

Safety of Soovu™ Heating Devices for Pain Relief

Integrative Skin Science and Research

Prepared for Soovu Labs, Inc.

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**INTEGRATIVE
SKIN SCIENCE
AND RESEARCH**

Introduction

Local heat application has been used to help soothe stiff joints, relax muscles, and reduce inflammation.

Materials and Methods

Study Participants

This study was conducted from June 18, 2019 to August 7, 2019 and was approved by IntegReview, an independent institutional review board. All participants provided written informed consent prior to participation and received financial compensation. Twenty-five healthy participants were recruited and screened for eligibility at the Integrative Skin Science and Research site. Participants were excluded if they have a history of acute or chronic disease that would likely interfere with or increase the risk on study participation, have clinically significant unstable mental disorders, or have a history of psychological illness or condition that would interfere with their ability to understand and follow the requirements of the study.

The average age of the participants was 29 years old, and their ethnicities were as follows: Asian (11), White/European (7), Latino (4), Middle Eastern (3).

Study Design

The study was conducted over ten days and consisted of two visits.

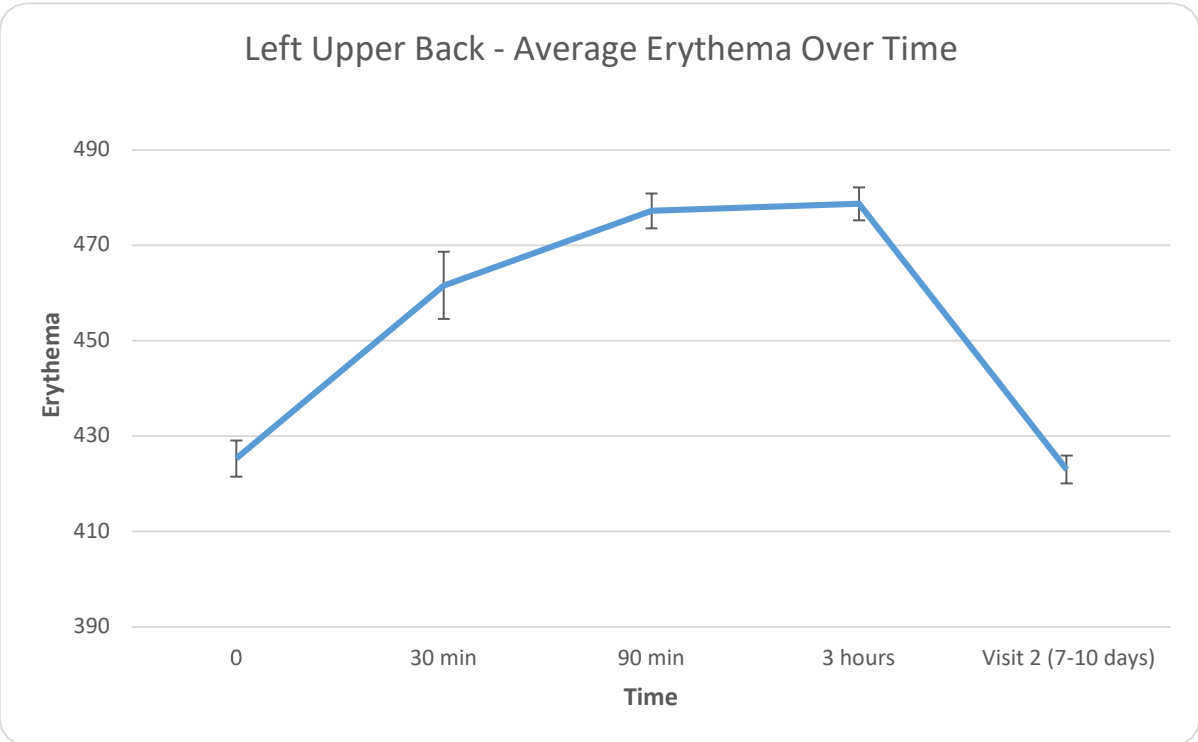
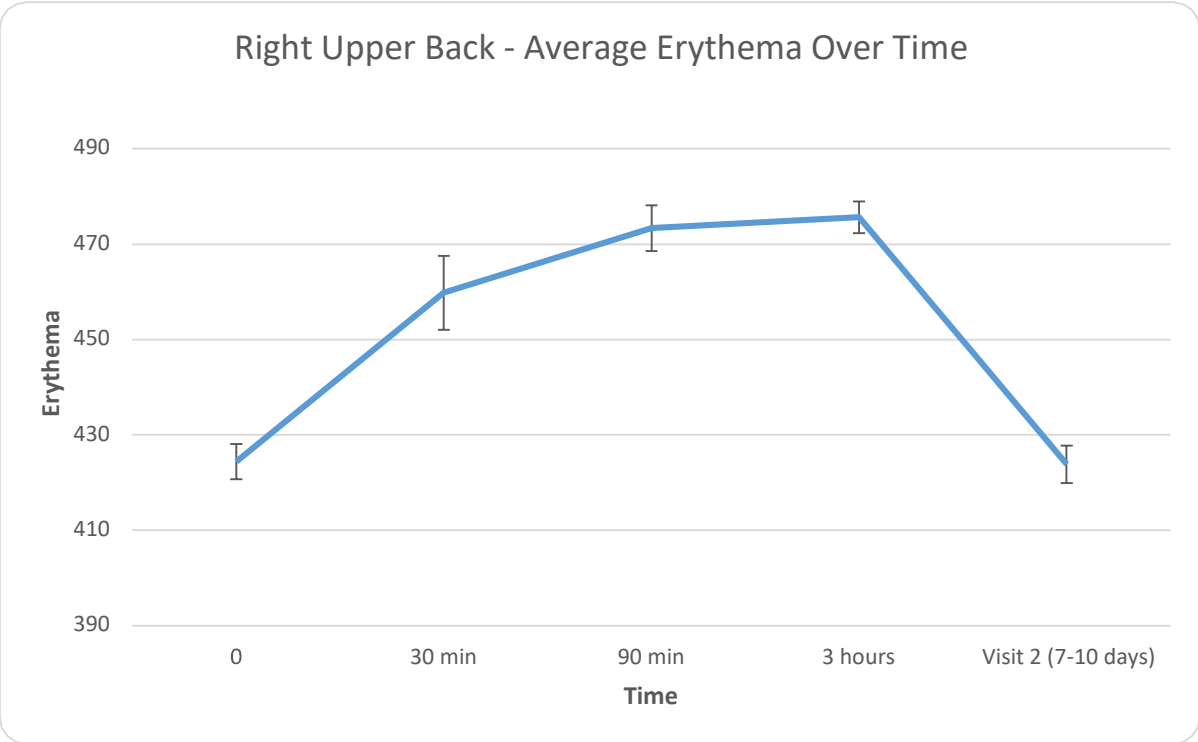
The Soovu heating devices for this study were designed by Soovu Labs, Inc. These devices are designed for eventual commercial sales as a noninvasive, non-prescription, over-the-counter devices that provide heat to temporarily reduce muscle aches and pains. The maximum temperature of the heating device is 113°F. The device briefly pulses up to the maximum temperature 113°F for 10 seconds after which power is turned off and the temperature drifts to 104°F. In one a single 10-minute treatment cycle there are a number of pulses up to 113°F. After each treatment cycle there is a three-minute lockout period of no heating. The devices are constructed following documented ANSI/AAMI ES60601-1, ANSI/AAMI HA60601-1-11, IEC 60601-1-2, IEC 60529, ISO 10993-5, and 10993-10 safety standards.

