

PROTOTYPE DEVELOPMENT OF A PROTOCOL FOR LOW INTENSITY LASER AS TREATMENT FOR INJURIES

DESARROLLO DE UN PROTOTIPO DE PROTOCOLO LÁSER DE BAJA INTENSIDAD PARA EL TRATAMIENTO DE HERIDAS

DESENVOLVIMENTO DE UM PROTÓTIPO DE PROTOCOLO DE LASER DE BAIXA INTENSIDADE PARA TRATAMENTO DE FERIDAS

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ABSTRACT

Objective: To develop the prototype of a protocol regarding low intensity laser as treatment for lesions caused by pressure or diabetes related ulcers. **Methodology:** A methodological study involving literature review based on the literature of the Latin-American and the Caribbean in Health Sciences database (LILACS) and the Nursing Database (BDENF), through the Health Virtual Library (BVS); Medical Literature Analysis and Retrieval System Online (MEDLINE) through PubMed; Web of Science; Cumulative Index of Nursing and Allied Health (CINAHL) and, EMBASE, optimized by filtering the search by utilizing a time scale limited between 2016 a 2022. **Results:** The prototype was developed, with 29 actions to be executed: 10 actions before procedure, 9 actions during procedure and, 10 actions afterwards. **Final considerations:** This study enabled the prototype's development, so the use of low intensity laser becomes a manner of more consistent and safe care, ensuring the bettering of assistance practices done by professionals.

Keywords: Low-intensity Light Therapy; Scaring; Diabetic Foot, Lesion caused by pressure, Clinical Protocols.

RESUMEN

Objetivo: Desarrollar un prototipo de protocolo láser de baja intensidad para el tratamiento de lesiones por presión y úlceras diabéticas. **Método:** Estudio metodológico que involucró revisión de literatura en las bases de datos de literatura latinoamericana y caribeña en Ciencias de la Salud (LILACS) y Base de Datos de Enfermería (BDENF), por la Biblioteca Virtual en Salud (BVS); Medical Literature Analysis and Retrieval System Online (MEDLINE) a través de PubMed; Web of Science; Cumulative Index of Nursing and Allied Health (CINAHL) y EMBASE, utilizando el filtro de búsqueda de tiempo de 2016 a 2022. **Resultados:** El prototipo de protocolo fue desarrollado con 29 acciones a realizar: 10 acciones antes del procedimiento, 9 acciones durante el procedimiento y 10 acciones después del procedimiento. **Consideraciones finales:** El estudio permitió la creación de un protocolo prototipo para el uso del láser de baja intensidad para una atención más consistente, segura y que asegure la mejora de las prácticas de cuidado de los profesionales.

Palabras clave: Terapia de luz de Baja Intensidad; Cicatrización; Pie Diabético, Lesión por Presión, Protocolos Clínicos.

RESUMO

Objetivo: Desenvolver um protótipo de um protocolo de *laser* de baixa intensidade para tratamento de lesões por pressão e úlceras diabéticas. **Método:** Estudo metodológico envolvendo revisão de literatura nas bases Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS) e Base de Dados de Enfermagem (BDENF), pela Biblioteca Virtual em Saúde (BVS); *Medical Literature Analysis and Retrieval System Online* (MEDLINE) através da PubMed; *Web of Science*; *Cumulative Index of Nursing and Allied Health* (CINAHL) e EMBASE, com a utilização do filtro de busca temporal de 2016 a 2022. **Resultados:** Desenvolveu-se o protótipo de protocolo com 29 ações a serem executadas: 10 ações antes do procedimento, 9 ações durante o procedimento e 10 ações após o procedimento. **Considerações finais:** O estudo possibilitou a criação de um protótipo de protocolo de uso de *laser* de baixa intensidade para um cuidado mais consistente, seguro e que a garanta a melhoria das práticas assistenciais dos profissionais.

Palavras-chave: Terapia com Luz de Baixa Intensidade; Cicatrização; Pé Diabético, Lesão por Pressão, Protocolos Clínicos.

INTRODUCTION

The World Health Organization defines that a patient's safety, considered to be constant and intimately related to the patient's service, has as its goal to reduce risks of unnecessary damage to a acceptable minimum⁽¹⁾.

The error incidence that occurred through health related practices of assistance caused hospital institutions to implement protocols, aiming to promote safe care, as to reduce the occurrence of possible adverse events throughout the caring processes⁽²⁻³⁾.

