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Calibration and Maintenance of Low Power Laser Devices: Descriptive Study

Calibración y mantenimiento de aparatos de láser de baja potencia: estudio descriptivo

Calibragem e manutenção de dispositivos laser de baixa potência: estudo descritivo

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Abstract: Introduction: The low-power laser is a technique used in several areas of health: physiotherapy, dentistry, otorhinolaryngology and dermatology, among others. To achieve therapeutic effects, the dosage is essential and depends on the energy levels emitted by the device. Objective: To know the status of calibration and maintenance of low power laser therapy devices, in physiotherapy services or counterparts of institutions in Montevideo - Uruguay. Method: A descriptive, cross-sectional study was conducted in physiotherapy services in Montevideo, Uruguay. 20 low-power laser devices were analyzed. Results: 7 of the devices evaluated remained within the appropriate emission limits. Of the 13 lasers outside the limits to deliver adequate emission, 6 had a slight mismatch, 1 had a moderate mismatch, and 6 presented a severe mismatch. Among the total devices evaluated, only 6 had performed a previous calibration and only 2 of these were within the recommended times frames. Conclusion: A large number of low-power laser devices with imbalances in their emission was observed. In most cases, low-power laser devices are not properly maintained. Equipment should be timely calibrated in order to offer safe and effective therapy to users.

Keywords: low-level light therapy; calibration; biomedical technology assessment.

Resumen: Introducción: El láser de baja potencia es una técnica utilizada en varias áreas de la salud: fisioterapia, odontología, otorrinolaringología y dermatología entre otras. Para lograr los efectos terapéuticos la dosificación es fundamental y depende de los niveles de energía emitidos por los equipos. Objetivo: conocer el estado de calibración y mantenimiento de los equipos de laserterapia de baja potencia, en servicios de fisioterapia u homólogos de instituciones de Montevideo – Uruguay. Método: se realizó un estudio descriptivo, transversal en servicios de fisioterapia de Montevideo - Uruguay. Se analizaron 20 equipos de láser de baja potencia. Resultados: 7 de los aparatos evaluados se mantuvieron dentro de los límites adecuados de emisión. De los 13 láser fuera de los límites para entregar una emisión adecuada, 6 tenían un desajuste leve, 1 presentaba un desajuste moderado y 6 presentaban un desajuste severo con dosis nulas o que no generaban emisión. Del total de equipos evaluados sólo 6 habían realizado una calibración previa y sólo 2 de estos, se encontraban dentro de los tiempos recomendados. Conclusión: se observó un gran número

de equipos de láser de baja potencia con desajustes en su emisión. En la mayoría de los casos no se lleva un correcto mantenimiento de los aparatos de láser de baja potencia. Se entiende relevante que los equipos sean calibrados para poder ofrecer una terapéutica segura y efectiva a los usuarios.

Palabras claves: terapia por luz de baja intensidad; calibración; evaluación de la tecnología biomédica.

Resumo: Introdução: O laser de baixa potência é uma técnica utilizada em diversas áreas da saúde: fisioterapia, odontologia, otorrinolaringologia, dermatologia, dentre outras. Para obter efeitos terapêuticos, a dosagem é essencial e depende dos níveis de energia emitidos pelo equipamento. Objetivo: conhecer o estado de calibração e manutenção de equipamentos de laserterapia de baixa potência, em serviços de fisioterapia ou congêneres de instituições em Montevideu - Uruguai. Método: estudo descritivo, transversal, realizado em serviços de fisioterapia em Montevideo, Uruguai. 20 equipamentos de laser de baixa potência foram analisados. Resultados: 7 dos aparelhos avaliados permaneceram dentro dos limites de emissão adequados. Dos 13 lasers fora dos limites para entregar a emissão adequada, 6 tiveram uma leve incompatibilidade, 1 teve uma incompatibilidade moderada e 6 apresentaram uma incompatibilidade grave. Do total de equipamentos avaliados, apenas 6 haviam realizado uma calibragem prévia e apenas 2 destes estavam dentro do prazo recomendado (1 ano). Conclusão: observou-se um grande número de equipamentos de laser de baixa potência com desequilíbrios em sua emissão. Na maioria dos casos, os dispositivos a laser de baixa potência não recebem manutenção adequada. Acredita-se importante que os equipamentos sejam calibrados para oferecer uma terapia segura e eficaz aos usuários.

Palavras-chave: terapia com luz de baixa intensidade; calibragem; avaliação da tecnologia biomédica.

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Introduction

Low-power laser is a technique used in several health areas, such as physiotherapy, [1] dentistry, [2] otorhinolaryngology, [3, 4] and dermatology, among others. [5] Basically, it is the emission of photons with defined characteristics. The best known are monochromaticity, coherence, and collimation, which allow the generation of a light beam with a defined wavelength, with its parallel photons and in phase. Depending on the medium used for their generation, different emission parameters can be obtained. Laser light therapy takes part in Europe in the 1960s and continues to develop until today. [6] It has applicability for multiple

dysfunctions and pathologies, being analgesic effects, [1, 7, 8] anti-inflammatory [9, 10] healing of different tissues such as skin and nervous tissue, [11, 12] and prevention of muscle damage and fatigue, [13-15] the most recognized.

