

Original Article

Posterior thigh thermal skin adaptations to radiofrequency treatment at 448 kHz applied with or without Indiba[®] fascia treatment tools

KONSTANTINOS FOUSEKIS, PT, MSc, PhD^{1)*}, GEORGIOS CHRYSANTHOPOULOS, PT¹⁾, MARIA TSEKOURA, PT, MSc, PhD¹⁾, DIMITRIS MANDALIDIS PT, MSc, PhD²⁾, KONSTANTINOS MYLONAS, PT, MSc¹⁾, PAVLOS ANGELOPOULOS, PT, MSc¹⁾, DIMITRA KOUMOUNDOUROU, MD, MSc, PhD³⁾, VICKY BILLIS, PT, MSc, PhD¹⁾, ELIAS TSEPI, PT, MSc, PhD¹⁾

¹⁾ Department of Physical Therapy, University of Patras: 6 Psarron, Egio, Achaia 25100, Greece

²⁾ School of Physical Education & Sport Science, National & Kapodistrian University of Athens, Greece

³⁾ Department of Pathology, University of Patras, School of Medicine, Greece

Abstract. [Purpose] This study aimed to evaluate the posterior thigh's skin thermal responses to 448-kHz radiofrequency-based therapy applied either in the form of standard application (Indiba[®]Activ) or combined soft tissue treatment (Indiba[®]Fascia treatment). [Participants and Methods] Ten healthy males (22 ± 3 years of age, weight 75.2 ± 4.9 kg, height 178.5 ± 4.7) received four different treatments which included a) Indiba[®]Activ (IA) radiofrequency treatment, b) Indiba[®]Fascia (IF), c) Indiba[®]Activ placebo (IAP) and d) Indiba[®]Fascia Placebo (IFP) in the posterior thigh of their dominant lower limb, while the non-dominant served as the control. Skin temperature was recorded pre- and post-treatment and every minute until the surface temperature reached pre-treatment levels using a wireless infrared thermometer. [Results] Both radiofrequency-based therapy groups IA and IF led to a significant increase in skin temperature compared to placebo applications. The IF intervention led to an average retention of elevated temperature for 164.2 minutes compared to 54.8 minutes of IA, 23.17 of IFP and 17.6 minutes of IAP. [Conclusion] These findings indicate that radiofrequency treatment at 448 kHz can induce and sustain significant thermal skin adaptations reflecting an increased blood circulation and metabolism of underlying tissues.

Key words: Hamstrings, Skin temperature, Radiofrequency treatment

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INTRODUCTION

Electrotherapy has been used for decades by health professionals, especially physiotherapists, in the rehabilitation of neuromusculoskeletal pathologies and injuries. Electrotherapy modalities can be divided into modalities that provide electrical stimulation, such as transcutaneous electrical nerve stimulation (TENS) and interferential therapy, and modalities that increase the temperature of the tissues, thereby enhancing the nourishment and oxygenation of the area as well as cellular activity, such as short/microwave diathermy, laser and radiofrequency treatment. An additional category of electrotherapeutic agents is those that transfer non-thermal energy to the body with the aim of improving membrane permeability, thus promoting tissue regeneration, such as ultrasound, laser therapy and, again, low-intensity radiofrequency (RF) applications¹⁾.

Radiofrequency treatment is a therapeutic approach used in the treatment of most musculoskeletal and sports injuries. One

*Corresponding author. Konstantinos Fousekis (E-mail: kfousekis@upatras.gr)

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of the most effective radiofrequency treatments is Indiba®Activ treatment at 448 kHz, a frequency that has been associated with pain reduction and improved functionality in patients with musculoskeletal disorders²⁻⁴). This wavelength promotes ion mobilisation between the intracellular and extracellular matrix and restores cell membrane permeability. The energy generated at 448 kHz improves cell membrane permeability, enhancing intracellular and extracellular exchange and tissue regeneration.

Furthermore, high-intensity radiofrequency treatment at 448 kHz can induce significant hyperthermia, which can lead to a considerable increase in cell metabolism and accelerated recovery. These hyperthermal adaptations to radiofrequency treatment are based on vasodilatation, causing a targeted local increase of blood perfusion and decreases in muscle tension and spasm, increased oxygen and nutrient supply, and healing acceleration⁵).