Protocols are tools containing specifications and operational details about various makings in the Nursing field (i.e. what is done, who does it and, how is it done). Those should be developed within the principles of evidence-based practice so they can bring safety to users and professionals⁽⁴⁾.

Under this perspective, the protocols for technology incorporation to assistance practices have been highlighted in the literature as a strategy to provide safer and more efficient care, which favors the standardization of practices which would prevent imperfect, negligent or imprudent care⁽⁵⁻⁶⁾. Therefore, the development of such patterns of operationalization regarding health care technology is justified by the incessant will to make such practices systematic.

Low intensity laser (LIL) is an incorporated technology to a nurse's assistance practices, regulated since 2018 by the Nursing Federal Council⁽⁷⁾. Despite promising results

regarding the use of LIL in the treatment of diverse wound types, studies still present disparate parameters related to the lack of protocol⁽⁸⁾. That being said, thorough investigation is necessary regarding the effect of LIL on the human tissue, along with the most effective parameters for wound treatment.

In essence, this article has as its goal to develop the prototype of a protocol regarding the use of LIL in the treatment of lesions caused by pressure and diabetes related ulcers.

METHODOLOGY

This is an applied study in the modality of technology production and literature research, accomplished through the Federal University of the state of Rio de Janeiro's master program.

A protocol's prototype was developed after integrative literature review, which followed the Theory of Mendes, Silveira and Galvão as reference, to insure that the following stages would be completed: identifying a theme and selecting research hypotheses or questions, establishing criteria of inclusion and exclusion, defining what information is to be extracted from the selected studies, evaluating studies to be included in the review, interpreting results and, presenting the synthesized knowledge gathered.

The research was made based on data gathered from the Latin-American and the Caribbean in Health Sciences database (LILACS), the Nursing Database (BDENF), Medical Literature Analysis and Retrieval

System Online (MEDLINE) through PubMed, Web of Science, Cumulative Index of Nursing and Allied Health (CINAHL) and EMBASE. The criteria of inclusion used for the selection of the articles were published in Portuguese, Spanish and English, and conveyed care related themes and the use of LIL in the treatment of lesions caused by pressure and diabetes related ulcers, which examined care or clinical protocols regarding the use of laser therapy in wounds, available online, in the period between 2016 and 2022.

The following data was excluded: editorials; letters; studies involving animals or exclusively *in vitro* data (i.e., with no wounds' irradiation in alive patients); studies which did not offer data regarding dosimetry and other used parameters and, the ones involving the treatment of wounds of different etiologies other than lesions caused by pressure or diabetes related ulcers. Furthermore, studies involving High Intensity laser and light-emitting diode (LED) were also excluded. Reviews which analyzed randomized trials developed in animals or *in vitro* were considered suitable for this paper.

The following platforms were used in order to find key words: Descriptor in Health Science (DeCS), Medical Subject Headings (MeSH) and independent database CINAHL:

