Acellular dermal matrix treats lower extremity full-thickness skin defect on one-stage without skin graft or flaps

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Research

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Abstract

Background Self-repair of lower limb wounds has always been one of the research hotspots. Flaps and skin graft are the preferred treatment for lower extremity wound reconstruction. However, these treatments have many disadvantages, such as secondary damage, poor healing quality. In recent years, the use of acellular dermal matrix has emerged as an alternative treatment option for extremity ulcers.

Methods This study aimed to explore whether acellular dermal matrix can be used as a single treatment to promote wound healing. 7 patients with lower extremities cutaneous deficiency exposing bone or tendon, was covered by Pelnac, which was an acellular dermal matrix product approved by China Food and Drug Administration. All the wound was treated by Pelnac without flaps and skin graft. The external dressing was changed every 10 days.

Results After a maximum of 20 weeks, all the wounds were completely healed. During the 12 months follow-up period none of the patients developed skin wear on the treatment area. All patients maintained their postoperative ambulatory ability. All patients were satisfied with the appearance and feeling after wound healing.

Conclusions These findings may mean acellular dermal matrix is a novel method offering opportunity for treatment of lower extremities cutaneous deficiency exposing bone or tendon. It also has the potential to close wounds of all uninfected, non-ischemic, full-thickness cutaneous deficiency.

Background

The skin is the biggest organ covering the human being. Loss of continuity of normal anatomic structures and function of the skin results in a wound(1, 2), which based on their time frame of healing can be classified as acute wound or chronic wound. In everyday pathology wounds remain a challenging clinical problem, with early and late complications presenting a frequent cause of morbidity and mortality(3, 4). And the acute wound is a common health problem, with an estimated 11.8 million wounds were treated in emergency departments in USA(5, 6). Wounds are also characterized based on the wound depth and area of skin affected(7). According to degree of skin injury, wounds can be divided into partial-thickness wounds and full-thickness wounds(8). There are numerous therapy methods be used to treat different types of wounds, such as negative pressure wound therapy, bioengineered tissue alternatives, pedicle flaps, free tissue transfer. Based on the “Reconstruction Pyramid” ,which is a guide for wound healing, these treatments are arranged hierarchically, from minimally invasive procedures for small and superficial wounds, to highly complex procedures for large, deep, and complicated soft tissue defects(9). For instance, due to lack of redundant or pliable surrounding soft tissue, wounds in foot or ankle often need be closed by various kinds of flaps. However, the flap has many disadvantages, for example, secondary damage, poor appearance and high operation requirements.

Therefore, tissue engineering dressings has better application prospects than the flap surgery. Acellular dermal matrix (ADM) is a promising method in treating used as soft tissue replacement and can enhance

the quality of wound repair(10–12). In recent years acellular dermal matrix (ADM) has been used in in treatment of deep tissue defect combining with split-thickness skin graft and negative pressure wound therapy(13, 14). However, ADM also has its disadvantage that it cannot achieve epithelial tissue physiological regeneration and repair independently(15). Now, we found that a porcine acellular dermal matrix can promote the complete healing of the wound.

Methods

This study was approved by the Hospital Ethics Committee of the Huazhong University of Science and Technology of Tongji Medical College. All patients agreed with the inclusion of their treatment and healing process (with pictures) in the present study by informed consent. We used Pelnac, which is the artificial dermal product approved by China Food and Drug Administration in mainland China, for wound treatment. Pelnac double layer is composed of atelocollagen sponge layer and a silicone layer.

7 consecutive patients suffered lower extremities cutaneous deficiency with bone or tendon exposed were treated in our Department from December 2014 to January 2017. This prospective study included a 12-month follow-up. The overall study period was 3 years. Patients' age ranged between 8 and 55 years (mean age 40.6 years). All the patients did not suffer from flap or fascia flap surgery. None of our patients present vascular disease or diabetes. The postoperative sensory status was evaluated with the two-point discrimination and the total active motion.

All the surgical procedures were performed under epidural anesthesia with the patient in a supine position. A tourniquet was placed around the lower limb to limit intraoperative bleeding. After debridement and hemostasis, the wound was rinsed with H2O2 and 0.1% povidone iodine 3 times. Then, the wound was covered by Pelnac following the manufacturer's protocol. Shortly, the Pelnac was trimmed for fitting the shape and size of the wound, and then immersed in saline for 15 seconds before coverage. The Pelnac was fixed on the defect by sutures (5/0 Prolene). Drainage holes with small size were made in the silicon film for facilitating exudation. The external dressing was changed every 10 days. The silicon film was not detached from the wound until the wound healed completely.

