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Calibration of low-level laser therapy equipment*

Aferição dos equipamentos de laser de baixa intensidade

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Abstract

Background: Despite the increase in the use of low-level laser therapy (LLLT), there is still a lack of consensus in the literature regarding how often the equipment must be calibrated. **Objective:** To evaluate the real average power of LLLT devices in the Greater São Paulo area. **Methods:** For the evaluation, a LaserCheck power meter designed to calibrate continuous equipment was used. The power meter was programmed with data related to the laser's wavelength to gauge the real average power being emitted. The LLLT devices were evaluated in two ways: first with the device cooled down and then with the device warmed up for 10 minutes. For each condition, three tests were performed. The laser probe was aligned with the power meter, which provided the real average power being emitted by the LLLT device. All of the data and information related to the laser application were collected with the use of a questionnaire filled in by the supervising therapists. **Results:** The 60 devices evaluated showed deficit in real average power in the cooled-down and warmed-up condition. The statistical analysis (ANOVA) showed a significant decrease ($p<0.05$) in the real average power measured in relation to the manufacturer's average power. On average, the most common dose in the clinics was 4 J/cm^2, and the most desired effects were healing and anti-inflammatory effects. According to the World Association for Laser Therapy (WALT), 1 to 4 J of final energy are necessary to achieve these effects, however only one device was able to reach the recommended therapeutic window. **Conclusion:** The LLLT devices showed a deficit in real average power that emphasized a lack of order in the application of this tool. The present study also showed the need for periodical calibration of LLLT equipment and a better technical knowledge of the therapists involved.

Key words: low-level laser therapy; gauging; calibration.

Resumo

Contextualização: A laserterapia de baixa intensidade (LBI) vem sendo cada vez mais utilizada, porém ainda não há consenso na literatura quanto ao tempo em que os equipamentos devem ser submetidos à aferição ou calibragem. **Objetivo**: Analisar a potência média real (PmR) dos equipamentos de LBI na região da Grande São Paulo. **Métodos:** Para análise dos equipamentos, utilizou-se um potenciômetro (Lasercheck), próprio para aferição de equipamentos contínuos, o qual foi programado com dados referentes ao comprimento de onda do laser a ser avaliado, obtendo-se assim a PmR emitida. Os equipamentos foram analisados de duas formas: uma, com o LBI desaquecido, e outra, após 10 minutos de uso (aquecido), sendo que três análises foram feitas para cada condição. A caneta emissora foi acoplada ao potenciômetro, o qual fornecia a PmR emitida pelo LBI. Todos os dados e informações referentes à aplicação do laser foram coletados por um questionário respondido pelos responsáveis. **Resultados:** Os 60 equipamentos avaliados mostraram déficit na PmR com os equipamentos desaquecidos e aquecidos. A análise estatística (ANOVA) mostrou diminuição significativa ($P<0,05$) da PmR aferida em relação à potência média do fabricante (PmF). Em média, a dose mais empregada nas clínicas foi de 4 J/cm^2, tendo os efeitos de cicatrização e anti-inflamatório como os mais desejados. Segundo a *World Association for Laser Therapy* (WALT), para atingir esse efeito, necessita-se de 1 a 4 J de energia final, sendo que apenas um dos 60 aparelhos conseguiria atingir a janela terapêutica preconizada. **Conclusão:** Os equipamentos de LBI apresentam um déficit acentuado na PmR, o que mostra uma desordem na utilização desse recurso. Neste estudo, observou-se a necessidade de aferição periódica dos aparelhos de LBI bem como melhor conhecimento técnico dos profissionais envolvidos.

Palavras-chave: terapia laser de baixa intensidade; aferição; calibragem.

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Introduction

Low-level laser therapy (LLLT) has been investigated and used clinically for over 30 years, which justifies the increasing interest in the effects of laser and the significant amount of scientific publications in the literature[1-3]. Therefore, LLLT equipment users should have knowledge of physical and biochemical principles to make better use of its resources. LLLT devices can have pulsed or continuous emission and the wavelengths most commonly used range from 630 nm to 1300 nm, thus including visible and invisible (infrared) light spectra[1].