Heating devices were applied to the following locations on each participant's upper body: upper back, lower back, abdomen, and inner upper arms. Two devices were applied to each location for a total application of eight devices per participant. Participants underwent 25

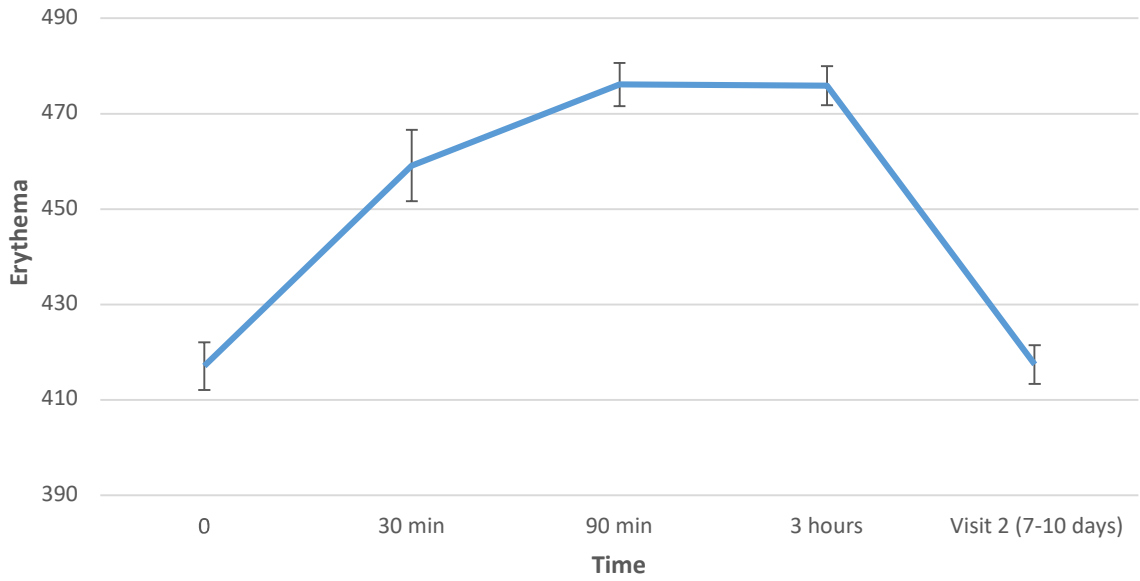
ten-minute treatment cycles during the first visit. Photographs of the locations, trans-epidermal water loss measurements, and skin colorimeter measurements were taken at the following time points: baseline, after 2 treatment cycles (30 min), after 8 treatment cycles (90 min), after 15 treatment cycles (3 hours), and at the second visit (7-10 days from the first visit). Participants were also instructed to complete a visual analog scale (VAS) assessment for pain at all the previously mentioned time points.

Data

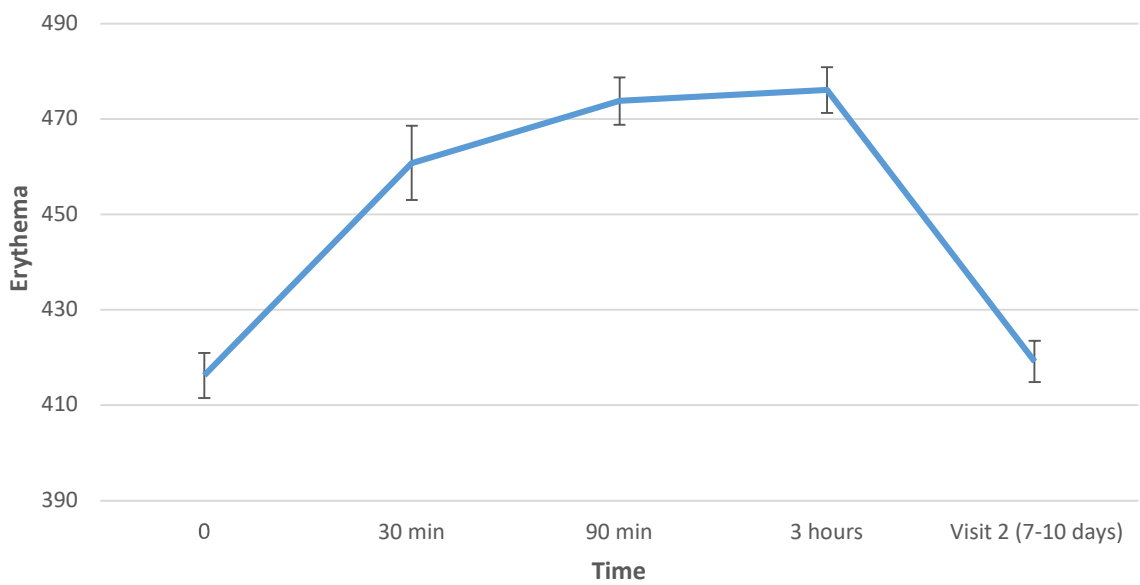
Erythema (erythema is reported in arbitrary units)



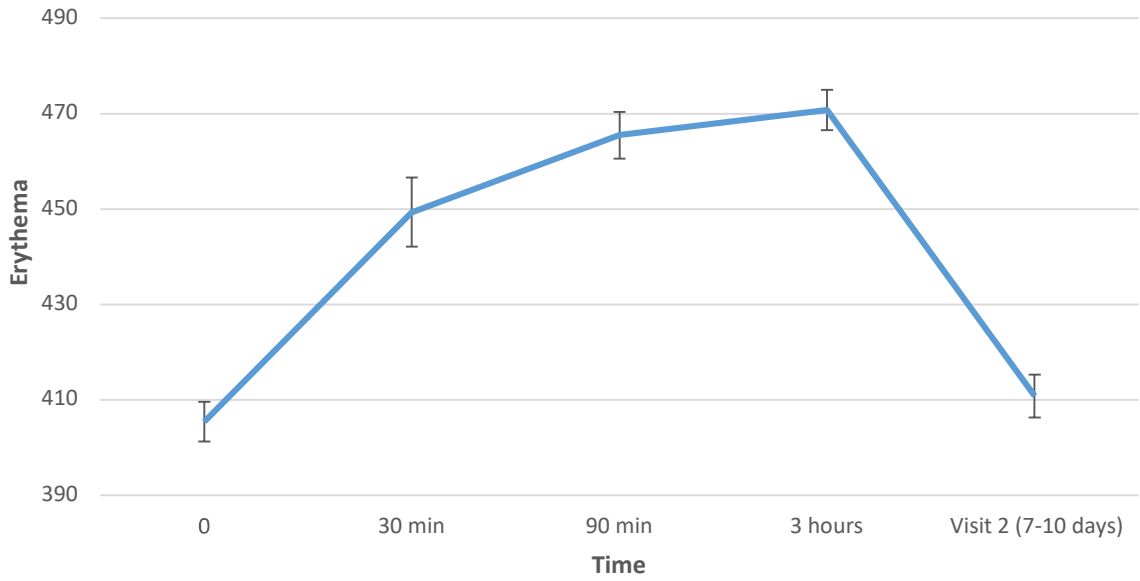
Right Lower Back - Average Erythema Over Time



