an acceptable aesthetic appearance (75%) and a satisfying functional recovery

and burn scars, including wounds created by removing giant nevi and ulcer repair [14, 23-29]. However, no study has evaluated one-stage application after large tumor resection. The application is simple, and it is possible to cover large defects. Moreover, no donor site morbidity was observed. The major disadvantage is that the healing time is longer than that after placement of traditional autologous skin flaps for large and deep wound [18, 30-31]. However, we found that Pelnac[®] was effective, providing durable coverage via a simple and well-tolerated procedure without donor site morbidity. In addition, early detection of local tumor recurrence is possible, and unlike autologous skin flaps, Pelnac® preserves the original surgical margins. Thus, the wound can be temporarily closed, resulting in pathological results [32]. Using an artificial dermis does not preclude skin graft placement if one-step surgery is insufficient. A highquality surgical bed is essential for the vascularization of the artificial dermis. In six (40%) of our patients, Pelnac® was applied directly to the bone, with satisfactory results. As some studies have found that Pelnac® triggered peripheral neoangiogenesis in the dermal matrix of an avascular wound bed [26], we used a Kirschner wire to drill the bony surface and induce punctate bleeding. This improved the reliability and efficiency of the simple and safe operation.

Although the results are encouraging, caution is needed when wounds are infected, treating patients with diabetes, heavy smokers, patients receiving radiotherapy, and those on long-term glucocorticoids. Two of our patients received radiation after surgery; one exhibited mild new-onset skin necrosis that healed spontaneously without residual deficits. The dermal substitute provided excellent support, and the new skin was pliable and aesthetically acceptable.

Conclusion

Reconstruction of a large area of skin after cancer resection remains challenging. To our knowledge, this is the first report to evaluate one-stage Pelnac[®] reconstruction of complex wounds following cancer resection. Although auto skin grafting is a reliable reconstruction method, it is invasive, may cause complications in the donor area, and may be associated with aesthetic complications and a high failure rate. In our clinical series, the application of Pelnac[®] resulted in satisfactory cosmetic outcomes with low morbidity, few complications, and good patient satisfaction. We believe that this artificial dermis is a reliable alternative for reconstructing complex wounds after cancer resection. Further research with histological evidence and an increased number of cases is needed to strengthen these findings.

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Conflicts of interest

The authors indicated no potential conflicts of interest.

Author contributions

All authors contributed to data acquisition and interpretation and reviewed and approved the final version of this manuscript.

Data availability statement

Not applicable.

Ethical approval

Not applicable.

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