

# Large-volume lipolysis assisted by low-level multifrequency laser in obesity: Short-term weight trajectories and postoperative complications

Lipólisis de gran volumen asistida por láser multifrecuencia de bajo nivel en obesidad: Trayectorias de peso a corto plazo y complicaciones postoperatorias

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## SUMMARY

**Introduction:** Obesity is a chronic and complex syndrome resulting from the interactions of genetic, environmental, metabolic, and psychological factors. Current pharmacologic treatments often yield limited, unsustainable weight loss; thus, bariatric surgery and large and giant-volume liposuction have emerged as viable options for its control. **Objective:** This study aimed to assess Laser-assisted with large-volume liposuction in weight reduction effectiveness in obese adults and to describe the early postoperative complications of this procedure. **Method:** A non-experimental, analytical, prospective, clinical study conducted on 101 adult subjects of both sexes with

obesity underwent large-volume laser-assisted lipolysis (LAL). The changes in weight-related variables before and after the first three postoperative months and the early surgical complications (within 30 days) were reported. **Results:** A significant reduction in the obese proportion was observed, favoring normal-weight and overweight patients. Significant BMI, %TWL, and %EBMIL decreases were observed during the patient's follow-up at months 1, 2, and 3. Mortality associated with this procedure was 0%. The incidence of surgical complications was 7%, mainly mild to moderate according to CD classification, with no life-threatening episodes. **Conclusions:** Large and mega-volume LAL is an effective and safe technique for massive weight reduction in patients with Obesity.

**Keywords:** Laser-assisted lipolysis, overweight, obesity, large-volume lipolysis.

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## RESUMEN

**Introducción:** *La obesidad es un síndrome crónico y complejo resultante de la interacción de factores genéticos, ambientales, metabólicos y psicológicos. Los tratamientos farmacológicos actuales a menudo producen una pérdida de peso limitada e insostenible; así, la cirugía bariátrica y la liposucción de grandes y gigantes volúmenes han surgido como opciones viables para su control.* **Objetivo:** *Este estudio tuvo como objetivo evaluar la efectividad de la liposucción de gran volumen asistida por láser en la reducción de peso en adultos obesos y describir las complicaciones posoperatorias tempranas de este procedimiento.* **Método:** *Estudio clínico prospectivo, analítico, no experimental, realizado en 101 sujetos adultos de ambos sexos con obesidad sometidos a lipólisis asistida por láser (LAL) de gran volumen. Se informaron los cambios en las variables relacionadas con el peso antes y después de los primeros tres meses posoperatorios y las complicaciones quirúrgicas tempranas (dentro de los 30 días).* **Resultados:** *Se observó una reducción significativa de la proporción de obesidad, favoreciendo a los pacientes con peso normal y con sobrepeso. Se observaron reducciones significativas en el IMC, %TWL y %EBMIL durante el seguimiento del paciente en los meses 1, 2 y 3. La mortalidad asociada con este procedimiento fue del 0 %. La incidencia de complicaciones quirúrgicas fue del 7 %, principalmente de leves a moderadas según la clasificación de la EC, sin episodios que pusieran en peligro la vida.* **Conclusiones:** *LAL de gran volumen y megavolumen es una técnica efectiva y segura para la reducción masiva de peso en pacientes con obesidad.*

**Palabras clave:** *Lipólisis asistida por láser, sobrepeso, obesidad, lipólisis de gran volumen.*

## INTRODUCTION

Obesity is a chronic, progressive, and complex management disease (1-3), characterized by a global increase in body fat deposits by a complex interaction between genetic, environmental, metabolic, psychological, and endocrinological factors, leading to the expression of a unique obese phenotype, which is known as classical polygenic Obesity (4,5). Currently, epidemiological, clinical, and experimental evidence strongly supports the assertion that Obesity is a risk factor for a wide range of chronic diseases, including metabolic syndrome (6), type 2 diabetes mellitus (T2DM) (7), hypertension (8), dyslipidemia (9),

cardiovascular diseases (CVD) (10), certain respiratory disorders (11), osteoarthritis (12), psychosocial disorders (13), and various types of cancer, such as esophageal, colon, pancreatic, prostate, and breast cancer (14).

In the last four decades, there has been a concerning increase in the prevalence of Obesity in countries with Westernised lifestyles, making this disease one of the foremost global public health challenges because of its impact on morbidity, mortality, and, consequently, national healthcare systems (15-18). According to the most recent regional and national prevalence estimates presented in the 2023 World Obesity Atlas report (19,20), it is projected that by 2035, approximately one in four individuals (almost 1.9 billion) will suffer from Obesity. More than half of the global population (51 %, equivalent to over 4 billion people) will be overweight or obese. If current trends persist, the worldwide economic impact of weight excess could reach \$4.32 trillion annually, equivalent to 3 % of the Global Gross Domestic Product (GDP) (19,20).

Obesity medical treatment is complex and often unsuccessful, as lifestyle-focused interventions alone have proven ineffective in achieving significant long-term weight loss in most patients. For instance, it has been reported that between 30 % and 66 % of the weight lost through such measures is regained within the first year after treatment completion, and over 95 % of the weight has been regained within five years (21). Furthermore, in those who have successfully responded to these measures, long-term weight loss has seldom exceeded 5 % in total body weight reduction (22). On the other hand, Obesity is one of the last significant areas not effectively addressed by pharmacological intervention. Although the near future seems promising with the development of new anti-obesity drugs, there are currently no options that provide significant and sustainable long-term weight loss (23,24). As a result, surgical procedures such as bariatric surgery, large-volume lipolysis, and giant-volume liposuction have become important choices for morbid obesity treatment and obesity with morphofunctional skin alterations (25-32).

