THE THERMAL SAFETY OF HIGH POWERED CLASS IV LASER ON FEMALE LATERO-POSTERIOR THIGHS: ANALYSIS WITH INFRA-RED THERMOGRAPHY

Larissa Gomes dos Santos[1]
Osvaldo Soares de Araújo Júnior[2]
Luara Alves Faria[3]
Paulo Ricardo França[4]
Patrícia Sardinha Leonardo[5]
Alberto Souza de Sá Filho[6]
Rodrigo Alvaro B. Lopes Martins[7]

SUMMARY

Introduction: Photobiomodulation using Class 3B lasers has been used to treat esthetic and muscle-skeletal conditions for decades. Recently, High Powered Lasers (Class IV) have also been introduced to treat esthetic problems, it has raised reasonable criticism regarding safety and possible increases in skin temperature. The aim of the present study was to evaluate possible skin temperature changes after irradiatiation using Infra-red thermography. **Methods:** Twenty-five female and four male participants were enrolled in the study. After, skin temperature profiles of both side of the flanks were recorded using infra-red thermography before and 1,5 and 10 min after photobioodulation with a High Powered Class IV Laser with total energy of 1464 Joules (14.6 J/Cm2). **Results:** No significant changes in skin temperature were produced after laser irradiation with both probes in both groups of female and male participants. **Conclusions:** We conclude that Class IV Laser when applied in scanning mode to the male and female hip regions did not induce any temperature changes immediately after irradiation or after 1, 5 or 10 minutes. In the energy doses used in this protocol, the high-powered Class IV Laser was considered completely safe to use for treatment.

Keywords: Phtobiomodulation; class IV laser; thermography; laser therapy.

1,2,3,4,5,6,7 E-mail contato: larigomessantos@hotmail.com - Evangelical University of Goiás – UNIEVANGÉLICA

Introduction

Photobiomodulation Therapy (PBMT) using low-power lasers and LEDs has been used for over thirty years to treat various diseases, particularly those with a significant inflammatory component, such as musculoskeletal and central nervous system disorders. Its applications include conditions like tendonitis, osteoarthritis, chronic low back pain, cervical pain, cellulite, traumatic brain injury, psoriasis, and others [1-5].

Recently, with advancements in photobiomodulation technology, high-powered lasers (Class IV) have also been used to treat pain and inflammatory conditions. New treatment protocols combining different wavelengths and pulse rates have been introduced in clinical practice for treating inflammatory diseases [6-9]. However, the use of high-powered Class IV lasers for therapeutic purposes has raised valid concerns about safety and the potential for increasing skin temperature. The key challenge has been proving that, despite using high-powered lasers, variations in pulse rate and the applicator's spot size can achieve a therapeutic effect with low light intensity while still allowing tissue penetration. With the development of infrared thermal technology, this is now possible. Infrared thermography represents an important non-invasive tool capable of providing real-time, in-vivo evaluations of local skin temperature.

In 2022, Lopes-Martins et al. [10] demonstrated that infrared thermography is a valuable tool for cellulite diagnosis. The main advantages of thermography are its speed of data collection, real-time image interpretation and safety.

MATERIAL AND METHODS

This study was approved by the Ethical Committee (Register number 19708719.3.0000.5503). After receiving authorization from the Ethics and Research Committee and obtaining consent through the Free and Informed Consent Form (ICF), the proposed protocol was initiated.

This clinical trial is quantitative and exploratory, utilizing a Class IV high-powered therapeutic laser (Summus Medical Laser) operating at four sequential wavelengths in six steps. Twenty female and four male participants were enrolled. Female participants with gynoid lipodystrophy (cellulite) in the flanks and who met the inclusion criteria

were selected, while male participants served as negative controls for gynoid lipodystrophy.

All participants were Caucasian females with phototypes I to V. A Gynoid Lipodystrophy Assessment Protocol was applied, covering aspects such as clinical history, physical examination, and lipodystrophy classification.

Laser Irradiation

Upon arrival, volunteers acclimated for 15 minutes before treatment with the P4 Class IV Laser, which utilized two probe emitters (4.9 and 19.6 cm^2) and four wavelengths (650, 810, 915, and 980 nm) at a maximum power of 25W. The laser, applied in six steps, delivered 1464 Joules over 100 cm^2 with a scanning mode and a velocity of 1 cm/sec.

Participants had a Body Mass Index (BMI ≤ 29.9 kg/m^2), exhibited "orange peel" skin on the thighs (LDG grades 2 or 3 according to the Curri scale), had regular menstrual cycles (26-30 days), used the same oral contraceptive for at least three months, maintained a stable weight for at least three months (less than 2.0 kg variation), were sedentary, and did not use cosmetics affecting local circulation. Exclusion criteria included pathology or injury at the lateral hip, possible or confirmed pregnancy, metallic prosthesis near the irradiation site, menopause, recent surgery in the area of laser application, and use of NSAIDs, corticosteroids, or antibiotics during the period. Table 01 demonstrates the laser irradiation parameters used in this study.