According to in vitro studies, the effects of light activate mechanisms of cellular metabolic control. Such mechanisms involve acceleration of the electron transport chain, increase in the synthesis of adenosine triphosphate (ATP) and decrease in intracellular pH. These reactions form the basis of the effects of LLLT[4-6].

Laboratory studies, conducted mostly in animals, show strong evidence that LLLT has the ability to modulate inflammatory processes and relieve acute pain conditions triggered by lesions in soft tissues. This activity may occur through the decrease in nerve conduction, release of endogenous opioids, increase in angiogenesis and, consequently, increase in local microcirculation[7,8]. It may also have inhibitory effects on the release of prostaglandins, cytokine levels, and cyclooxygenase (Cox2), and it may accelerate cell proliferation, collagen synthesis and tissue repair[9,10]. However, several topics still need to be clarified and standardized for a safe and effective use. Some of these topics concern the type of LLLT, wavelength and dose, which may change the desired effect during the use of this equipment[1].

According to Fukuda and Malfatti[11], many therapists and researchers have based their choice of laser dose on energy density or fluence (ΔE), but the wide variety of LLLT equipment may lead to differences in therapeutic results because the parameters vary according to manufacturer. This poses another problem in relation to the clinical reproducibility of the research, because when the same values are used in different equipments, there are differences in the total energy emitted to the tissue.

Other important aspects in the variability of clinical outcomes and in the quality of the proposed treatments are the electrotechnical failures of LLLT equipment, as well as the amount of energy being delivered to the tissue. There is still little concern among therapists and manufacturers about the frequency with which the equipment needs to be calibrated[12-14]. Thus the aim of the present study was to analyze the real average power (RAP) of LLLT devices and therapeutic doses applied during the use of this tool in clinics, physical therapy practices, universities, outpatient units, and hospitals in the Greater São Paulo area.

Methods

Survey of LLLT equipment

This was a calibration study of LLLT equipment used in clinics, physical therapy practices, universities, outpatient units, and hospitals with physical therapy service in the Greater São Paulo area. Initially, 261 locations were found through healthcare directories, Internet search engines and personal knowledge. All locations were contacted by phone or personal visit. Only 140 had LLLT equipment, and 52 of them could not be evaluated because the supervising therapist did not allow access or because the equipment was being repaired.

At the 88 establishments where the tests were performed, there were 127 devices, 60 of which were selected for evaluation as they were continuous-wave devices. They were divided into seven brands (six national and one imported) with 11 different models. Thirteen devices had red laser (eight with 660nm wavelength and five with 670nm) and 47 infrared (ten with 808nm wavelength, 26 with 830nm, and 11 with 850nm; Figure 1).

The study included LLLT devices in perfect condition, with a minimum of three months of use within the scope of physical therapy.

Questionnaire

For the data collection, we designed a questionnaire to be filled in before the evaluation with information about the equipment, such as brand, model, laser color, manufacturer average power (MAP), and wavelength. We also included questions about the device's main operator, such as main desired therapeutic effect, dose used to achieve this effect[15], information about their knowledge of the need of calibration, and whether the device had undergone maintenance and calibration. Information was collected from the user manuals, and when these were not available, we contacted the respective companies by telephone and/or email.

Procedures

Before the data collection, a consent form was given to the therapists responsible for the equipment to inform them

of the absence of physical hazards to the equipment, physical and emotional stress, or expenses to the therapists. The RAP was gauged with a power meter (Lasercheck, Coherent, USA) calibrated by the manufacturer prior to the study and with ±5% accuracy. The power meter has a full wavelength range between 400 and 1064nm, and it is intended for the evaluation of continuous emission equipment. This tool has a protective lens used for equipment with a MAP above 10 mW. Below this level, the protective lens remained open according to manufacturer instructions.