Traditionally, liposuction and other surgical procedures removing localized fat deposits have

been regarded as secondary Obesity treatment compared to bariatric surgery because, in the past, traditional liposuction could not remove a sufficiently large fat volume. However, with the advent of some refinements such as vacuum-assisted liposuction, the tumescent technique, and the photonic energy introduction, namely laser-assisted lipolysis (LAL), procedures like large-volume liposuction (5 fat liters aspiration), mega-volume liposuction (aspiration of 8 liters), and the giant or mega-volume liposuction (12 liters or more) have been achieved in a safely way (33,34). These procedures offer quicker recovery, reduced postoperative pain, improved aesthetic outcomes, and significantly decreased early postoperative complications (35). Based on the above description, this study aimed to assess LAL weight reduction effectiveness in adults with Obesity and to describe the early postoperative complications of this procedure.

## METHODS

### Study design

This research is a non-experimental, analytical, prospective, clinical study conducted on 101 adult subjects of both sexes with obesity diagnosis according to BMI diagnostic criteria according to the World Health Organization (WHO) (36), who consecutively sought care at a tertiary-level institution specialized in obesity management. This study analyzed the changes in weight-related variables during the first three postoperative months and the early complications (within 30 days) by the Clavien-Dindo classification system (37).

### Ethical Aspects

This study adhered to the legal Colombian framework for confidentiality and information privacy (Law 1581/2012 and Decree 1377/2013). This study was approved by the Institutional Review Board of the Obesity and Aging Clinic through its Ethics Committee. All participants were informed about the surgical intervention's nature, purpose, and technique, as well as its advantages, risks, and potential complications.

The medical team addressed questions and concerns regarding the procedure using technical yet easily understandable language. All participants signed an informed consent form allowing participation in this research and clinical data use for research purposes, ensuring that individual information would not be disclosed.

### Laser-assisted lipolysis (LAL) surgical protocol

The complete surgical procedure was performed in three stages:

#### Pre-operative stage

All patients underwent an initial medical assessment with an entire medical history, particularly concerning cardio-metabolic comorbidities and skin diseases. Therefore, in this stage, a thorough skin inspection was conducted regarding its thickness, laxity, and lesions. This process determines the body areas requiring laser lipolysis. All participants underwent standard laboratory studies, including a complete blood count (CBC), a complete metabolic panel with lipid tests, endocrine tests (fasting insulin, cortisol, prolactin, and thyroid-stimulating hormone), and a resting 12-lead electrocardiogram.

A second medical consultation was conducted with the plastic surgeon's team to review the laboratory test results, discuss the surgical procedures, and determine whether the patient was a candidate for surgery. If the intervention was approved, an assessment by the anesthesiology specialist was performed. Finally, four days before surgery, participants underwent a 40-minute external low-level red (650 nm) and infrared (980 nm) with a Lipolaser device (Lipolaser LPL9002™, Colombia), directly applied to the skin in all areas to be treated during surgery. The purpose was to initiate adipose tissue lysis before the surgical procedure.

#### Operative stage

**Preliminary preparation.** Following a 12-hour fasting period, general anesthesia with profound sedation was administered. Subsequently, the intervention areas were marked, and rigorous

asepsis and antisepsis procedures were employed in all surgical regions. Surgical drapes were meticulously positioned to maintain sterility.

**Areas selected for intervention.** The addressed regions in this study were as follows: 1. Abdomen, 2. Lumbar region; 3. Anterior and posterior (dorsal) thorax (with pexy and breast prosthesis placement in women), 4. Arms and, 6. Legs.

**Patient setup.** In the case of the lumbar region approach, the patient was placed in a prone decubitus position. The surgical table was set at an angle inducing slight vertebral column flexion to optimize access to the lumbar region. Subsequently, incision sites were marked along the maximal subcutaneous fat fold axis. For the abdominal region approach, the patient was positioned in a supine decubitus position with a slight hyperextension, and a substernal incision was made to provide easy and secure access to the costal margin and the upper hemi-abdominal region.

Additionally, two small incisions were made at the suprapubic line to access the lower hemi-abdomen, and bilateral incisions were made in both the flanks and iliac crest. In the case of the anterior chest, incisions were made at the axillary level, and for the posterior chest, two incisions were made at the scapular and infrascapular lines. In the legs, incisions were made on both the inner part of the thighs and knees. In the case of the gluteal regions, the first incision was on the top of this region, and the other one was in the lower gluteal line. In the case of face LAL, two incisions were made at the infraauricular zone and chin.

**Tumescent Solution Infiltration.** A 1 to 2 mm incision was made with a N° 11 scalpel, followed by a # 4 atraumatic cannula insertion and an intradermal infiltration with a solution prepared with one adrenaline ampoule diluted in 1 000 cm<sup>3</sup> of 0.9 % NaCl solution within an infusion bag at 150 mmHg pressure and 200 cm<sup>3</sup>/minute infiltration rate. The needle movements were deliberately slow to ensure optimal tissue expansion.

**Laser-assisted lipolysis (LAL).** LAL includes a laser device targeted to cause a selectively fat photo-thermolysis. This study employed a

multifrequency laser-lipolysis device (Lipolaser LPL9002™, Colombia) for the entire procedure. This low-power cold laser device has 533, 650, and 980 nanometers wavelengths. This equipment complies with international safety standards for electro-medical devices (IEC 601-1) and laser equipment (IEC 825) (Table 1).

