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Safety Evaluation of Vaser® in Body Contouring Improvement Liposuction

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Abstract

Introduction: Liposuction has been submitted to constant evolution since its consolidation and systematic use. The aid of the third generation ultrasonic technology VASER® (Vibration Amplification of Sound Energy at Resonance) aims to bring more safety and satisfactory results, especially with the desire to achieve greater definition with superficial liposuction.

Methods: In the period between 2015 and 2017, 76 patients had undergone liposuction for body contouring improvement in Santa Monica Hospital Center, in the city of Erechim. We evaluated the results, the possible complications and the safety of VASER®.

Results: The routine use of VASER® produces improvement in body contouring procedures. The device's emulsification associated with multilevel liposuction allows achieving better definition and the characterization of anatomical landmarks.

Conclusion: VASER® associated liposuction allows the plastic surgeon to achieve refined results with the preservation of patient's safety.

Keywords: Patient's safety; Adipose tissue; Lipodystrophy; Post-operative complications

Introduction

Liposuction is currently one of the main procedures executed by plastic surgeons. During decades of utilization, an important number of innovations were added to traditional liposuction, generating more comfort for the surgeon and obtaining better results [1].

Historically, many approaches have been utilized for the removal of adipose tissue during liposuction [2]. Along the natural process of refinement, improvements were achieved in perfecting diverse aspects of the procedure, such as the surgical techniques, the cannulas utilized and the use of adjuvant devices. In this aspect, it is a process without a foreseeable ending line. There are no final objectives, only marks to be surpassed. Traditional liposuction still faces the burden of being a procedure that many times is extenuating, as well as presenting restriction on variation of techniques. In that sense, any initiative capable of generating decrease on the mechanical toll and stress, or innovation that amplifies the variations on the handling of cellular subcutaneous tissue are potential optimizers of results [3,4].

The use of ultrasound in surgical procedures is not new. By the end of 1980's and the beginning of 1990's, Scuderi and Zocchi were the pioneers in ultrasound application in the selective emulsification in fat removal for body contouring [5,6]. The first generation of devices for ultrasonic assisted liposuction was developed by SMEI Company, in Italy. The instrument by SMEI consisted in solid probes of 4-6 mm which emulsified fat in a frequency of 20 kHz.

Still in the 1990's there were introduced devices of a second generation, such as Lysonix 2000 (Lysonix Inc. Carpinteria, CA). In this case, emulsification and suction occurred simultaneously through the "golf-tee" and "bullet-design" cannulas, in a frequency of 22.5 kHz. During the same period, the Mentor Corporation introduced their devices of body contouring, the "Mentor Contour Genesis devices". With a hollow cannula of 3.0 mm and 5.1 mm in a frequency of 27 kHz. The excessive energy transferred to the tissues, combined with the elimination of the protective solution due to the simultaneous suction, resulted in significant complications [5].

The popularity of ultrasonic assisted liposuction diminished by the end of 1990's. In 2001, Sound Surgical Technologies introduced VASER®, a third generation device which was created to improve safety and reduce the energy transferred to the tissues, maintaining the efficiency. It possesses a solid probe which emulsifies fat efficiently at 36 kHz, with important tissue preservation in the proximity. The tunable nature of the system allows almost all areas of the body to be treated in a safe and efficient way. Presently, VASER® is considered the "gold standard" in high definition for body contouring [7-10].

The resonance concept VASER® is based in two basic premises: The frequency of 36 kHz is next to the resonance of fat; and for that reason there is less energy transfer to other tissues. Furthermore, the adipose cells, much larger in size comparatively to other adjacent tissues (blood vessels, nerves, conjunctive tissue), are more susceptible to ultrasonic energy [11,12].

The equipment uses probes of 2.2 mm-4.5 mm of diameter with grooves next to the tip to improve the efficiency on energy transmission and adipose fragmentation. The larger the diameter of the probe, the higher ultrasonic energy can be dispersed. The

equipment possesses also an intermittent activation mode- pulsed ultrasonic energy delivery. This mode makes use of high frequencies of vibration in a non-continuous activation, diminishing the total tissue energy applied, maintaining the efficiency [11].