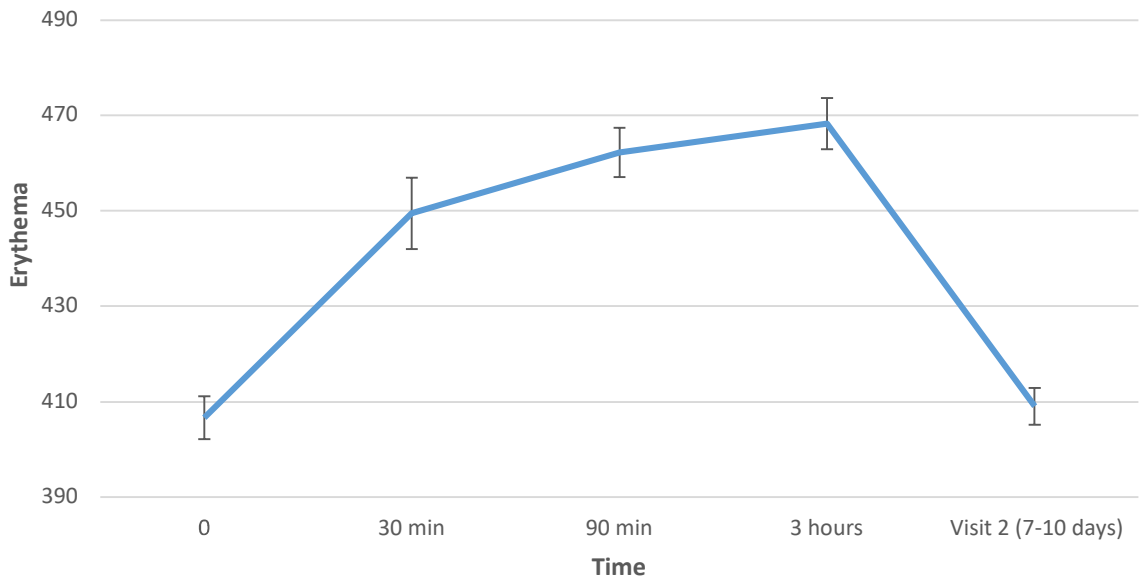
Left Lower Back - Average Erythema Over Time



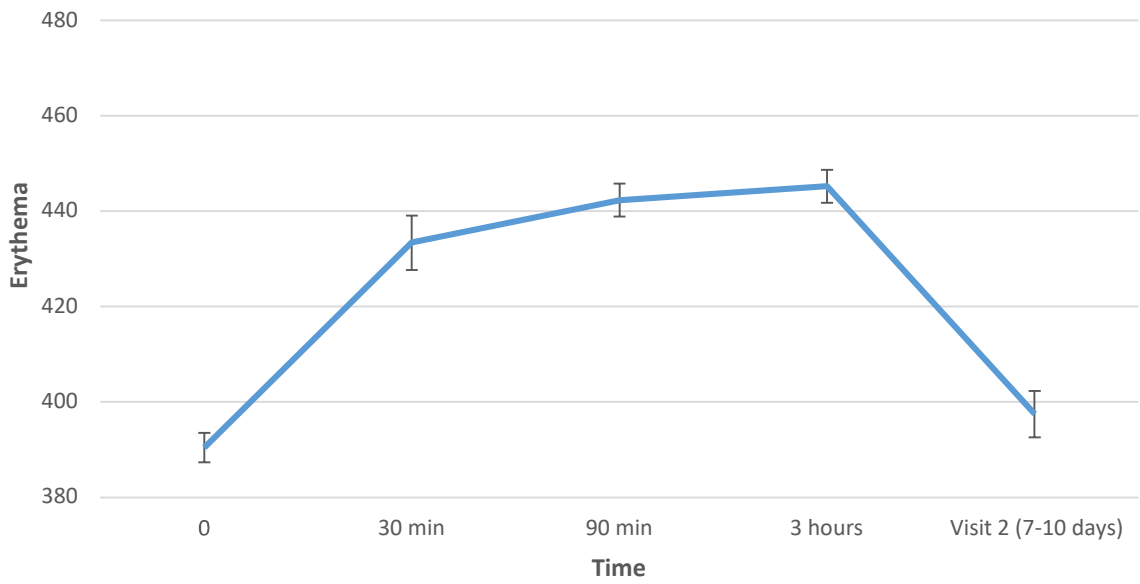
Right Abdomen - Average Erythema Over Time



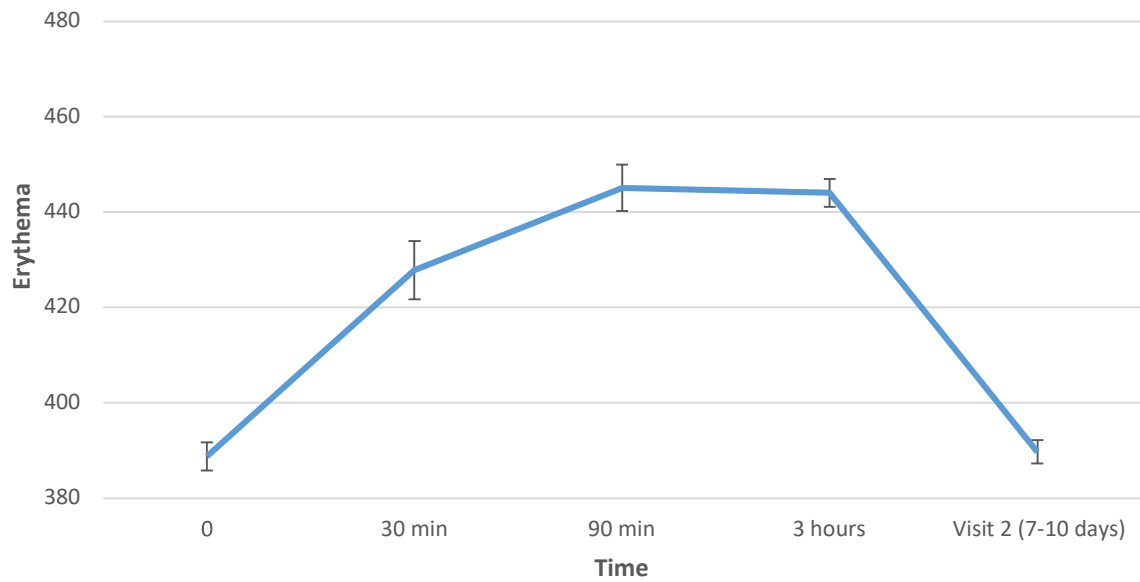
Left Abdomen - Average Erythema Over Time