All regions underwent the same four-step technique as follows:

- a. Green laser application. Green laser therapy is the first in laser-assisted lipolysis. Its primary function is vasoconstriction induction, which reduces bleeding and the likelihood of fat embolus formation. The laser fiber is inserted through a 2 mm caliber cannula, followed by slow forward and backward cannula movements within the subcutaneous adipose tissue, initially in a deep plane, then in an intermediate plane, and finally in the superficial plane.
- b. Red laser application. This wavelength laser aimed to induce adipocyte lysis, resulting in the release of triacylglycerides. In this step, the perception of fat consistency changes by palpation (from a solid to a liquid phase), and the absence of resistance to the laser cannula passage indicates a complete adipose tissue liquefaction.
- c. Fat evacuation via vacuum device. Liquid fat was aspirated using a suction device (Wells Johnson Co. Tucson, AZ, USA) with 5, 4, or 3 mm straight and curved cannulas. Slow movements were performed in the same order as during laser application, starting in the deep plane and concluding in the superficial plane. Overall, this process is minimally traumatic, resulting in the collection of liquefied, yellowish fat with minimal to no blood.
- d. Infrared Laser Subdermal skin stimulation. This wavelength laser's function is skin tightening, resulting in its adhesion to the underlying muscle. The technique was the same as in the red laser for 3 to 6 minutes in each treated area.

#### Early Postoperative Follow-Up

After the surgical procedure, the incisions were sealed with Micropore® tape and covered

with sterile gauze and dressings. Subsequently, a low-pressure elastic bandage was applied, and the patient was promptly transferred to the recovery room and closely monitored for 4 hours while undergoing a liquid food tolerance test. Following, the patient was relocated to their hospital room and remained under nursing staff care for 24 hours until medical clearance was granted.

Postsurgical care sessions were initiated on the second day, encompassing hyperbaric chamber treatments, low-level laser external therapy (Lipolaser LPL9002™, Colombia), pressotherapy, and a 5-minute drainage routine over five days. The patient underwent daily evaluations for ten days and monthly assessments for the subsequent three months.

Table 1. Some Lipolaser LPL9002 technical features.

Lasers	Features	Main effect
Green	A 532 nm wavelength diode-pumped solid-state laser (DPSSL) with a 3 mm beam diameter at the focal point.	Vasoconstriction
Red	650 nm laser wavelength with a combination of gallium (Ga), aluminum (Al), and arsenic (As) within the active semiconductor (GaAlAs) and a beam diameter at the focal point of 3 mm.	Adipocyte lysis
Infrared	980 nm wavelength gallium (Ga), aluminum (Al), and arsenic (As) laser (GaAlAs) within the active semiconductor, and a beam diameter at the focal point of 3 mm.	Skin tightening

**Weight-related variables outcome reporting**

The BMI diagnostic categories according to the World Health Organization (Normal weight, overweight, and grade I, grade II, and Grade III obesity) were displayed as a crosstab (absolute and relative frequencies) against the observation time (baseline and first, second and third postoperative months) to analyze the changes in proportions alongside the follow-up times.

Then, the executive summary of The American Society for Metabolic and Bariatric Surgery (ASMBS) outcome reporting standards recommendation was employed to provide a uniform method of findings report throughout the medical literature (38). In this regard, the following weight loss metrics were presented:

1. Initial BMI of the cohort
2. Change in BMI ( $\Delta$ BMI):  $\Delta$ BMI = (Initial BMI) – (Postop BMI)
3. Percent of total weight loss (%TWL): %TWL

$$= [(Initial Weight) - (Postop Weight)] / [(Initial Weight)] \times 100$$

4. Percent excess BMI loss or Percentage Excess of Weight Loss (%EBMIL or %EWL): %EBMIL =  $[\Delta$ BMI / (Initial BMI – 25)] x 100.
5. The cumulative  $\Delta$ BMI for each month and the monthly BMI reduction were also calculated.

It is important to highlight that although the Percent Excess BMI Loss and the Percentage Excess of Weight Loss have different equations, their outcomes are similar and interpreted similarly.

**Early Surgical Complications, according to the Clavien-Dindo Classification**

A surgical complication was defined as any deviation from the ideal postoperative course that is not inherent to the procedure and did not

include treatment failure. This study assessed the surgical complications using the Clavien-Dindo classification system (CDCS) (37). CDCS is based on the therapeutic implications of perioperative surgical complications (37). This system has been validated in patients undergoing bariatric surgery (39), abdominoplasty (40), and lower body contouring surgery (41-42), providing a straightforward and objective means to standardize complications based on their severity and resolution. In this regard, the complication type, treatment administered, and the outcome experienced were analyzed and subsequently classified into one of the five categories proposed by the CDCS:

**Grade I:** Any complication that does not require medical or surgical treatment.

**Grade II:** Complication that requires pharmacological treatment but not active intervention.

**Grade III:** Complication that necessitates surgical, radiological, or endoscopic treatment, either without general anesthesia (IIIa) or with general anesthesia (IIIb).

**Grade IV:** Potentially life-threatening complications requiring intensive care, such as single-organ failure (including dialysis) (IVa) and multiorgan failure (IVb).

**Grade V:** Complications resulting in death.

In concordance with the CDCS recommendations, patients with more than one complication were classified based on the most severe complication. For this work, Grades I, II, and IIIa were considered mild, while Grades IIIb, IV, and V were considered major complications.

### Statistical Analysis

Statistical analysis was performed using the statistical software SPSS (version 25.0; IBM, Chicago, Illinois), the R statistical computing environment (44), the flextable for R (45), and ggStatPlot for R (46). All R statistical packages were loaded and executed within the RStudio integrated development environment (IDE) (47).

Categorical variables were displayed in tables as absolute and relative frequencies. Proportion comparisons were assessed with Fisher's exact test, and the proportion changes along time measures were compared with Friedman's test and the Durbin-Conover post-hoc test for pairwise contrast. On the other hand, quantitative variables were expressed as means  $\pm$  SD or medians, as appropriate, following normality and homoscedasticity verification, and compared using Student's t-tests (for two groups) or one-way ANOVA (for comparisons involving more than two groups) along with the Bonferroni post-hoc test. Welch's t-test or the respective non-parametric tests, such as the Mann-Whitney U test or the Friedman test with the Durbin-Conover post-hoc test, were employed in cases where these assumptions were unmet. A p-value  $< 0.05$  was considered statistically significant.

