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A novel multifrequency low-level laser-assisted mastopexy technique: An analysis in 231 consecutive patients

Una nueva técnica de mastopexia asistida por láser de baja intensidad multifrecuencia: Un análisis en 231 pacientes consecutivas

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SUMMARY

Introduction: *The downward nipple-areola complex (NAC) displacement below the inframammary fold characterizes breast ptosis (BPt). This study aimed to evaluate the efficacy of a novel mastopexy technique in patients with BPt with and without breast prosthesis placement.* **Methods:** *A longitudinal study was performed on 231 women diagnosed with BPt treated with a novel low-level multifrequency laser-assisted mastopexy. Change in BPt was assessed according to Regnault's system and the sternal notch-to-nipple distance (SNND) at the first, second, and third post-operative months. Additionally, the incidence and nature of complications within the first 30 days post-surgery were evaluated according to the Clavien-Dindo system.* **Results:** *Before surgery, all patients (100 %) presented with breast ptosis. A significant increase in the percentage of patients without BPt was observed across the three-month follow-up from 0 % before surgery to 90 % in the third month (p<0.001 for all proportion comparisons). The SNND exhibited a significant reduction in all measured points, p<0.001 for all comparisons. When the patients were grouped according to prosthesis placement (or not), the between-group pairwise comparisons revealed non-significative differences for each evaluation time. The within-group comparisons showed a significant time-dependent reduction in NSSD in both groups (p<0.001). The procedure shows a low 4 % complication incidence with no mortality.* **Conclusions:** *Low-power multifrequency laser-assisted mastopexy is an effective and safe procedure for repositioning the NAC in patients with BPt with a very low complication rate.*

Keywords: *Breast ptosis, mastopexy, breast lifting, laser-assisted lipolysis, laser-assisted mastopexy, laser therapy.*

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RESUMEN

Introducción: *El desplazamiento del complejo areola-pezón (CAP) por debajo del surco submamario caracteriza la ptosis mamaria (PM). El objetivo de este estudio fue evaluar la eficacia de una nueva técnica de mastopexia en pacientes con PM con y sin implante mamario.* **Métodos:** *Se realizó un estudio longitudinal en una cohorte de 231 mujeres diagnosticadas de BPt tratadas con mastopexia asistida por láser de multifrecuencia de bajo nivel evaluando el estado de la ptosis mamaria según el sistema de Regnault y la distancia entre la escotadura esternal y el pezón (SNND). Además, se evaluó la incidencia y la naturaleza de las complicaciones en los primeros 30 días postoperatorios según el sistema Clavien-Dindo.* **Resultados:** *Antes de la cirugía, todas las pacientes (100 %) presentaban algún grado de ptosis mamaria, pero se observó un aumento significativo del porcentaje de pacientes sin PM a lo largo de los tres meses de seguimiento desde 0 % antes de la cirugía al 90 % en el tercer mes (p<0,001 para todas las comparaciones de proporciones). La SNND mostró una reducción significativa en todos los puntos de medición. Cuando las pacientes se agruparon según la colocación (o no) de prótesis, las comparaciones entre grupos no revelaron diferencias para cada momento de evaluación. Las comparaciones dentro de los grupos mostraron una reducción significativa de la NSSD en función del tiempo en ambos grupos (p<0,001). El procedimiento presenta una baja incidencia de complicaciones del 4 %, sin mortalidad.* **Conclusiones:** *La mastopexia asistida por láser multifrecuencia de baja potencia es un procedimiento eficaz y seguro para reposicionar el NAC en pacientes con BPt con una tasa de complicaciones muy baja.*

Palabras clave: *Ptosis mamaria, mastopexia, elevación mamaria, lipólisis asistida por láser, mastopexia asistida por láser, terapia láser.*

INTRODUCTION

Breast ptosis (BPt) is characterized by the nipple-areolar complex (NAC) displacement below the inframammary fold (1,2). The most important risk factor for developing BPt is aging, a natural phenomenon impacting the breast's soft tissues due to decreased collagen synthesis via fibroblast senescence (3), which reduces skin elasticity and progressive weakness in supporting fibrous structures. In addition, low estrogen levels during menopause (4) contribute to mammary adipose tissue reduction and skin aging progression (5). Other factors like important weight loss, macromastia, pregnancy, and both alcohol and tobacco consumption interact with aging and genetic factors modifying the breast tissue architecture (6), affecting the BPt course and treatment response (7).

Mastopexy, a cornerstone of breast aesthetics surgery, aims to restore the breasts to a more youthful position by repositioning the NAC to an "ideal" location, typically around 19-21 centimeters from the sternal notch (8-10). Several well-established breast lift surgical techniques, such as the crescent, concentric, vertical, and inverted-T mastopexy, have been developed to correct the NAC position upward (11-17), but regrettably, the skin excess removal dictates the resulting scars. In this regard, several authors have the "inverted T" and "short-inverted T" techniques, which aim to shorten the horizontal incision. In contrast, the radical horizontal segment elimination gives rise to the "L" and "J" scar techniques (18-21). This pattern, however, has the midline proximity drawback, increasing the hypertrophic scar risk (21). In this regard, the "single vertical scar" technique (22,23), as seen in the Lassus technique, a vertical ellipse resection is performed without undermining the skin, resulting in a large final vertical scar that may cross the inframammary fold (22). Lejour follows the same method as Lassus, but his markings ensure a crease-free areola because the vertical scar will soften over time due to skin contraction (23,24). In the circumvertical technique, the final vertical scar does not cross the inframammary sulcus, and the folds are evenly distributed around the areola and the vertical wound (12).

The periareolar technique has emerged as a refined approach for mild to moderate breast hypertrophies where limited skin resection is necessary or when no more than 2 cm in nipple elevation is necessary (9). The rationale is that as the breast size increases, the amount of skin resected also increases, involving skin excess absorption within the periareolar scar, which generates eccentric forces that can expand the NAC and the final scar (25).

Consequently, regardless of the specific mastopexy technique employed, this procedure is invariably accompanied by a range of complications, particularly in wound healing (26), especially when the procedure implies a single-stage augmentation mastopexy to correct deflated ptotic asymmetric breasts because this procedure requires an equilibrium between skin reduction and concurrent volume enhancement (27). Due to this dilemma, there are more chances for complications, like fat necrosis, skin loss, infections, seromas, hematomas, suboptimal aesthetic outcomes, nipple sensitivity reduction, BPt recurrence, and NAC loss (28).