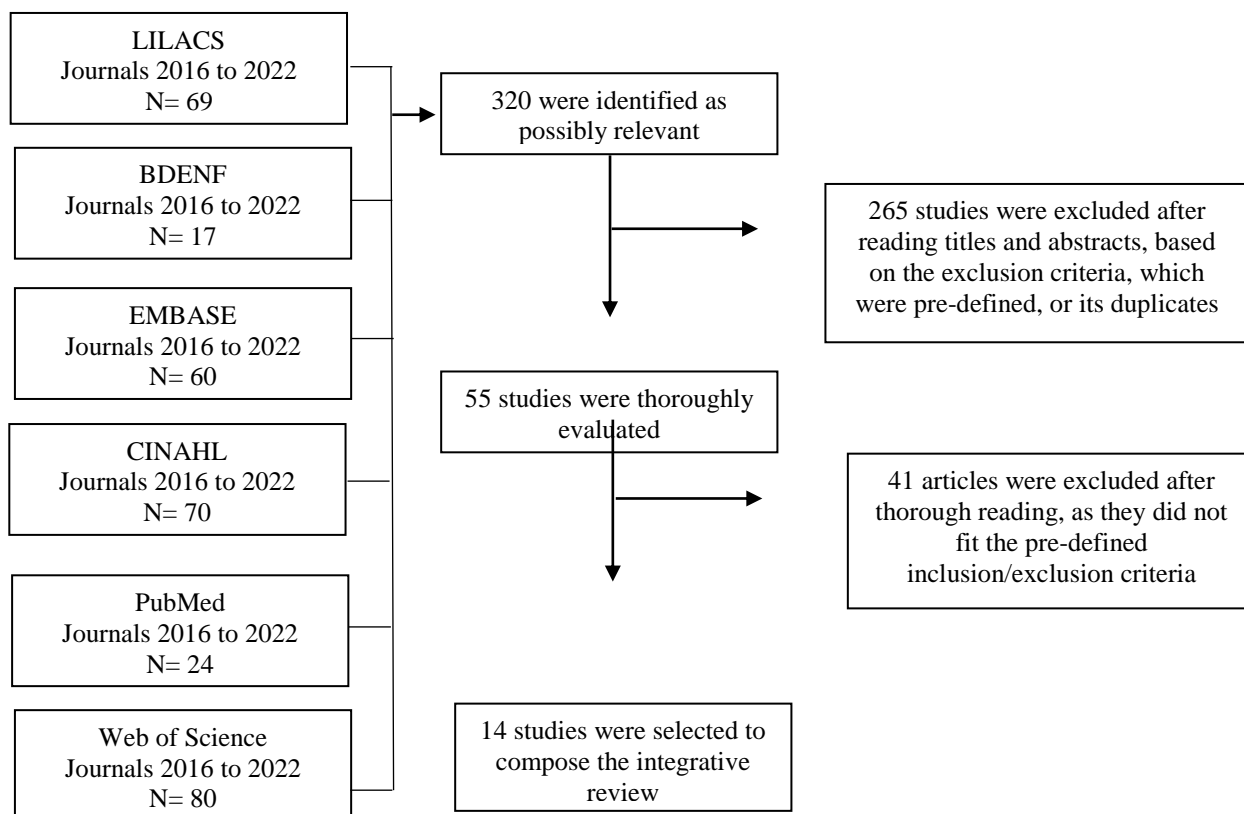
low level light therapy OR LLLT OR laser biostimulation OR laser therapy OR photobiomodulation therapy AND wounds and injuries OR wound healing OR diabetic foot OR pressure ulcer. The key words search was adapted to the specifications of each platform.

After defining the studies' sample for the development of the assistance protocol, a thorough and comprehensive reading of the material was conducted in order to extract the necessary information to develop the protocol's prototype.

RESULTS

Initially, the database search resulted in 320 references, which were submitted to evaluation based on the inclusion and exclusion criteria. On this first analysis, based on the reading of titles and abstracts, 55 articles were selected.

Following the reading of the articles in its integrity, the articles that did not fit the inclusion criteria were excluded, as well as its duplicates. Hence, for analysis and discussion, 14 articles were used to compose this review. Image 1 shows the selection of the articles in each database platform.

Figure 1 – Flowchart of research strategy

Following critical analysis and thorough reading of the selected studies, the composition of the protocol's prototyped ensued.

On first consideration, two protocols were to be developed: a protocol of LIL to treat lesions caused by pressure and another for the treatment of diabetic related ulcers. Nevertheless, in the literature, the recommended dosimetry for both etiologies were practically the same, which enabled the development of a single protocol instead of one for each etiology.

However, during the data analysis of integrative review, a huge discrepancy was observed in the used parameters by different authors. Moreover, the majority of the studies did not contain all the necessary data of dosimetry in order to develop a protocol, or

presented dubious information, especially regarding energy's density, or applied energy. These common methodological flaws in various studies prevented the development of a protocol, and consequentially, a prototype to be validated in a later time was developed. Such prototype was developed through a randomized clinical trial and by specialists.

The following general and specific objectives for the protocol's prototype were:

General: Proving parameters related to the use of LIL in the treatment of lesions caused by pressure and diabetic ulcers.

