

# Cryopreserved Liquid Human Amniotic Tissue Allograft as a Novel Therapeutic Option for the Treatment of Chronic Diabetic Foot Ulcers

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## Introduction

Lower extremity chronic ulcerations, a serious complication of diabetes mellitus, remain a challenge.<sup>1-7</sup> They require treatments that promote rapid development of granulation tissue and ultimately re-epithelialization. The objective of this report is to demonstrate the efficacy of PalinGen® Flow, a chorion-free cryopreserved liquid human amniotic allograft comprised of structural extracellular matrix (ECM), biological proteins, and cellular components for the treatment of chronic diabetic foot ulcers.

## Materials and Methods

A surgery was performed on a 62 year old male with Diabetes Type II who presented with an infected ulceration to the plantar aspect of the left 5<sup>th</sup> metatarsal head and local cellulitis. Due to an incisional dehiscence noted at day 5 and no observed reduction in wound size, the decision was made to treat the wound with 2 ml of PalinGen® Flow mixed with sterile saline in a 1:1 ratio. The wound borders were infiltrated with the solution at the 12, 3, 6, and 9 o'clock positions utilizing a 22-gauge needle every other week, up to three treatments. Standard wound care procedures, including wound cleansing and debridement were performed prior to the application of PalinGen® Flow.

## Case Report

62 year old male with DM Type II, peripheral neuropathy, CKD stage 2, chronic pain, splenic vein thrombosis, pulmonary cocci, HTN, GERD and hypertriglyceridemia presented to the emergency department with an infected ulceration to the plantar aspect of the left 5<sup>th</sup> metatarsal head and local cellulitis. Upon presentation the ulcer measured (1.7cm x 1.5cm) and probed directly to bone. The ulcer tracked and tunneled, creating an exit wound to the dorsal lateral aspect of the foot measuring 1.5 x 0.5 cm. There was erythema, edema, and purulence noted with evidence of osteomyelitis on radiograph exam. The patient was admitted directly to the hospital and placed on empiric IV Unasyn.

## Case Report (cont.)

After immediate I&D and culture, the patient was scheduled for surgical resection of the 5<sup>th</sup> metatarsal head. A dorsal incision was utilized to excise the necrotic wound edges and metatarsal head to a clean margin. The skin edges were reapproximated with prolene suture and the left foot was dressed with DSD with proper offloading.



**Figure 1**

**Figures 1-2: POD #5**

On POD#5, incisional dehiscence was noted to the dorsal aspect, measuring 2.2 x 2.2 x 2.0cm. The incision was irrigated and lightly packed with sterile iodoform gauze and DSD and changed daily. Follow up 1 week later revealed a wound measuring 2.2 x 2.5 x 1.0cm. The wound base consisted of 60% granular, 40% fibrotic tissue with a viable bleeding base upon debridement. All clinical signs of infection had resolved.



**Figure 2**



**Figure 3**



**Figure 4**

**Figures 3-4: Initial treatment**

PalinGen® Flow was prepared utilizing sterile technique by mixing with normal sterile saline (preservative free) in a 1:1 ratio. The wound borders were infiltrated with the solution at the 12, 3, 6, and 9 o'clock positions utilizing a 22-gauge needle. The wound was then dressed with plain aquacel and DSD. Dressings were changed every other day with similar SOC dressings and patient was followed in clinic weekly.