In response to these challenges, in the past decades, numerous techniques aimed at refining breast surgery procedures have emerged. One such advancement is laser-assisted breast aesthetic surgery, which has evolved as an improvement over traditional liposuction techniques (29). This modality has gained widespread adoption in areas like body contouring and laser-assisted lipolysis because of its efficacy and safety, reducing surgical time with fewer complications (2,10,30). As has been seen in other procedures in cosmetic surgery, laser energy may improve breast surgical performance in technical aspects previously considered challenging, such as non-visible scars, with minimal pain and faster recovery (30). Thus, laser-assisted aesthetic surgery's rationale mainly relies on the specific effects of blood vessels, adipose tissue, skin, and fibrous structures (31,32). In this instance, Low-Level 530 nm diode-pumped solid-state (DPSS) green laser can be absorbed by hemoglobin (33,34), allowing for precise and controlled small blood vessel hemostasis, reducing both hematomas and ecchymosis during surgical procedures (35,36). Other laser-based techniques using 650-670 nm Gallium-Aluminum-Arsenide diode red laser (GaAlAs) cause selective adipose cell lysis, enabling fat extraction with minimal tissue trauma (37). Meanwhile, the infrared GaAlAs 980 nm laser primarily stimulates collagen formation, promoting a progressive and sustained skin-tightening effect (38-41).

This study aimed to evaluate the outcomes of 231 laser-assisted mastopexy procedures with or without breast prosthesis placement using a novel low-intensity multifrequency laser technology to maximize the appropriate NAC positioning.

MATERIALS AND METHODS

Patients and study design

A non-experimental longitudinal prospective cohort study was done on 231 women undergoing a scarless low-level laser-assisted mastopexy technique at the Clínica de Obesidad y Envejecimiento S.A.S., Bogotá, Colombia. The study assessed sternal notch-to-nipple distance (SNND) and the breast ptosis degree by the Regnault classification system at the first, second, and third postoperative months. It also describes the amount and types of complications within the first 30 days post-surgery.

Ethical issues

This study followed the Declaration of Helsinki of 1975 (42) and was approved by the Research Bioethics of Clinica de Obesidad y Envejecimiento S.A.S., Bogotá, Colombia. (Code 2020-0113-RC3, November 20th, 2020). The anonymized dataset is available at the Harvard Dataverse Scientific repository (43). All participants were provided informed consent for the procedure describing the surgical intervention technique, intent, 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.

Preoperative Stage

Patients attended an initial medical session, which included measuring the SNND distance with a graduated measuring tape, both for the left and right breasts. Subsequently, BPt was stratified according to the Regnault classification as follows (1):

First-degree or minor ptosis: the nipple lies at the submammary fold level, above the gland's lower contour and skin brassiere.

Second-degree or moderate ptosis: The nipple lies below the fold level but remains above the lower contour of the breast and skin brassiere.

Third-degree or major ptosis: the nipple lies below the fold level and at the lower contour of the breast and skin brassiere.

The preoperative workup consisted of routine labs, an EKG, and a Stress Test for patients at higher risk or over 40 years of age. The cardiologist completed the preoperative risk assessment. Then, a bilateral breast ultrasound was performed on all participants. Finally, a second medical consultation was held to review and discuss the laboratory and clinical test results to decide whether they were suitable for surgery or if prior treatment of any medical condition was required.

A pre-surgical protocol was implemented in each patient eligible for surgery, consisting of a skin surface GaAIAs (semiconductor) 650-670 nm red laser application for one hour in each breast three days before surgery. In addition, antibiotic prophylaxis was started two days before surgery. It was continued 14 days after surgery (Ampicillin/Sulbactam, 750 mg b.i.d orally for 16 days + metronidazole, 500 mg t.i.d orally for seven days or Levofloxacin 500 mg b.i.d orally for 16 + metronidazole 500 mg t.i.d for 7 days in the case of beta-lactam allergy or oral intolerance). Anesthesiologist performed a preoperative assessment of all patient's prior surgery.

Surgical Stage

Patient marking

Since the procedure involved lifting in three primary areas, each breast was divided into three zones (Figure 1):

Zone 1 or Thoracic Zone: This region extends from the inferior border of the clavicle to the superior breast border. Internally, it is delimited by the sternum border and externally by the anterior axillary fold.

Zone 2 or Axillary Zone: This encompasses the entire axillary area, from the anterior axillary fold, the axilla as a whole, and the lateral border of the breast to the 5th intercostal space, including the entire back area.

Zone 3 or Breast Zone: This comprises the breast itself, extending from the inferior mammary fold to the limits of the other two zones.

All three zones include skin, subcutaneous cellular tissue, mammary glands, ligaments, and muscle fascia. These are the layers of the skin up to the muscle where the laser can be incised. Once the marking was completed, the main surgeon confirmed the SNND and BPs using the Regnault classification system for the right and left breasts (1).

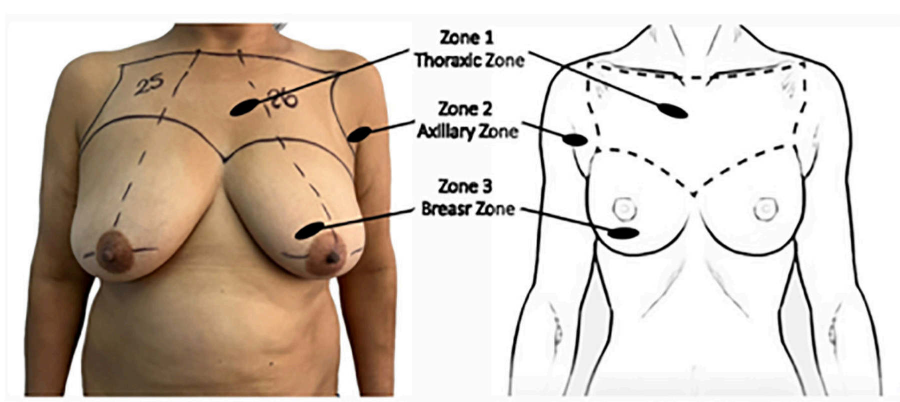


Figure 1. The three key zones in multifrequency low-level laser-assisted mastopexy.

Anesthesia and preliminary preparation

Before the incision, time out was done, confirming the surgical procedure and the breast to be operated on. With the patient under an 8-hour fasting regimen, general anesthesia with deep sedation was administered. The areas to be intervened were then antiseptically prepared, and sterile drapes were placed to initiate the surgery formally. The surgical procedure consisted of the following stages:

Breast infiltration with tumescent solution

Two small incisions of 2 mm were made with an # 11 scalpel: one at the upper edge of the breast at the anterior axillary line level and a second one at the lower breast edge at the anterior axillary line for both the right and left breast (Figures 2 and 3). This step was followed by a # 4 atraumatic cannula insertion and an intradermal infiltration with a solution prepared with 1 mL adrenaline ampoule (1 mg/mL) diluted in 1L of 0.9 % NaCl solution. Each breast was perfused in a hyperhumid infiltration pattern by the injection of 2L of this solution in small to normal-size breasts and 3L in the case of gigantomastia.

Multiprequency Low-level Laser-assisted mastopexy without breast prosthesis placement.

