# **Original Articles**

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## Clinical study to assess abdominal circumferential reduction after treatment with low-frequency diode laser

Estudo clínico para avaliar a redução da circunferência abdominal após tratamento com laser diodo de baixa frequência

#### **ABSTRACT**

**Introduction:** Obesity is a major health problem worldwide due to its high morbidity and mortality.

**Objective:** To evaluate the reduction of abdominal fat in volunteers who underwent low-frequency diode laser therapy.

**Methods:** A total of 60 volunteers (18 to 50 years of age, with a BMI of between 18.5 kg/m2 and 30 kg/m2, and who had abdominal fat), underwent a treatment performed twice a week for 31 days and were then evaluated. The abdominal circumference was evaluated in three locations, with photographic and ultrasound images taken of the studied area.

**Results:** There was a reduction in the abdominal circumference measurements in the evaluated sites, with dermal compression and a significant reduction of hypodermis verified through ultrasound.

**Conclusion:** The low-frequency diode laser therapy showed significant results in the reduction of localized fat and abdominal circumference measurements.

Keywords: laser; abdominal fat; lypolisis.

#### RESUMO

**Introdução:** A obesidade é um dos principais problemas de saúde no mundo, devido a sua elevada morbimortalidade.

**Objetivo:** Avaliar a redução da gordura abdominal em voluntários submetidos à terapia com laser diodo de baixa frequência.

**Métodos:** Foram avaliados 60 voluntários, entre 18-50 anos de idade, com IMC entre 18,5kg/m2 e 30kg/m2 e com gordura abdominal, com tratamento realizado duas vezes por semana, durante 31 dias. Avaliou-se a circunferência abdominal em três áreas, com tomadas de imagens fotográficas e ultrassom da área avaliada.

**Resultados:** Houve redução nas medidas da circunferência abdominal nas áreas avaliadas, com significativas compactação ultrassonográfica dérmica e redução ultrassonográfica da hipoderme.

**Conclusão:** A terapia com laser diodo de baixa frequência apresentou resultados significativos na redução de gordura localizada e medidas de circunferência abdominal.

Palavras-chave: laser; gordura abdominal; lipólise.

#### INTRODUCTION

Obesity is a major health problem worldwide due to its high prevalence and morbidity. It is diagnosed using the body mass index (BMI), an anthropometric indicator.<sup>1</sup>

The layout of fat in the central region, determined by waist circumference characterizes visceral obesity and is associated with metabolic disorders<sup>2-4</sup> such as hypertension, dyslipidemia, fibrinolysis, metabolic syndrome, chronic inflammatory process, atherosclerosis development acceleration, and may also result in cardiovascular or cerebrovascular events.<sup>1,5</sup>

Laser therapy is a non-invasive procedure that can be used to reduce localized fat. It uses a wavelength specific to adipose cells while preserving adjacent structures such as nerves, blood vessels, and skin.<sup>6</sup>

In the present study, the authors used a low-frequency diode laser device (685nm, 40mW, 1.3watts, 120Joules / cm $^2$  / 10 minutes) consisting of four plates with nine emission sources, which remained in contact with the skin during the session. Furthermore, the equipment has two lymphatic stimulation probes with a laser-emitting source at each, which are placed in the lymphatic drainage region of the treated area.

The present study is aimed at evaluating the reduction of abdominal fat in volunteers undergoing procedures with a low-frequency diode laser available on the Brazilian market.

#### **METHODS**

A total of 60 healthy female volunteers aged between 18 and 50 years, skin phototypes I to III (Fitzpatrick classification), with  $18.5 > BMI < 30.0 \text{ kg/m}^2$ , who had fat deposits in the abdomen were selected for evaluation. They were followed up for 31 days, after the study had received approval from the Institution's Research Ethics Committee.