## RESULTS

### General characteristics of the patients

This study included 101 obese patients consisting of 74 women (74.73 %) and 27 men (27.27 %) with a mean age of  $39 \pm 10$  years (Women:  $38 \pm 10$  years; Men:  $41 \pm 11$  years,  $p = 0.3$ ). When age was stratified into 5-year groups, it was noticed that 50 % of the sample was concentrated 31-35 (10.9 %), 36-40 (24.8 %), and 41-45 (13.9 %). This distribution pattern persisted, with similar proportions among men and women ( $p=0.23$ ).

Table 2 summarizes some clinical variables and provides a comparison between the sexes. The BMI arithmetic mean was  $38 \pm 6$  kg/m<sup>2</sup> for all the patients. Still, when comparing the BMI arithmetic mean by sex, the women had a lower but non-statistically significant BMI than men ( $37 \pm 5$  kg/m<sup>2</sup> vs.  $40 \pm 7$  kg/m<sup>2</sup>;  $p = 0.05$ , respectively). Concerning the personal pathological history, it was observed that most individuals were clinically healthy, except for their weight disorder. Table 2 displays the frequency distribution of these diseases, which did not exhibit a gender preference.

Table 2. Clinical features of the patients enrolled in the study.

Variables	Overall n = 101 <sup>1</sup>	Women n = 74 (74.73 %) <sup>1</sup>	Men n = 27 (27.27 %) <sup>1</sup>	p-value <sup>2</sup>
Age (in years) <sup>2</sup>	39 (10)	38 (10)	41 (11)	0.3
Age groups (in years)				0.23
18 – 25	14 (13.9)	10 (13.5)	4 (14.8)	
26 – 30	10 (9.9)	10 (13.5)	0 (0)	
31 – 35	11 (10.9)	6 (8.1)	5 (15.5)	
36 – 40	25 (24.8)	19 (25.7)	6 (22.2)	
41 – 45	14 (13.9)	11(14.9)	3 (11.1)	
46 – 50	10 (9.9)	8 (10.8)	2 (7.4)	
51 – 55	10 (9.9)	5 (6.8)	5 (18.5)	
56 – 61	7 (6.9)	5 (6.8)	2 (7.4)	
Baseline BMI (kg/m <sup>2</sup> ) <sup>2</sup>	38(6)	37(5)	40 (7)	0.050
Personal History <sup>3</sup>				
Hypertension <sup>3</sup>	6 (5.9 %)	5 (6.8 %)	1 (3.7 %)	0.9
Type-2 Diabetes <sup>3</sup>	1 (1.0 %)	1 (1.4 %)	0 (0 %)	0.9
Hypothyroidism <sup>3</sup>	4 (4.0 %)	4 (5.4 %)	0 (0 %)	0.6
Depressive disorders <sup>3</sup>	2 (2.0 %)	2 (2.7 %)	0 (0 %)	0.9
Polycystic ovary syndrome <sup>3</sup>	2 (2.0 %)	2 (2.7 %)	0 (0 %)	0.9
Hypertriacylglyceridemia <sup>3</sup>	1 (1.0 %)	1 (1.4 %)	0 (0 %)	0.9

<sup>1</sup>Mean (SD); n (%); <sup>2</sup>Welch Two Sample t-test; <sup>3</sup>Fisher's exact test

## Weight-related variables outcome reporting

### a. Changes in the proportion between BMI diagnostic categories before and after laser-assisted lipolysis surgery

All the patients at baseline were classified as obese according to BMI WHO cutoff points. Overall, the most prevalent BMI category was Obesity class II, with 42.4 %, followed by Obesity class I at 32.3 %, closely followed by Grade III Obesity at 27,3 % (Table 3). The baseline BMI by sex showed that Obesity grade II in women was the most prevalent category (47.29 %). In contrast, the most prevalent BMI category in men was Grade III obesity. These proportion differences between both sexes were statistically significant (p=0.041) (Table 3).

During the first post-surgery month, an important change in BMI diagnostic categories

was observed concerning the emergence of normal weight and overweight cases. This change was accompanied by a substantial reduction in the frequency of Grade II and Grade III obesity when compared to baseline (p<0.001) (Table 4). When sex distribution was examined, similar behavior was found, but the progression to overweight and normal weight was significantly higher in women than in men (p=0.022) (Table 3).

In the second post-surgery month, a significant change in BMI categories was still in progress due to a persistent increase in normal weight and overweight cases (p=0.001) (Tables 3 and 4). This change was accompanied by a substantial reduction in the frequency of Grade I and Grade II obesity. When the data distribution was analyzed by sex, similar behavior could be found, but the progression to overweight and normal weight was more pronounced in women than men (p=0.009) (Table 3).

Finally, by the third post-surgery month, BMI categories change due to a significant increase in normal weight cases and overweight cases stabilization ( $p < 0.001$ ) (Tables 3 and 4). This change was accompanied by a substantial reduction in the frequency of Grade I Obesity

and, to a lesser extent, a small decrease in Grade II and III obesity cases. The behavior by sex revealed that the Grade I and Grade II obesity proportions were higher in men than in women ( $p = 0.021$ ) (Table 3).

Table 3. Ponderal distribution according to BMI during the clinical evaluation period.