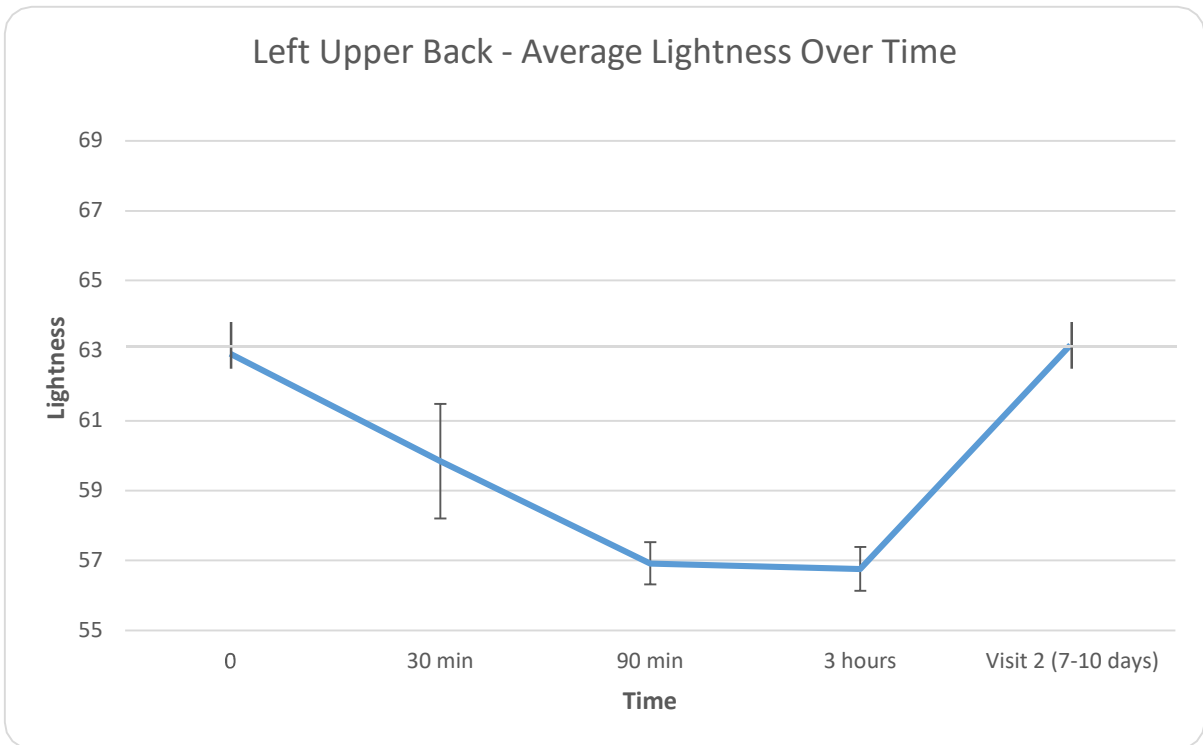
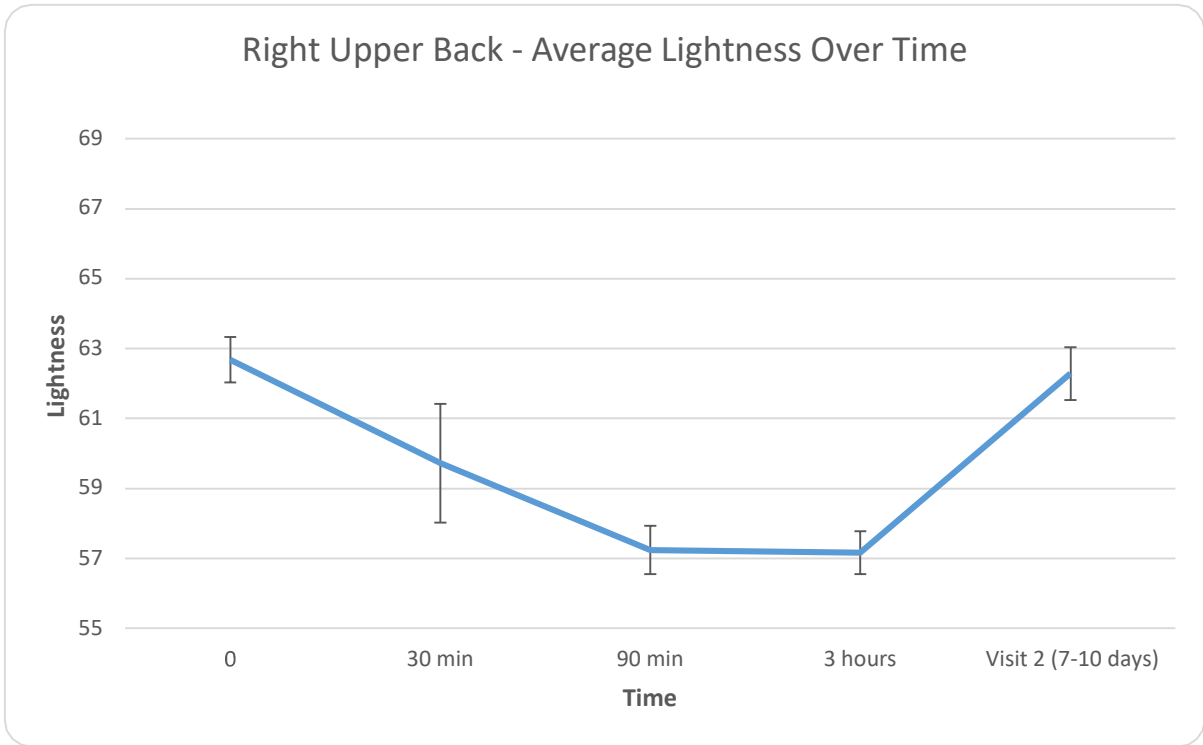
Right Upper Arm - Average Erythema Over Time



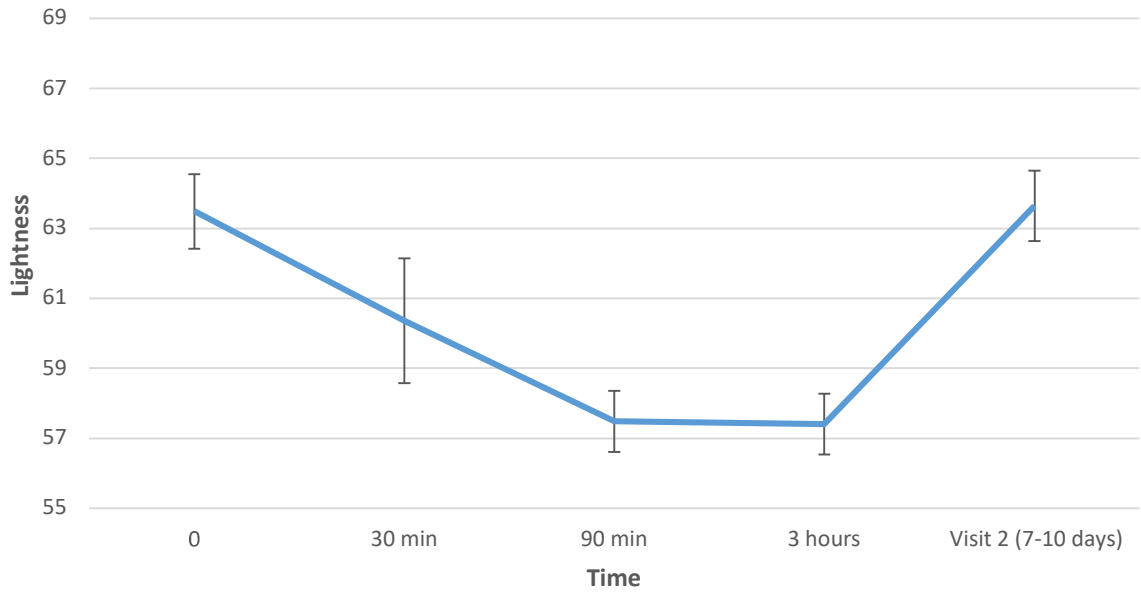
Left Upper Arm - Average Erythema Over Time



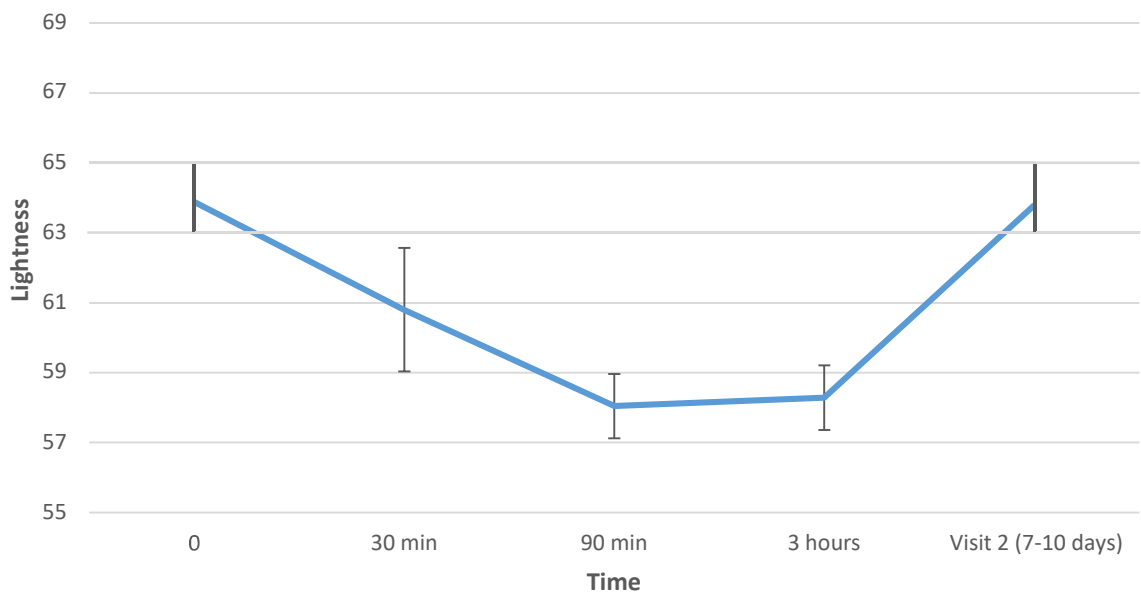
Lightness (lightness is reported in arbitrary units): A decrease in lightness indicates an increase in pigmentation and vice versa.