The visits occurred on the days 0 (D0), 3 (D3), 7 (D7), 10 (D10), 14 (D14), 17 (D17), 21 (D21), 24 (D24), 28 (D28), and 31 (D31). The following assessments were performed at each visit: evaluation of waist circumference (both before and after the laser application) in three predefined areas: upper (4.0 cm above the navel), median (on the navel) and lower (4.00 cm below the navel); measurement of the height of the navel from the floor (the patients were barefoot); application of a questionnaire to assess degree of pain (0-10 scale). In addition to these procedures, a satisfaction questionnaire (0-10 scale) was applied, the weight was measured, and the BMI was calculated at D0, D14, and D31 visits.

In each of these 10 visits, the volunteers underwent an application of a low-frequency diode laser (i-Lipo, Chromogenex Comércio, Importação, Exportação de Produtos

Médicos Ltda. ANVISA Class II. 80332760006; 685nm, 40mW, 1.3watts, 120Joules/cm²/10 minutes) for 20 minutes. The plates were placed on the skin in the region to be treated; two emission probes with the same wavelength were placed on the point of lymphatic drainage in the area.

As directed by the manufacturer the volunteers were asked to perform 30 minutes of aerobic activities during the subsequent 60 minutes. The clinical efficacy assessment was carried out by analysis of photographs and ultrasound examinations aimed at comparing the thicknesses of the dermis.

The descriptive statistics and the evaluation questionnaires allowed to draw conclusions about the participants' demographic profile. In order to analyze the changes between assessments, the ANOVA for repeated measurements, followed by the contrast profile test were used to compare the results of the physical measurements (waist circumference, weight, BMI, ultrasound data). Data were processed into ranks due to the lack of normal distribution. The significance level was set at 5.0%. The SAS (version 9.3) software was used to perform the analyses.

#### **RESULTS**

Fifty volunteers (from a total of 60) completed the study. Of these, 11 (22.0%) had skin phototype II, and 39 (78.00%) had phototype III, with a mean age of 39 years (range = 18 to 51 years).

The results of the evaluation of satisfaction with the laser application, immediately after each session was finished, were positive throughout the study period (D0 = 8.50; D14 = 8.62; D31 = 9.26), without statistically significant variation in the results in the comparison between visits (p = 0.4771; Table 1). Regarding the pain scale, 50 participants reported Grade 1 in all visits – except for one who reported Grade 2 pain on D0, progressing to Grade 1 in the other assessments (Table 2).

The variables weight (p = 0.9427; Table 3) and BMI (p = 0.9016; Table 4) did not present statistically significant reduction in the comparison between the visits and the baseline. Regarding the measurement of the navel's height, there was a statistically significant reduction in the comparative results between the visits and the baseline (D0 = 94.50 cm; D31 = 93.49cm; D0 vs. D31: 1.07% reduction; p < 0.0001) (Graph 1).

As depicted in Figure 2, the diode laser therapy decreased by 4% (p <0.0001; Graph 2A); 3.3% (p = 0.0026; Graph 2B) and 3.7% (p <0.0001; Graph 2C), respectively in the upper, median, and lower waist circumferences when measured before the laser session. Nevertheless, an interesting fact is that when evaluating these measurements after the completion of the session, it was observed that for the upper, median, and lower circumferential

| Table | Table 1: Degree of volunteer satisfaction with the treatment, seen at Do, D14, and D31, assessed shortly after the laser application |        |      |      |     |         |  |  |  |
|-------|--|--------|------|------|-----|---------|--|--|--|
| Visit | Mean   | Median | SD   | Min. | Max | P-value |  |  |  |
| Do    | 8.50   | 10     | 2.52 | 1    | 10  | 0.5586  |  |  |  |
| D14   | 8.62   | 10     | 2.17 | 1    | 10  |         |  |  |  |
| D31   | 9.26   | 10     | 1.59 | 3.00 | 10  |         |  |  |  |

|       | Table 2: Pain assessment, asked at every visit immediately after the laser application |    |    |     |    |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|-------|--|----|----|-----|----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Visit | Do   |    | D3 |     | D7 |     | D10 |     | D14 |     | D17 |     | D21 |     | D24 |     | D24 |     | D28 |     | D31 |     |
| Grade | F  | %  | F  | %   | F  | %   | F   | %   | F   | %   | F   | %   | F   | %   | F   | %   | F   | %   | F   | %   | F   | %   |
| 1     | 49   | 98 | 50 | 100 | 50 | 100 | 50  | 100 | 50  | 100 | 50  | 100 | 50  | 100 | 50  | 100 | 50  | 100 | 50  | 100 | 50  | 100 |