Variables	Overall n = 101 <sup>1</sup>	Women n = 74 <sup>1</sup>	Men n = 27 <sup>1</sup>	p-value <sup>2</sup>
<b>Ponderal classification at baseline</b>				0.041
Obesity class I	32 (32.3 %)	24 (32.43 %)	8 (29.7 %)	
Obesity class II	42 (42.4 %)	35 (47.29 %)	7 (25.9 %)	
Obesity class III	27 (27.3 %)	15 (20.27 %)	12 (44.4 %)	
<b>Ponderal classification one month post-surgery</b>				0.022
Normal weight	3 (3.0 %)	2 (2.7 %)	1 (3.7 %)	
Overweight	35 (35 %)	29 (39 %)	6 (22 %)	
Obesity class I	43 (43 %)	34 (46 %)	9 (33 %)	
Obesity class II	12 (12 %)	6 (8.1 %)	6 (22 %)	
Obesity class III	8 (7.9 %)	3 (4.1 %)	5 (19 %)	
<b>Ponderal classification two months post-surgery</b>				0.009
Normal weight	4 (4.0 %)	3 (4.1 %)	1 (3.7 %)	
Overweight	50 (50 %)	40 (54 %)	10 (37 %)	
Obesity class I	31 (31 %)	25 (34 %)	6 (22 %)	
Obesity class II	8 (7.9 %)	4 (5.4 %)	4 (15 %)	
Obesity class III	8 (7.9 %)	2 (2.7 %)	6 (22 %)	
<b>Ponderal classification three months post-surgery</b>				0.021
Normal weight	19 (19 %)	17 (23 %)	2 (7.4 %)	
Overweight	50 (50 %)	39 (53 %)	11 (41 %)	
Obesity class I	21 (21 %)	14 (19 %)	7 (26 %)	
Obesity class II	6 (5.9 %)	2 (2.7 %)	4 (15 %)	
Obesity class III	5 (5.0 %)	2 (2.7 %)	3 (11 %)	

<sup>1</sup>n (%)

<sup>2</sup>Fisher's exact test

Table 4. Comparison between BMI categories according to baseline, first month, second month, and three months after surgery.

Pairwise comparisons <sup>1</sup>		D-C test statistic	p-value <sup>2</sup>
Baseline	vs. First month	20.40	0.001
Baseline	vs. Second month	26.15	0.001
Baseline	vs. Third month	33.62	0.001
First month	vs. Second month.	5.75	0.001
First month	vs. Third month	13.22	0.001
Second month	vs. Third month	7.47	0.001

Friedman test:  $X = 244.23$ ; gl 3;  $p < 0.001$ . D-C: Durbin-Conover<sup>1</sup> post-hoc test



### b. Short-term changes in and ponderal standardized variables

**BMI at baseline and three months post-surgery.** At baseline, the overall BMI was  $37.89 \pm 5.6$  kg/m<sup>2</sup>; in other words, arithmetic means within Grade II obesity. When comparing this variable by sex, it is evident that women had a lower BMI, although not statistically significant, compared to men, with values of  $37 \pm 5$  kg/m<sup>2</sup> vs.  $40 \pm 7$  kg/m<sup>2</sup>,  $p=0.05$ . The BMI three months after surgery was  $28.99 \pm 4.67$  kg/m<sup>2</sup>. It is also noteworthy that women achieved a significantly lower BMI than men:  $28.08 \pm 3.98$  kg/m<sup>2</sup> vs.  $31.47 \pm 5.53$  kg/m<sup>2</sup>,  $p=0.001$ . Figure 1 illustrates the BMI trends and pairwise comparisons at baseline and the first, second, and third months postoperatively for both women and men, showing a significant reduction in BMI for both sexes in all pairwise comparisons ( $p<0.001$ ).

**BMI excess.** Overall BMI excess was  $12.52 \pm 6.85$  kg/m<sup>2</sup>. When compared by gender, it showed a predominance, though not statistically significant, in men with  $15 \pm 7$  kg/m<sup>2</sup> compared to women with  $12 \pm 5$  kg/m<sup>2</sup>,  $p=0.05$ . These findings suggest that men tend to seek interventions at higher BMI levels and with greater excess weight compared to women.

### Change in BMI at three months ( $\Delta$ BMI).

The overall change at three months in BMI was  $8.90 \pm 2.32$  kg/m<sup>2</sup>. When the data were analyzed by gender, no significant differences were observed between men  $9.01 \pm 2.26$  kg/m<sup>2</sup> and women  $8.61 \pm 2.51$  kg/m<sup>2</sup>;  $p = 0.058$ .

**BMI monthly reduction (in kg/m<sup>2</sup>).** The overall BMI reduction during the first, second, and third-month follow-up were  $-5.70 \pm 1.98$  kg/m<sup>2</sup>,  $-1.78 \pm 1.23$  kg/m<sup>2</sup>, and  $-1.42 \pm 0.89$  kg/m<sup>2</sup>, respectively. When this variable was grouped by sex, a significant difference was seen in the second month (Table 5).

**% Total Weight Loss (%TWL).** The %TWL for all participants was  $23.44 \pm 4.55$  %, with a higher percentage of weight loss observed in females at  $24.19 \pm 4.48$  % compared to males at  $21.39 \pm 4.23$  %;  $p=0.001$ .