Objective

Evaluate the safety on the use of the ultrasonic device of third generation VASER® in liposuction surgeries to improve body contouring. The collected data was compared with the medical literature [13,14].

Methods

The present work consists in a retrospective revision study of medical records of patients that were submitted to liposuction procedures with the aid of VASER® within the period of January 2015 to June 2017, at Santa Monica Medical Centre, in Erechim, Rio Grande do Sul, Brazil.

Selection of patients and criteria of inclusion and exclusion:

The patients included in the study were men and women, older than 18 years, presenting localized excess of subcutaneous fat. The criteria for exclusion were:

- Patients with limiting clinical conditions
- Women within the first year after giving birth, pregnant women or women that were breastfeeding
- Patients with serious problems of body self-image
- Inflammatory conditions of the skin present in the target area for therapeutic surgery
- Obesity (IMC > 30)
- Concomitant tummy tuck surgery

In this way, the analysis was conducted with 76 patients. The female patients were predominant, with 74 patients, representing 97.36% of the cases. Two male patients (2.67%) were submitted to liposuction with the aid of VASER®. The average age of women in the study was 39 years old (21 to 65 years old), and in men it was 37 years old. The general average IMC of the cases was of 24.64 kg/m^2. The performed procedures are described in the table below (Table 1).

Procedure	Number of patients
Liposuction in the abdominal area, flanks and back	31
Liposuction in the abdominal area and back with placing of breast implants	20
Liposuction in the abdominal area, flanks and back with mastopexia	8
Liposuction in the abdominal area and mastopexia with placing of implants	5
Liposuction in the abdominal area, flanks and back with mastopexia and placing of implants	3
Liposuction in the abdominal area with placing of breast implants	3
Liposuction in the lateral face of the thighs with placing of breast implants	2
Liposuction in the abdominal area	1
Liposuction in the abdominal area, flanks and back with correction of ginecomastia	2
Liposuction in the lateral face of the thighs	1

Table 1: Performed procedures.

Evaluation criteria

When it comes to liposuction, we utilized the routine criteria mentioned in the current literature referring to surgical complications. These can be classified according to the period of occurrence as detailed in the table below (Table 2).

Peri-operative complications (0-48 hours)	Recent Post-operative complications (1-7 days)	Late post-operative complications (1 week-3 months)
Cutaneous necrosis	Cellulite	Seroma
Lesion caused by cannula/portal/end-point	Paresthesia/Permanent transitory sensibility alteration	Prolonged edema
Anesthesia related complications	Hyperpigmentation/Hypopigmentation	Fibrosis

Table 2: Period of occurrence of surgical complications.

Pre-operative evaluation

All of the patients were evaluated previously to the surgical procedure by the staff of Anesthesiology of Santa Monica Hospital Centre. Laboratorial and complementary exams requested according to age and comorbidities. The patients were subjected to general anesthesia.

VASER® Technology

The ultrasonic technology is produced by a conversion of electric energy in sonic vibration waves through a handpiece. Such vibration moves a titanium probe in a constant frequency of 36 kHz. The interaction between the probe design and the sound reverberation on the tissue determines the efficiency of the system [15].

The subcutaneous cellular tissue which is found in a humid environment receives the sonic energy emanated by this probe. There are two functional mechanisms. The first and less frequent tears the cellular membrane by direct impact. The second principle is called cavitation, this phenomenon can be understood through the vibratory frequency of the sound wave that acts as an effect of compression and rarefaction, which are emitted by its distal rings. Microbubbles are formed in the tumescent liquid inside the adipose tissue. These evolve hundreds of adipocytes. The energy is gradually dispersed and the diameter of the microbubbles gradually increased until the moment of its rupture. In that exact instant, the adipocytes detach themselves

without damage to its architecture; nevertheless altering its physical density from solid to emulsified [16].

The cavitation and the mechanical rupture of the adipose tissue is selective, that is, the diameter of the adipose cell is larger than the adjacent tissue micro-architecture (blood vessels, muscular fibers, connective tissues), so being that this environment remains intact [16].

The equipment had enough power and precision to treat different body areas without the need to employ force to overcome zones of tissue resistance.