RF treatment can be applied through capacitive (CAP) or resistive (RES) electrodes that either pass radio frequency to the human body or through innovative fascial tools (Indiba®Tools) and combined soft tissue therapy (Indiba®Fascia). A previous study has shown the treatment of quadriceps with radiofrequency-based therapy at 448 kHz can significantly increase and sustain skin temperature. More specifically, both the CAP and the RES modes of RF treatment significantly increased the skin temperature at the quadriceps of healthy adults and sustained it over the 45-minute follow-up⁶).

Based on these findings, one would expect that the beneficial effect in terms of induced skin thermal adaptations will be even more significant if the application of radio frequencies is combined with the implementation of soft tissue techniques based on the specific tools mentioned above. However, there is still no research that has compared the cumulative effect of radiofrequency treatment application when applied by two different application modes and methods, either by simple contact and gentle sliding of the active electrodes on the skin or by intense friction and mobilisation of the fascia through specific dynamic fascial tools. In the context of this scientific research deficit, this study aimed to examine the posterior thigh thermal skin responses (thermal build-up, decay, retention) to 448-kHz radiofrequency-based therapy applied either in the form of a standard application (Indiba®Activ) or combined soft tissue treatment (Indiba®Fascia treatment).

PARTICIPANTS AND METHODS

The study sample consisted of 10 healthy males (22 ± 3 years of age, weight 75.2 ± 4.9 kg, height 178.5 ± 4.7), who were informed about the objectives of the study and signed a written consent to participate voluntarily in measurements. The study was approved by the Health and Human Sciences Ethics Committee of the University of Patras (Protocol number: HSK/PG/UH/00011).

Participants were asked not to consume beverages or perform intense physical exercise one hour before the beginning of the experiment to maintain their physical condition during the sessions. To receive treatment, the participants were asked to lie in a prone position by placing a cylindrical cushion under the ankle. The length of the posterior part of the femur was calculated in each participant by measuring the distance from the gluteal fold to the medial area of the popliteal region, and the mean of the distance was marked. After this point was spotted, a 10×20 prefabricated rectangle (which had four other holes on its four vertices) was placed on it to provide a standard thermal assessment of five points to all participants. The superficial skin temperature of the posterior femur at the dominant lower limb was recorded at these five points. The same measurements of the surface temperature using the same methodology were performed on the non-dominant lower limb (not the treated limb) which served as the control. The temperature measurement at these five points was performed every minute until the surface temperature reached pre-treatment levels.

Participants received four treatments (one intervention per week) which included a) Indiba Activ (IA) radiofrequency treatment, b) Indiba Fascia (IF), c) Indiba ACTIV placebo (IAP) and d) Indiba Fascia Placebo (IFP), thus forming four separate treatment groups. The order of attendance was randomised using a computer-generated randomisation chart and blinded from the participant.

The IA radiofrequency therapy was delivered using an Indiba Activ 802 device (Indiba S.A., Barcelona, Spain), which functions at a frequency of 448 kHz. Indiba Activ 802 equipment delivers RF energy in two modes: capacitive (CAP) and resistive (RES), the intensities of which are given as percent output. The CAP electrode has a polyamide coating that acts as a dielectric medium, insulating its metal body from the skin surface and forming a condenser with the treated tissue while the RES electrode is uncoated and passes RF energy directly through the body. Treatment IA was performed by applying the CAP mode for five minutes and the RES mode for 10 minutes to the hamstrings muscle group of the participants.

For the implementation of IF therapy, specific fascial electrodes–tools (Indiba Fascia Tools) were attached to the same equipment, allowing a combination of therapy by (a) hamstrings soft tissue mobilisation based on specialised techniques and manipulations proposed by the company and (b) of the treatment via the radio frequency 448 kHz. The duration of the IF treatment was also 15 minutes in total.

The IAS scale was used in both IA and IF therapy to determine the intensity of the thermal stimulus to be applied to each participant per intervention (Heat tolerance differs from person to person). IAS is a scale ranging from 1 (minimum heat sensation) to 10 (maximum heat sensation) proposed by the manufacturer to act as a communication channel between the therapist and the patient. IA treatment was delivered at the level VAS 8 (hyperthermia), which had to remain stable throughout the treatment procedure with continuous radiofrequency intensity adaptation, based on participants' reports. A manufacturer-supplied conductive cream was used as a coupling medium between the electrode and the skin surface.

The IAP and the IFP treatment procedures were performed in the same way as IA and IF, respectively, but without activating the radiofrequency device (with the machine virtually inactive) to ascertain the effect of manual friction by excluding the impact of radio frequencies at 448 kHz on the posterior thigh surface skin temperature. The measurement of the surface temperature of the posterior thigh was performed using a wireless infrared thermometer (Thermofocus 01500A3). This surface thermometer has a measurement accuracy of $\pm 0.3^{\circ}\text{C}$ between 20.0–42.5 $^{\circ}\text{C}$, with an accuracy of $\pm 0.2^{\circ}\text{C}$ between 36–39 $^{\circ}\text{C}$.