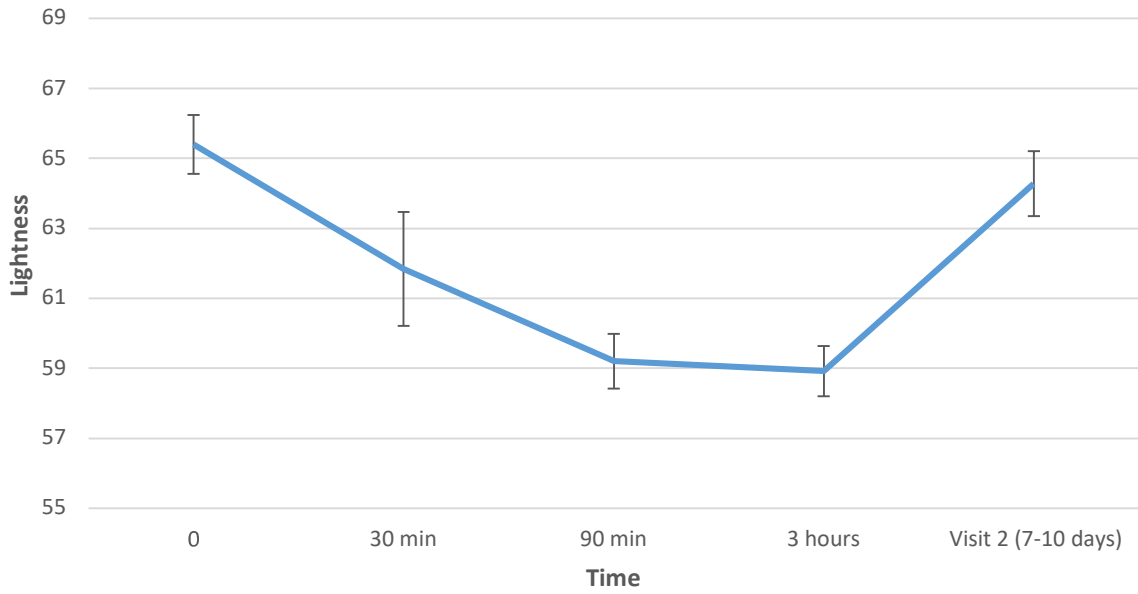
Right Lower Back - Average Lightness Over Time



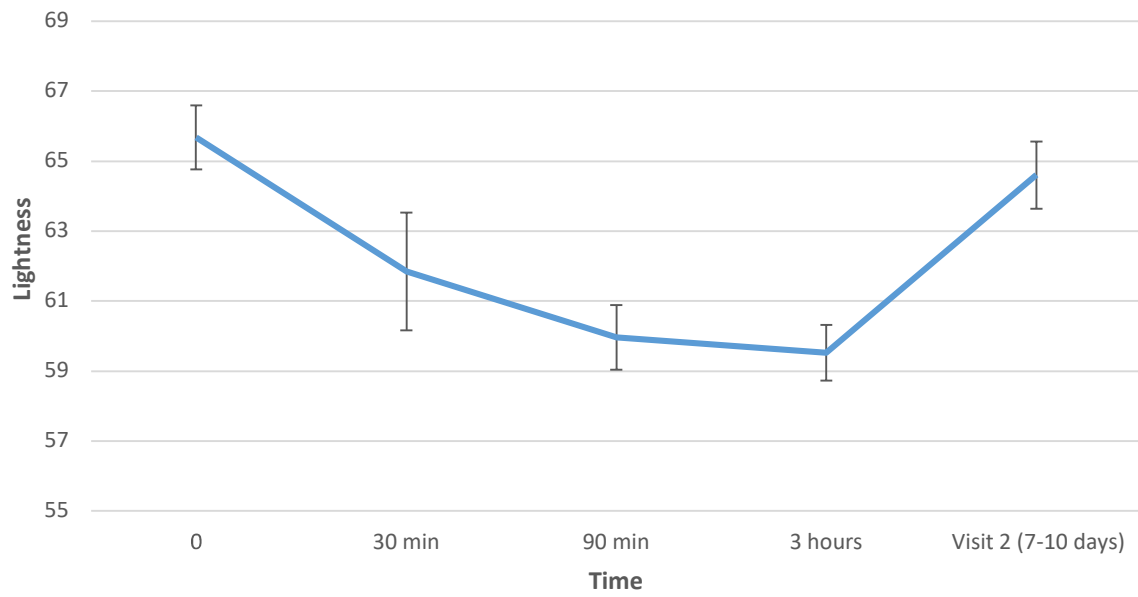
Left Lower Back - Average Lightness Over Time



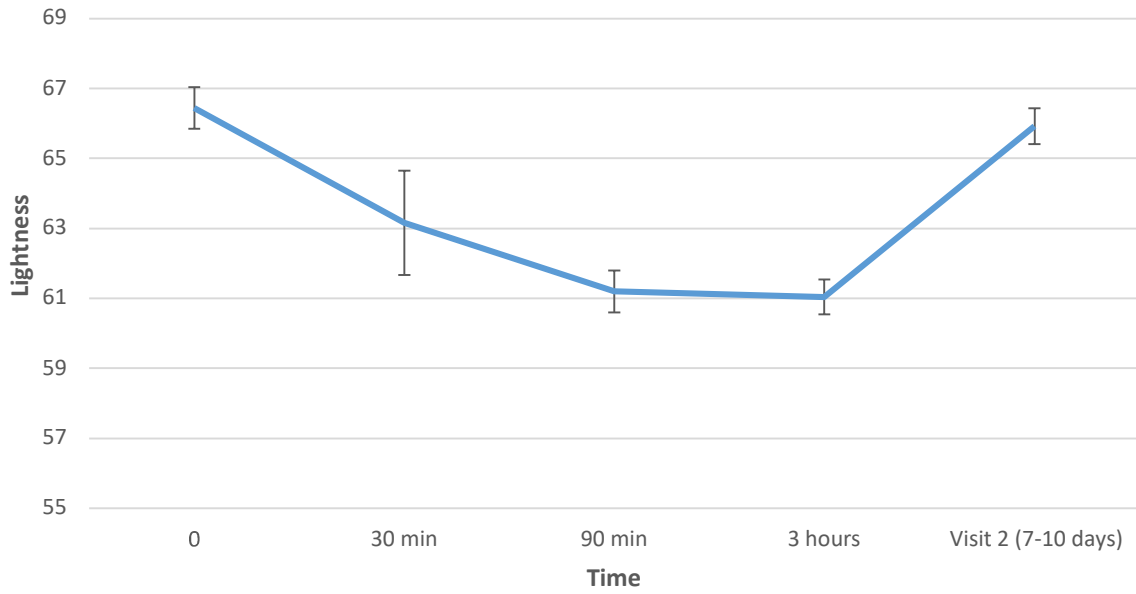
Right Abdomen - Average Lightness Over Time



