# 10 – ORIGINAL ARTICLE CLINICAL INVESTIGATION

# Effects of the Low-Level Laser Therapy (LLLT) in the process of healing diabetic foot ulcers<sup>1</sup>

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# ABSTRACT

**PURPOSE:** To evaluate the effects of the low-level laser therapy applying Laser on the tissue repair in ulcer carriers due to diabetes. **METHODS**: Sixteen type II diabetic patients, ulcer carriers in the lower limbs, participated in the research from which eight were in the control group and eight were submitted to the low-level laser therapy with a pulsed wave form, visible ray, wave length of 632.8 nm,

30 mW peak power, (Laser – HTM). The application time was of  $80 \text{ (4J/cm}^2)$  seconds. The application was punctual without contact (approximately 1mm of distance), the pen being held in a perpendicular position related to the wound, in equidistant points. There were 12 appointments, of which three were done weekly in alternated days. Photograph records and an application of the brief inventory of pain were done before and after 30 days of follow-up.

**RESULTS:** There was a significant decrease in the size of the wound when compared to the control group (p<0.05). The pain was also reported as having an intense improvement in the treated group.

**CONCLUSION:** The low-level laser treatment seems to be an efficient method, viable, painless and of low costs concerning the tissue repair ulcers in a diabetic foot.

Key words: Laser Therapy, Low-Level. Diabetic Neuropathies. Diabetic Foot.

# Introduction

One of the most common complications of diabetes is the diabetic foot, characterized by the infection, ulceration and/ or destruction of the deep tissues associated to neurological anomalies and in many degrees of the peripheral vascular disease in the lower limbs. In Brazil, it is believed that it responds to 40-70% of the non-traumatic amputations on the lower limbs. Besides the resources spent with extended hospitalization, rehab and a great necessity of home care there are the indirect costs due to a loss of productivity, to individual costs and to the considerable impact in the quality of life. Provided with the knowledge about the natural history and epidemiology of such terrible disease, managers and health professionals have the tools to interfere in different moments, seeking to avoid or to delay the progressive damages that it imposes<sup>1</sup>.

The diabetic foot peers as one of the most striking neuropathies on the quality of life of the individual, and in the health system resources. Studies pointed to a multidisciplinary practice and the specialization of the staff to be viable strategies to reduce costs and increase the efficiency of the procedures. Such strategies are able to generate reductions in the rate of limb amputations which vary from 40-90% in different casuistries<sup>2,3</sup>.

The ulcer treatment in the diabetic foot requires a multidisciplinary approach, including revascularization and surgical procedures, as well as the infection treatment, physiotherapeutic rehabilitation with electric phototherapeutic resources to control edema, pain, metabolic disorders, tissue malnutrition, co morbidities, precise treatment of the wound and biomechanics' decompression. Therefore, the specialized attention to the ulcers should be available to all patients as well as a priority in the amputation prevention<sup>4</sup>.

Low level laser therapy (LLLT), also called soft laser, is known to supply direct biostimulative light energy to body cells. The absorbed laser energy stimulates molecules and atoms of cells but does not cause rapid or significant increase in tissue temperature<sup>5</sup>. Low-energy laser radiation was found to have a stimulating effect on cells, and high-energy radiation had an inhibiting effect. The application of lasers to stimulate wound healing in cases of nonhealing ulcers has been recommended<sup>6</sup>.

Therefore, the usage of (LLLT) presents itself as being a new therapeutic proposal, seeking the cure of these injuries, the improvement on the quality of life of the affected individuals, as well as the reduction of the costs of the treatment in the health system.

# Methods

The present study honors the instructions of the 466/12 Resolution of the National Committee of Ethics in Researches (CONEP) and was submitted to appreciation by the Ethic Committee of the Faculdade Diferencial Integrada (FACID), under the approved ruling: CAAE: 40818114.4.0000.5211. Those involved in the research signed a Written Consent Form (WCF).

#### Research description

It is a clinical case study, controlled, randomised, interventional, of quality-quantity character.

#### Place and period of execution

Developed in the Physiotherapy Service in the Hospital Getúlio Vargas (HGV), Dirceu Mendes Arcoverde Outpatient Care, in Teresina-PI, from February, 2015 until July, 2015.