Statistical Analysis

Statistical analysis consisted of the comparison between sick side and healthy side with two-point discrimination and the total active motion, which was performed by using the Wilcoxon signed-rank test. Statistical significance was set at $P < 0.05$.

Results

In this study, 7 patients (range, 6–62-year-old) were treated with Pelnac for covering wounds with bone or tendon exposure (range, 5–49.5 cm2) in the lower extremity. All wounds resulted from Tissue removal and debridement. And the defects were filled Pelnac by suturing in place. Final wound healing occurred within 13 weeks in average (range, 7–20 weeks) One or 2 linear scars were left in original wound area,

depending on the shape of wound. The width of scars varied 1 to 15 mm depending on the size of wounds.

Outcome

After 12 months of follow-up the regenerates skin sensation and joint movement on all patients were evaluated. The results showed that although there was a difference between the two senses on the healthy side and the affected side, the feeling of individual patients basically returned to normal. After one year of follow-up, the healed wound was free of significant pain, and the range of motion of the joint averaged 90% of that of the healthy side (Table 1). None of the patients showed signs of skin damage and trouble walking. All persons return to normal daily life. Specific cases can be seen in Fig. 1, 2, 3.

Table 1
Sensation, pain and movement after wound healing

	Site of wound	**2-PD(mm)**		**VAS**	**TAM(%)**
NO.		Uninjured side	Injured side		
1	Front of ankle	13.2	15.2	2	90
2	Achilles tendon area	15.7	20.8	3	93
3	Big toe	5.4	7.3	1	94
4	Achilles tendon area	14.7	19.2	2	85
5	Achilles tendon area	19.1	23.9	3	84
6	Big toe	6.5	7.3	1	-
7	Whole foot	16.3	18.2	2	90
mean		12.99 ± 5.13	15.99 ± 6.49*	2.0 ± 0.8	89.3 ± 4.1
2-PD, two-point discrimination					
VAS, Visual Analogue Scale/Score					
TAM, total active motion, the percentage of movement on the affected side relative to the healthy side					
*, p = 0.015					

Discussion

ADM has long been used as soft tissue replacement and commonly be used in the field of wound healing and tissue repair and reconstruction(16). Generally, the use of ADM to repair wound was combined with skin graft or negative-pressure wound therapy (NPWT)(17, 18). There were only a few studies show that

ADM can repair the regeneration of full-thickness skin defects without skin graft or flap surgery(19–21). In our article, we show that ADM can replace skin graft and flaps to promote the regeneration of full-thickness skin defects. Compared with skin and flaps, ADM has some advantages as follows. Firstly, patients treated with ADM did not need suffering donor damage. All volunteers do not need to take skin and flaps from other parts of the body. Secondly, in this study, although the wound healing time by treated with ADM was longer than that by skin graft or flaps surgery. However, the overall courses of disease were no significant difference between two therapeutic method.

We analyze the reason was that all patients treated by ADM acquired one-stage healing and did not require a second operation. Lastly, the healing quality of wound treated with ADM were better than that of wound cured with skin or flaps surgery. Between the suffered limb and the healthy one, the passive motion or active motion of lower limb joints were similarly. Not only that, the regenerative skin had fine appearance and feel.

However, we cannot take the specimen from a wound that has healed to further detect. This was a disadvantage in this study. Nonetheless, previously our laboratory found that a few wounds treated with ADM appeared the phenomenon of hair regeneration(20). And we through rats' experiments showed that the ADM may promote the stem cell immigration. However, the detailed mechanism of ADM improving the wound healed completely was not clear.

Conclusions

At present, the gold standard of wound treatment is skin grafting and skin flap surgery. However, these two ways of treating wounds do have shortcomings. In this study, ADM was used as the main treatment method to replace skin flap and skin graft, which can achieve the goal of wound healing and the healing quality was satisfactory. In conclusion, for selected patients, 1-stage Pelnac reconstitution can be considered as a novel method for inducing regrowth of epidermis and hair follicles. And more researches could be warranted.