A laser lipolysis device (Lipolaser LPL9002™ , Colombia) was employed throughout the procedure. This multifrequency, low-power cold laser device has 532, 650 and 980 nanometers

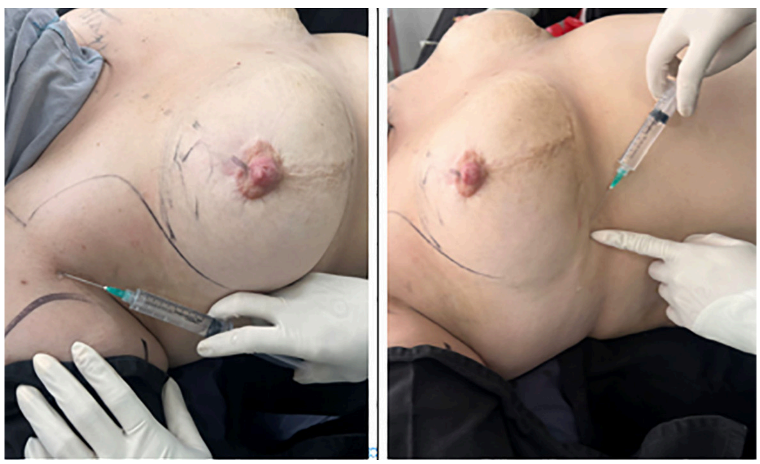


Figure 2. Local anesthesia infiltration in the anterior axillary line at both the upper breast edge and the lower breast edge.

Figure 3. Scalpel incisions in the anterior axillary line at both the upper breast edge and the lower breast edge.

wavelengths. This equipment complies with international safety standards for electromedical devices (IEC 601-1) and laser equipment (IEC 825). Each laser fiber was placed within a 1.2 mm caliber atraumatic 30 cm long cannula. The surgical procedure usually lasts 40 to 60 minutes approximately, and all regions undergo the same four-step technique as follows:

The 532 nm and 900-milliwatt green laser was the first applied. Its vasoconstrictive effect ensured little or no blood loss. The cannula was inserted through the two previous incisions, followed by slow forward and backward movements in the mid-thickness of the flap in each region for one to three minutes.

The second laser applied was the 650 nm red laser. The primary function of this laser is to induce adipocyte lysis, leading to triacyl glyceride release in areas targeted for fat extraction, specifically in zones 1 and 2. If breast reduction is the intended procedure, this laser was already applied in Zone 3, which encompasses the breast tissue. The laser exposure time was sufficient to achieve fat liquefaction perceived by changes in adipose tissue by palpation (from a solid to a liquid phase) and the absence of resistance to the laser cannula passage. Once the fat was adequately liquefied, it was meticulously aspirated, mirroring the laser application sequence, ensuring removal throughout the entire thickness of the flap by slow, controlled movements, using straight and curved cannulas of 5, 4, or 3 mm in diameter connected to a suction device (Wells Johnson Co., Tucson, AZ, USA). This process is generally minimally traumatic and results in liquefied, yellowish fat accumulating with minimal or no blood.

Finally, a 980 nm and 900-milliwatt infrared laser was applied for 5 minutes in each zone into the subdermal space to promote skin retraction. In this regard, Zone 2 is particularly responsive to laser-induced retraction. The rationale of these steps relies on Zone 1 and Zone 2 being left free so that Zone 3 can be moved. This process facilitated the entire breast mass manipulation until a correct position was achieved. In the case of laser-assisted lipolysis mastopexy with implant placement, the prosthesis was placed through a sub-mammary or sub-areolar approach after laser therapy. Then, the implant was placed in a retromuscular place as follows.

Mastopexy with Breast Prosthesis Placement

The submammary approach was the primary access route employed in this study. The surgical technique was performed as follows:

A 3-5 cm horizontal incision was made at the level of the future inframammary fold, with the exact length determined by the implant volume. Two-thirds of the incision was positioned lateral to the breast midline to minimize visibility. A slightly lower incision was necessary in larger implant cases (>350 mL). For implants smaller than 225 mL, the new inframammary fold was placed 6.5 cm below the inferior pole of the areola; for 225-300 mL implants, incision size was 7 cm; and for implants larger than 325 mL, incision size was 8 cm. Farabeuf retractors were then placed, and dissection was performed with scissors, extending superiorly to the inferolateral border of the pectoralis muscle.

A Digital dissection was made to develop an avascular plane beneath the pectoralis major for pocket construction. The inferior and medial attachments of the pectoralis muscle to the ribs and sternum were detached, and a retro pectoral pocket tailored was created to accommodate the breast prosthesis. Finally, the pocket was irrigated with povidone-iodine solutions, followed by saline solution. The implant was inserted into the retro pectoral pocket, and closure was performed in three layers.

Nevertheless, the periareolar approach for retro pectoral implant placement was employed when the Benelli technique was necessary to recentre the NAC in patients with a poorly defined inframammary fold or even to perform a glandular expansion procedure. It is challenging to perform in patients with a small NAC with a minor axis of less than 3.5 cm. The procedure was performed as follows:

An inferior hemiareolar incision was made with a cold scalpel at the junction between light and dark skin, followed by subcutaneous fat and the breast gland sectioning in the frontal plane down to the pectoralis muscle using Gillies hooks and then achieving exposure with Farabeuf retractors. Digital dissection was performed to develop an avascular plane beneath the pectoralis major muscle. Detachment of the inferior and medial attachments of the pectoralis muscle to the ribs and sternum was then performed to create a retro pectoral breast pocket adapted to the implant. The pocket was irrigated with saline and povidone-iodine, followed by a saline rinse. The implant was inserted into its retro pectoral pocket, and the skin was closed with absorbable and a continuous intradermal suture.

The procedure, from initial skin incision to final wound closure, was completed, on average, in one-hour timeframe.

Post-operative follow-up

After surgery, the first lymphatic drainage session was performed using the Vodder method (44)moving fluid in the skin, increasing lymphomotoricity, and softening fibrosis, with the positive side effects of reducing pain and relaxing tense muscles. Another difference from other methods is the technique of stretching skin, not sliding it. Because of the fluid content in lymphedema, which is different from all other edemas, the combination of MLD with compression treatment is the only solution for this pathology. Depending of it severity, each case requires individualized treatment. Phase 1 (intensive treatment, and then, the breasts were covered with a compressive bandage covered with Micropore® tape and fitted with a high-pressure bra for non-prostheses mastopexy and a low-pressure bra for procedures performed with prostheses. One hour later, the patient was transferred to the recovery room, and a liquid food tolerance test and ambulation were initiated. Subsequently, the patient is discharged from the recovery room and is taken to a hyperbaric chamber session (Leader Life ACR 60-72 Monoplace Hyperbaric Chamber Colombia) for 1 hour (45). Once the hyperbaric session was completed, the patient was discharged home and began post-surgical care sessions the following day. During these sessions, hyperbaric treatments, external low-level laser therapy (Lipolaser LPL9002™, Colombia), pressotherapy, and a 5-minute drainage routine for five days were performed. The patient underwent daily evaluations for ten days and monthly evaluations for the following three months.