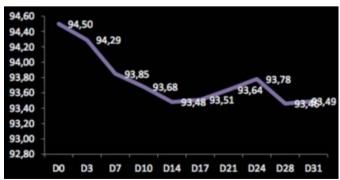
| Table 3: Weight variation – Do (baseline before the application), D14, and D31 after the laser application |       |        |      |       |       |         |  |  |
|--|-------|--------|------|-------|-------|---------|--|--|
| Visit  | Mean  | Median | SD   | Min.  | Max   | P-value |  |  |
| Do   | 65.13 | 66.75  | 7.50 | 49.50 | 85.60 | 0.9427  |  |  |
| D14  | 65.71 | 66.30  | 7.92 | 46.80 | 89.50 |         |  |  |
| D31  | 65.63 | 66     | 7.85 | 46.50 | 88.90 |         |  |  |

| Table 4: BMI variation – Do (baseline before the application), D14, and D31 after the laser application |       |        |      |       |       |         |  |  |
|---|-------|--------|------|-------|-------|---------|--|--|
| Visit   | Mean  | Median | SD   | Min.  | Max   | P-value |  |  |
| Do  | 26.03 | 26.14  | 2.17 | 21.15 | 30    | 0.9016  |  |  |
| D14   | 25.86 | 25.89  | 2.37 | 20    | 31.60 |         |  |  |
| D31   | 25.85 | 25.95  | 2.32 | 19.86 | 32.01 |         |  |  |

| Table 5: E | Evaluation of the reduc |        | asurements from th<br>rding the thickness o | e ultrasonography (Do)<br>of the dermis | as compared with the | ose taken on D31, |
|------------|-------------------------|--------|---|---|----------------------|-------------------|
| Visit      | Mean                    | Median | SD  | Min.                                    | Max                  | P-value           |
| Do         | 0.16                    | 0.15   | 0.04  | 0.03                                    | 0.27                 | 0.0003            |
| D31        | 0.13                    | 0.13   | 0.03  | 0.08                                    | 0.22                 |                   |

| Table | e 6: Evaluation of the re |        | nography's baseline in garding the dermis' |      | compared with those | taken on D31, |
|-------|---------------------------|--------|--|------|---------------------|---------------|
| Visit | Mean                      | Median | SD   | Min. | Max                 | P-value       |
| Do    | 1.32                      | 1.09   | 0.62                                       | 0.49 | 3.44                | 0.0229        |
| D31   | 1.05                      | 1.01   | 0.45                                       | 0.36 | 2.56                |               |

measurements, the reduction was 4.0% (Graph 2B), 3.47% (Graph 2D), and 4.0% (Graph 2F), respectively (all with p <0.0001). When carrying out the before and after analysis, the circumferential measurements were always lower after the application, suggesting that the technology had an immediate effect on the decrease of the measurements.