As a standard, all devices were evaluated in two ways: first, immediately after being switched on (cooled-down condition), then after 10 minutes of use (warmed-up condition). There were three tests with the warmed-up device and three with the cooled-down device, after which the mean for each condition was calculated. The lens of the laser probe was cleaned with disposable gauze and a swab moistened in hydrated ethyl alcohol, and the evaluation was performed in a room with the lowest possible lighting to avoid interference.

To begin the evaluation, the dose was set in two ways as each device has a different form of emission (energy density and final energy). It must be noted, however, that this difference did not interfere with data collection because the evaluated parameter was the device's RAP compared to the MAP. Thus, after performing the pilot project, the standard dose of 4 J or 4 J/cm^2 was set depending on each device's form of emission.

Next, the power meter was set to the device's wavelength, and the laser probe was aligned at a 90° angle. The laser beam was fired and the power meter was turned on simultaneously, which provided the RAP emitted by the LLLT device (Figure 2). These RAP values were also within the standards of the Brazilian National Standards Association (Associação Brasileira de Normas Técnicas [ABNT]), which allows an output variation of up to 20%[12-14].

Pilot project

A prior study was conducted to standardize the dose to be gauged on all devices. Different doses of energy were tested (2, 4 and 6 J) on the same LLLT device with MAP equal to 100mW and 808nm wavelength. After data analysis, no significant difference was found in the MAP gauged in the described doses (p=0.2). Therefore, to gauge the RAP, the standard energy dose was set to 4 J or 4 J/cm^2 because it allows a radiant exposure time compatible with the performance of the entire gauging procedure. With this selected dose, the analysis would not exceed 15 minutes, thus avoiding

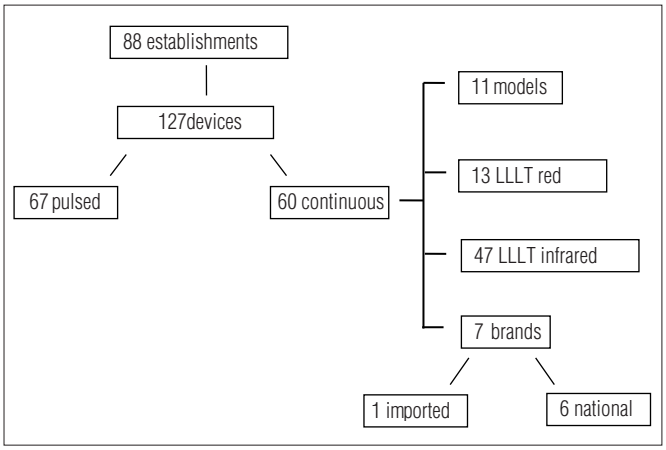


Figure 1. Diagram with the model of the study in relation to the survey of the equipments.

Figure 2. Simulation of the analysis of a LLLT equipment and the consequent gauging of the real average power by the power meter.

inconvenience to the therapists. To compare both evaluators, we included statistical analyses performed by means of the t-test for independent samples (p=0.80) and the intraclass correlation coefficient (ICC=0.81). According to the results, both evaluators were considered to be appropriately trained to perform the measurement.

Data analysis

To better understand and employ the analysis, the devices were divided into four groups according to the time of use: group 1, 3 months to 2.5 years (n=18); group 2, 2.5 to 5 years (n=12); group 3, 5 to 7.5 years (n=10); and group 4, 7.5 to 10 years (n=20). After data collection, the statistical software GraphPad InStat was used for processing. First, the Kolmogorov-Smirnov (K-S) test was performed to verify

data normality, with a significance level of 5%. We chose a non-parametric test for analysis of variance (ANOVA) with Friedman's post-test to compare MAP, RAP (warmed-up) and RAP (cooled-down).