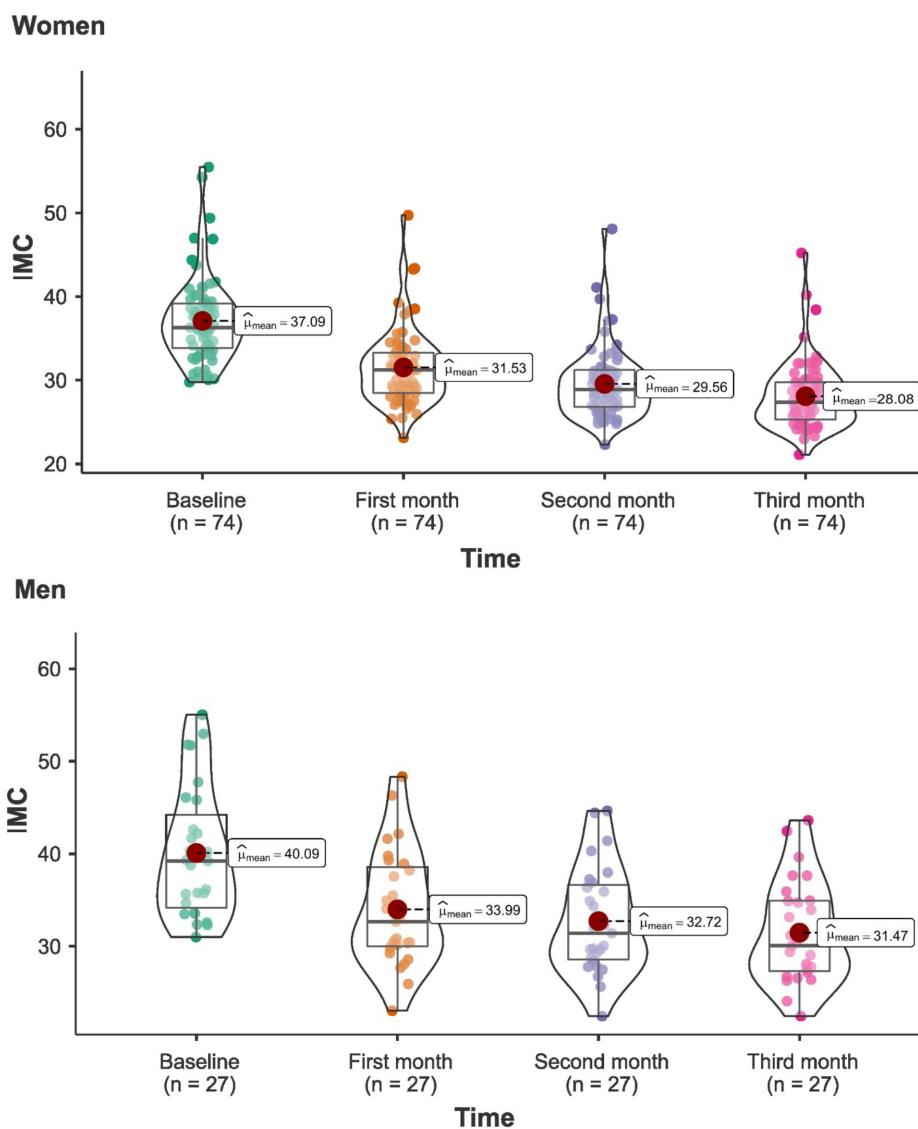
**Percent excess BMI loss or percent excess of weight loss (%EBMIL or %EWL).** Overall, there was a  $77.25 \pm 25.70$  % in this variable. A most important loss was seen in women, with  $81.80 \pm 25.05$  % compared with the  $64.78 \pm 24.14$  % ( $p=0.001$ ) observed in men.

Table 5. Laser-assisted lipolysis significantly changed standardized ponderal variables during the evaluation period.

Variables	Overall n = 101 <sup>1</sup>	Women n = 74 <sup>1</sup>	Men n = 27 <sup>1</sup>	p-value <sup>2</sup>
BMI at Baseline	38(6)	37(5)	40(7)	0.050
BMI at three months	28.99 (4.67)	28.08 (3.98)	31.47(5.53)	0.001
BMI Excess	13(6)	12(5)	15(7)	0.050
Change in BMI at 3-months ( $\Delta$ BMI)	8.90(2.32)	9.01(2.26)	8.61(2.51)	0.5
BMI monthly reduction				
BMI reduction in the first month	-5.70(1.98)	-5.56(1.96)	-6.09(2.02)	0.2
BMI reduction in the second month	-1.78(1.23)	-1.97(1.31)	-1.27(0.82)	0.002
BMI reduction in the third month	-1.42(0.89)	-1.48(0.92)	-1.24(0.78)	0.2
%TWL	23.44(4.55)	24.19(4.48)	21.39(4.23)	0.001
%EBMIL (or %EWL)	77(26)	81.80(25)	66.76(24.14)	0.003
Total volume aspirate in LAL (Litres)	13.77(5.54)	13.19 (4.82)	15.35 (7.03)	0.082

<sup>1</sup>Mean (SD); <sup>2</sup>Welch Two Sample t-test.

Abbreviations:  $\Delta$ BMI: Change in BMI; %TWL: Percent of total weight loss; %EBMIL: Percent excess BMI loss. %EWL: Percent of excess weight loss, a metric equivalent and with the same result of %EBMIL LAL: Laser-Assisted lipolysis



Test: Friedman's (Non-parametric repeated measure ANOVA). Pairwise test: Durbin-Conovan,  $p$  value adjusted by Bonferroni's method. All pair-wise comparison between follow-up times were significant at 0.001  $p$ -value.

Figure 1. Large-volume Laser-assisted lipolysis significantly diminishes BMI in obese patients.

### Early surgical complications, according to the Clavien-Dindo classification system

The overall incidence of early surgical complications was 7 %. Mild complication incidence according to Clavien-Dindo classification (Grade I to Grade IIIb) was 7 %, and the incidence of major complications (IV to V), including mortality rate, was 0 %. Grade I complication was a case of persistent pain

(more than 20 days), the Grade II complications were two cases of acute anemia treated with blood transfusions, Grade IIIa complications were two burns that required intervention with local anesthesia, and finally, two IIIb grade cases, one abdominal ulcer that required a minidermolipectomy, and another case presenting bilateral nipple-areola complex necrosis requiring surgical reconstruction (Table 6).