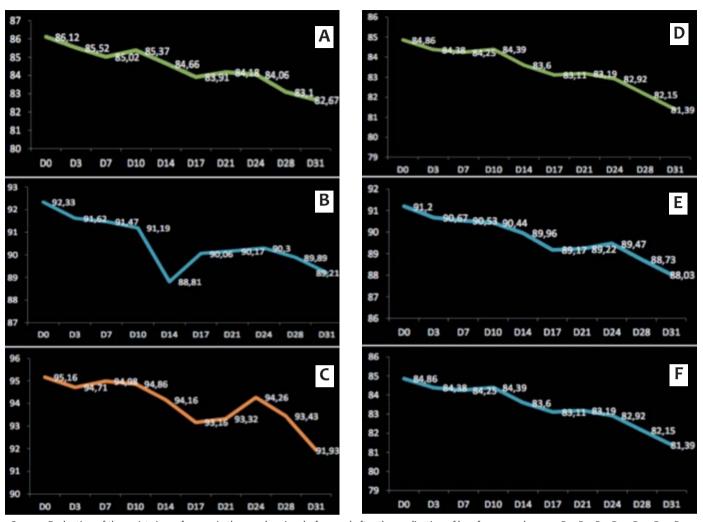
GRAPH 1: Evaluation of the height of the navel relative to the ground on Do, D3, D7, D10, D14, D17, D21, D24, D28, and D31

The analysis of the ultrasound data also showed a significant reduction from the baseline measurements (D1), and those taken on D31 of the dermis and hypodermis (18.75% and 20.45%, respectively; p <0.0003 for the dermis and p = 0.0229 for the hypodermis) (Tables 5 and 6, respectively; Figure 1). The reduction of abdominal thickness can also be visualized through the photographs taken on D0 and D31 (Figure 2).

### **DISCUSSIONS**

Central or visceral obesity is closely related to potentially life-threatening cardiovascular complications. <sup>1,5</sup> Behavioral measures based on lifestyle changes, weight loss, physical activity, and cessation of harmful habits (smoking, alcohol use) are key for primary and secondary prophylaxis of these events. <sup>7</sup>

Jackson *et al.* published the benefits of using a diverse, low frequency diode laser device (532nm) to treat gynoid lipodystrophy in 34 volunteers (three 30-minute applications per week, in the region of the thighs and buttocks). A group with the same number of volunteers underwent a "placebo"



GRAPH 2: Evaluation of the waist circumference in the navel region, before and after the application of low frequency laser on Do, D3, D7, D10, D14, D17, D21, D24, D28, and D31. Above the navel's height (before A, after D), at the navel's height (before B, after E) and below the navel's height (before C, after F).

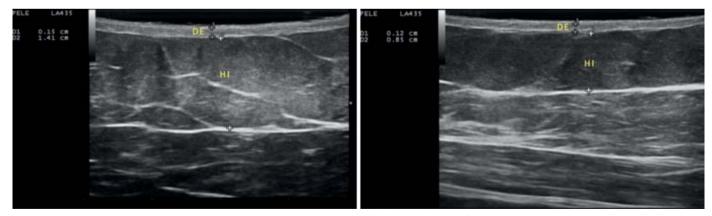


FIGURE 1: Evaluation of an ultrasound image obtained before (DoA) and after (D<sub>3</sub>1B) the application of low-frequency laser (DE - dermis, HI - hypodermis).

treatment (without emission of energy).8 For these authors, 19/34 (55.8%) of the volunteers had a statistical reduction of one level in the Nurnberger-Muller scale, as compared with 3/34 (8.8%) from the untreated group. The treated group also saw an improvement in their body circumference, weight, and

body mass index. Six weeks after the end of the study, four volunteers from the treated group still had favorable results, a fact that was not observed in the untreated group.

Although there was no reduction in weight and body mass index in the volunteers of the present study, the low fre-





FIGURE 2: Evaluation of the photographic image of the abdominal region obtained before (DoA) and after (D<sub>3</sub>1B) the low frequency laser application

quency diode laser therapy showed significant results for the reduction of localized fat, which were demonstrated through the reductions in the abdominal circumference measurements, the change in the height of the navel, and the ultrasound scale of the hypodermis. Also, there was dermal compression by the ultrasound. These results are unprecedented in the literature regarding the technological device studied.

#### CONCLUSIONS

The results obtained demonstrate the potential of the low potency diode laser to become an auxiliary technology in the reduction of abdominal fat. •

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