Novel Biomaterial Containing Gelatin, Manuka Honey, and Hydroxyapatite Enhanced Secondary Intention Healing Versus Standard Secondary Intention Healing in Mohs Surgical Defects on the Head and Distal Lower Extremities-A Randomized Controlled Trial: Pilot Study

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ABSTRACT

Background: Randomized, comparative studies evaluating augmented secondary intention healing (SIH) compared with conventional SIH in dermatologic surgery are limited. This study aimed to evaluate whether the use of a novel biomaterial enhances SIH, particularly in shortening time to complete reepithelialization.

Objective: The purpose of this study was to elucidate whether a novel biomaterial containing gelatin, manuka honey, and hydroxyapatite enhances SIH when compared with conventional SIH for surgical defects after Mohs micrographic surgery (MMS) on the head and distal lower extremities.

Materials and methods: Thirty-seven patients were enrolled in this randomized controlled trial. Patients undergoing MMS on the head or distal lower extremities were eligible for recruitment. After clear surgical margins were obtained post-MMS, patients were randomized to receive standard SIH or biomaterial enhanced SIH. Patients had regularly scheduled follow-ups with questionnaires at each visit until complete re-epithelialization was achieved.

Results: Overall, there was no significant difference in time to re-epithelialization between standard SIH and biomaterial-enhanced SIH. However, there was a significant decrease in pain scores and skin thickness in the biomaterial-enhanced SIH group.

Conclusion: Biomaterial-enhanced SIH is noninferior to standard SIH and produces less pain and favorable skin thickness compared with standard SIH. ClinicalTrials.gov listing: NCT04545476.



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TABLE 1. Patient Characteristics		
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Characteristics	Head	Distal Lower Extremities
Total patients Males	21 18	16 5
Females	3	11
Age (in years) Mean Range	71.4 35–85	69.5 59–92
Tumor type Basal cell carcinoma Squamous cell carcinoma Squamous cell carcinoma in situ	9 10 2	2 14 0

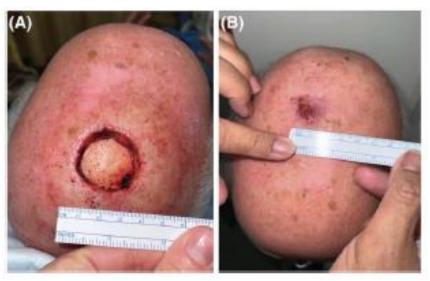


Figure 1. Assessment of wound in the group. (A), Final wound defect upon clearance of tumor, Day 0. (B) Complete re-epithelialization at Day 47.



Figure 2. Assessment of wound in the control group. (A) Final wound defect upon clearance of tumor, Day 0. (B) Complete reepithelialization at Day 34.