## Case Report (cont.)



**Figure 5**



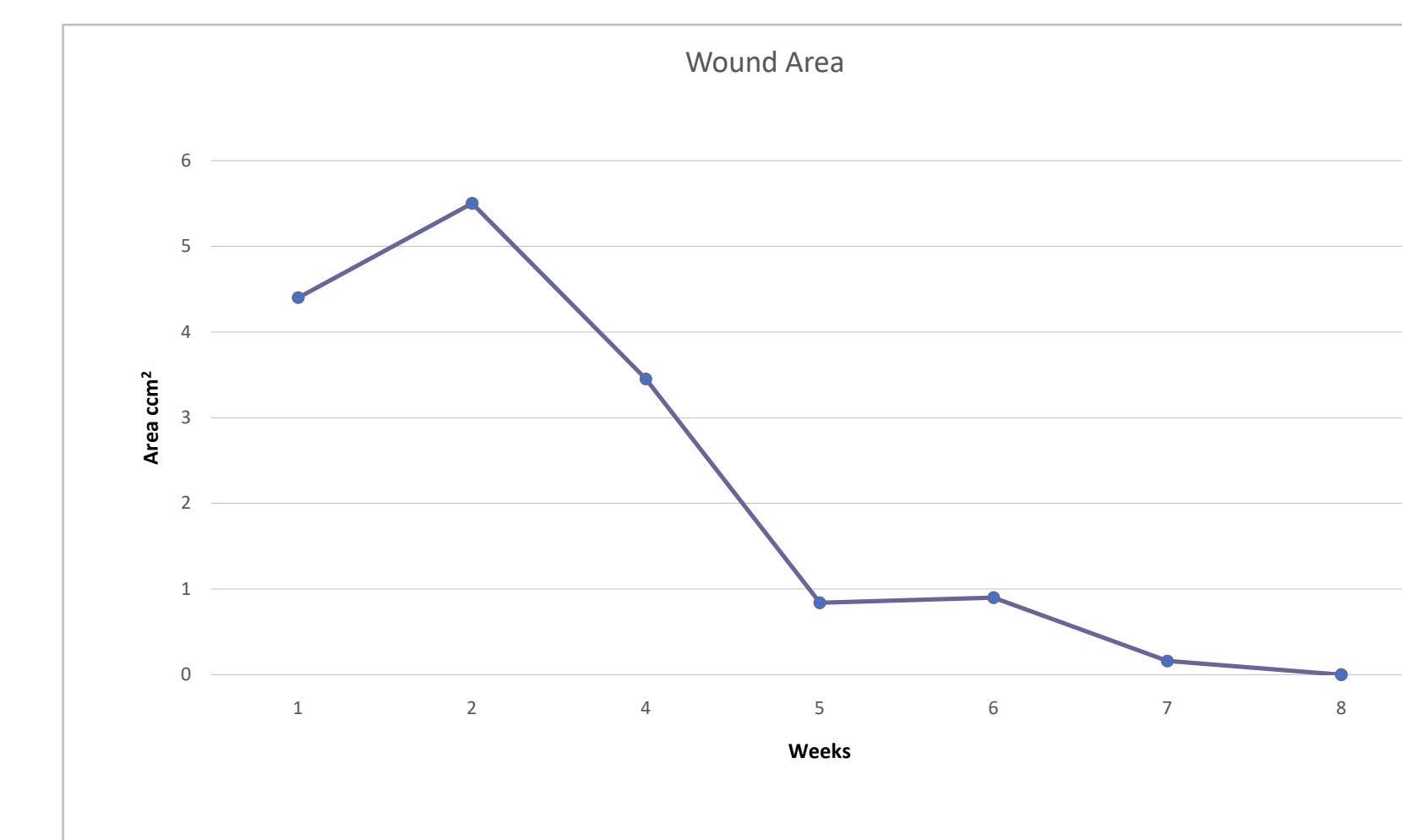
**Figure 6**

**Figure 5: Treatment 3. Figure 6: Healed.**

At the two-week post PalinGen® treatment visit, the wound measured 2.3 x 1.5 x 0.3cm, without noted tunneling or deep probe. The base was 80% granular and 20% fibrotic tissue without drainage, odor or evidence of infection. A third PalinGen® treatment was performed two weeks later. The wound at this visit measured 1.0 x 0.9 x 0.2cm with a 90% granular, 10% fibrotic wound base. Two weeks later the wound was considered healed. Continued protective measures were taken to prevent re-ulceration, including extra depth diabetic shoe and custom offloading trilaminate inserts.

## Results

A total of three 2 mL PalinGen® Flow treatments were performed two weeks apart to achieve complete epithelialization, and showed that patient achieved full closure of dehiscent diabetic wound with PalinGen® Flow in 7 weeks. There were no adverse events or safety concerns associated with PalinGen® Flow treatments, and patient's surgical site remains closed to date.



**Graph 1**

**Graph 1: Healing at 8 weeks.**

## Conclusions

The outcome of this study supports the use of a chorion-free cryopreserved liquid amniotic tissue allograft as a safe and effective therapy in hard to treat diabetic foot wounds and surgical dehiscence. PalinGen® is an excellent intradermal periwound therapy that provides a healthy anti-microbial,<sup>1-4</sup> regenerative wound environment and contributes to the development of angiogenesis and more expedient wound healing, establishing PalinGen® Flow as a novel therapeutic option for managing complex diabetic foot ulcers.

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## Acknowledgements

The Southern Arizona VA Health Care System provided the facilities for this research. Clinical background and product support provided by Amnio Technology.