Specific:

1. Ensuring the correct application of LIL, contributing to the acceleration of wounds' scaring process;

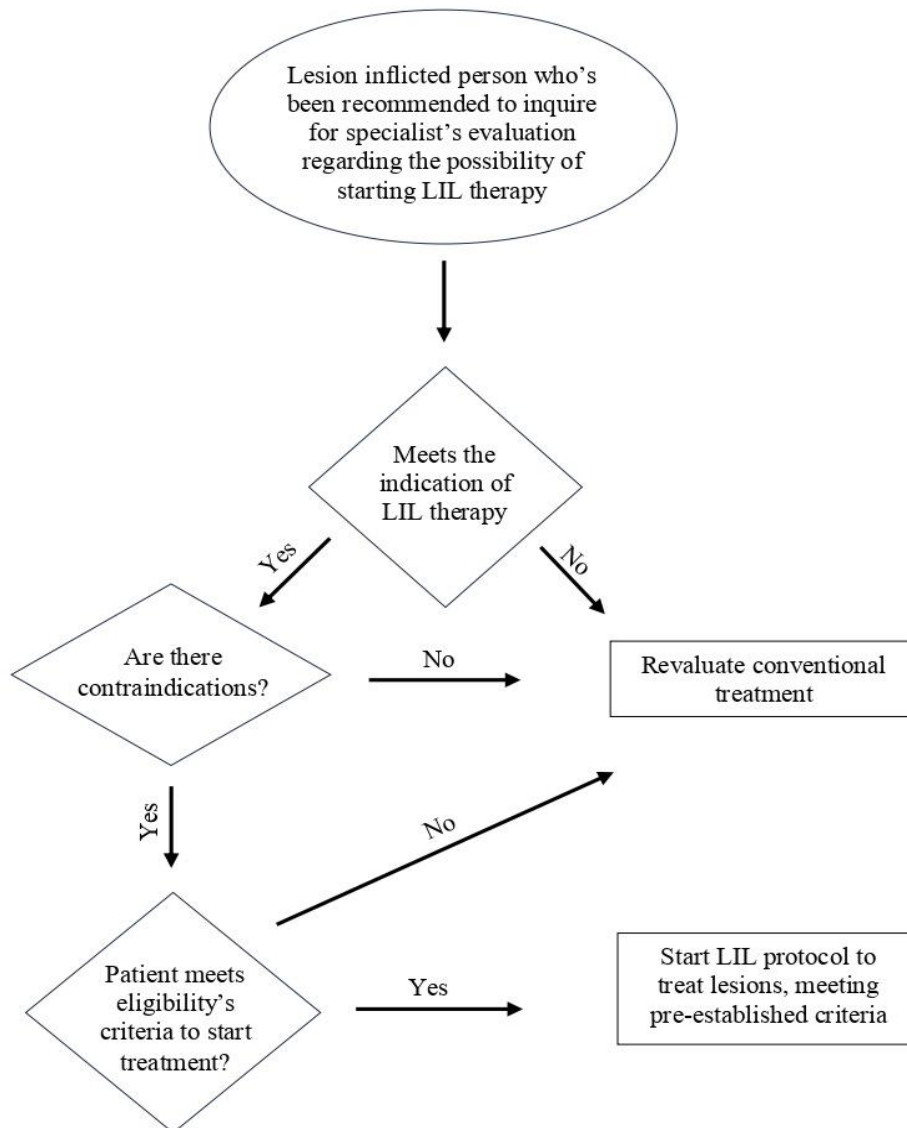
2. Offering a safe “therapeutic window” in the treatment of lesions caused by pressure and diabetic related ulcers with LIL as an accessorial therapy method;
3. Providing subsidies to enable the incorporation of this technology by the National Committee of Technology Incorporation in the Sistema Único de Saúde* (CONITEC); *Brazilian Public Health System.

4. Favor and instrumentalize, in a systematic manner, nursing assistance to patients affected by lesions caused by pressure or diabetic ulcers.

Nurses trained in LIL technique will be able to use the protocol.

The recommendations for this protocol’s prototype apply to all adult hospitalized patients or patients in ambulatories, and who match the eligibility criteria in the flowchart, showed in image 2.

Figure 2 – Flowchart to eligibility for LIL treatment



This eligibility flowchart for the use of LIL in the treatment of lesions caused by pressure and diabetic related ulcers was made to help nurses trained in LIL therapy to recommend or advise against the use of this technology and to establish the necessary criteria applied to patients who are recommended to pursue this therapy.

The detailing of the flowchart is described below:

Team's Assignments

- General Nurse or Auxiliary Physician: evaluate skin lesion and request a specialist's opinion to the Dressing Committee, and delegate to a nurse who is specialized and trained in LIL;
- LIL trained and specialized nurse: evaluate skin lesion and recommend patient for LIL therapy according to the specifications of the flowchart.