Monthly Follow-up Visits

Patients were evaluated monthly to monitor the SNND distance measures on both the right and left breasts. A comprehensive clinical examination evaluated surgical complications within <30 post-operative days.

Early Surgical Complications, according to the Clavien-Dindo Classification

A surgical complication was defined as any deviation from the ideal post-operative 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) (46). CDCS is based on the therapeutic implications of perioperative surgical complications (46). This system has been validated in patients undergoing bariatric surgery (47,48), abdominoplasty (49,50) the definition, rate (4%-70%, and lower body contouring surgery (49,51,52) the procedure is prone to complications. Herein, we stratified complications timewise. Furthermore, we examined whether the weight loss method - bariatric surgery or lifestyle changes - affected the frequency or severity of complications. In this single-centre retrospective analysis, we included 158 patients with massive weight loss undergoing body contouring surgery between 2009 and 2015. We recorded 96 complications in 80 patients, with an overall rate of 51%. Most complications (80.2 %), 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 recom-mendations, patients with more than one complication were classified based on the most severe complication. Grades I, II, and IIIa were considered mild for this work, while grades IIIb, IV, and V were considered major complications.

Statistical analysis

Statistical analysis was performed using the R statistical computing environment (53) running in Jamovi, a free, open-source statistical software program built in R programming language (54). Categorical variables were displayed in tables as absolute, relative, and cumulative frequencies. Proportion comparisons were made using Pearson's Chi-Square or Fisher's exact tests. The proportion changes in BPt degree along time measures were compared with Friedman's test and the Durbin-Conover post-hoc test for pairwise contrast. Quantitative variables were expressed as means ± SD (in parenthesis) or medians and percentiles as appropriate. If normality and homoscedasticity were met, quantitative variables comparisons were made using Student's t-test (for two groups) or repeated measures ANOVA with the package LME4 for R (55) (for more than two-time measures in patients with and without prosthesis placement). Welch's t-test or Trimmed means robust ANOVA was employed in cases where these assumptions were unmet. GGPlot2 library for the R environment was used to generate proportion stacked bars and paired boxplots (56). A p-value < 0.05 was considered statistically significant.

RESULTS

General characteristics and demographic features

This study reports the clinical data of 231 patients undergoing Multifrequency low-level laser mastopexy.

Qualitative variables: In general, 75 % were in the 30-49 age group, and 75 % had some body weight excess (42 % overweight and 33 % obese). Seventy-five percent of the participants recognized themselves as ethnically mixed, and eighty percent reported having at least one child (63 %, 1-2 children), while 80 % reported breastfeeding their children. Regarding alcoholic beverages and tobacco consumption, 90 % of participants did not drink alcohol, and 94 % did not smoke. Regarding prosthesis placement during mastopexy, 125 (54 %) patients did not receive breast prostheses, implantation was not performed, and 106 (46 %) breast prosthesis was implanted. The detailed distribution of these characteristics is shown in Table 1.

Quantitative variables: The age arithmetic mean was 40.13 (8.71) years, with a minimum age of 19 years and a maximum of 59 years. BMI arithmetic mean was 28.9 (5.14) kg/m^2, with an average excess weight of 16.93 (13.15) kg. The arithmetic mean of the SNND before surgery was 28.26 (3.85) cm for the right breast and 28.11 (3.90) cm for the left breast, while an arithmetic mean of 177 (52.33) mL of fat was extracted during the procedure, and the mean prosthesis volume was 400 (69.33) mL. The rest of the descriptive statistics are shown in Table 2, including percentile distribution.

Baseline quantitative variables according to breast prosthesis use: When the patients were stratified according to breast prosthesis placement or not, we found that those programmed not to receive prosthesis had a higher BMI than those who decided to get prosthesis (30.03 kg/m^2 *vs.* 27.14 kg/m^2, $p<0.001$). No significant differences between these groups concerning age and right and left SNND were found (Table 3).

Personal pathologic history: A thorough review of the patient's records revealed that 74.% had no significant past medical conditions—however, the remaining 26 % of patients presented with noteworthy comorbidities. Specifically, 24 % of patients had a history of hypothyroidism, 10 % presented with hypertension, and 10 % had depression (See Supplementary Material, Table 1C).

Table 1. Qualitative variables of the participant.

Variables	n	%	Cumulative %
Age groups			
<30	26	11	11
30-39	88	38	49
40-49	86	37	87
50-59	31	13	100
BMI categories			
Normal weight	57	25	25
Overweight	96	42	66
Obesity I	52	23	89
Obesity II	19	8	97
Obesity III	7	2	100
Ethnicity			
African-Colombian	9	4	4
Hispanic Whites	60	26	30
Mixed	162	70	100
Alcohol consumption			
No	209	90	90
Yes	22	10	100
Tobacco consumption			
No	216	94	94
Yes	15	6	100
Breastfeeding			
No	47	20	80
Yes	184	80	100
Parity			
0	47	20	20
1	67	29	49
2	78	34	83
3	24	10	94
4	11	5	98
5	2	1	99
6	2	1	100
Prosthesis placement			
No	125	54	54
Yes	106	46	100

Breast ptosis degree changes before and after surgery in all patients

Before surgery, as expected, all patients had some degree of breast ptosis with a clear predominance of grade III ptosis in 53 % (n=122) of the participants. After a mastopexy, a significant variation in the ptosis degree was observed throughout the three months of post-operative evaluation, highlighting that the number of patients without BPt increased significantly to 42 % (n=97) in the first month, 58 % (n=133) in the second month and 90 % (209) in the third month. All these changes were statistically significant when compared at the four measurement times ($p<0.001$) (Table 4, Graph 1 and Supplementary material Table 2C).

SNND distance before and after low-level laser-assisted mastopexy in all participants

Table 5 shows the mean and median SNND measures before and at each post-operative evaluation time. A progressive and sustained decrease in the arithmetic mean SNND distance at each post-operative measurement was observed, from 28.26 (3.85) cm to 18.79 (1.95) cm for the right breasts and from 28.11 (3.90) cm to 18.64 (2.21) cm in the left breasts. It should be noted that significant differences were found when comparing all SNND measurements at the different observation times in both the right and left breast ($p<0.01$ in all comparisons). If this distance reduction is translated to percentual changes, the overall reduction in the third month in SNND was 30 % in both the right and left

Table 2. Baseline quantitative variables in the participants

	Mean	Median	SD	Min	Max	Percentiles 25th	50th	75th
Age	40.13	40	8.71	19	59	34.00	40.00	46.00
BMI	28.70	27.75	5.14	19.38	50.47	25.22	27.75	32.16
Ideal weight	57.46	57.00	5.09	46.00	77.00	54.00	57.00	60.00
Weight excess	16.93	14.30	13.15	0.00	69.00	7.00	14.30	24.00
SNND before surgery (RB.)	28.26	27	3.85	21	39	26.00	27.00	1.00
SNND before surgery (LB.)	28.11	27	3.90	20	39	26.00	27.00	31.00
Fat volume extracted (mL)	177.34	180	52.33	0	290	150	180	200
Prosthesis volume (mL)*	400	400	69.33	175	650	375	400	425

* = Calculated in 106 patients who receive prosthesis placement. Abbreviations: BMI: Body Mass Index. SNND: Sternal Notch to Niple Distance. RB: Right breast. LB: Left Breast. SD: Standard deviation.