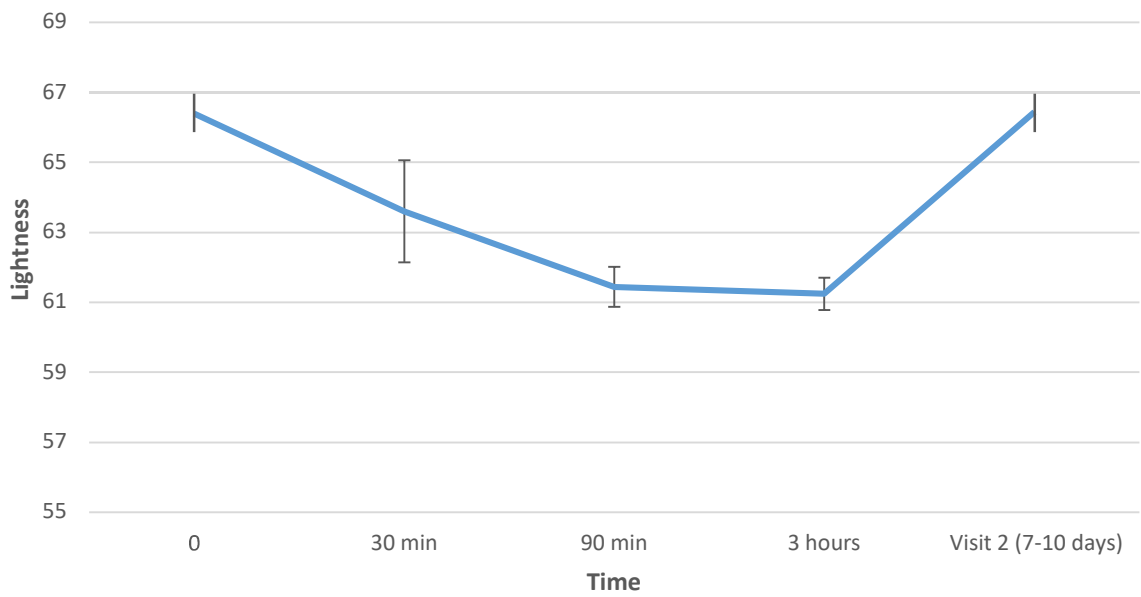
Left Abdomen - Average Lightness Over Time



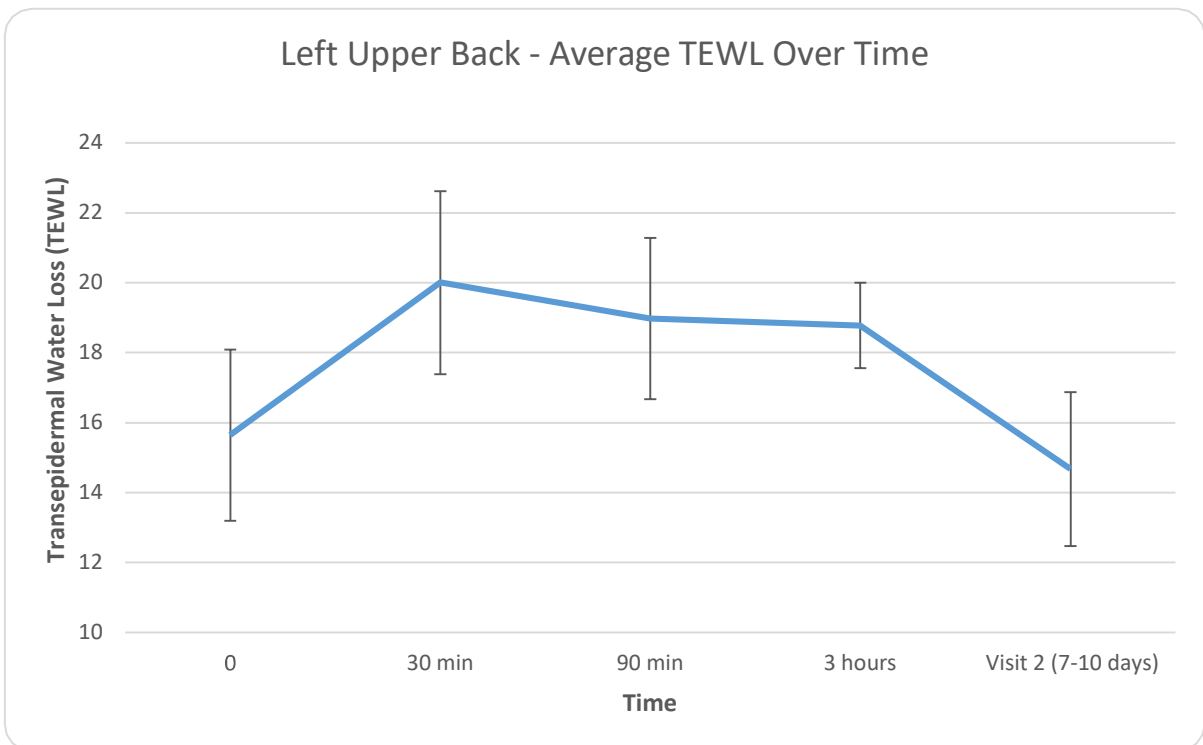
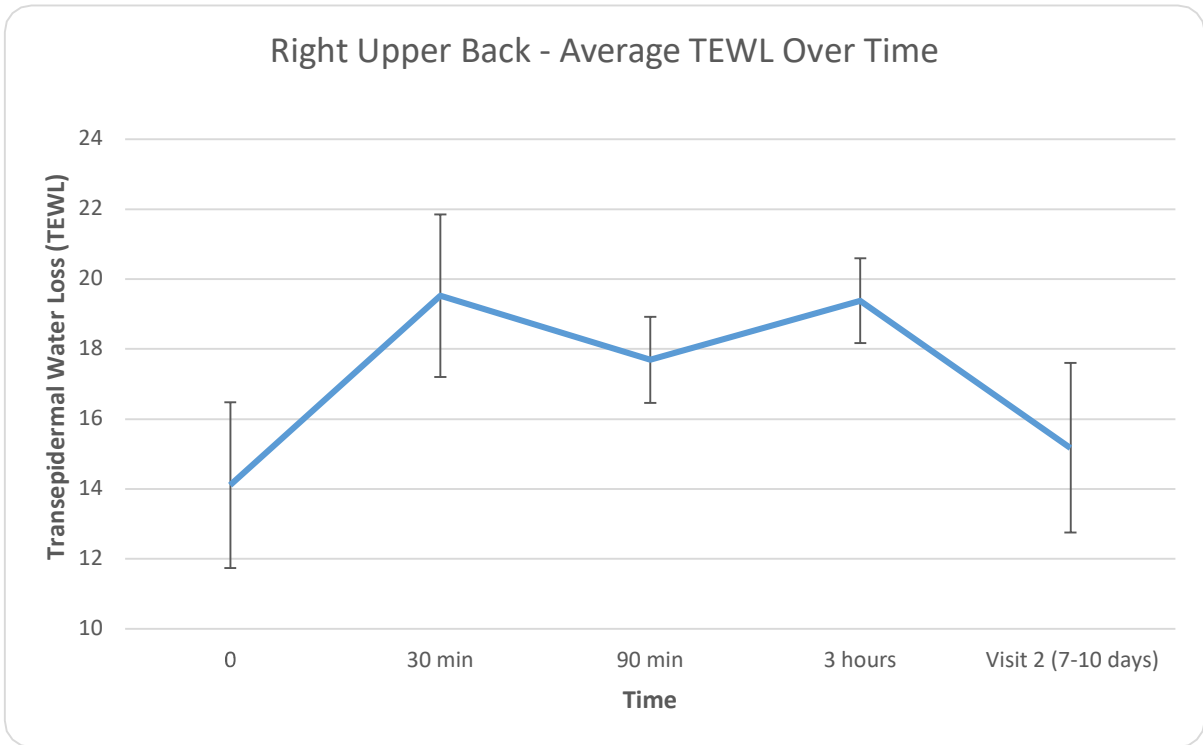
Right Upper Arm - Average Lightness Over Time