#### Population and sampling

The sample was composed by 16 non controlled type IIdiabetic patients, ulcer carriers in the lower limb chosen randomly in the Diabetic Foot Outpatient Care located in the Referral Center of Diabetes Lineu Araújo. The patients from this place were evaluated by an angiologist who, after characterizing the ulcer, referred them to the Physiotherapy section of the HGV for a new evaluation of the treatment. In the sequence the patients were divided into two groups in a randomly manner. **Group 1,** Control Group: 8 patients; **Group 2:** (GTL): 8 patients treated with LLLT.

#### Procedures

<u>Monitoring strategy of Group 1</u> - Control Group (CG): patients were instructed to use only sodium chloride (saline solution 0.9%), regarding the daily asepsis of the ulcer, after 30 days they returned to the physiotherapy service for the reevaluation process.

<u>Treatment strategy with LLLT</u> – **Group 2 (LTG)**: after the cleansing of the ulcer using sodium chloride solution (saline solution 0,9%), the patient was placed in a comfortable position, offered protection goggles for the phototherapy, similar equipment was used by the therapist. 12 procedures were done, of which three were weekly procedures, in alternated days. The Lower Level Laser used in this study was with pulsed wave form, visible ray, wave length of 632.8 nm, peak potency of 30 mW, (Laser -HTM). The application time was of 80 (4 J/cm<sup>2</sup>) seconds. The application was punctual without contact (approximate distance of 1 mm), with the pen being held perpendicular to the wound, in equidistant points around it. In both groups the ulcer was measured in square centimeters (cm<sup>2</sup>), The Image J<sup>®</sup> software, was used to measure the total area of ulcers. Photographic records were made in the first appointment and in the last one, after the 30 day follow-up.

# Pain evaluation

Visual analogical scale was applied, for the quantification of it, in a numerical scale from zero to ten, where ten indicated the maximum of pain and zero the absence of it.

#### Statistical analysis

The results were submitted to the Mann-Whitney U test, the Student's t test. The significance level established for the statistic test was of p<0.05. The computer program Graph Pad Prism 5.0 was used as a statistic package.

#### Results

In Figure 1 it can be observed that, after a period of therapeutic intervention using the low level laser it was noticed an improvement in the size of the wounds, with a significant process of tissue repair, where the average found was reduced. Statistically significant results with p<0.05. The size of the wounds related to the control-group can be observed in the moment of the evaluation, the group which kept only the asepsis care and did not receive any intervention, after 30 days had the ulcers measured again (Figure 2). A patient from the control-group progressed into a transfemoral amputation (Figure 3). There was an increase in their size, statistically significant results with p=0.01, characterizing a worsening in the patient's condition (Figure 4).



FIGURE 1 - Average size of the wounds before and after the intervention.



**FIGURE 2** - Ulcers submitted to the intervention with the low level laser, before and after.



**FIGURE 3** - Patients from control-group with a significant progress in the size of the wound. The third picture shows the patient who progressed to a transfemoral amputation, Fontaine IV Classification.



**FIGURE 4** - Patients from the control-group with a significant progress in the size of the wound.

As an important data, there is the result of the characterization of the pain in patients submitted to the laser intervention, which had a significant improvement in the algic state after the procedures, with an average of 9 dropping to a 5, this probably happens due to the analgesic effect of this therapy. The control-group there was not an adjustment of the pain, with a presentation of the algic state very similar to the evaluation, after 30 days of follow-up, without a significant improvement in this group.



**FIGURE 5** - Graph of representation of the algic state before and after the Laser intervention, and Control group.

# Discussion

In another study made with the objective to analyze the effects of low level laser in the dermal wound repair in rats it was observed that the groups irradiated with the laser presented a fibroblast proliferation superior to that of the control group, as well as an increase in the number of fibroblasts in ten days. Showing that the laser favored the healing and, that the process was quickened in the groups that received more than one application<sup>7</sup>. These results support the present study in which the tissue repair in the group submitted to the laser treatment was attested.

Also in an additional study which had the objective of investigating the behavior of the dermal wounds induced in the dorsal region of 12 Wistar rats (*Rattus norvegicus*), it was seen that in the group submitted to the application of the laser there was an increase of the neovascularization and in the fibroblast proliferation, and a decrease in the quantity of the inflammatory infiltrate in the surgical injuries suggesting thus that the LLLT is an efficient method in the process of modulation of the tissue

repair, contributing significantly to a faster and more organized scar tissue repair. The treatment was done with a low level laser, of 870 nm, with a dosage of  $3.8 \text{ J/cm}^{28}$ .