Table 3. Baseline quantitative variables according to breast prosthesis use.

Prosthesis	n	Mean	Median	SD	t	Statistic	p
Age (Years)	No	125	40.37	41	9.35		
	Yes	106	39.84	39.00	7.93	6 256	0.466
BMI (kg/m^2)	No	125	30.03	28.93	5.42		
	Yes	106	27.14	26.52	4.32	4 492	<0.001
Ideal weight kg)	No	125	57.47	57.00	4.90		
	Yes	106	57.45	57.00	5.33	6 616.50	0.987
SNND before surgery in cm (RB.)	No	125	28.68	27	4.04		
	Yes	106	27.77	27.00	3.57	5 673.00	0.057
SNND before surgery in cm (LB.)	No	125	28.51	28	4.13		
	Yes	106	27.63	27.00	3.58	5 782.50	0.093
Weight excess (kg)	No	125	20.21	18.00	14.04		
	Yes	106	13.06	10.18	10.86	4 521.50	<0.001

Abbreviations: BMI: Body Mass Index. SNND: Sternal Notch to Niple Distance. RB: Right breast. LB: Left Breast. SD: Standard deviation.

breasts. Comprehensive pairwise comparisons are depicted in Supplementary Material (Table 3C).

In addition, a Welch's t-test was performed to compare the SNND at three months between the right and left breasts, thus verifying symmetry in terms of breast length and NAC placement at the same height. In this regard, the right breast SNND in the 3rd month exhibited an arithmetic mean of 18.79 ± 1.95 cm and a median of 19 cm, while left breast SNND had an arithmetic mean of 18.64 ± 2,21 cm and a median of 19 cm. The means comparison showed non-significant differences; p = 0.4, demonstrating no differences in SNND between breasts.

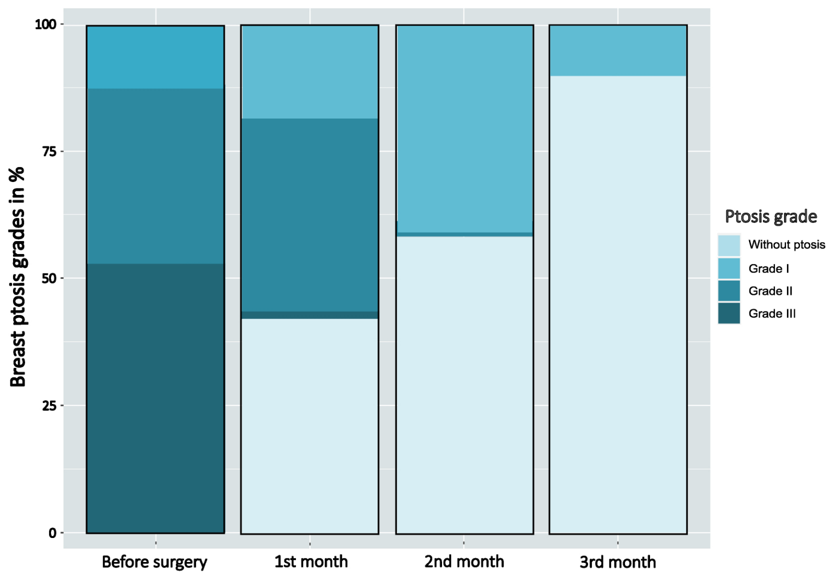
SNND distance after laser-assisted mastopexy in patients with and without breast prosthesis

Multifrequency low-level laser mastopexy significantly reduced NSSD distance in patients with and without prosthesis placement in both the right and left breast in a well-defined time-dependent manner (Table 6 and Graph 2). The within-group effect for the right breast comparisons in arithmetic mean showed significant differences in NSSD reduction when comparing all evaluation times (Graph 2, panel A), p for the tendency <0.001. The ANOVA for the repeated measures chart is shown in the Supplementary material, Table 5 C). Regarding

Table 4. Proportions in breast ptosis grade before and after multifrequency low-level laser-assisted mastopexy

Ptosis degree	N	%	Cumulate %
Before surgery			
I	28	12	12
II	81	35	47
III	122	53	100
1st month			
Without ptosis	97	42	42
I	42	18	60
II	89	39	99
III	3	1	100
2nd month			
Without ptosis	133	58	58
I	95	41	99
II	3	1	100
3rd month			
Without ptosis	209	90	90
I	22	10	100

Note: Ptosis degree according to Regnault classification (I, II, II degrees). Friedman test: χ^2: 600.84; gl: 3; p<0.001 in all proportion's comparison according to time (Before surgery, 1st, 2nd, and 3rd month) with Durbin-Conover post-hoc test (See Suplementary material, Table 2C).



Graph 1. Temporal changes in ptosis degree proportions in low-level laser-assisted mastopexy. Before surgery, most of the patients presented with grade III (50 %) and grade II (25 %) breast ptosis. Notably, there was a progressive increase in the proportion of patients with no breast ptosis starting from the first post-operative month (42 %), reaching 90 % at the three-month mark. Changes in ptosis degree proportions at each of the four-time points were statistically significant by the Friedman test: χ^2: 600.84; df: 3; $p < 0.001$, with post-hoc comparisons by the Durbin-Conover test (see Supplementary Material, Table 2C).

the left breasts, the previous results are closely followed as expected (Graph 2, panel B), p for the tendency <0.001. Tables 4C and 5C in the Supplementary material show the repeated measures ANOVA model assessing the SNND x time interactions and prosthesis placement (Yes/No).

Moreover, concerning the between-groups effect, in the NSSD pairwise comparison by prosthesis placement (No/Yes) in each evaluation time (before, 1st month, 2nd month, and 3rd month), non-statistical differences were found in the right and left breasts (Table 6, Figures 4 and 5).

Early surgical complications (<30 days), according to the Clavien-Dindo system

The incidence of early complications in this series of patients was 4 % (n=9). These complications were two patients (1 %) who presented generalized pain and required specialized intervention (Grade II), four patients (1.75 %) with areola necrosis (Grade IIIb), and three seromas (Grade IIIb) (1.25 %) who required surgery under general anesthesia.

DISCUSSION

BPt is characterized by CAP lowering below the breast fold and skin redundancy in the lower breast pole (1). While some women may retain a youthful NAC position throughout their lives, several well-established risk factors contribute to eventual BPt in most females. When the breast's supporting structures, such as pectoral muscles, skin, crests of Duret and Cooper's ligaments, begin to lose firmness and BPt develops (2,4), expressed as the typical downward breast displacement and excessive skin fold formation (4). In addition, BPt can also manifest within two opposite situations: 1) A breast tissue reduction, such as following significant weight loss (4)

Table 5. SNND in low-level laser-assisted mastopexy in all participants.