According to the international organization World Association for Laser Therapy (WALT), the dosage depends on the total energy (E) in each application, per point or in the sum of several points expressed in Joules (J). In 2010, it issued its revised recommendations following these concepts since, before that year, it was proposed as a way of dosing the energy density (DE) as the main parameter expressed in J over square centimeters (J/cm2). [16, 17]

By having several ways of expressing its dose, this technique generates confusion, and clinical trials and laboratory studies differ in nomenclature, reaching conclusions that can be misinterpreted. It has been recommended to unify criteria and continue improving the information provided in the methodology of the studies carried out. [1, 18, 19]

For the dose to be calculated correctly, it is necessary to know the output power (P) of the device in continuous lasers, or the average power (Pm) in pulsed lasers, and the time that it remains active. After obtaining the data from the device, the different parameters can be manipulated to arrive at the dose required for each case. Applicators generally have a single, unvarying P, and the DE or emission time (TE) can be modified to deliver more or less energy. The TE, expressed in seconds (s) is obtained by dividing the E, by the P expressed in Watts (W). [6]

The regional background that was published comes entirely from Brazil, being a reference, about research in the area of photobiomodulation. Along these lines, in 2007 Bertolini et al. published a work in which the authors studied the aspects of safety, maintenance and compliance with international standards, in addition to the power emitted by 31 low-power laser equipment in the city of Paraná, Brazil, finding that almost 39 % remained within the appropriate emission values. [20]

A study carried out by Fukuda and collaborators was focused on measuring the Pm of laser equipment used in institutions in São Paulo, Brazil. They also collected information regarding the time of use of the equipment, the most used doses and whether they received maintenance. The results showed that of the 60 low-power laser equipment evaluated, only 8 were within the limits allowed by the national standards of that country.

This range is set to +/- 20 % of the P or Pm reported by the manufacturer. Most of the equipment that was within the parameters had less than two and a half years of use (6 of the 8 equipment with correct emission parameters). [21] In the study by Gelain et al., the authors focused on the output power, also taking note of all the safety components that the equipment should have, such as warning labels, eye protection, manuals, important information such as laser parameters, etc. None of the places evaluated complied 100 % with the safety requirements, and of 9 teams measured, 4 were within the recommended parameters. [22] Another study with similar characteristics was the one published by Yoshida and collaborators, where it was found that only 1 equipment out of 9 evaluated, contemplated all the safety requirements, and only 2 were within the recommended emission parameters. [23]

According to the information presented above, it is common for institutions to use equipment in poor operating conditions, being a serious problem since treatments focused on restoring the function of users who trust in health institutions to recover from various dysfunctions are proposed. Therefore, it is important to know the state of calibration and maintenance of low-power laser therapy equipment, in physiotherapy services or counterparts of institutions in Montevideo, Uruguay.

Material and Methods

A descriptive and cross-sectional study was carried out in physiotherapy services in Montevideo, Uruguay. Sampling was for convenience. 20 low-power laser equipment were analyzed within 15 private services in the city of Montevideo. All equipment was in use at the time of data collection, between the months of March and August 2020.

The data referring to the maintenance guidelines were collected through an interview with the person in charge of the equipment and transferred to a spreadsheet.

The real average power (Pmr) was measured with a Lasercheck model potentiometer of USA origin of the Coherent brand, which allows the selection of the wavelength, and records the emission in milliWatts (mW). [24] Three measurements are made 30 seconds apart to reduce handling errors and the highest value [21] is taken. Calibration is understood as the action of measuring and comparing with known references. In this case, the Pmr is measured and compared with the P or Pm that the manufacturers declare in their technical manuals.

Prior to data collection, the person responsible for the team signed an informed consent explaining the confidentiality criteria of the data obtained.

Results

Of the total number of devices (*n*=20) that participated in the study, 11 had a mean power reported by the manufacturer of 100 mW, 1 of 54 mW, 2 of 40 mW, 3 of 30 mW, 1 of 15 mW, and 2 of 10 mW. In terms of wavelength, 16 devices were 904 nanometers (nm), 3 830 nm, and 1 905 nm. It was observed that all the equipment remained within the infrared emission spectrum. 7 teams had a low frequency of use, 8 moderate, and 5 intense, at the time of data collection. Regarding the time of use, 16 had a time greater than 2 years, and 4 a time of use less than 2 years.

