A Pilot Study Lower Leg Post-Moh's Wounds Utilizing A Novel Axolotl Wound Matrix* with Predictive Cost Analysis

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INTRODUCTION

Lower extremity wounds in the United States pose an economic and challenging aspect of post-acute care in populations that undergo Mohs surgical resections and have adverse outcomes that result in open, non-healing sites. The added cost of these cases for the post- operative failure contributes to the overall financial responsibility of the treating dermatological surgeon and adds comorbidity to these patient populations that already have immunocompromised integument systems. The challenge with most of these patients is based on wound location, wound bed physiology and abnormal healing pathways that have derailed the normal healing cascade. This pilot study utilized a novel new xenograft made from the skin of Axolotl (Ambystoma mexicanum). The axolotl has innate attributes for scar free healing of skin wounds, can regenerate limbs and organs (including heart, spinal cord, and brain), and is one of only a few vertebrate animals capable of regeneration throughout its life (Neoteny). The axolotl is the oldest, self-sustaining laboratory animal having been bred in captivity and studied for over 150 years. This animal has regenerative capabilities that remodel, regrow, and restore damaged tissue with results superior than those seen in human tissue repair.

METHODS

A total of 10 patients were enrolled at a single-site center and treated exclusively by the author in the clinic. All patients underwent a full history and physical examination with ABI assessment. All patients enrolled qualified with a minimum of 4 weeks of non- progressive healing post-Mohs surgery. patients were female and 3 male. Average age was 81.1 (range 69-92). Average ABI for all patients was 1.05 (range 0.92 to 1.33). The initial wound size average was 2.98 cm2 (range 2.1 cm2 to 8.2 cm2). All patients underwent normal saline irrigation and cleansing with sharp surgical debridement weekly with digital photography and wound measurements calculated with a remote clinical imagery system.** The axolotl wound matrix was applied per manufacturer instructions. Secondary dressing of non-adherent oil immersion dressing, non-adherent polyurethane foam, gauze and stretch bandage with a self-adherent wrap. Dressings were left on for 1 week duration and removed in-clinic, re-assessed and re-applied by the author as necessary.