SNND	Time	Mean (cm)	Median (cm)	Cumulative % changes	SD
Right breast*	Before surgery	28.26	27		3.85
	1st month	23.00	23	-15	2.73
	2nd month	20.56	20	-26	2.03
	3th month	18.79	19	-30	1.95
Left breast*	Before surgery	28.11	27		3.90
	1st month	22.96	22	-18	2.73
	2nd month	20.61	20	-26	2.07
	3th month	18.64	19	-30	2.21

Note: Robust ANOVA of trimmed means (level 0.2). *: Significative differences at $p<0.001$ level in all pairwise S.N.N.D. comparisons according to time for each breast S.N.N.D. (See complementary material, Table 3C). The cumulative percentage reduction is shown in parenthesis next to the median. Bootstrapping for effect size CI computation (samples 599). Abbreviations: SNND: Sternal Notch to Nipple Distance. RB: Right breast; LB: Left breast. SD: Standard deviation.

Table 6. NSSD changes according to prosthesis placement (Yes/No) by time in the right and left breast

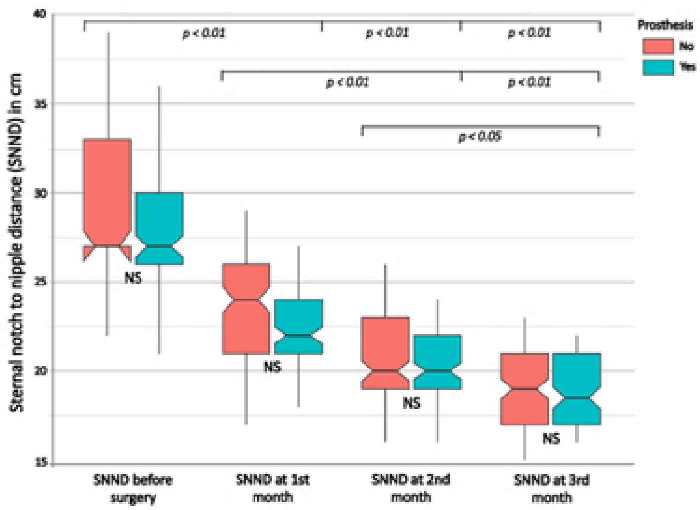
NSSD (cm)	Prosthesis placement	N	Mean	Median	SD	P
Right Breast						
Before surgery	No	125	28.68	27	4.04	NS
	Yes	106	27.77	27	3.57	
1st month	No	125	23.33	24	2.85	NS
	Yes	106	22.61	22	2.53	
2nd month	No	125	20.70	20	2.17	NS
	Yes	106	20.41	20	1.85	
3rd month	No	125	18.90	19	2.00	NS
	Yes	106	18.67	18.50	1.89	
Left Breast						
Before surgery	No	125	28.51	28	4.13	NS
	Yes	106	27.63	27	3.58	
1st month	No	125	23.20	23	2.84	NS
	Yes	106	22.67	22	2.58	
2nd month	No	125	20.70	20	2.20	NS
	Yes	106	20.50	20	1.91	
3rd month	No	125	18.74	19	2.19	NS
	Yes	106	18.51	18.50	2.24	

Abbreviations: SNND: Sternal-notch to nipple distance. SD: Standard deviation. For the ANOVA model, see Complementary Material, Tables 4C and 5C.

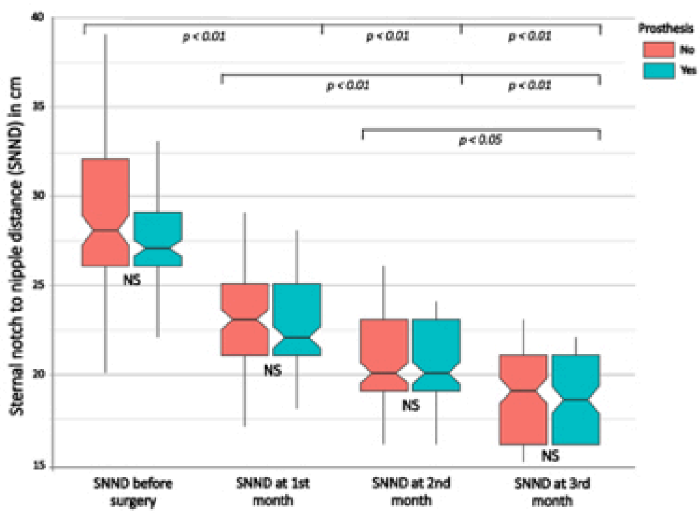
causing relative skin abundance compared to the diminished parenchymal volume (2) (or 2) A mammary hypertrophy, in which excessive breast weight and gravity drive excessive stretching in supporting ligaments and ductal structures, sometimes in an asymmetric pattern, causing both breast sag and droop.

The objectives of mastopexy (with or without prosthesis placement) are breast reshaping, volume redistribution, and the NAC repositioning. At the same time, reductive mastoplasty (with

A



B



Graph 2. SNND behavior before and after laser-assisted mastopexy with and without prosthesis placement in the right (upper panel) and left (Lower panel) breasts. Note that Laser-Assisted Mastopexy significantly reduces SNND at the 1st, 2nd, and 3rd post-operative month for both, with or without prosthesis placement. Moreover, pairwise comparison between patients with or without prostheses in each observation time revealed non-difference between both treatment modalities. For repeated measures of the ANOVA model, see the complementary material, Tables 4C and 5C.

or without pexy) aims to achieve the same aesthetic results, adding a breast size reduction for functional purposes (57). These interventions aim to produce an aesthetically pleasing and long-lasting appearance, minimizing scarring, improving recovery, and preventing complications (48,50,58). In this regard, traditional mastopexy techniques have demonstrated consistent efficacy in NAC repositioning, but scar visibility remains the primary concern for patients undergoing

Figure 4. Low-level multifrequency laser-assisted mastopexy without prosthesis placement. Left: Before surgery. Right: three months after surgery

Figure 5. Low-level multifrequency laser-assisted mastopexy with prosthesis placement. Left: Before surgery. Right: three months after surgery.

mastopexy (21). Traditional techniques, particularly the periareolar incision, often result in well-hidden scars within the natural contours of the breast. However, an important limitation of this approach is that combining mastopexy with implant breast augmentation is limited in accommodating larger implant volumes (17). The incision around the areola restricts access for implant insertion, potentially limiting the size of the prosthesis. Another limitation of this approach is the inefficacy when an extensive tissue rearrangement is necessary; consequently, it may not be ideal for severe BPt because this technique does not achieve the same lift effect as other approaches (such as vertical or anchor-shaped incisions) that allow more extensive tissue reorganization. Vertical and anchor incisions, while more visible, are typically placed in discreet locations and tend to fade over time. However, individual healing responses and skin elasticity influence scar appearance (24).