Table 01: The laser irradiation parameters considering 100 cm2 of skin area in a matrix of 10 X 10 cm2

Step	Wavelength (nm)	Irradiation Time (seconds)	Average Power (W)	Frequency (Hz)	Area (Cm2)
1	650	60	0.2	500	100
2	810	60	6	500	100
3	915	60	6	500	100
4	980	60	6	500	100
5	650	60	0.2	500	100
6	810	60	6	500	100

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Thermographic Image Acquisition

Image acquisition was performed with the S65 camera (FLIR system, Sweden). The Camera has a measurement range of -20 ° C to 120 ° C, accurate to 1%, sensitivity of 0.05 ° C, infrared spectral band of 7.5 and 13 µm, refresh rate of 60 Hz and autofocus.

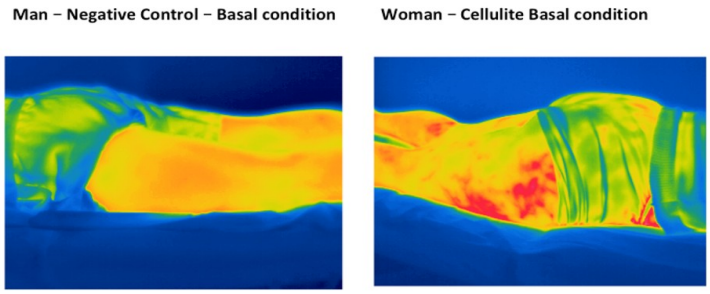
Statistical Analysis

For repeatability, the mean and mean error were expressed in proportion to the mean for each thermal parameter and for each measurement. The ANOVA test was used to compare results between each measure.

RESULTS

The Female Group consisted of 20 participants and the anthropometric data as well as cellulite classification can be observed in Table 02. Figure 01 demonstrate infra-red images of male and female volunteers in basal conditions.

Figure 01: Typical Infra-red thermography showing the differences between male and female in basal conditions



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Temperature changes after laser irradiation

The hip temperature was monitored beforeand after laser irradiation in 3 different times, in order to evaluate possible temperature changes directly induced by the equipment or as a consequence of vasodilatation. Two different probes were used with 25 and 50 mm diameter. The Table 02 shows the absolute changes on the surface hip temperature after laser irradiation using the 25 and 50 mm probes in scanning mode.

Table 02: Average Temperature in Celsius Degrees

	Basal	**1 Min**	**5 Min**	**10 Min**
Female 25 mm	27.77 + 1.75	28.48 + 1.74	28.08 + 1.65	28.01 + 1.76
Female 50 mm	27.32 + 1.7	28.02 + 1.6	27.7 + 1.6	27.66 + 1.55
Male 25 mm	28.65 + 0.4	29.1 + 0.6	28.7 + 0.5	28.45 + 0.5
Male 50 mm	28.5 + 0.2	28.85 + 0.2	28.45 + 0.3	28.05 + 0.3

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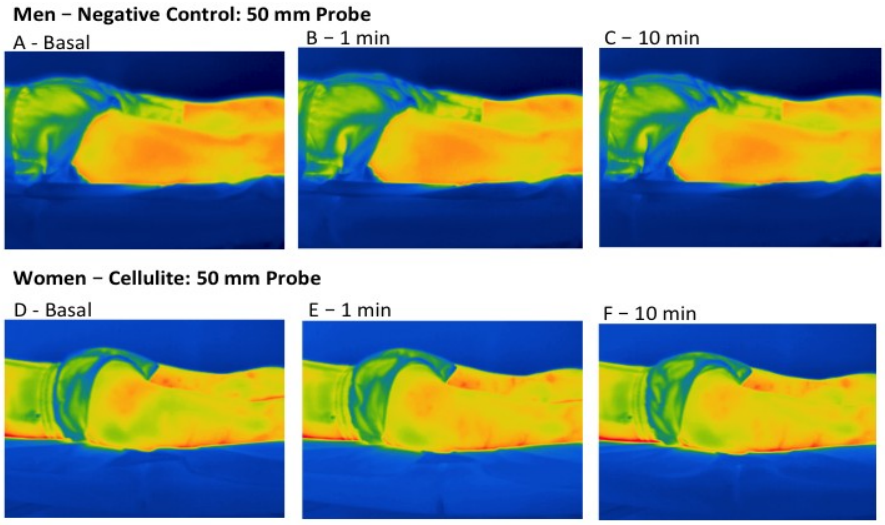
The temperature of the hips was monitored by infra-red thermography in the participants. Figure 02 illustrates the effects of laser irradiation on male and female skin.

Figure 02: Typical Infra-red thermography of the effects of Laser irradiation on male and female skin in Basal conditions and 1 and 10 min after laser irradiation



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CONCLUSIONS

Our present study is the first to investigate thermal effects of Class IV lasers with the technology of Infra-red thermography. We conclude that Class IV Laser when applied in scanning mode to the hip regions did not induce any temperature changes immediately after irradiation or after 1, 5 or 10 minutes. In the energy doses used in this protocol, the high-powered Class IV Laser was considered completely safe to use for treatment.

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