

# A Pilot Study of Lower Extremity Wounds Utilizing A Novel Synthetic Self-Assembling Peptide Matrix

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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 Nanoparticle Synthetic Self-Assembling Peptide Matrix (SAPM\*) made of proprietary peptide synthesized from naturally occurring amino acids as a primary treatment pathway for initiating wound closure. Upon exposure to the ions in the wound, SAPM self-assembles into a nano-fiber network that mimics an extracellular matrix. It provides a physical barrier to mitigate contamination, modulate inflammation and a scaffold to facilitate tissue growth and repair.

## Methods

A total of 12 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. 9 patients were female and 3 male. Average age was 80.0 (range 69-92). Average ABI for all patients was 1.04 (range 0.82 to 1.33). The initial wound size average was 4.0 cm<sup>2</sup> (range 2.1 cm<sup>2</sup> to 8.2 cm<sup>2</sup>). 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 SAPM 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 10. Average number of applications across all 12 patients was 4.4 applications. The 4-week reduction of surface area reduced on average to 2.0 cm<sup>2</sup>, reflecting a 50% PAR. Average time to close was 6.9 weeks (range 5-10). All but 2 of the wounds closed by week 8. There were no adverse reactions or failures of the nanoparticle peptide during the clinical study. There were no recurrences within 6 weeks of closure.

PATIENT NO.	GENDER	AGE	RACE	ABI	WEEK 0	WEEK 4	NO. APPLICATIONS	CLOSURE WEEK
1	F	92	W	0.99	4.2	3.1	3	8
2	F	85	W	1.04	2.6	0.5	3	6
3	M	78	W	1.1	5.7	2.7	5	8
4	F	90	W	1.03	8.2	5.2	8	10
5	F	83	H	0.92	3.3	1.2	4	6
6	F	88	W	0.96	3.8	2.7	7	10
7	M	69	W	0.82	4.7	2.1	5	7
8	F	73	W	1.2	5.4	2.5	5	8
9	F	81	W	1.14	2.1	0.4	3	5
10	M	72	H	1.33	2.8	0.9	3	5
11	F	68	W	0.95	2.5	0	3	4
12	F	82	W	1.01	2.7	0.7	4	6
		<b>AVERAGE</b>	<b>80.1</b>	<b>1.0</b>	<b>4.0</b>	<b>1.8</b>	<b>4.4</b>	<b>6.9</b>

## Discussion and 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 SAPM per unit averages \$2500.00 and based on average numbers of applications, the average cost of these cases is \$11,000. While this shows an increase of \$7,848, when aggregated over the difference in treatment time (52 weeks - 6.9 weeks = 45.1 weeks) then the cost per additional week of care is \$1011.26 when not using this advanced therapy. Overall, the use of a SAPM in these cases has a higher cost, but the pilot data shows when aggregated versus the standard of care, the cost-savings is in utilizing the advanced technology.

## Limitations

This study has significant limitations. As a single site center study 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.

## Conclusion

As described, the use of a SAPM in complicated post-operative post-Mohs lower 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 \$1011.26 per week. All patients completed the treatment regimen without adverse reactions. Because the cost of the SAPM 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

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