



Radiofrequency Hyperthermia Safety Study



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Introduction

Mild Hyperthermia (MH) has been used for thousands of years to help decrease pain, improve blood flow to tissues, aid lymphatic drainage. Although the complete mechanisms are not yet understood, there is evidence that MH may be beneficial for wound healing and cancer treatment (augment the delivery of chemotherapeutic agents) (1, 2)

Despite these observations MH has been slow to be established and adopted, possibly due to wide variations in technical specifications of heating devices; difficulty to quantify and standardize.

Methods

Our study evaluated the safety and tolerability of ThermoField radiofrequency device. This is a novel approach to MH by using lightweight, portable radiofrequency system that induces heat in the exposed tissue topically with a controlled feedback loop to maintain a specific and precisely controlled temperature. Previous veterinary medicine studies had encouraging results (3).

We enrolled 20 healthy volunteers, with ages ranging from 18 to 61 years old. They were treated weekly for 45 minutes for a total of 4 weeks. Ten participants were treated with 42°C and ten participants were treated with 40 °C. The device was used on the right calf only, while the left served as a control for image analysis.

Tissue blood perfusion was measured by laser scanning doppler and skin temperature was measured using infrared thermography. Subjective pain scores along with photographs of the treated area were documented weekly

Results

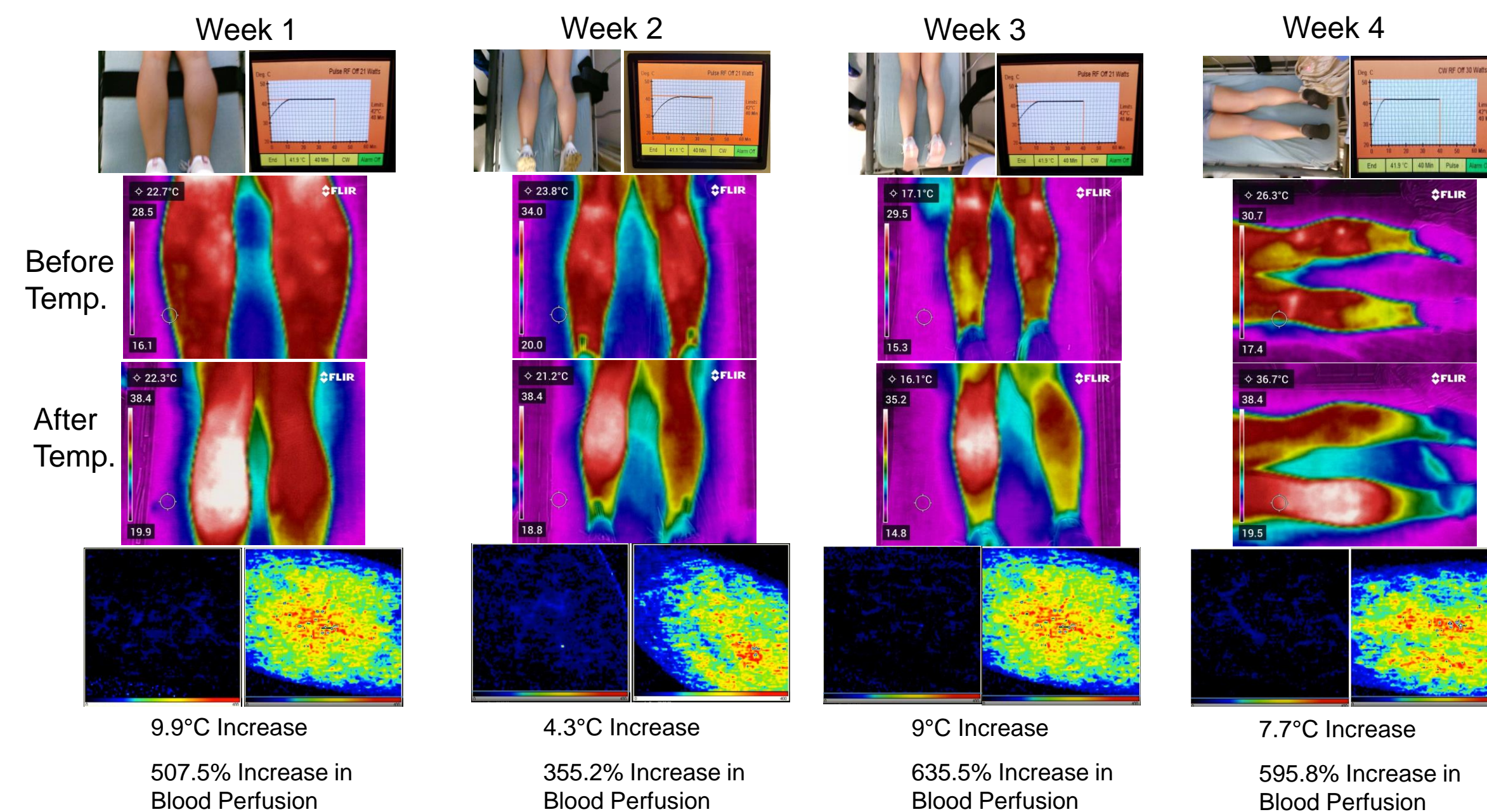
Blood perfusion increase was noticed in a range from 170% up to 756 % with an average 432 %, measured 5 minutes post treatment. Subjects treated with 40 °C had an average increase of 372.7 % and subjects treated with 42 °C had an average increase of 502 %

Temperature increase average was 6.8°C. Subjects treated with 40°C average increase was 6.5 °C and subjects treated with 42°C had an average increase of 7.2 °C.

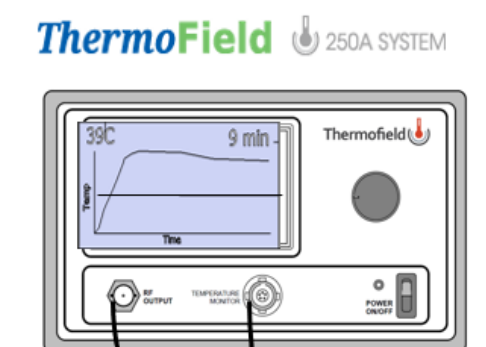
Subjective pain scores were 0 (zero) except for 1 participant reported score 1 on week 3 and one participant reported score 2 with each treatment.

Three of the subjects treated with 42 °C were noticed to have minor skin erythema.

SAMPLE PATIENT – age 41 – 50



Week 8



ThermoField radiofrequency device.



Contact pad for the ThermoField radiofrequency device.

Project Goal: To demonstrate that application of the ThermoField temperature controlled radiofrequency device is safe for dermal application for generating elevated temperatures and increases blood flow.

Discussion

This study demonstrates safety and good tolerability of hyperthermia radiofrequency ThermoField device especially with 40 degrees °C group with objective and reproducible physiologic effects: **increased soft tissue temperature and increased blood perfusion.**, which is critical for healing of chronic soft tissue wounds.

No complications were noted at this temperature and the patient satisfaction was high.

This data will be used to design additional human studies for the management of complex soft tissue healing and may offer additional benefits in pain mitigation or augment clinical standards of care.

References:

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- [3] S.M. Gillette, M. Dewhirst, E. Gillette, D. Thrall, R. Page, B. Powers, S. Withrow, G. Rosner, C. Wong, D. Sim, Response of canine soft tissue sarcomas to radiation or radiation plus hyperthermia: a randomized phase II study, International Journal of Hyperthermia. 8 (1992) 309–320