The temperature was recorded at the five aforementioned evaluation points a) before the application of the treatments, b) after the 15' application and c) every minute until the surface temperature subsided in pre-treatment levels. The temperature measurement at the untreated lower limb was done every five minutes. All measurements were performed at the Human Evaluation and Rehabilitation Laboratory of the Physiotherapy Department of the University of Patras, where the ambient temperature was kept constant at 25 $^{\circ}\text{C}$ during the experiment.

The applications in all therapies (IA, IF, IAP, IFP) were conducted using a digital metronome (48 BPM). In IA and IAP treatments, the procedure was applied with an eight-point motion, covering all five pre-fixed points. IF and IFP treatment was applied with linear (wave) and semi-circular (razor) strokes, as suggested by the Ergon IASTM Technique⁷, at a 60° angle of application, ensuring that the tool passed through the pre-fixed points at the same speed and frequency.

Differences in pre-treatment temperature values were evaluated by Friedman's non-parametric test (separately at both lower limbs) for all four treatment intervention groups. The absolute temperature difference between the post- and pre-intervention measurements was transformed to a percentage change for better representation of the study findings. The same statistical test (Friedman's non-parametric test) was utilised to evaluate the effect of the four treatment interventions (IF, IA, IFP, IAP), on skin thermal adaptations due to non-compliance with the normality test, in combination with the small sample size (N=10). Post-hoc controls used the Dunn-Bonferroni method. The same procedure, regarding the effect on temperature change, was followed for both the treated and non-treated lower limb to exclude other effects outside the intervention. Furthermore, the Monte Carlo method (simulation technique) with a desired confidence interval of 99% and 10,000 samples was applied in all non-parametric tests to increase the accuracy of the results.

By satisfying the normality condition, Repeated Measures ANOVA (RMA) test was used for the comparative evaluation of the effect of four various treatment interventions on the retention time of the increased temperature at the treated lower limb. For the statistical analysis of the data, the statistical software SPSS-25 was used. Statistical significances were tested at the $p=0.05$ probability

RESULTS

Table 1 presents the average posterior thigh skin temperature data before and after the treatment interventions, the percentage change in the mean temperature after the 15 min treatment and the duration of elevated temperature (in minutes) for the treated side.

Friedman's non-parametric test did not reveal a significant statistical difference in skin temperature before the interventions in all four treatment groups for both the treated ($\chi^2(3)=2.28$, $p=0.52$) and non-treated side ($\chi^2(3)=1.30$, $p=0.73$). The same result was obtained by the simulation method for both the treated ($p=0.55$, Lower Bound 99% CI=0.54, Upper Bound 99% CI=0.56) and non-treated side ($p=0.75$, Lower Bound 99% CI=0.74, Upper Bound 99% CI=0.76). A statistically significant difference in posterior thigh skin temperature variations after the 15 min treatment was revealed between the disparate interventions at the treated lower limb ($\chi^2(3)=18.398$, $p=0.0005$) but not for the non-treated one ($\chi^2(3)=2.19$, $p=0.53$). The same result was obtained by the simulation method for the treated ($p=0.0005$, Lower Bound (99% CI)=0.0005, Upper Bound

Table 1. Descriptive data of the average posterior thigh skin temperatures before and after treatment interventions

		Temperature ($^{\circ}\text{C}$)	Temperature ($^{\circ}\text{C}$)	% variation of	Duration of elevated
		before treatment	15 min after treatment	temperature	temperature (min)
		Mean	Mean	Mean	Mean
Treated side	Indiba fascia	36.0	39.7	+10.6	164.2
	Indiba activ	36.0	39.9	+10.7	54.8
	Indiba fascia placebo	35.6	35.7	+0.04	23.7
	Indiba activ placebo	35.5	34.9	-1.8	17.6
Non-treated side	Indiba fascia	35.5	35.4	-0.3	-
	Indiba activ	35.6	35.5	-0.1	-
	Indiba fascia placebo	35.6	41.7	+0.2	-
	Indiba activ placebo	35.4	35.3	-0.4	-

The percentage change in the mean temperature after the 15 min treatment and the duration of elevated temperature (in minutes) for the treated side.