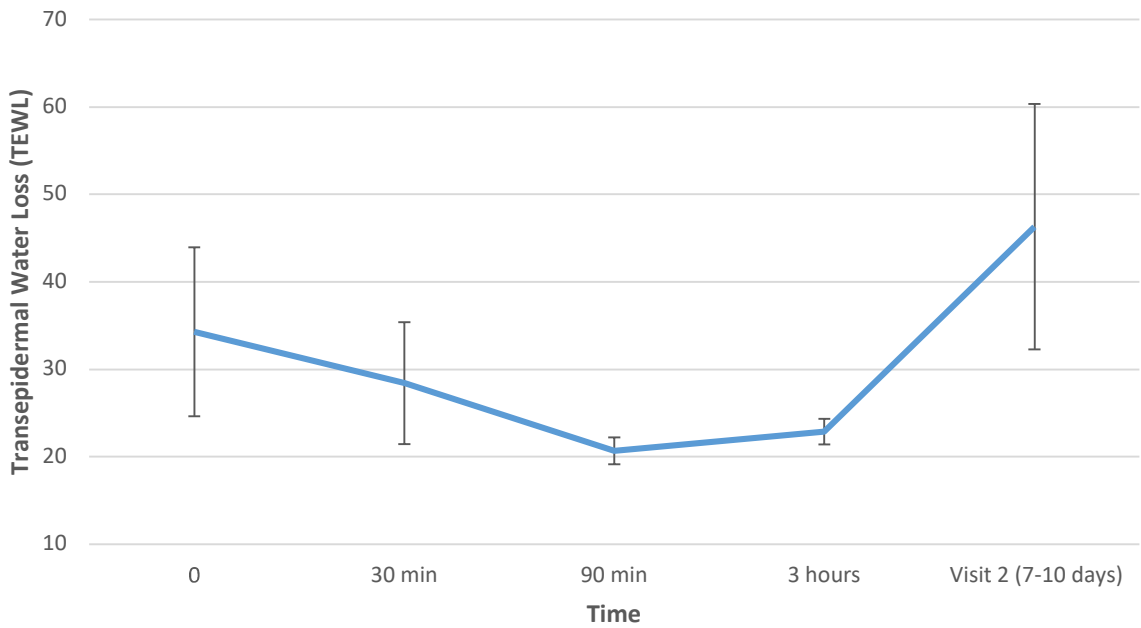
Left Upper Arm - Average Lightness Over Time



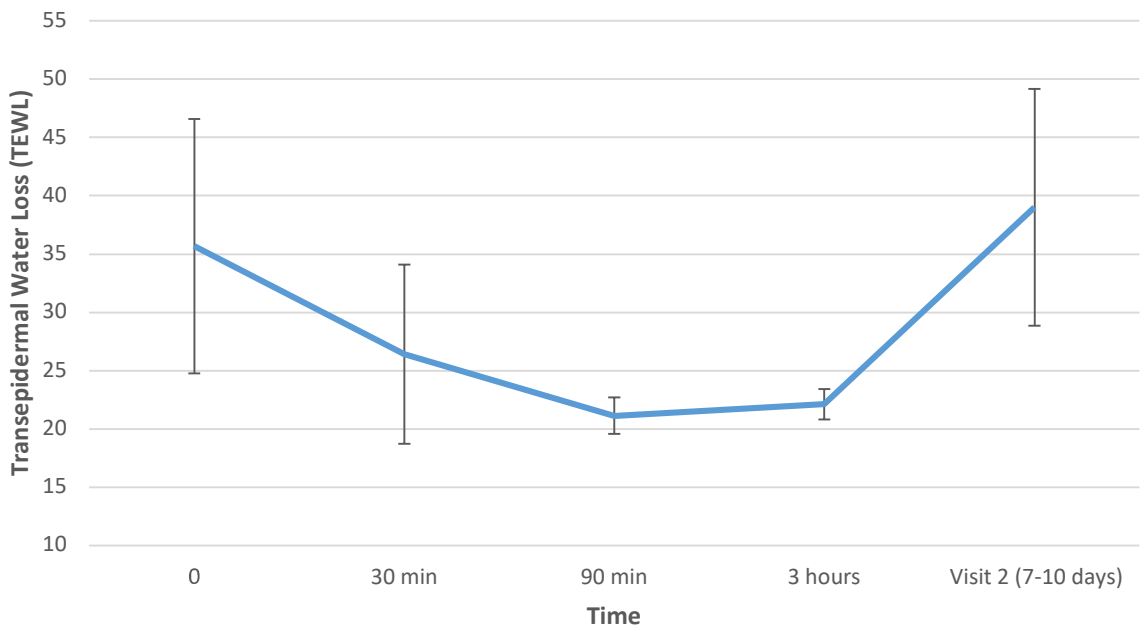
Trans-Epidermal Water Loss (the units of TEWL are g/m²/hr)



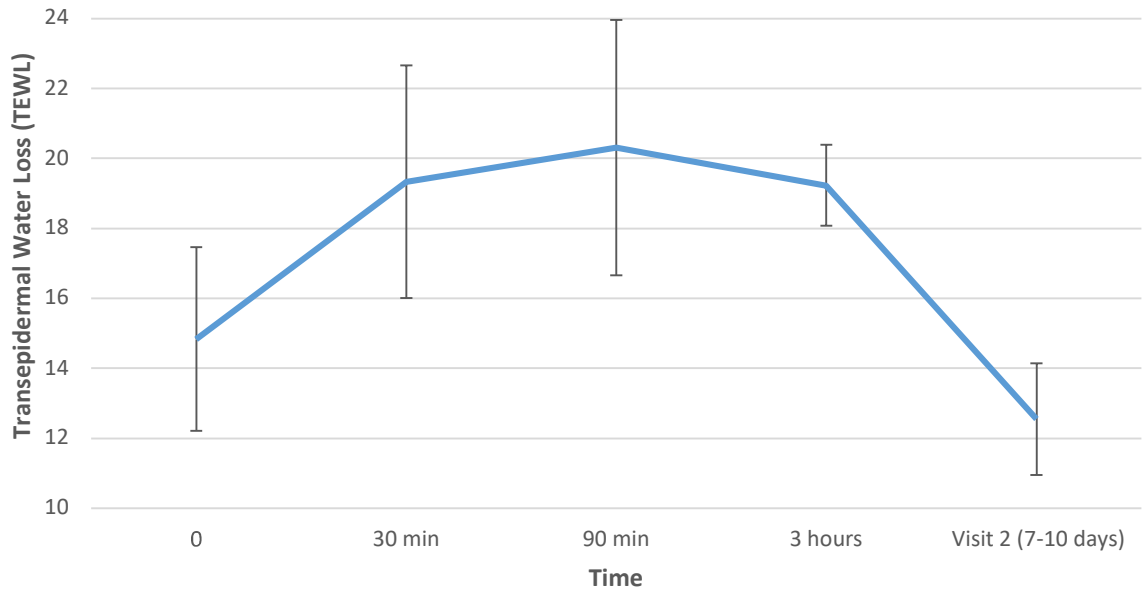
Right Lower Back - Average TEWL Over Time