In this respect, although laser-assisted techniques (LAT) have been widely applied in other areas of cosmetic surgery, few studies have focused on laser-assisted procedures in breast aesthetic surgery with or without prosthesis placement. LAT offers advantages over traditional surgical methods, including improved precision, reduced recovery time, and potentially better aesthetic outcomes (29,59-62). Therefore, given the established efficacy of laser therapy in various plastic surgery domains, this study explored the efficacy and safety of a novel multifrequency low-level laser-assisted mastopexy technique involving minimal visible scarring in a cohort of 231 patients with BPt, evidenced by: 1) the patients without BPt at the 1st, 2nd, and 3rd post-operative months; 2) the changes in the SNND distance before and at the 1st, 2nd, and 3rd post-operative months; and 3) the incidence of early surgical complications (<30 days) according to the Clavien-Dindo classification system.

To the best of our knowledge, this is the first study exploring the effect of multifrequency low-level laser-assisted mastopexy in a large patient cohort and quantifying the surgical success by both evaluating the number of patients achieving a non-breast ptosis state and by monthly SNND measuring for three months. In this regard, at the start of the study (pre-surgery), all patients (100 %) presented with BPt at the initial evaluation. Interestingly, after surgery, there was a progressive and significant increase month by month in the proportion of patients without BPt from 42 % in the first month, 58 % in the second month and 90 % in the third month ($p<0.01$), demonstrating an important and significantly BPt correction by multifrequency low-level laser treatment. Moreover, contrary to the intuitive expectation of an immediate improvement in BPt, as seen in procedures involving skin excision and surgical NAC repositioning, multifrequency low-level laser-assisted mastopexy exhibited a gradual transition from ptosis diagnosis to an impressive final no-ptosis diagnosis in 90 % of the patients. That is, a dynamic process progressing throughout the three-month observational window.

Moreover, SNND serial measurements confirmed an elevation of the NAC of 30 % from 27 cm at baseline to 19 cm three months after surgery for any right or left breasts; this change represents, on average, an 8 cm lifting effect in 3 months, for both with or without prosthesis placement as a whole. A subsequent analysis of SNND with or without implants over time was made to exclude the influence of prosthesis placement on this variable. In this respect, the multivariate analysis showed a non-statistic difference in ANOVA in between-groups comparison analysis (with/without prosthesis), confirming that SNND values were not influenced by prosthesis placement for right and left breasts. On the other hand, the within-group analysis, that is, SNDD changes according to time, demonstrates that both treatments (with or without prosthesis) significantly reduce the SNND values. Additionally, no significant interaction was observed between time and prosthesis, indicating a similar rate of SNND reduction in both groups.

This study does not employ any traditional surgical technique for volume reduction or tissue rearrangement, suggesting that the important lifting effect observed is attributable to the unique properties of the LPL9002™ lipolaser, a multifrequency low-level laser system. In this context, low-level lasers (LLL) are low-energy lasers that affect biological systems through non-thermal means (63). This area of investigation started with Mester et al., in 1967, who reported the non-thermal laser effect on mouse hair growth (64). In this regard, low-level laser therapy (LLLT) is the application of light to a biological system to promote tissue changes by a photochemical effect in which light is absorbed and causes a chemical change without ablative or thermal mechanisms. This feature is clinically translated into fast tissue regeneration, inflammation reduction, skin retraction, and pain relief.

The low-power visible light affects living biological systems when the photons are absorbed by electronic bands belonging to some molecular photo-acceptors called chromophores (65). Tissue attenuation of light is significantly greater in the blue-green spectral region compared to the red spectrum. This disparity is attributed to the robust absorption of shorter wavelengths by key tissue chromophores, such as hemoglobin and melanin, coupled with increased light scattering at these frequencies. Conversely, water exhibits substantial absorption of infrared light beyond 1100 nanometers. Consequently, the therapeutic LLLT application predominantly employs red and near-infrared light within the 600-1100 nanometer range (66).

LPL9002™ lipolaser employs a combination of three specific laser wavelengths (533 nm, 650 nm, and 980 nm) that interact to support structures within the breast to achieve the lifting effect. The rationale behind these wavelengths is the effects on adipose tissue, skin, and fibrous structures (67). In this sense, the green 530 nm diode-pumped solid-state laser (DPSSL) laser stimulates clothing within small vessels, thus promoting hemostasis during surgical procedures (68). This wavelength is effectively absorbed by hemoglobin (68) within blood vessels, allowing both precise and controlled small blood vessel sealing, minimizing blood loss, contributing to hematomas, ecchymosis prevention, and faster recovery (69). The DPSS green laser provides precision when working in areas near important blood vessels, especially in the breast. The low thermal effect on the surrounding tissues ensures a better surgical experience and improved recovery (70,71). On the other hand, the GaAlAs 650-670 nm red laser causes selective fat cell lysis and transitory micropores formation during the lipolysis procedure, allowing fat extraction with minimal tissue trauma (37,72–75). 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 observed in this study (38,76,77).

Unfortunately, due to the novel nature of this technique, there are no comparable studies to contrast our results. Nevertheless, some works have employed mono or dual-laser frequency alongside breast liposuction, such as in a 12 consecutive patient study reported by Ingram et al. (29), addressing laser energy as an adjunct to liposuction using the "Slim Lipo" Nd: YAG laser (Palomar ASPIRE, USA) with 924 and 975 nm wavelengths before and after the liposuction step to produce a skin thickening effect. The baseline SNND was, on average, 28 cm (median: 28 cm, range: 26-31 cm), and post-operative, all patients exhibited a significative elevation of both nipples (median: 3.36 cm, as above, and the degree of nipple elevation on one side was strongly correlated with that on the other side (29). Regrettably, the authors do not report the NAC beyond the immediate post-operatory period. Another study by Sánchez et al. (78) reported the mirrored "D" technique and laser-assisted liposuction in 46 female patients between 20 and 66 years old. Their results showed no surgical revision, post-operative infection, or NAC necrosis; 5 cases of NAC epidermolysis were treated with flavonoids and horse chestnut without sequelae. A breast-QTM evaluation showed high satisfaction with the procedure (86 %), but regrettably, there were no SNND measuring changes. It should be emphasized that the mirror D-technique leaves a visible 6 cm on average.

In contrast, our technique leaves only a minimal scar on the lower edge of the areola in the case of laser-assisted mastopexy with prosthesis placement, no visible horizontal submammary or vertical scars, and no visible scars in the case of mastopexy without implant placement. Thus, our procedure allows ptotic breast repositioning with better aesthetic results. In another study, Abboud et al. (61), studied 94 women (188 breasts) with a new non-laser technique (electrically assisted liposuction with loop placement) and reported a 7.3 cm elevation in NAC. However, it should be noted that our low-level laser technique did not require loops to achieve NAC elevation, as neo-collagen synthesis and skin tightening achieved breast tissue reconfiguration.