Table 1. Distribution of equipment according to the average power granted by the manufacturer and the wavelength

	Wavelength (nm)			
Medium power (mW)	**830 nm**	**904 nm**	**905 nm**	**TOTAL**
100		11		11
54		1		1
40		2		2
30	3			3
15			1	1
10		2		2
TOTAL	3	16	1	20

Source: Own elaboration (2022)

Table 2. Distribution of equipment according to time and level of use

	Use time		
Level of use	**> 2 years**	**< 2 years**	**TOTAL**
Low	5	2	7
Moderate	7	1	8
Intense	4	1	5
TOTAL	16	4	20

Source: Own elaboration (2022)

Table 3. Distribution of equipment according to calibration prior to this study and the time corresponding to it

	Time since last calibration			
Previous calibration	**Never calibrated**	**> 1 year**	**< 1 year**	**TOTAL**
Yes	0	4	2	6
No	14	0	0	14
TOTAL	14	4	2	20

Source: Own elaboration (2022)

Tabla 4. Equipment distribution according to the calibrated Pmr, whether or not it is within the permitted range (+/- 20 %) and the severity of the mismatch (between 50 and 80% = slight mismatch, between 5 mw and 50% = moderate, and less than 5mw = severe)

	Severity of mismatch				
Calibrated emission	**No mismatch**	**Slight**	**Moderate**	**Severe**	**TOTAL**
Out of the allowed range	0	6	1	6	13
Within the allowed range	7	0	0	0	7
TOTAL	7	6	1	6	20

Source: Own elaboration (2022)

Discussion

All the equipment that was included in the study was within the infrared spectrum because it involved wavelengths longer than 730 nm. This is defined by the type of laser generator, using a diode made up of semiconductor materials, to which an electric current is administered and subsequent generation of photons. By not including any equipment within the visible spectrum, which is generally obtained through the stimulation of a mixture of gases, helium, and neon (He-Ne) being the most used, [25] it was not possible to identify whether or not they present, greater wear with the different variables consulted.

The results referring to the emission of the calibrated Pmr coincided with the values stated in the background, with between 11 % and 39 % of devices being within the permitted Pmr ranges. [20, 21, 22, 23] In this study, it was observed that 7 of 20 devices evaluated remained within the appropriate emission limits. Of the 13 lasers outside the limits to deliver adequate emission, 6 had a slight mismatch, where Pmr levels remained between 50 % and 80 % of the P expressed by the manufacturers, 1 had a moderate mismatch between 50 % and 5mW and 6 presented a severe mismatch with null doses (less than 5 mW) [25] or that did not generate emission. Of the total equipment evaluated, only 6 had performed a previous calibration and only 2 of these were within the recommended times, being less than 1 year. [26, 27]

The present work reflects a situation that involves different actors such as health professionals, users who receive treatment, institutions that manage physiotherapy services, companies that sell calibration services. It also entails the responsibility of the professional training institutions that play a fundamental role from early education in the correct use and maintenance that the different therapeutic modalities need. These findings are consistent with studies carried out in South America, and to which is added the lack of awareness about the use of protective equipment for professionals. [23]

This study may be the beginning to propose other investigations, detect the main causes of the problem, and be able to modify them to achieve adequate management of this clinical resource in the different physiotherapy services in the country. The lines of work that could be projected are aimed at adequate training both in undergraduate studies and for professionals who are already working in the clinical field. Likewise, managers of physiotherapy services and centers, technical services of institutions and calibration companies would benefit from training in this regard. Due to the lack of policies aimed at monitoring quality standards in this area, it may be interesting to start proposing standards and processes that guarantee the correct state of the equipment, as well as its maintenance.

Those responsible for the equipment studied did not know what type of calibration was being performed. They did not know, for example, that there is an indirect method of measuring the voltage that reaches the diode, which allows mathematically deducing that P should emit the same. But in this method the wear suffered by the materials that make up the laser diode is not considered. Therefore, it is necessary to observe the calibration method used by the different technical services of the companies that provide the calibration and adjustment of low power therapeutic laser devices to know if the measurements can be correlated.

Among the limitations, the small sample included is considered, since to observe differences between the groups within and outside the recommended range they were very heterogeneous. All the institutions that participated in the study specialized in the care of people with dysfunctions of the musculoskeletal system, preferring longer wavelengths, which limits the absorption of energy in deeper tissues. [28] However, low-power lasers are used as the only treatment or as a complement to others, aimed at seeking local biological effects, having an analgesic, anti-inflammatory, and healing action. [29, 30] In this sense, services focused on skin treatment, dentistry and aesthetics could be included for future studies, to observe the behavior of equipment with this type of wavelength.

Conclusions

A large number of low-power laser devices were observed to have emission imbalances, and very few devices met manufacturers' recommended maintenance guidelines. It is concluded that it is relevant that the equipment be calibrated in a timely manner, to be able to offer safe and effective therapy to users. It is also believed that it is the responsibility of the institutions to carry out adequate maintenance and revisions to their equipment. Other future research should focus on detecting the causes of the current problem and being able to implement preventive strategies, possibly through education. Likewise, more research would be beneficial to generate supplies and manage policies that guarantee the quality of the equipment used in the clinical setting.

Despite the small sample, the subject is of scientific and ethical interest, since the safety and efficacy of a widely used therapeutic tool is at stake. In addition, there is incomplete scientific evidence and lack of consensus in the literature regarding the use of low-power laser therapy, both in dosage according to the different devices and pathologies to be treated. Likewise, there is a lack of consensus on the frequency of calibration and maintenance, so it is important to generate discussion in this regard.

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E. B. has contributed in a, b, c, d, e; M. d. C. F. in a, d, e.

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