Recommendations of LIL

- Patients inflicted by chronic lesions with visible skin tissue;
- Patients inflicted by acute lesions or intense chronic pain;
- Absence of satisfactory therapeutic response after three weeks of conventional therapy;
- Patients inflicted by acute lesions belonging to a risk group, such as obesity, diabetes, circulatory problems and, Braden inflicted bed-ridden patients ≤ 14 .

Counterindication

- Pregnant women;
- Oncological patients;
- Cardiopathic patients with pacemaker or digitalis;
- Glaucoma patients.

Eligibility criteria

- Patients who are recommended to undergo treatment (as described above);
- Persons who express a will to start LIL treatment and who have adhered completely to the proposed treatment;
- Patients and/or family members (in case of patients who are unable to legally make decisions) should be oriented

about the therapy and sign a free and clear understanding consent term (TCLE), that should be archived in the patient's medical record.

Requirements for therapy use

- Specialist's opinion requesting evaluation for starting LIL therapy, recommending treatment, signed and stamped by trained nurse;
- Signed and annexed TCLE to patient's medical record;
- Utilization of protection spectacles in all sessions for both patient and health professional;
- Treatment in an appropriate location, with little people circulation and laser signaling.

It is important to highlight that the protocol's prototype was developed and structured based on three domains, which are characterized by three periods regarding assistance in conducting the procedure: before procedure, during procedure and after procedure. The proposal is constituted by 10 actions to be done before procedure, 9 actions during procedure and 10 afterwards.

Table 1 presents the LIL protocol's prototype proposal for treating lesions caused by pressure and diabetic related ulcers.

Table 1 – Low Intensity Laser Protocol's Prototype in the treatment of lesions caused by pressure and diabetic related ulcers. Rio de Janeiro (RJ), Brazil.

LOW INTENSITY LASER PROTOCOL FOR THE TREATMENT OF LESIONS

CAUSED BY PRESSURE AND DIABETIC RELATED ULCERS – FOR NURSES

Objective: Provide parameters related to LIL, in order to guarantee the correct laser application, as to contribute to the speeding of scaring of lesions caused by pressure and diabetic related ulcers.

Targeted at: Nurses trained in LIL.

Formulation/year: 2022	Review/year: 2022	Evaluation board/year: 2022
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Formulated by: Name of responsible nurse	Review by: Name of responsible nurse	Evaluated by: Name of evaluator
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BEFORE LIL APPLICATION:

- ✓ Explain procedure to patient/family member;
- ✓ Fill Free and Clear Understanding consent term and ask for patient/Family member’s signature;
- ✓ Certify the lack of counterindications, i.e.: pregnant women, oncological patients, medications that unleash photosensitivity to the skin, cardiopathic patients in use of pacemakers or digitalis, glaucoma patients.
- ✓ Gather necessary material: physiological saline solution 0,9%; PHMB solution; sterile gauze; sterile gloves; procedure appropriate gloves; indicated dressing for the lesion; plasters; scissors; measuring tape to measure lesion’s size; camera or mobile phone with a camera for photographic record; LIL device; protection spectacles for patients and professionals;
- ✓ Perform sanitization of hands and using adequate individual protection equipment (gloves, smock, hat, mask);
- ✓ Be in possession of all material on a clean and smooth table or bench;
- ✓ Protect the edge of the laser device with transparent shrink-wreck;
- ✓ Using curtains and signs that signals the use of laser to guarantee that the place is secure regarding the exposure to other people;
- ✓ Place the patient in the most comfortable position for the duration of the procedure;
- ✓ Offering the use of protective spectacle to the patient.

DURING THE PROCEDURE:

- ✓ Remove patient’s bandage;
- ✓ Evaluate characteristics of the wound: surrounding area; edges; the wound itself: state of the wound; secretion, signs of infection, odor;
- ✓ Cleaning the wound with saline solution and PHMB according to the institution’s protocol;



- ✓ Measuring the wound (length and width) and getting photographic record;
- ✓ The procedure must be conducted in a precise manner, by producing continuous emission in contact with the wound (device's edge protected by transparent shrink-wreck). The device must be positioned by making a 90 degrees angle with the wound and the distance between points should be of 1 centimeter;
- ✓ Irradiate firstly the wound's edges and then the wound itself;
- ✓ Apply LIL therapy according to the following parameters: wavelength: 658 – 660 nm, red light spectrum; power: according to the device's availability, which may vary from 30 mW to 100 mW; start with energy's density of 2 J/cm², which could reach up until 6 J/cm²; time of exposure will vary according to the lesion's area and energy applied;
- ✓ Doing the procedure twice or thrice a week (evaluate wound's aspect and size, as well as proposed treatment's response);
- ✓ Ensuring the patient's well-being, and that they have no complaints regarding the procedure.