Concerning surgical complications, mastopexy, and breast implant placement are associated with general and specific complications inherent to any surgical procedure, such as hematoma, infection, wound healing delay, wound dehiscence, areola-skin necrosis, implant disruption and silicon leakage, BPt recurrence, anaplastic large cell lymphoma, and poor scars quality, including hypertrophic scar (59,60). In a meta-analysis of thirty-four studies published from 1980 through 2016 conducted by Di Summa et al. (26) assessing non-implant mastopexy techniques outcomes in 1888 patients, the overall complication rate was 10.4 %. In this meta-analysis, the most common complications were scar-related (3 %, including hypertrophic or unesthetic appearance) and nipple–areola-related problems (2.9 %, including distortion, asymmetry, and reduction sensation). Our study found a complication incidence according to the Clavien-Dindo system of only 4 %. Hence, Multifrequency Low-level laser-assisted mastopexy was associated with low and non-life-threatening early surgical complications within 30 days. These complications were represented by two Grade II cases presenting generalized pain requiring specialized intervention and four IIIb cases requiring re-intervention under general anesthesia (4 areola necrosis and three seromas).

This study introduces a novel low-level laser-assisted mastopexy technique, demonstrating promising clinical results related to a minimally invasive approach, minimal scarring, excellent CAP repositioning, and low complication rates; it is important to acknowledge certain limitations. While the cohort study design employed in this research enables examining outcomes over time, it is limited by its observational nature. It needs a comparison group with another mastopexy technique, such as a traditional surgical or alternative laser approach.

CONCLUSIONS AND FUTURE DIRECTIONS

The low-level multifrequency laser-assisted mastopexy technique is an effective and safe procedure for NAC repositioning at the third postoperative month without evident scars and with fewer complications than those reported in traditional mastopexy techniques. A medium—to long-term follow-up is necessary to determine the longevity of this technique's ptosis correction with and without breast prosthesis placement. To further elucidate the benefits and risks of this innovative approach, a randomized controlled trial comparing it to conventional mastopexy and other laser mastopexy techniques is recommended for future research.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Research Bioethics of Clinica de Obesidad y Envejecimiento S.A.S., Bogotá, Colombia. (Code 2020-0113-RC3, November 20th, 2020).

Informed Consent Statement and ethical issues: Informed consent was obtained from all subjects involved in the study. None of the patients received any financial compensation for undergoing this procedure.

Data Availability Statement: Full data supporting the reported results can be found at the Harvard Dataverse Repository. Cubillos, G. (2024). Laser-Assisted mastopexy dataset (V2 ed., p. 1). Harvard Dataverse. https://doi.org/doi:10.7910/DVN/6MGOZF.

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Supplementary Material

Table 1C. Personal disease history in the study participants

Conditions	n	%	Cumulated %
None	170	74	74
Hypothyroidism	24	10	84
High blood pressure	10	4	88
Depression	10	4	93
Pre-diabetes	7	3	96
Asthma	2	0.8	96.8
Migraine	2	0.8	97.2
Irritable bowel disease	1	0.4	98
Atopic Dermatitis	1	0.4	98.4
Dyslipidaemia	1	0.4	98.8
Systemic lupus erythematosus (SLE)	1	0.4	99.2
Insulin resistance	1	0.4	99.6
Allergic rhinitis	1	0.4	100

Table 2C. Comparison between breast ptosis grades proportions according to Regnault´s classification according to observation times.

D-C Statistic				p-value
Re-surgical ptosis grades proportions	*vs*	1st month ptosis grades proportions	35.65	< 0.001
Pre-surgical ptosis grades proportions	*vs*	2nd month ptosis grades proportions	52.75	< 0.001
Pre-surgical ptosis grades proportions	*vs*	3rd month ptosis grades proportions	62.14	< 0.001
1st month ptosis grades proportions	*vs*	2nd month ptosis grades proportions	17.11	< 0.001
1st month ptosis grades proportions	*vs*	3rd month ptosis grades proportions	26.49	< 0.001
2nd month ptosis grades proportions	*vs*	3rd month ptosis grades proportions	9.38	< 0.001

Abbreviations: D-C statistics: Durbin-Conover post-hoc test.

Table 3C. p values and 95 % confidence interval in SNND pairwise comparison in patients undergoing Low-Level laser Assisted Mastopexy. 95 % CI

Time		psi-hat	p-value		Lower	Upper
Right breast						
Before surgery	*Vs*	1st	5.14	< 0.001	4.10[a]	6.17*
Vs	2nd	7.40	< 0.001	6.43[a]	8.38*	
Vs	3rd	9.13	< 0.001	8.15[a]	10.1*	
1st month	*Vs*	2nd	2.27	<0.001	1.49[a]	3.04*
Vs	3rd	3.99	< 0.001	3.21[a]	4.77*	
2nd month	*Vs*	3rd	1.73	< 0.001	1.03[a]	2.42*
Left breast						
Before surgery	*Vs*	1st	4.94	< 0.001	4.01[a]	5.86*
Vs	2nd	7.10	< 0.001	6.23[a]	7.97*	
Vs	3rd	9.06	< 0.001	8.14[a]	9.99*	
1sr month	*Vs*	2rd	2.17	< .001	1.38[a]	2.95*
3rd	4.13	< .001	3.28[a]	4.98*		
2nd month	*Vs*	3rd	1.96	< 0.001	1.18[a]	2.75*

Table 4C. Repeated measures ANOVA model (Right breasts)

Dependent variable:	
	SNND
Constant	-5.352***
	(0.177)
Time 1st month	-7.984***
	(0.177)
Time 2nd month	-9.784***
	(0.177)
Time 3rd month	-0.906**
	(0.361)
Prosthesis	0.192
	(0.261)
Interactions	0.616**
	(0.261)
TimeSNND:Prosthesis Yes	0.680***
	(0.261)
Constant	28.680***
	0.245)
Observations	924
Log Likelihood	-1,912.035
Akaike Inf. Crit.	3,844.070
Bayesian Inf. Crit.	3,892.357

Note: *p<0.1; **p<0.05; ***p<0.01

Table 5C. Repeated measures ANOVA model (Left breasts)

Dependent variable:	
	SNND
Constant	-5.312***
	(0.186)
Time 1er mes	-7.816***
	(0.186)
Time 2do mes	-9.768***
	(0.186)
Time 3er mes	-0.880**
	(0.372)
Prosthesis	0.350
	(0.275)
Interactions	0.684**
	(0.275)
TimeSNND:Prosthesis Yes	0.645**
	(0.275)
Constant	28.512***
	(0.252)
Observations	924
Log Likelihood	-1,953.198
Akaike Inf. Crit.	3,926.396
Bayesian Inf. Crit.	3,974.683

Note: *p<0.1; **p<0.05