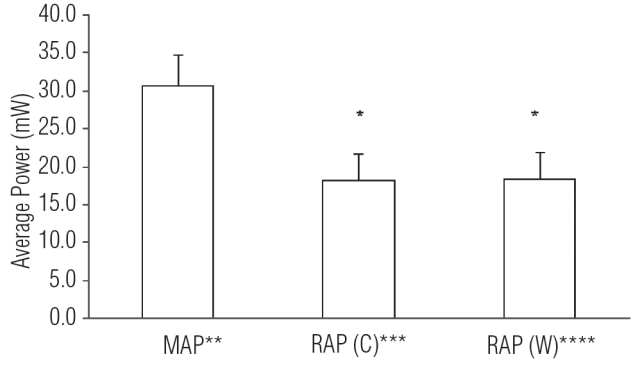
Results

The average MAP was 30.7 mW, the RAP of the cooled-down devices was 18.1 mW, and the RAP of the warmed-up devices was 18.3 mW. The correlation between RAP and MAP, including all cooled-down devices, was extremely significant ($p<0.001$). The same happened when comparing MAP and RAP with the warmed-up devices ($p<0.001$; Figure 3). The percentage of RAP deficit in relation to MAP with the cooled-down devices was 64.3%, and 63.7% with the warmed-up devices (Table 1).

The analysis results showed that among the 60 evaluated devices, only eight were within the standards set by the ABNT[12,14], therefore, 52 devices had RAP outside the standard range. The analyses according to time of use showed the following average deficits: group 1, 34.73%; group 2, 65%; group 3, 68.40%; and group 4, 90.70%. The ΔE most commonly used by the therapists was 4 J/cm^2 per point, and the most desired therapeutic effects were healing and anti-inflammatory effects.

It must be noted that, among the 18 devices in group 1, only two had undergone maintenance, and six were within ABNT standards. The questionnaire filled in by the therapists showed that 16 of them used the dose in ΔE and two used total energy, but none of the devices reached the desired therapeutic window. Of the 12 devices in group 2, only six had undergone maintenance, and only one was within ABNT standards. All therapists used the dose in ΔE, and none of the devices reached the therapeutic window.

Among the ten devices in group 3, seven had undergone maintenance, but none were within ABNT standards. As noted in the previous group, all therapists used the dose in ΔE, and none of the devices reached the therapeutic window. For group 4, only ten of the 20 devices had undergone maintenance, and one was within ABNT standards; the dose was in ΔE, and only one device reached the desired therapeutic window (Table 2). It is worth noting that the distribution into four groups was only used to analyze the data from the questionnaire; it was not maintained, therefore, for gauging the RAP.



* Significant difference in relation to the MAP; ** Manufacturer average power; *** Real average power with cooled-down equipment; **** Real average power with warmed-up equipment.

Figure 3. Average power (average±SEM) of devices for the three evaluated conditions.

Discussion

The present study aimed to show the actual condition of LLLT equipment used in clinics and physical therapy practices in the Greater São Paulo area, finding a lack of order in the use and maintenance of this therapeutic resource. The evidence shows that the devices are not within the standards of inspection agencies. The therapists also lack technical knowledge in choosing the ideal dose, type of laser and methods to achieve the real desired therapeutic effect.

After prolonged use, LLLT devices are prone to degradation of the laser radiation structure, which decreases the power of radiation emitted by the devices[16]. Therefore, annual calibration should be conducted in accordance with the specifications found in the manuals provided by manufacturers

Table 1. Results of the evaluations performed in the three conditions.

N	Type		MAP [a]	RAP [b]	RAP [b]	Deficit	Deficit
	R *	I.R. **	(mW)	(mW) C+	(mW) W++	C+ (%)	W++ (%)
60	13	47	30.7 (±4)	18.1 (±3.6)	18.3 (±3.6)	64.3 (±4.6)	63.7 (±4.6)

* Red; ** infrared; [a] manufacturer average power; [b] real average power; + cooled-down; ++ warmed-up.

Table 2. Information of the data contained in the questionnaire, distributing the equipments in four groups.

Groups	Time of Use	n	ABNT	Therapeutic Window (WALT)
Group 1	3 mo.-2.5 yrs	18	6 within standards	18 did not reach
Group 2	2.5-5 yrs	12	1 within standards	12 did not reach
Group 3	5-7.5 yrs	10	0 within standards	10 did not reach
Group 4	7.5-10 yrs	20	1 within standards	1 reached / 19 did not reach

in order to achieve a truly functional application of this therapeutic method. Considering that electrical devices used by therapists may be mishandled over the years, it is very difficult to predict when and how the faults will occur, or even how to prevent them[12-14]. The analysis conducted in the present study shows the reality of LLLT equipment and highlights the fact that the minority of the analyzed devices had undergone calibration, further compromising the quality and effectiveness of treatment.