Abbreviations

PD, two-point discrimination; ADM, acellular dermal matrix; NPWT, negative-pressure wound therapy; TAM, total active motion, the percentage of movement on the affected side relative to the healthy side; VAS, Visual Analogue Scale/Score

Declarations

Ethics approval and consent to participate

All patients or their relatives provided informed consent, and the study was

approved by the ethical committee of Tongji Medical College, Huazhong University of Science and Technology.

Consent for publication

All authors consent to publication in Military Medical Research.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

LGC analyzed and interpreted all data presented in this paper and served as the primary author for the manuscript. ZP and LHL treated the patient and collected all patient data. PH guided the idea of the full text. CJH participated in the design and coordination and helped to draft the manuscript.All authors read and approved the final manuscript.

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Figures

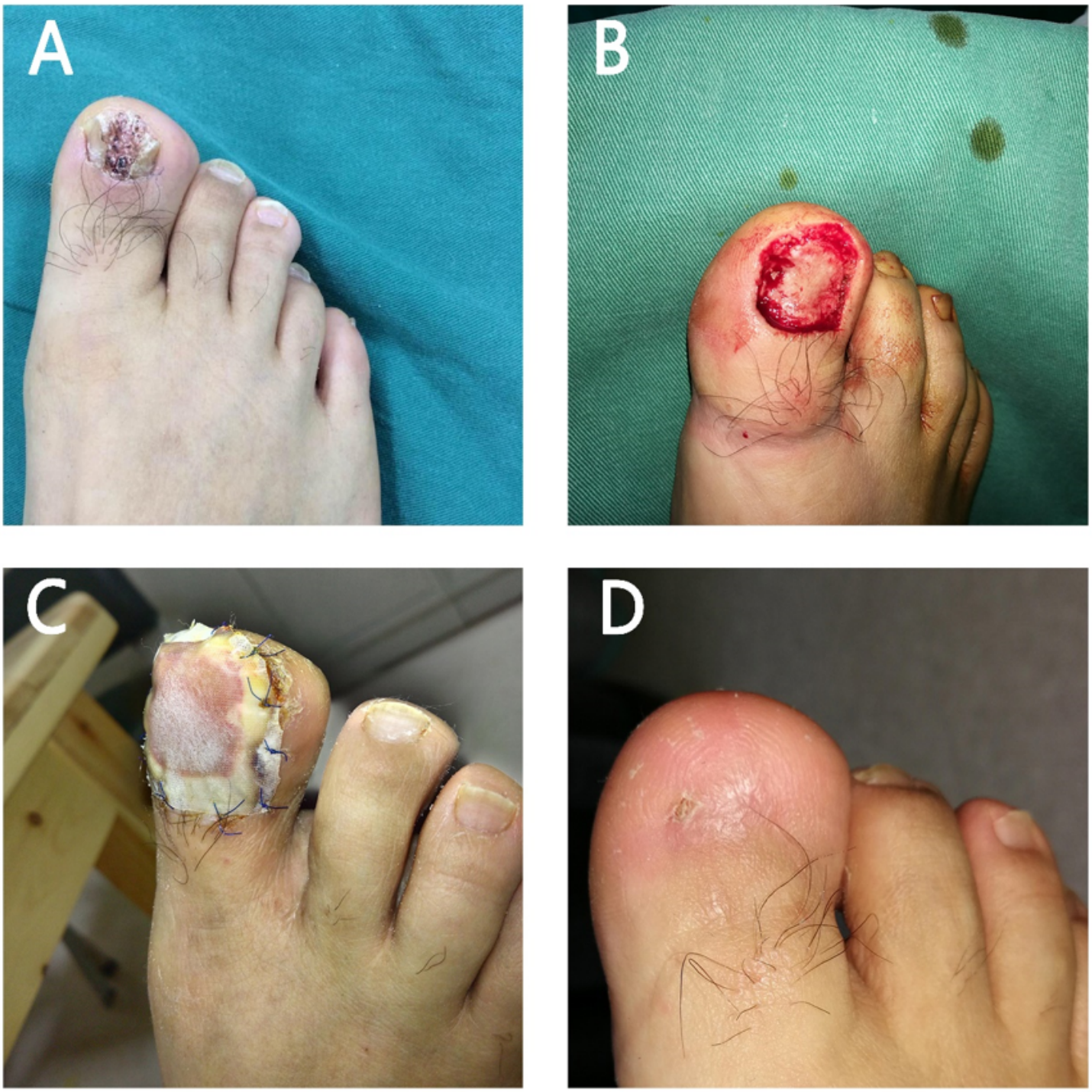

Figure 1

Case 1 (41-year-old male): A, Big toe chronic fungal infection. B, after resection of the lesion, an armor bed defect with last phalanx exposure. C, the wound was covered with Pelnac. Wound healed for 22 weeks. After half a year of wound healing, there was only one small scar and a new skin texture.

