Assessment of thermal safety of a new medical device using high energy pulsed heat: A novel standardized approach

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PURPOSE

Local heat has been used to help soothe stiff joints, relieve pain, relax muscles, and reduce spasms. Recent studies support that the pain-relieving properties of heat may be related to a peripheral interaction with transient receptor potential vanilloid (TRPV) channels and/or small diameter peripheral nerves. Further, the analgesic response to heat may be related to the amount of thermal energy applied to the skin and underlying receptors. Parameters of thermal energy such as absolute temperature, rate of temperature rise, and duration of heating are thought to affect the number and degree of stimulation of peripheral thermal sensitive receptors. A new medical device (Soovu Labs Inc.) uses high energy pulsed heat to stimulate peripheral receptors and recent studies indicate that 30 minutes of stimulation can produce over two hours of pain relief. This novel approach of using high energy pulsed heat to stimulate and recruit receptors required the development of a standardized approach to assess thermal safety of this device. As such, this study developed a testing paradigm using objective measures to evaluate the safety of this new device.

METHODS

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 (Sacramento CA). 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). The study was conducted over ten days and consisted of two visits. All skin evaluations and results analyses were conducted independently by Integrative Skin Science and Research staff.

The heating devices were designed by Soovu Labs, Inc. These devices are designed for eventual commercial sales as a noninvasive, drug-free, over-the-counter devices that provide pulsed heat to temporarily reduce muscle aches and pains. The maximum temperature of the heating device is 45°C. The device pulses up to the maximum temperature 45°C for 10 seconds after which power is turned off and the temperature drifts to 40°C. 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.

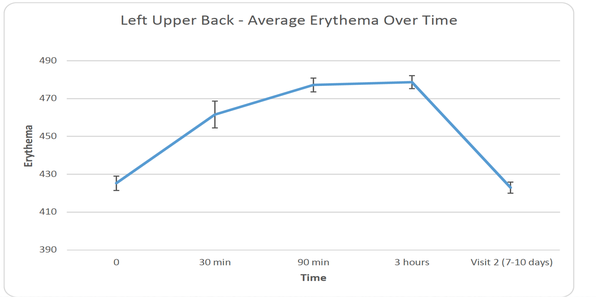
Heating devices were applied to the following locations on each participant's upper body: upper back, lower back, abdomen, and inner upper arms. Two devices were applied to each location for a total application of eight devices per participant. Participants underwent 25 ten-minute treatment cycles during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

Photographs of the locations, transepidermal water loss measurements (TEWL), 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 return visit (7-10 days from the first visit).

RESULTS

Erythema:

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

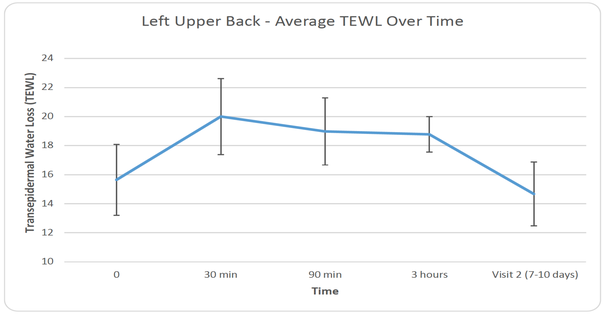


Lightness:

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 measures returned to baseline by Visit 2 indicating that there was no prolonged pigmentation after device exposure.

Transepidermal Water Loss:

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



CONCLUSIONS

The heating devices were well tolerated with no adverse effects due to the device's heating mechanism. There were 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. The devices were equally safe at all tested anatomical sites: upper arm, upper back, lower back, and the lower abdomen.

The amount of thermal energy used in this experiment greatly exceeded what is anticipated in a commercial device and there was no evidence of skin damage at either the short term or longer-term assessment. It is hypothesized that pain relief from thermal stimulation displays a "dose-like" response whereas more energy delivered produces better analgesia up to a point limited by nociception or tissue injury. In this case the device delivered high temperature thermal stimulation in brief pulses producing analgesia while reducing thermal energy delivered to the skin and increasing the margin of safety. The study design offers a standardized safety testing approach and may be applied to other cutaneous heating devices whether electrical or chemical based.

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