ABNT regulations NBR IEC 601-2-22 and IEC 60825-1 and ABNT Technical Report 60825-8 IEC recommend a variation no greater than ±20% in relation to the output power of the manufacturer[12-14], however the present study found that only eight of the 60 evaluated LLLT devices were within this standard. The evaluation of the MAP in relation to the RAP found a difference of 64%, reflecting the lack of order in the use of this tool. These findings explain why only one device reached the therapeutic window recommended by the World Association for Laser Therapy (WALT)[15].

Regarding the application method, the vast majority of therapists used the dose based on ΔE. Of the 60 devices, only two provided the direct calculation of the final energy as a parameter, but due to their deficit in RAP, they failed to reach the desired therapeutic window. One device reached the treatment threshold as it was the only one that applied a high ΔE and the only one within ABNT standards, leading to the real desired therapeutic effect.

In a study that conducted comparative simulations between national LLLT devices, the authors concluded that ΔE does not seem to be the parameter that best describes the dose to be used, as it can vary from device to device given that its parameters will be different when compared to other brands and LLLT models[11]. This fact corroborates the results of the present analysis. Furthermore, it was observed that, even in devices with high RAP and within ABNT standards, it would not be possible to reach the recommended therapeutic window due to the therapist's lack of knowledge regarding the desired dose. In the present study, the therapists based their dose on ΔE only, and the main value was 4 J/cm^2, aiming to achieve anti-inflammatory and healing effects. According to the WALT, 1 to 4 J of final energy are needed to achieve these effects, thus the therapists would need to use a higher ΔE[15].

This can be seen in the evaluation of two randomized controlled trials. The first trial applied LLLT in patients with osteoarthritis of the hand, with standard dose in ΔE equal to 3 J/cm^2. The results obtained in the study showed no significant differences between groups, indicating that the ΔE may have been too low, not reaching the therapeutic window[15,17]. The second trial was conducted in patients with low back pain, divided into three groups: the first received LLLT combined with exercises; the second received LLLT only; and the third performed exercises only. According to the dose parameters provided in this trial, the parameters established by the WALT were met as were the therapeutic effects desired by the researchers. Thus, the two groups that received LLLT showed a significant difference in pain level when compared to the group that performed exercises only[15,18].

The current lack of standardization in the calibration of devices used in physical therapy also includes therapeutic ultrasound (TUS). The results showed an excessively long period between calibrations, thus interfering in the therapeutic effect of the device. Some studies point to the need for periodic calibration of TUS devices[19,20]. This emphasizes the importance of conducting periodical checks on the devices, giving the therapist a resource with greater reliability and reproducibility. It has also been stated that scientific research should follow the same path, i.e., calibrate equipment prior to a study[19-21].

The analysis of these studies and their results leads us to believe that, to make better and more efficient use of the beneficial effects of LLLT, it is extremely important that the average power of the device be within ABNT standards and that the physical therapist be able to dose the applied energy correctly[12-15]. Therefore, there is a need for annual or even biannual calibration of LLLT devices, investments in quality improvement by manufacturers, and more technical knowledge for therapists who use these devices.

A limitation of the present study was that only laser devices with continuous emission were evaluated, as the power meter used was specific to continuous emission. For future studies, we propose that the devices be calibrated again to analyze a possible change in the current scenario and the inclusion of devices with pulsed emission.

Conclusion

LLLT devices used in clinics, physical therapy practices and hospitals located in the greater São Paulo area showed a marked deficit in average power, which shows a lack of order in the clinical use of this tool. Moreover, many of the devices were not within ABNT standards, and the applications may not be reaching the recommended therapeutic window, showing the need for periodic calibration.

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