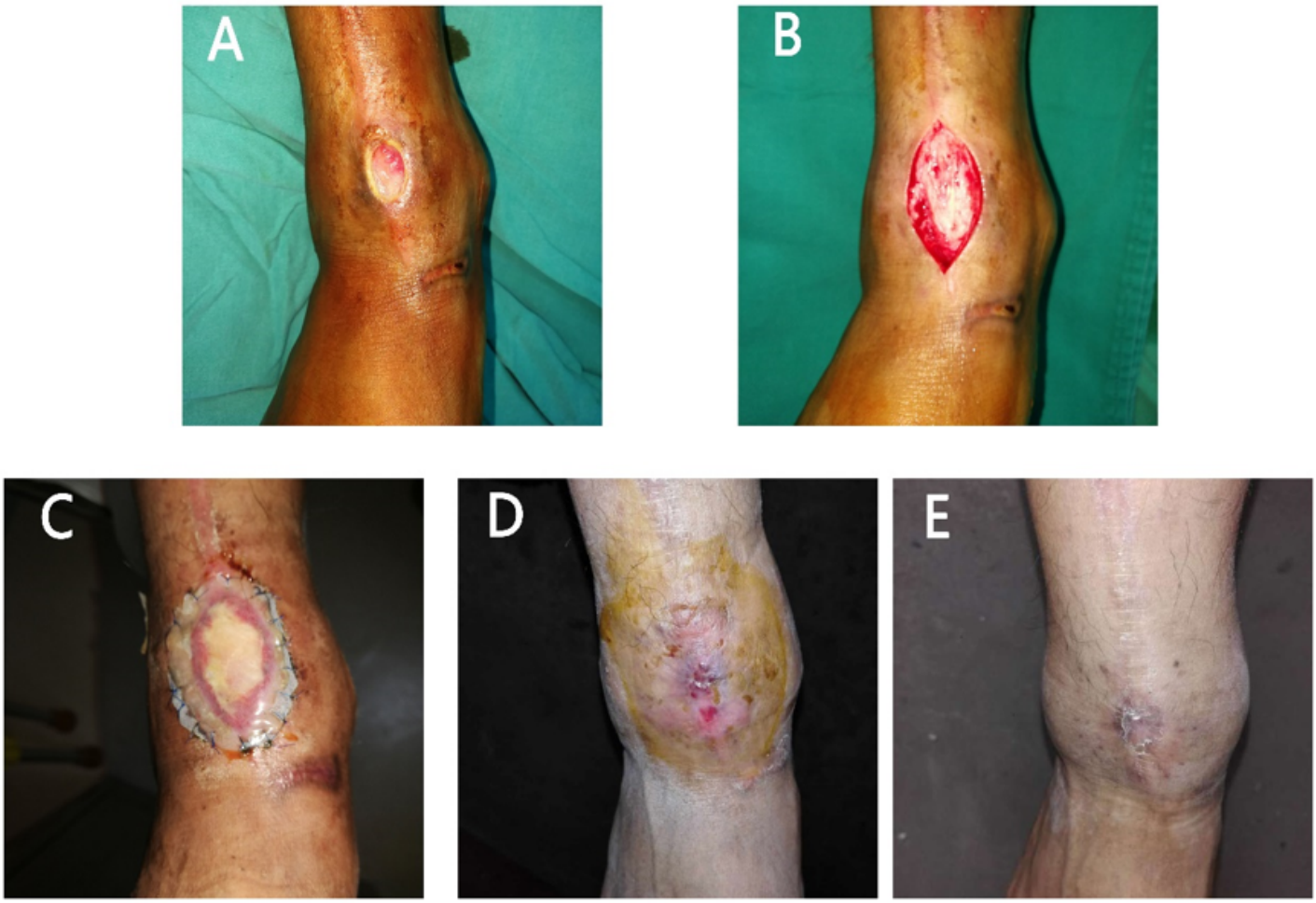

Figure 2

Case 2 (35-year-old male): A, Chronic ulcer in front of the ankle. B, Skin defect after enlarged excision. C, the wound was covered with Pelnac. D, 3 months after after the operation. E, 8 months after surgery, wound healed with a small “O” type linear scar.

