Cryopreserved Liquid Human Amniotic Tissue Allograft as a Novel Therapeutic Option for the Treatment of a Stage 3 Pressure Ulcers of the Right Malleolus: a Case Report

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Introduction

Pressure ulcers remain a major health problem in the United States with a significant impact on patient morbidity, mortality and health care costs. Non-healing pressure ulcers require invasive therapy, however, some challenges still exist for adequate coverage of the wound. Amniotic tissue allograft is a valuable therapeutic measure to overcome these challenges.[1,2] Amniotic tissues are also non-immunogenic and contain variety of bioactive molecules.[3-5] 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, biologically active proteins, and cellular components for the treatment of a chronic stage 3 pressure ulcer of the right malleolus.

Material and Methods

A 78-year-old male with a stage 3 pressure ulcer had been treated with standard of care and advanced therapy including 10 applications of Grafix® Core over a period of 5 months. The wound responded well to treatment initially but by the fifth month, healing halted and the wound deteriorated. A decision was then made to use an alternative advanced therapy using PalinGen® Flow. The wound borders were infiltrated with the allograft at the 12, 3, 6, and 9 o'clock positions utilizing a 22-gauge needle. A total of four implantations were performed over a 12-week period.

Results

A total of four 0.5 mL PalinGen® Flow treatments were performed to achieve complete epithelialization, and showed that patient achieved full closure of the pressure ulcer with PalinGen® Flow in 12 weeks. Upon the first application, the wound measured 0.3 x 0.3 x 0.2 cm. Within 10 days of the application, the wound area had decreased by 89% (The wound size was 0.1 x 0.1 x 0.2 cm). Three additional implantations were performed at day 26, 46, and 86. Starting from the second week, the patient did no need necrotic or subcutaneous tissues debridement. After 2nd injection, the wound size was increased to 0.3 x 0.2 x 0.2 cm due to scabbing, however, the wound size was decrease in size back to 0.1 x 0.1 x 0.2 cm post 3rd injection. During the treatment course, a significant amount of granulation tissue was observed with improvement of the peripheral vasculature. There were no adverse events or safety concerns associated with PalinGen® Flow treatments, and patient's surgical site remains closed to date.

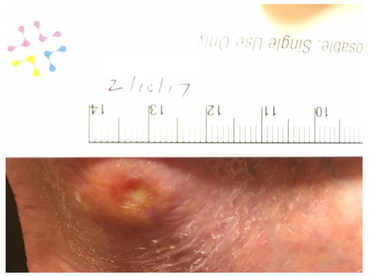


Figure 1. Initial wound on Day 0 post 1st injection of PalinGen® Flow. The wound size was 0.3 x 0.3 x 0.2 cm.

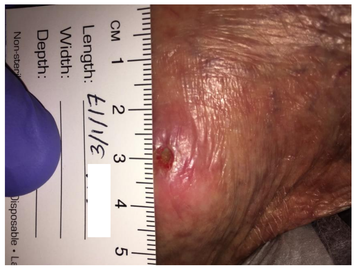
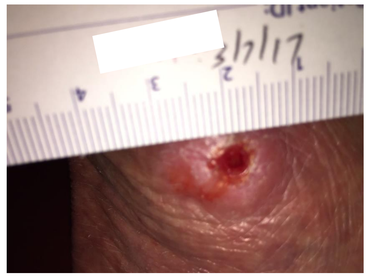


Figure 2. The wound on 2nd injection of PalinGen® Flow. After 10 days post 1st injection, the wound size was 89% decreased, the size was 0.1 x 0.1 x 0.2cm with improvement in the peripheral vasculature.

Figure 3. 1 week after 2nd injection of PalinGen® Flow. Significant amounts of granulation tissue developed causing increased necrotic and scabbed tissue. Due to scabbing, the wound size was increased to 0.3 x 0.2 x 0.2 cm.



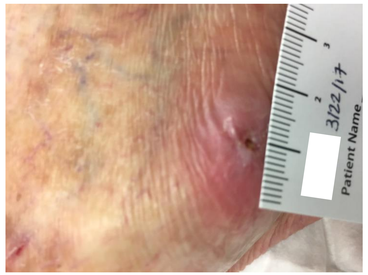


Figure 4. The wound post 3rd injection of PalinGen® Flow. The wound size was decreased tp 0.1 x 0..x 0.2 cm.

Figure 5. 4 weeks after final injection of PalinGen® Flow. The wound was completely closed with remaining redness and inflammation of the skin.

Conclusion

The outcome of this study supports the use of a chorion-free cryopreserved liquid amniotic tissue allograft as a safe and effective therapy in treating stage 3 pressure ulcers, establishing PalinGen® Flow as a novel therapeutic option for managing complex foot ulcers.

References

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