Table 6. Early (30-days) postoperative complications, according to the Clavien-Dindo classification

Postoperative complications grading	Overall n = 101	Women n = 74	Men n = 27	p-value <sup>1</sup>
<b>Grades</b>				0.2
No complications	94 (93 %)	69 (93 %)	25 (93 %)	
Grade I	1 (1.0 %)	0 (0 %)	1 (3.7 %)	
Grade II	2 (2.0 %)	2 (2.7 %)	0 (0 %)	
Grade III <sup>a</sup>	2 (2.0 %)	2 (2.7 %)	0 (0 %)	
Grade III <sup>b</sup>	2 (2.0 %)	1 (1.4 %)	1 (3.7 %)	

<sup>1</sup>Fisher's exact test

## DISCUSSION

Body contouring surgeries are among the most frequently sought procedures in cosmetic surgery. According to the 2022 report from the American Society of Plastic Surgeons, of the nearly 1.5 million cosmetic surgical procedures performed in 2022, liposuction (325 669 procedures) emerged as the first most popular procedure, experiencing a 23 % surge compared to 2019 (48).

Over the past three decades, technological advancements like laser technology have been introduced to enhance liposuction, improve outcomes, and offer expedited recovery. However, the initial steps of this technology were not without stumbles; for example, the initial failure in Dressel's 1990 report to conclusively demonstrate clear clinical advantages in laser liposuction resulted in the Food and Drug Administration (FDA) lack of clearance for this innovative technique (49). However, a pivotal breakthrough occurred in 1994 when Apfelberg conducted an FDA-approved study (subsequently expanded in 1996) using a neodymium-doped yttrium-aluminium-garnet (Nd-YAG) laser delivered through a 600µm fiber inserted into a 4 or 6mm cannula. In this study, Apfelberg showed the potential advantages of the LAL, including reduced bleeding and ecchymoses, pain, discomfort, and edema (50,51). Since this groundbreaking investigation, subsequent reports consistently underscored the superiority of LAL over the conventional liposuction technique.

Furthermore, one of the most noteworthy aspects of laser implementation was the

stimulation of new collagen synthesis and enhanced skin tightening following the procedure, a phenomenon initially reported by Badin et al. (52). Remarkably, the first laser to receive FDA approval was the 1064 nm Nd-YAG laser (SmartLipo, Cynosure), marking a milestone in the evolution of LAL, becoming in a widely adopted approach for removing unwanted fat and improving skin texture. Since receiving FDA approval in 2006, studies (53-55) have consistently reinforced initial clinical observations, demonstrating reductions in fat accumulation, shorter recovery periods, and enhanced skin firmness. The mechanism underlying laser lipolysis involves fat liquefaction, the coagulation of small blood vessels, an increase in fibroblast numbers, and the stimulation of new collagen production, resulting in subsequent skin tightening and improved tissue elasticity (56,57).

In this regard, the Lipolaser LPL9002<sup>TM</sup> lipolysis device employed in this study has the advantage of three low-power cold lasers at wavelengths of 533, 650, and 980 nanometers, with no need for external cooling during the surgery, thus reducing the burn risk. To date, there are 20 experience years in using low-intensity external photonic therapy directly on the skin to treat Obesity, with or without liposuction (58,59). However, to our knowledge, this is the first device combining three (Multifrequency) low-potency level lasers for subdermal use during large-volume lipolysis, and unlike external lasers, Lipolaser LPL9002<sup>TM</sup> delivers energy directly to the adipose tissue. An additional advantage of this equipment is external therapy laser outputs at the

same wavelengths for skin surface application.

The rationale behind these specific wavelengths is the specific effects on adipose tissue and skin (60). In this sense, the green 530 nm DPSSL laser effectively stimulates clotting in small vessels, thus promoting hemostasis during surgical procedures (61,62). Its ability to be absorbed by hemoglobin in blood vessels allows for precise and controlled small blood vessel sealing, minimizing blood loss, contributing to hematomas and ecchymosis prevention, faster postsurgical recovery, and enhancing patient comfort (61). Additionally, the DPSSL laser enables greater precision when working in delicate areas near important blood vessels, especially in body contouring and facial aesthetic surgeries with minimal thermal damage to surrounding tissues, ensuring a better surgical experience and improved recovery (63). On the other hand, the GaAlAs 650-670 nm red laser has demonstrated the ability to cause selective fat cell lysis during the lipolysis procedure, allowing a massive fat extraction with minimal tissue trauma (64). Alternatively, although the infrared GaAlAs 980 nm laser has been employed to break selectively fat cell membranes, this wavelength's main feature is stimulating skin's collagen formation, contributing to a skin-tightening effect (65-67).

In our study, LAL was associated with a 7 % rate of non-life-threatening early surgical complications within 30 days, primarily Grade I to IIIa according to the Clavien-Dindo classification and was managed with minor procedures. Unfortunately, no studies have employed laser equipment with three simultaneous low-level wavelengths during large-volume and mega-volume liposuction, and the literature reporting complication data is typically comprised of isolated clinical cases or studies with small sample sizes that were not designed with sufficient power to detect complications. Nevertheless, the complication rate in our study is lower than those reported in a recent meta-analysis conducted by Gilardino et al. (68). They analyzed 60 studies involving 21 776 patients undergoing classical aesthetic liposuction, where the overall complication rate was 12 %. When categorizing according to specific complications, the incidence of contour irregularities was found to be 2 %, seroma 2 %, hematoma 1 %, surgical site infection 1 %, fibrosis or induration, and

pigmentary changes 1 %, among others. On the other hand, in a study conducted by Katz et al. (69), a total of 537 consecutive Laser-Assisted Liposuction (LAL) procedures were performed using a 1064-nm Nd:YAG laser, revealing a complication rate of 0.93 %, and a touch-up rate of 3.5 %. The researchers did not provide data on the volume of extracted fat or report the mean or distribution of BMI, factors that can influence the complication rate. In our work, all patients underwent extractions of substantial fat volumes, including those with high BMIs, which may account for the difference in the complication rate. Notably, our study did not require touch-ups or reinterventions despite the high volumes of fat extracted.