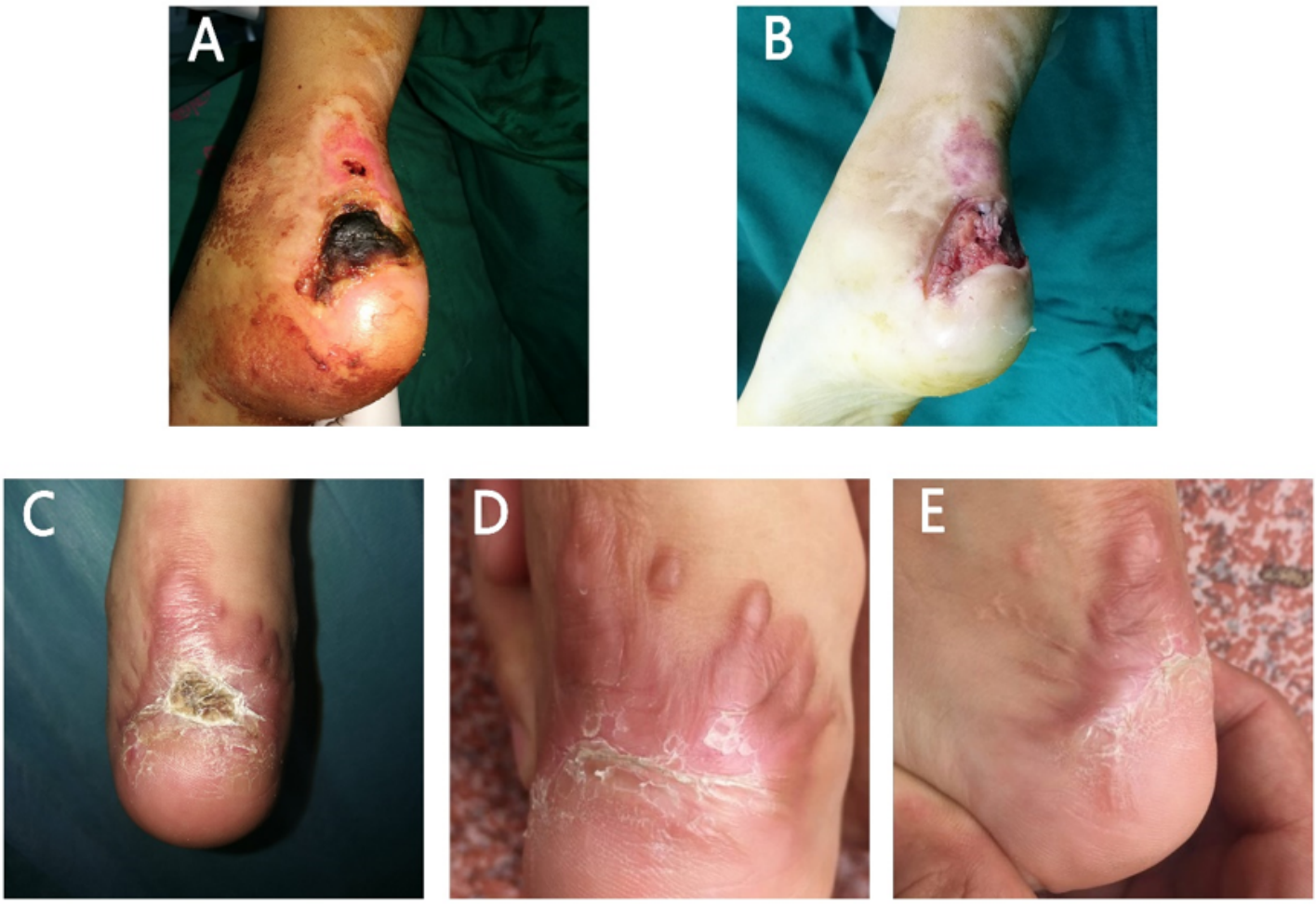

Figure 3

Case 2 (10-year-old boy): A, Skin necrosis after traumatic injury in the Achilles tendon. B, Skin defect with Achilles tendon exposed after excision. C, 3 months after after the operation. D and E, 12 months after surgery.