(99% CI)=0.0005) and non-treated side ($p=0.55$, Lower Bound (99% CI)=0.54, Upper Bound (99% CI)=0.56).

Post-hoc tests using the Dunn method and the Bonferroni correction for peer-to-peer comparisons between intervention groups showed significant statistical differences between the effects of IAP and those of IA and IF interventions. In particular, the 15-minute therapeutic application of IAP caused an average decrease in the posterior thigh's skin temperature by 1.8%, while the IA and IF interventions led to a significant increase of 10.7% ($p=0.002$) and 10.6% ($p=0.003$), respectively. There were no significant distinctions ($p>0.05$) in skin temperature increase between the IA and IF treatment interventions.

Friedman's test did not reveal a statistically significant difference in temperature variation between the interventions ($\chi^2(3)=2.19$, $p=0.53$) at the non-treated lower limb. The same result was obtained by the simulation method ($p=0.55$, Lower Bound (99% CI)=0.538, Upper Bound (99% CI)=0.56).

Post-hoc analysis, using the Bonferroni correction, showed significant variations between the mean values of measurements for the duration of the retention of the variable temperature in all other pairwise combinations, except the pair IFP and IAP ($p=0.15$). The IF therapeutic intervention led to significantly higher retention of the posterior thigh skin temperature compared with all other therapeutic interventions. More specifically, IF led to an average elevated temperature of 164.2 minutes compared to 54.8 minutes ($p=0.00$) of IA, 23.17 of IFP ($p=0.00$) and 17.6 minutes of IAP ($p=0.00$). The retention time of elevated skin temperature from the application of IA was also significantly higher ($p=0.00$) than that of the interventions IAP and IFP.

DISCUSSION

Radiofrequency treatment constitutes a modern therapeutic approach to the rehabilitation of musculoskeletal disorders. All of these therapeutic modalities, ranging from classical massage, treatment of myofascial trigger points, transverse friction and active release techniques to novel myofascial release techniques with hands or IASTM tools, have been associated with improvements in patient functionality, mainly in terms of the peripheral joint range of motion. To our knowledge, this is the first study to evaluate the posterior thigh's thermal skin responses (thermal build-up, decay, retention) to 448-kHz radiofrequency-based therapy applied either in standard application form (Indiba[®]Activ) or combined soft tissue treatment (Indiba[®]Fascia treatment).

The first significant finding of this study is that the application of 448 kHz radiofrequency-based therapy is itself capable of inducing significant gains in the posterior thigh's superficial skin temperature. This type of radiofrequency-based therapy for 15 minutes either in the classic form of light treatment of the electrodes or in the combination of myofascial application therapy led to a significant increase in skin temperature compared to placebo applications that evaluated the effect of friction and myofascial mobilisation of soft tissues without the application of radiofrequencies. In particular, the 15-minute therapeutic application of Indiba Fascia Placebo caused an average increase in the posterior thigh skin temperature by +0.04%, while the Indiba Activ and Indiba Fascia interventions led to a significant increase of 10.7% and 10.6%, respectively. These findings are in full agreement with the results of Kumaran et al.⁽⁶⁾, who reported that 448 kHz radiofrequency-based therapy applied with typical electrode and sliding of the tools can significantly increase quadriceps' skin temperature. The above results reinforce earlier findings of increased skin temperature from exposure to RF (predominantly shortwave frequencies) treatments. The findings of temperature increases from the combination of radiofrequency and musculoskeletal techniques with specialised tools cannot be compared or confirmed by corresponding research findings, as there is no such research to date.

The second, most innovative finding of this study is the application of 448 kHz radiofrequency-based therapy with soft tissue treatment besides significantly increasing skin temperature after 15 minutes of therapeutic application preserved it for a particularly long time after the end of treatment. More specifically, the Indiba Fascia procedure led to a significant increase in the surface temperature of the skin which was maintained for over 164 minutes, compared with Indiba Activ treatment that sustained elevated skin temperature for 55 minutes after the end of treatment. This latest finding agrees with Watson and Kumaran's results reporting a corresponding 45-minute retention time of elevated quadriceps skin temperature after IA treatment at 448 kHz⁽⁶⁾. The superiority of this combined application highlights the therapeutic value of soft-tissue mobilisation at the level of skin temperature's physiological adaptations. Furthermore, based on the finding that the application of myofascial therapy without the use of RF treatment at 448 kHz resulted in an increase in skin temperature that was maintained for 23 minutes after treatment, it appears that the combined application of RF treatment with myofascial techniques and strokes doubles the therapeutic effect in relation to the individual application of the above procedures. These findings, although important and innovative, cannot be confirmed or questioned regarding their validity, as there is no corresponding research to date based on the fact that the equipment and techniques used and evaluated in the present study are innovative.