On the other hand, in a retrospective study conducted by Reynaud et al. (70) on 334 patients undergoing laser-assisted diode lipolysis with a 980 nm laser, it was found that there were no major complications. However, almost all patients experienced ecchymoses, which contrasts with our study, where the frequency of bruising and bleeding was observed in only 2 cases. Overall, the literature reports that this procedure is safe, especially when larger volumes of fat are extracted, and general anesthesia is necessary.

There is no doubt that the introduction of the tumescent technique in 1987 revolutionized the feasibility of safe, comprehensive body contouring through single-session large-volume liposuction, with the patient under regional anesthesia complemented by local anesthetic administered selectively in specific areas or general anesthesia in situations such as when targeting regions above the subcostal region (upper trunk, lateral chest, gynecomastia, breast, arms, and face), or as per patient preference. The classification of large-volume liposuction is based on safety and aesthetic considerations, with a 5 000-L aspirate defining large-volume liposuction, an 8 000-L aspirate categorizing mega-volume liposuction, and an aspirate of 12-L or more designating giganto-volume liposuction (33,34).

In our study, an average volume of 13.77 liters (Females: 13.9 L and males: 15.35 L) was aspirated, placing most procedures performed in this study into the category of mega-volume and giganto-volume liposuctions. This fact holds significant implications from the indications

for this type of surgery beyond mere aesthetic procedures. Achieving weight loss of more than 15 % of total body weight reaches an effectiveness exceeding that attainable with anti-obesity drugs, with the advantage of immediate weight reduction and without leaving aesthetic sequelae such as excess redundant skin, a commonly reported issue in post-bariatric patients. In other words, multifrequency laser-assisted lipolysis in mega-volume and giganto-volume procedures could be considered a genuine bariatric intervention.

To the best of our knowledge, this is the first laser-assisted lipolysis study that has analyzed weight changes using standardized metrics from two perspectives. Firstly, in terms of the proportion of individuals classified by BMI before and after surgery, and secondly, the BMI trajectories analyzed by standardized metrics employed in studies assessing weight reduction efficacy for traditional bariatric surgery techniques or studies evaluating the effectiveness of anti-obesity medications. This approach revealed a significant shift from baseline (where all participants were obese) to a final point at the third month, where 70 % of individuals were categorized as normal weight or overweight.

Regarding net weight loss, the most common metric to evaluate the efficacy of any drug or procedure is BMI decrease. A remarkable and statistically significant reduction of 8.9 kg/m<sup>2</sup> in BMI (9.01 kg/m<sup>2</sup> in females and 8.61 kg/m<sup>2</sup> in males) was observed when BMI behavior was analyzed. This BMI reduction falls within the range of weight loss observed in traditional bariatric surgical procedures, as we will discuss further.

In terms of percentages (represented by %TWL), the patients collectively lost 23.44 % of their body weight, and in terms of the percentage of BMI lost (% BMIL), it amounted to 77 % overall (81 % in women and 66.76 % in men). Any medication to date has not attained these achievements and is comparable to the weight losses achieved by procedures such as Vertical Sleeve Gastrectomy (VSG) or Roux-en-Y Gastric Bypass (RYGB), as evidenced when contrasting our data with those from a recent meta-analysis conducted by Oslan et al. (71). In this meta-analysis, postoperative weight loss outcomes were compared in 9 randomized control trials (RCTs) for VSG versus RYGB in 865 patients.

It was reported that the twelve-month excess weight loss (EWL) for VSG ranged from 69.7 % to 83 %, and for RYGB, it ranged from 60.5 % to 86.4 %. In another meta-analysis conducted by Han et al. (72), which was based on 18 studies (N = 2917 participants) and included nine randomized control trials and nine non-randomized interventional studies, they found that the excess weight loss (EWL) for LVSG ranged from 28.3 % to 78.8 %. For RYGB, it ranged from 28.5 % to 81.6 %.

Despite many publications highlighting the effectiveness of low-level laser usage in body weight, abdominal circumference, and BMI in conjunction with liposuction, most of these have been applied externally. To date, and following an extensive literature review, this is the first study utilizing subdermal low-level laser-assisted lipolysis in mega-volume and giganto-volume that has evaluated its effect on standardized variables reporting weight loss efficacy. Only one study conducted by Elmeherat et al. (73) addressed the impact of large-volume liposuction on body weight and total body fat in 31 overweight and obese patients (BMI ranging from 25 to 35) and in patients with localized fat accumulation in individuals of normal weight. Preoperatively, the mean BMI was (32.5±2.6 kg/m<sup>2</sup>), while postoperatively, after three months, the mean was (30.45±2.74 kg/m<sup>2</sup>), and after six months, the mean was (28.83±2.87 kg/m<sup>2</sup>). As can be observed, the BMI reduction was considerably lower than in our study, possibly due to the inclusion of individuals with normal weight and the absence of laser therapy in their study.

## CONCLUSIONS

Our results show that large, mega, and giant-volume LAL is an effective and safe technique for weight reduction. BMI, %TWL, and %EBMIL experienced a drastic reduction similar to those observed in VSG and YRGB. We recommend conducting controlled clinical trials to investigate this technique's effectiveness in the medium and long term and its efficacy compared to other bariatric procedures.

**Conflict of Interest:** The authors declare no conflicts of interest.

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