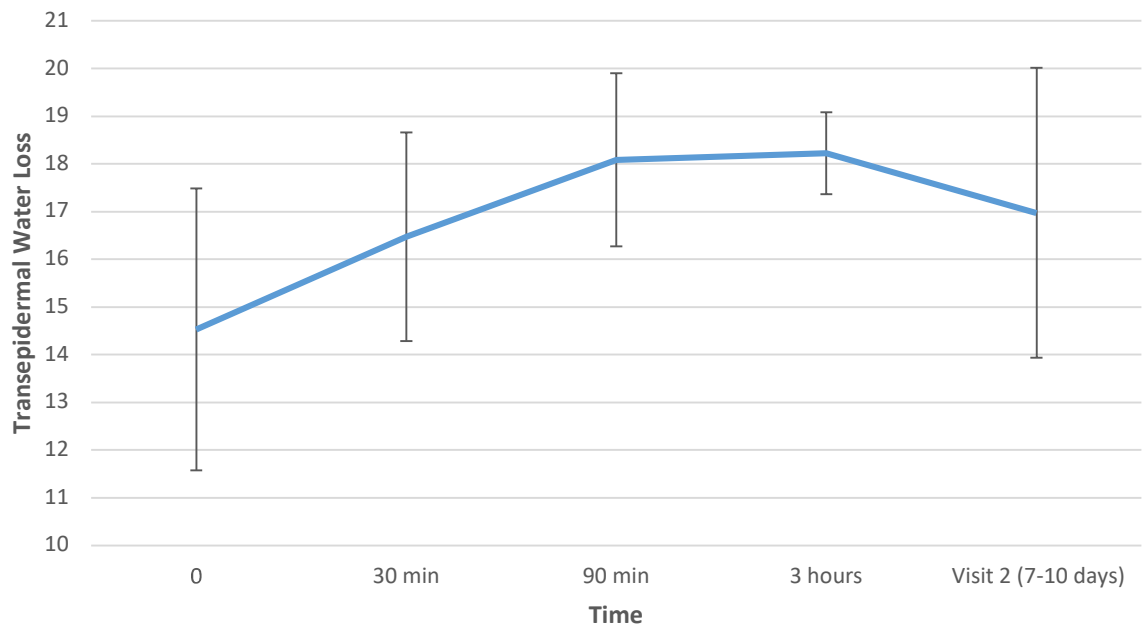
Left Lower Back - Average TEWL Over Time



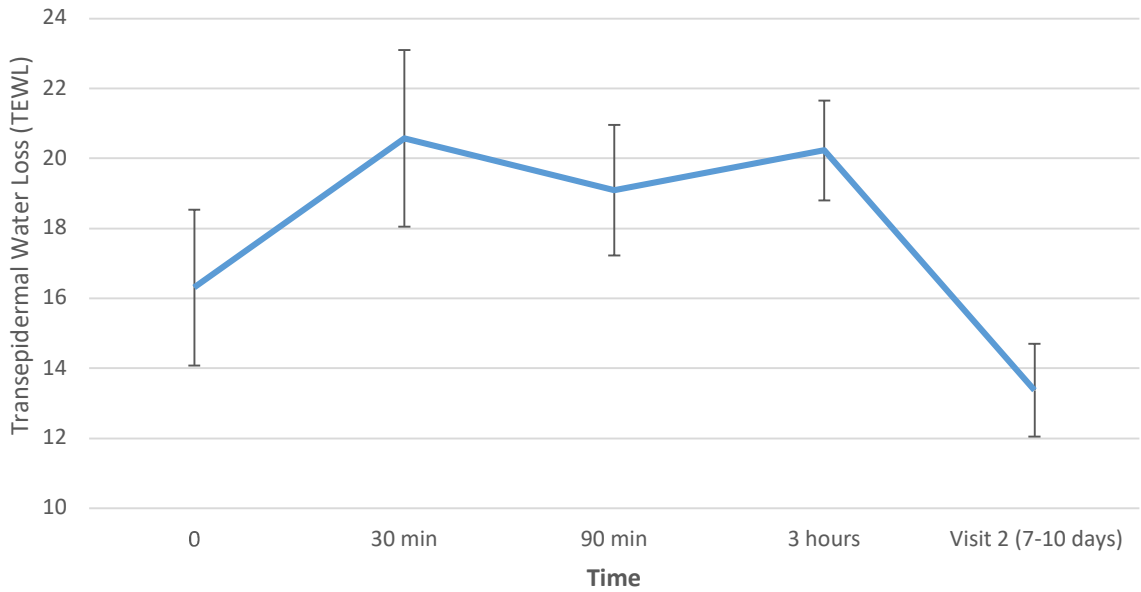
Right Abdomen - Average TEWL Over Time



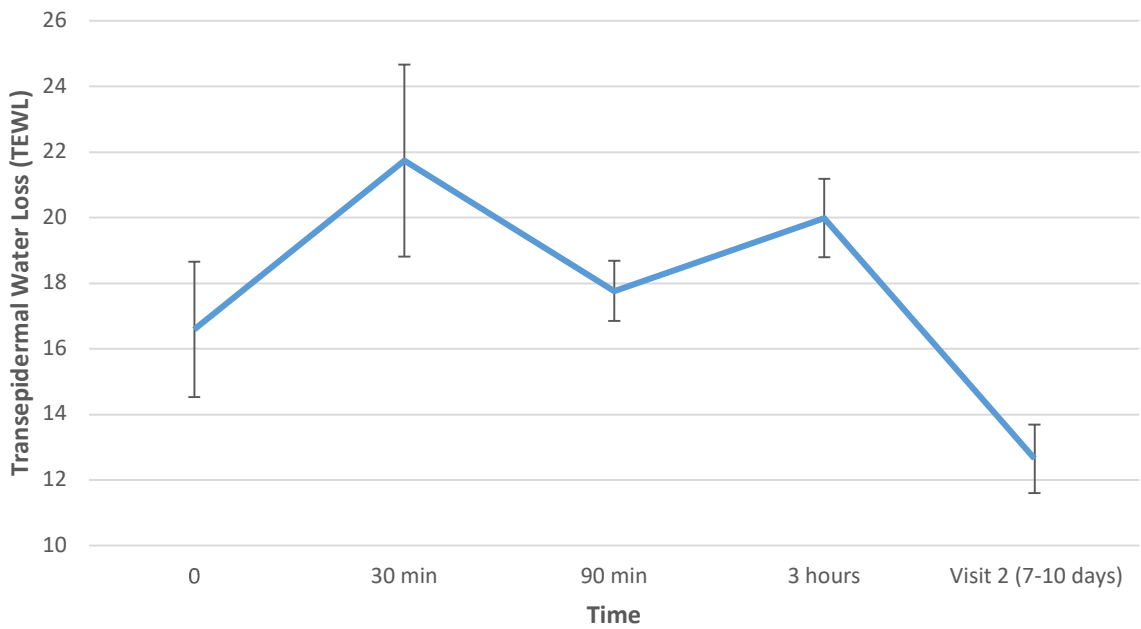
Left Abdomen - Average TEWL Over Time



Right Upper Arm - Average TEWL Over Time



Left Upper Arm - Average TEWL Over Time



Discussion

Erythema

The average erythema increased over time in all locations during Visit 1, but returned to baseline by Visit 2 indicating that there was no prolonged erythema after the device exposure.

Lightness

The average lightness decreased over time in all locations during Visit 1, indicating that there was a slight increase in pigmentation during the treatment cycles. However, all of the measures returned to baseline by Visit 2 indicating that there was no prolonged pigmentation after device exposure.

TEWL

The average TEWL increased over time during Visit 1 in the following locations: right and left upper back, right and left abdomen, and right and left inner upper arms. The average TEWL decreased over time during Visit 1 in the right and left lower back. In all locations, the average TEWL returned to baseline by Visit 2.

Conclusion

It was determined that the Soovu heating devices were well tolerated with no adverse effects due to the device's heating mechanism. We noted no episodes of post-inflammatory hyperpigmentation or persistent erythema with use of the devices. While there were temporary changes in the erythema, skin lightness (pigment), and transepidermal water loss, all of these measures returned to baseline. Pain was minimal during the treatment cycles. The devices were equally safe at all tested anatomical sites: upper arm, upper back, lower back, and the lower abdomen.

Some participants experienced thin scaling from the adhesive of the magnetic stickers and were advised to moisturize those areas of skin. One participant experienced allergic contact dermatitis due to the adhesive of the magnetic stickers but this was noted as a contact dermatitis and was not related to the heating mechanism of the devices. The contact dermatitis resolved within a week of treatment with no long-term effects.