First-in-Human Clinical Study to Assess the Safety of MAP Wound Matrix in Patients with Clean Wounds after Mohs Micrographic Surgery (MMS) for Skin Cancer

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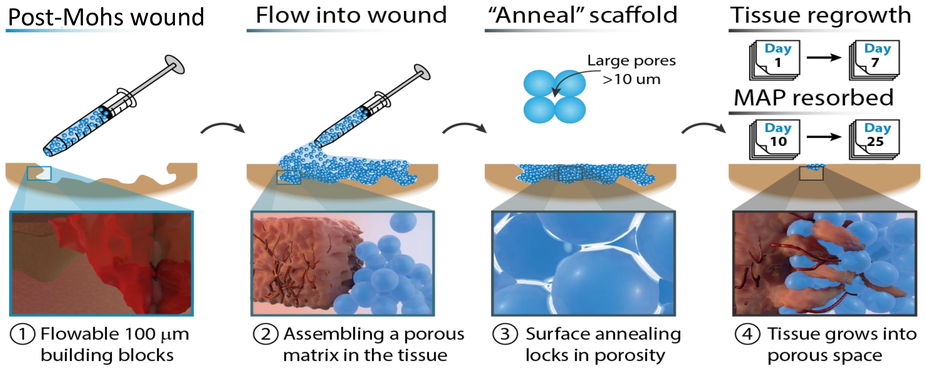
Introduction

The Clinical Challenge in Skin Surgical Oncology

- Basal Cell Carcinomas (BCC) or Squamous Cell Carcinomas (SCC) affect over 5 million patients every year in the United States alone.
- Acute surgical oncology resection sites of BCCs and SCCs are frequently addressed with Mohs micrographic surgery (MMS). A significant number of these patients require surgical resection that exposes bone, muscle, or fascia.
- The recovery of these surgical sites is challenging, costly, and requires careful management to optimize healing and minimize complications. The most prevalent complications of post-operative wound management following MMS are infection and **scarring from dermal atrophy and scar contracture**. Currently, there is neither a one-size-fits-all approach nor a single standard treatment to post-Mohs wound care.

MAP Wound Matrix, a Revolutionizing Scaffold

Microporous **A**nnealed **P**article (**MAP**) **Wound Matrix** is a 'smart' flowable and resorbable wound matrix with a unique porous microenvironment that enables rapid tissue integration without eliciting a foreign body response. The MAP Wound Matrix enables, with a single application, a new treatment for wounds of any shape without the use of cells, biologics or growth factors.



MAP Wound Matrix is delivered to the wound as a flowable concentrated hydrogel microsphere solution, and then, upon white light exposure, is transitioned *in situ* to a robust scaffold. The resultant scaffold displays a functional open pore structure with microscale porosity (pore size: 10 - 50 µm) to allow free movement of cells to build new tissue prior to enzymatically mediated material resorption.

- **Flowable**
- **Any wound shape**
- **Single application**
- **Bioresorbable**
- **Rapid tissue integration**
- **No foreign body response**
- **Synthetic matrix**
- **No cells, no biologics, no growth factors, no animal-derived products**

Objective of the Study

The purpose of this first-in-human clinical study was to evaluate the safety of the MAP Wound Matrix when used in the treatment of clean wounds after skin cancer surgery with MMS compared to a standard hydrocolloid dressing (DuoDerm®).

References

1. D.R. Griffin, *et al*, *Nature Materials*, ***2015*** 14: 737–744.
2. D.R. Griffin, *et al*, *Nature Materials*, ***2021*** 20: 560–569.

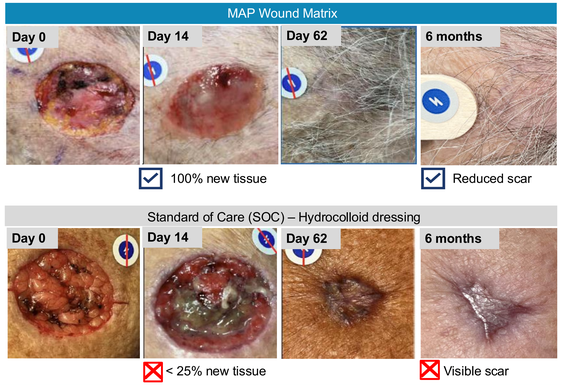
Methods

Forty (40) subjects underwent skin cancer surgery via MMS in three clinical sires. Post-surgery, subjects were randomly assigned to investigational (MAP Wound Matrix) or standard of care (SOC, hydrocolloid dressing) treatment in a 2:1 ratio. Uniquely, the study design does not exclude patients with complex wounds or that are suffering from immunodeficiency. MAP Wound Matrix is applied only once after surgery, while the SOC is reapplied (i.e., every 3-4 days for the first two weeks). Subjects were followed through multiple follow-up visits, either in clinic or virtual for up to six months. The primary endpoint is the incidence of serious adverse device effects (SADE) in subjects treated with MAP Wound Matrix, compared to the SOC treatment group. Secondary assessments include standard clinical wound assessment, recording any needed interventions, digital wound imaging, device assessment, pain questionnaires, and recording any non-serious adverse events.

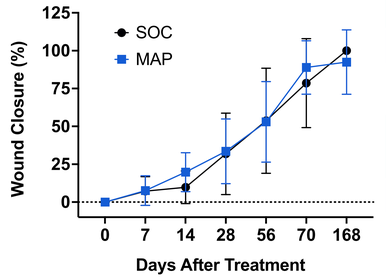
SWFIT Skin and Wound™ technology was used to capture 2D wound images and trace wound area. LifeViz Micro™ from Quantificare was used to capture 3D wound images.

Results

- **No Serious Adverse Device Effects**
- **No delay in wound closure**
- **Improved wound bed score**
- **Reduced scar score**



Wound Closure

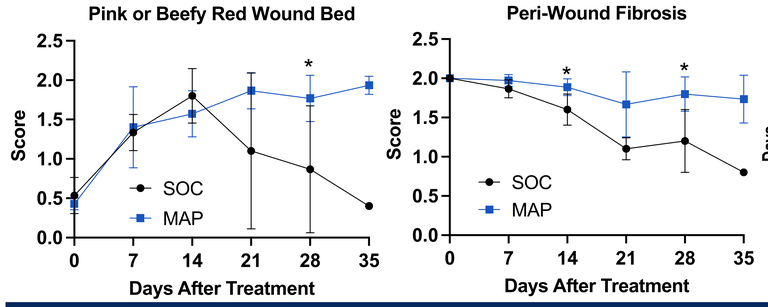


	Mean time to complete wound closure
SOC	73 ± 30 days
MAP	73 ± 16 days

	% subjects with complete wound closure by 12 weeks
SOC	82%
MAP	86%

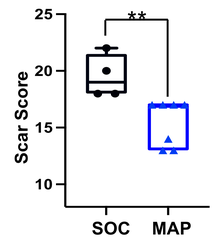
Data for 33 patients

Improved Wound Bed Score (WBS) in the First 10 Patients



* $p < 0.05$, n = 10

Reduced Scar at 6 Months



** $p < 0.01$, n = 11

Conclusion

Study results indicate the MAP Wound Matrix can be applied to clean wounds after MMS without SADEs. In addition, these data suggest that MAP Wound Matrix has the potential to affect wound healing after cancer resection via a single treatment. The potential of a product to improve tissue formation over bone, cartilage, or fascia while reducing complications of scar contracture and dermal atrophy would address a significant unmet medical need for patients undergoing skin cancer surgery.

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