With the objective of evaluating the epithelial, conjunctive and bone tissue submitted to LLLT in an experimental model the alveolar reproduction was done in a research in which the experimental group was submitted to laser application with the following parameters  $660 \text{ nm} - 7.5 \text{ J/cm}^2$ ;  $660 \text{ nm} - 15 \text{ J/cm}^2$ ;  $780 \text{ nm} - 7.5 \text{ J/cm}^2$ ; and  $780 \text{ nm} - 15 \text{ J/cm}^2$ . As a result, the epithelial and conjunctive tissues showed unusual and fast-growing cellular renovation during the irradiation period. It can be concluded that, the laser provided to the epithelial and conjunctive tissues regular cellular renovation, contributing to the tissue repair process<sup>9</sup>.

On the basis of the parameter that 50% of the non traumatic amputations in lower limbs happen in diabetic people the number of amputation cases attributed to the Diabetes Mellitus was estimated<sup>10,11</sup>. One of the patients in the control group evolved to a transfemoral amputation, according to the Fontaine classification. Even having received instructions about daily asepsis of the wound, which confirms the necessity of a more efficient therapy to avoid a possible amputation.

In a study that involved patients with the diabetic foot syndrome, it was verified that a significant reduction in the amputation and death ratio pointed to an economic efficiency of the development and creation of specialized departments or centers for the proper treatment of these patients<sup>10</sup>. Specialists had already pointed that the assistance to the diabetic with recurrent ulcers presented a lower frequency of amputation as an end when done by a specialized clinical staff<sup>11</sup>.

The tissue repair process is of extreme importance for a fast reestablishment of these patients, the return to their labor activities depends on it, since most of them are still in an active production phase of life. Avoiding possible amputations, which would compromise the quality of life of these individuals and would bring a strong financial impact to the public finances, increasing the costs with possible hospital admission, inputs and disability remuneration.

The low level laser therapy is a painless method, non invasive, at a low cost and practically without side effects<sup>12</sup>. Its bio-modular action in the tissues allows a faster tissue recovery; with effective pain relief action especially in the first fifteen days of the treatment<sup>13</sup>.

Recent studies proved the efficiency of this resource for the treatment of many kinds of ulcers<sup>14</sup>. The ulcer in the lower limb is characterized by a circumscribed or irregular loss of the integument (dermis and hypodermis), usually related to the vascular, arterial or venous system<sup>15</sup>. The employment of sources of low level light, like Light Emiting Diode – LEDs) or low level laser, can propitiate an optional therapeutic resource to the conventional ones or be used combined with them, with a low cost benefit and proven efficiency in the ulcer treatment<sup>16</sup>.

The pain relief action was demonstrated in the intervention group, the pain was characterized from zero to ten, where ten was the maximum of pain and zero the absence of it, the average in the experimental group was of 9, after the therapy application the patients reported an average of 5, with a significant improvement in the mood, in the capacity to move around independently, with a return to basic daily life activities resulting in a better mood and quality of life.

In a study done to evaluate the effects of low level laser over pain and edema on rats' calcaneus tendon submitted to an experimental trauma an experimental treatment with a laser irradiation of 670nm and dosage of 2J/cm<sup>2</sup>, 4J/cm<sup>2</sup> and 8J/cm<sup>2</sup> was done in the calcaneus tendon of the animals. The results showed that there was the formation of an edema in all of the groups after the injury and that for the treated groups there was a decrease in the edema. Demonstrating that the treatment with low level laser led to a reduction in the edema of the animals with tendinae trauma<sup>17</sup>. That confirms the findings of our research, in which a similar methodology was applied and there was also a decrease of pain with the usage of the low level laser.

#### Conclusion

The low level laser seems to be an efficient method, viable, painless and of low cost in the tissue repair of ulcers in the diabetic foot, the biomodulation and the analgesic effect are significant for the reestablishment of these patients, preventing possible amputations, improving the quality of life and favoring a lower financial impact in the resources destined to this clinical institution.

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