Final results regarding the posterior thigh thermal skin responses (thermal buildup, decay, retention) to 448-kHz radiofrequency-based therapy applied either in the form of standard application (Indiba[®]Activ) or combined soft tissue treatment cannot be deduced from this research under the weight of its limitations. The most important limitation of the present study is the relatively low number of participants. To counteract this limitation, the Monte Carlo method (simulation technique) with a desired confidence interval of 99% and 10,000 samples was applied in all non-parametric tests to increase the accuracy of results. The fact that the participants of this study were young people also makes it difficult to apply these conclusions to older people, whose soft tissues and fascia have altered mechanical properties, such as increased thickness and stiffness.

Despite its limitations, the clinical value of the findings of this research is particularly important. In particular, the findings

of this study are important in the clinical setting based on the documented effects of thermotherapy at both the rehabilitation and prevention of musculoskeletal injuries and pathologies. The retention of elevated skin temperature for such a long time after the end of treatment especially reflects the significant physiological adaptations created in the deeper tissues and reflects the increased blood supply caused by induced internal vasodilation. In addition, other important effects one might assume accompanies these adaptations, as they are associated with elevated local temperature, are increased temperature, lymphatic/venous drainage and tissue elasticity. Elevated temperature can increase oxygen uptake and accelerate tissue healing, and thermotherapy also has a softening effect, thus increasing the extensibility of collagen tissues, decreasing muscle spasms and accelerating the absorption of hematomas. In addition, heat therapy triggers a decrease in pain, especially in painful syndromes, by inhibiting the pain signal and exerting pressure on the back muscles.

In conclusion, radiofrequency treatment at 448 kHz applied with or without specific IASTM tools (Indiba Fascia Treatment) is itself capable of inducing significant gains in the posterior thigh's superficial skin temperature. Impressively, the application of the 448 kHz radiofrequency-based therapy in combination with specific soft tissue treatment led to a significant increase in the surface temperature of the skin which was maintained for over 164 minutes compared with IA treatment that sustained elevated skin temperature for 55 minutes after the end of treatment. The above adaptations can be explained by the combined therapeutic effect of both manual applications and friction on the skin of the tools as well as of the hyperthermal treatment and endogenous heat production and retention from the radiofrequency treatment at 448 kHz. In any case, more research is needed to support such innovative findings that can significantly modify the treatment strategies of preventing and rehabilitating musculoskeletal pathologies and injuries.

Conflict of interest

None.

REFERENCES

- 1) Watson T, editor: Electrotherapy E-Book: evidence-based practice. Elsevier Health Sciences, 2008.
- 2) Kumaran B, Watson T: Treatment using 448kHz capacitive resistive monopolar radiofrequency improves pain and function in patients with osteoarthritis of the knee joint: a randomised controlled trial. *Physiotherapy*, 2019, 105: 98–107. [[Medline](#)] [[CrossRef](#)]
- 3) Yokota Y, Tashiro Y, Suzuki Y, et al.: Effect of capacitive and resistive electric transfer on tissue temperature, muscle flexibility and blood circulation. *J Nov Physiother*, 2017, 7: 1–7. [[CrossRef](#)]
- 4) Stasinopoulos D: The effectiveness of 448 kHz capacitive resistive monopoles radiofrequency in acute lateral elbow tendinopathy: a case report. *Ann Clin Case Rep*, 2019, 4: 1613.
- 5) Takahashi K, Suyama T, Onodera M, et al.: Clinical effects of capacitive electric transfer hyperthermia therapy for lumbago. *J Phys Ther Sci*, 1999, 11: 45–51. [[CrossRef](#)]
- 6) Kumaran B, Watson T: Thermal build-up, decay and retention responses to local therapeutic application of 448kHz capacitive resistive monopolar radiofrequency: a prospective randomised crossover study in healthy adults. *Int J Hyperthermia*, 2015, 31: 883–895. [[Medline](#)] [[CrossRef](#)]
- 7) Fousekis K, Eid K, Tafa E, et al.: Can the application of the Ergon® IASTM treatment on remote parts of the superficial back myofascial line be equally effective with the local application for the improvement of the hamstrings' flexibility? A randomized control study. *J Phys Ther Sci*, 2019, 31: 508–511. [[Medline](#)] [[CrossRef](#)]