Treatment of a Non-Healing Wounds of the Right Chest Wall Involving Exposed Bone Using a Cryopreserved Liquid Amniotic Tissue Allograft: a Case Report

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Introduction

Chronic wounds, venous leg ulcers, diabetic foot ulcers, arterial insufficiency and pressure ulcers, impose significant morbidity and mortality in millions of Americans especially the elderly population. Bioactive molecules and growth factors play a significant role in wound healing process. Amniotic tissue allograft is valuable source of bioactive molecules, many type of cells, growth factors, cytokines, and extracellular matrices (ECM). In addition, this has unique functions, such as non-immunogenicity, re-epithelialization effect, anti-microbial, anti-fibrotic, anti-inflammatory properties from natural healthy amniotic tissue.[1-3] The objective of this report is to evaluate the efficacy of PalinGen® Flow, a chorion-free cryopreserved liquid human amniotic allograft comprised of structural ECM, biologically active proteins, and cellular components for the treatment of a non-healing wound of the right chest wall involving exposed bone.

Material and Methods

A 87 year old female presented with three chronic, non-healing wounds of the right chest wall involving exposed bone and positive culture for E Faecalis growth. Over a five-month period, the patient underwent a total of 90 Hyperbaric Oxygen Therapy sessions, two weeks of an Advanced Wound Care Vac, a SNPA VAC for over 6 weeks, one OR debridement, and two Integra applications. The wounds failed to close and a decision was then made to use an alternative advanced therapy using 1.0 mL of PalinGen® Flow to treat the wounds. The wounds 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

Upon the first implantation, the superior most, the lower medial, and the lower right wounds measured 2.5 x 3.6 x 0.5 cm, 1.3 x 1.7 x 0.4 cm, and 0.6 x 1.1 x 0.3 cm, respectively. The superior most wound was shown granulation tissue and peripheral vascularization post 1st injection, and continued improved with evidence of epithelial tissue growth. The tow lower wounds showed some peripheral vascularization and evidence of granulation tissue post 2nd injection. After 3rd injection, the superior most wound showed significant epithelial tissue growth and completed wound closure. The edges of the lower wounds showed increased granulation and vascularization. By the end of the trial, the superior most wound was closed with mildly red epithelial tissue present. The lower medial wound measured 1.0 x 1.4 x 0.5 cm and the lower right measured 0.8 x 0.9 x0.5 cm. There were no adverse events or safety concerns associated with PalinGen® Flow treatments, and patient's surgical site remains closed to date.

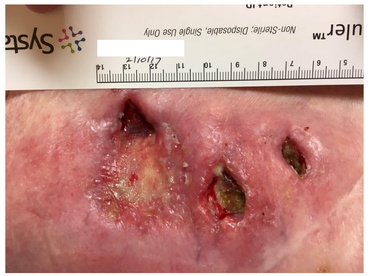

Figure 1. Initial wound on Day 0 post 1st injection of PalinGen® Flow. The superior most wound, the lower medial wound, and the lower right woud sizes were 2.5 x 3.6 x 0.5 cm, 1.3 x 1.7 x 0.4 cm, 0.6 x 1.1 x 0.3 cm, respectively.

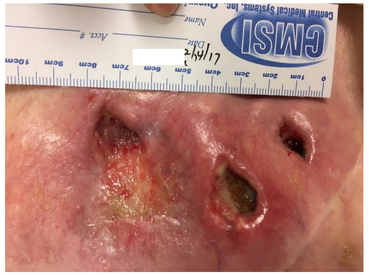

Figure 2. 4 days post 1st injection of PalinGen® Flow. Granulation tissue and peripheral vascularization were shown in most superior wound after 1st injection. The two lower wounds experienced no visible changes.

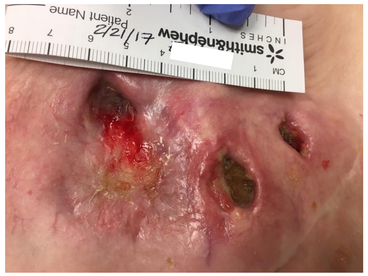

Figure 3. 10 days after 1st injection of PalinGen® Flow. The most superior wound showed continued improvement. Minimal improvement of the lower tow wounds with significant debridement.

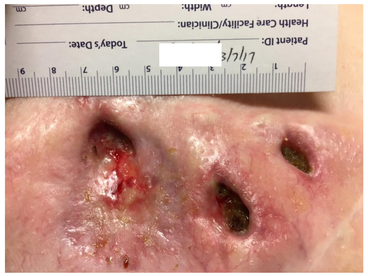

Figure 4. The wound post 2nd injection of PalinGen® Flow. The superior most wound showed epithelial tissue growth.

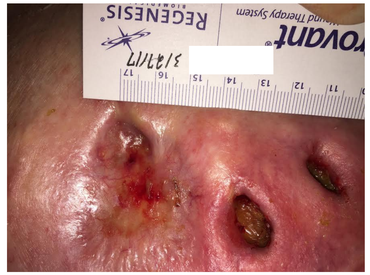

Figure 5. The wound post 3rd injection of PalinGen® Flow. Significant epithelial tissue growth showed in the superior most wound with complete closure. The edges of the lower wounds showed increased granulation and vascularization.

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 non-healing wounds with exposed bone, establishing PalinGen® Flow as a therapeutic option for managing complex wounds.

References

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