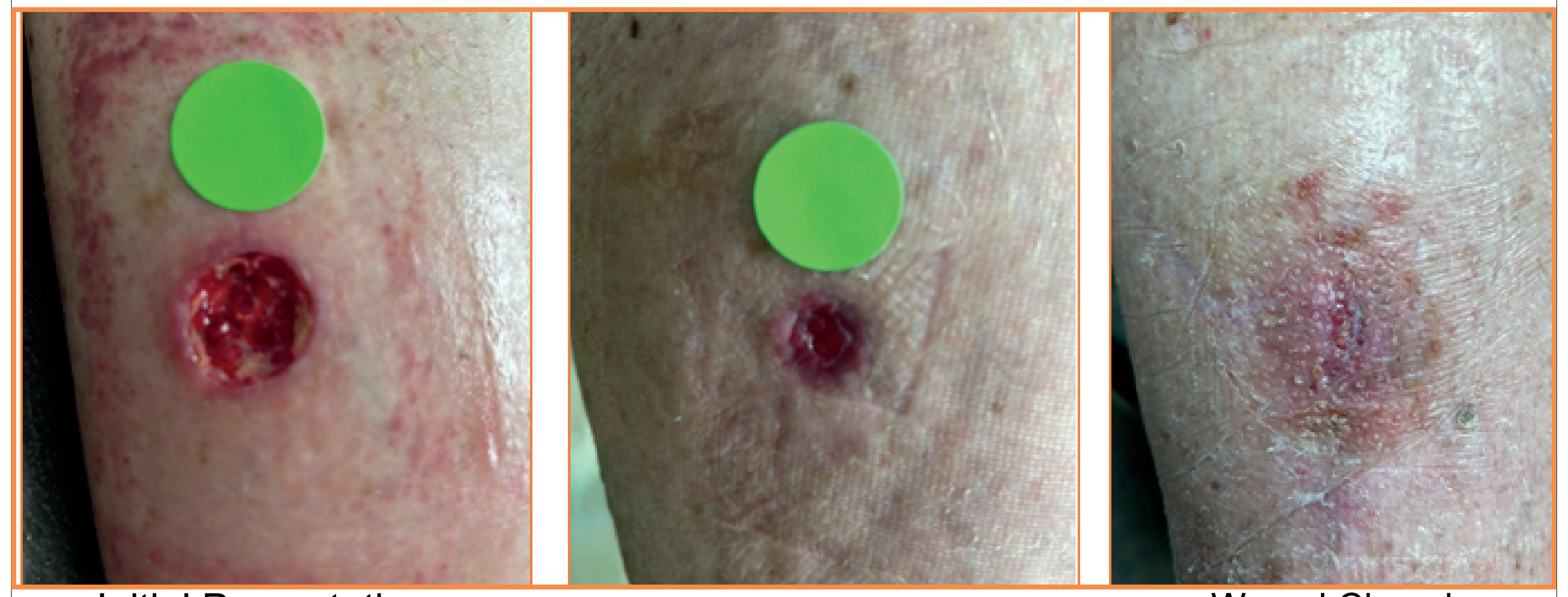
CASE 1

Initial Presentation

CASE 2

Initial Presentation Wound Closed

CASE 3



Initial Presentation Wound Closed

RESULTS

All patients achieved wound closure by week 8. Average number of applications across all 12 patients was 2.8 applications. The 4-week reduction of surface area reduced on average to 0.65 cm2, reflecting a 79% PAR. Average time to close was 4.6 weeks (range 3-8). All wounds closed by week 8. There were no adverse reactions or failures of the axolotl wound matrix during the clinical study. There were no recurrences within 6 weeks of closure.

PATIENT	SIDE	GENER	AGE	RACE	ABI	WEEK 0	WEEK 4	WEEK 8	APP#	CLOSED	CANCER
1	RIGHT	F	92	W	0.99	4.2	3.1	0	3	8	SCC
2	LEFT	F	85	W	1.04	2.6	0	CLOSED WEEK 5	3	4	SCC
3	LEFT	M	78	W	1.1	5.7	0.5		3	5	BCC
4	RIGHT	F	90	W	1.03	3.2	0.3	0	3	5	SCC
5	RIGHT	F	83	H	0.92	3.3	1.2	CLOSED WEEK 6	3	6	SCC
6	LEFT	F	88	W	0.96	2.2	0	CLOSED WEEK 4	3	3	BCC
7	LEFT	M	69	W	0.82	1.5	0	CLOSED WEEK 3	2	3	BCC
8	RIGHT	F	73	W	1.2	2.26	0	CLOSED WEEK 4	2	2	SCC
9	LEFT	F	81	W	1.14	2.1	0.4	CLOSED WEEK 5	3	5	SCC
10	RIGHT	M	72	H	1.33	2.8	0.9	CLOSED WEEK 5	3	5	SCC
			81.1		**1.05**	**2.986**	**0.64**		**2.8**	**4.6**	

DISCUSSION AND PREDICTIVE COST ANALYSIS

The failure of grafting post-Mohs is very rare and infrequent. Less than 2% of all cases arise to a level of complication necessitating advanced wound closure. The costs involved with standard of care for a lower extremity wound that is non-progressive is approximately $14,152 over 13 weeks. The cost of the axolotl per unit averages $1387.93 and based on average numbers of applications, the average cost of these cases is $13,990.34. When aggregated over the difference in treatment time (52 weeks – 4.6 weeks = 45.4 weeks) then the cost per additional week of care is $782.86 when not using this advanced therapy.

Overall, the use of axolotl matrix in these cases has a higher initial cost, but this pilot data shows when aggregated versus the standard of care, the cost-savings is in utilizing the advanced technology earlier in the wound episode.

LIMITATIONS

This study has significant limitations. As a single site center the population data set does not provide enough data for comparative or longitudinal analysis. More patients and additional site centers to conduct a randomized controlled trial would be beneficial. Increasing the Intent-to-treat population (ITT) to a power of > 160 patients will prove to be a more reliable outcome study.

CONCLUSION

As described, the use of an axolotl wound matrix in complicated post-operative post-Moh slower extremity wound failures show a significant increase in healing time with a more rapid return to normal life. The additional cost increases incurred when using this versus standard of care is noticeable, The overall aggregate savings over a 52-week period shows a significant reduction of cost of $782.96 per week.

All patients completed the treatment regimen without adverse reactions. Because the cost of the axolotl wound matrix is fixed with most US Medicare contractors, the predictive cost model is effective in establishing a prospective cost analysis in the future. This poses a significant finding that can be used effectively as an immediate modality in failed post-Mohs cases of the lower extremities.

REFERENCES

1. Denis, J.-F., Lévesque, M., Tran, S. D., Camarda, A.-J. & Roy, S. Axolotl as a Model to Study Scarless Wound Healing in Vertebrates: Role of the Transforming Growth Factor Beta Signaling Pathway. Adv. Wound Care 2, 250–260 (2013).
2. Nussbaum SR, Carter MJ, Fife CE, DaVanzo J, Haught R, Nusgart M, Cartwright D. An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic NonhealingWounds.ValueHealth.2018Jan;21(1):27-32. doi: 10.1016/j.jval.2017.07.007. Epub 2017 Sep 19. PMID: 29304937.
3. Lantis Ii JC, Lullove EJ, Liden B, McEneaney P, Raphael A, Klein R, Winters C, Huynh RN. Final efficacy and cost analysis of a fish skin graft vs standard of care in the management of chronic diabetic foot ulcers: a prospective, multicenter, randomized controlled clinical trial. Wounds. 2023 Apr;35(4):71-79. doi: 10.25270/wnds/22094. PMID: 37023475.

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Dr. Lullove maintained complete independence in the development of this research study.