AFTER THE PROCEDURE:

- ✓ Remove protection spectacles (the patient's and the professional's);
- ✓ Put on sterile glove;
- ✓ Utilize the proper dressing for the wound in treatment;
- ✓ Protecting the adjacent skin to the lesion with a cream/spray barrier;
- ✓ Position the patient comfortably;
- ✓ Remove sterile gloves and put on procedure appropriate gloves;
- ✓ Remove transparent shrink-wreck from the device and sanitize it according the fabricant's instructions;
- ✓ Remove procedure appropriate gloves;
- ✓ Sanitize protection spectacles with water and soap;
- ✓ Add all information related to the procedure and eventual patient's complaints to their medical records.

Subtitles: LIL– Low Intensity Laser; PHMB – Polyhexametileno biguanida.

Source: Elaborated by the authors, 2022.

DISCUSSION

The current diversity in procedures that involve nursing professionals' actuation, in addition to the constant need to organize and

develop safe and interdisciplinary actions, demand the elaboration, divulgation and adoption of tools that would enable

instrumentalizing the auxiliary actions of a health team^(5,10).

Baring this in mind, the development of instruments and protocols for the conduction of actions of care in health have been a very encouraged practice recently. Various authors point out that such protocols are able to improve assistance, favoring scientifically supported practices, minimizing errors and, establishing limits for professional actions⁽¹¹⁾.

The present study contemplates the development of LIL protocol's prototype for the for the treatment of lesions caused by pressure and diabetic ulcers, targeting standardization of care and recommended doses for its use. The decision to develop the LIL prototype for the specified etiologies was based on epidemiological importance of diabetic related ulcers in Brazil and worldwide, and due to the significant incidence of lesions caused by pressure in the state hospitals of Rio de Janeiro. Such frequent incidence was a strong indicator of nursing assistance's quality, which makes its prevention and treatment extremely relevant. Furthermore, the influence of *diabetes mellitus* on the scaring of lesions caused by pressure should be taken into consideration.

This prototype has 29 actions to be executed before, during and after LIL procedure. The steps before application regard preparation of the material to be used and patient's positioning. At this stage, the equipment protection with shrink-wreck and the use of protection spectacles are thoroughly explained

and are imperative for both professional and patient.

Next, the actions to be performed during procedure refer to the procedure's parameters. The integrative review which preceded the development of this prototype showed that, for both etiologies (i.e., lesions caused by pressure and diabetic related ulcers) the described parameters were very similar. The only found difference was the recommended power, which was 10mW for lesions caused by pressure and 30 mW for diabetic related ulcers. Other than that, parameters did not differ. Thus, a single prototype for both etiologies, as opposed to one prototype for each etiology, was initially planned.

Finally, the actions to be performed after procedure include the appropriate choice of dressing, equipment's sanitation, patient's positioning and comfort, and the filling of patient's medical record.

FINAL CONSIDERATIONS

The data obtained from the integrative review were disparate and, many times, lacked fundamental information about used parameters. As to ensure standardization and the possibility of comparison between results, studies should contain the following information: wavelength, energy's density, power, power's density, optical beam's size, type of laser's procedure (continuous or pulsing), application mode (punctual or sweeping), treatment time, pulse's frequency (repetition), number of sessions and

aspect of the treated tissue. Those parameters were found in previous studies. With that being said, researchers should be attentive to methodological strictness, using all parameters cited above, so studies are suitable for comparative analysis.

Thus, this study presents the development of a LIL protocol's prototype for treating lesions caused by pressure and diabetic related ulcers, so to guide nurses trained in laser therapy regarding the best parameters for optimal wound scaring and systematization of care implicated in such practice.

Using this prototype as a base, it would be possible to promote the subsidy for the development of following studies in the future, which should strive to validate a safe and efficient LIL protocol for wound scaring, making sure of its applicability in assisting wound care.

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Author contributions

The authors contributed substantially to the design and/or planning of the study; in obtaining, analyzing and interpreting data, as well as in writing, critical review and final approval.

Declaration of conflict of interest.

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