VASER® is composed by an integrated system, formed by a display (ultrasound), handpiece, probes (special astraumatic rod), suction tower by Ventx® system (ventilated aspiration system), integrated system of irrigation and triggering pedals. This complete equipment unites all the apparatus needed for the realization of the liposuction surgery in an organized manner, offering safety, comfort and practicality to the surgeon (Figure 1).

Figure 1: VASER® System (vibration amplification of sound energy at resonance).

Protection portals ("Skin ports")

Parts utilized in the surgical access with protection purposes, of which are routinely inserted into the gluteal fold, anterior and posterior axillary topographies, pubic area, umbilical scar and infra mammary fold. It is worth pointing out that they prevent and protect these areas from thermal lesions caused by ultrasonic vibrations and of trauma caused by repetitive movement (Figure 2).

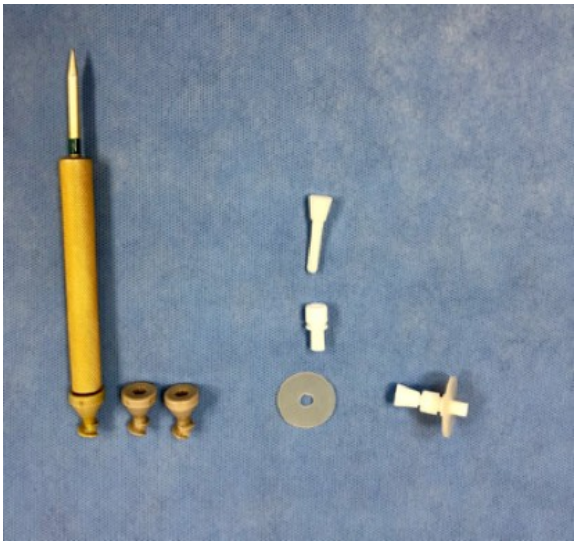

Figure 2: Portals with adequate design for the variations of diameter of ultrasonic probes.

Handpiece

Instrument to conduct sonic impulse directly connected to the ultrasound with sockets for the probes to be utilized. They need continuous socket revision with the "wrench" to dissipate the sound waves in vertical direction (Figure 3).

Figure 3: Handpiece with probes and "wrench".

Cannulas

Atraumatic system of cannulas for the collection of the emulsified tissues. They possess amplitudes and configurations for variable anatomic unities (Figure 4).

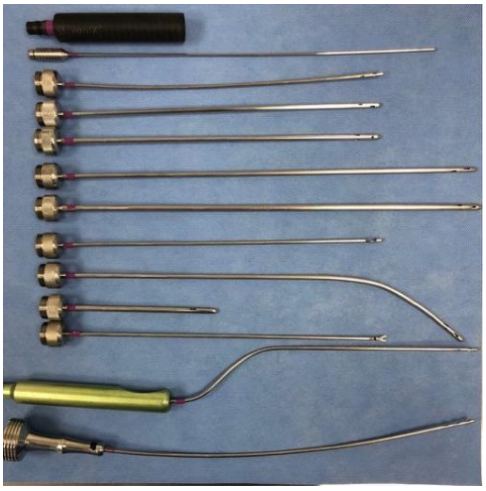

Figure 4: Set of cannulas of the Ventx® system, in sequence from top to bottom: adjustment knob, infiltration cannula 3.0, liposuction cannulas 3.0 mm, 3.7 mm, 4.6 mm short, 4.6 mm long, 5.0 mm basket cannula, 4.6 mm curved cannula, "baby" cannula for the armpits, 3.0 mm toledo cannula, 3.0 mm lower limbs cannula and 4.0 mm fat insertion cannula.

Probes

The equipment possesses probes of different diameters with grooves next to the tip which transmit the energy (Figure 5). The larger the probe diameter, the larger amount of energy is dissipated. They possess formatting for all anatomic unities [17].

Figure 5: VASER® ultrasonic probes. From left to right: 4.5 mm probe, 3.7 mm probe/2 rings, 3.7 mm probe/3 rings, arrow probe, 2.9 mm probe/3 rings and Saturn probe.

Pre-surgical marking

During the physical evaluation, an analysis of the distribution of adipose tissue by the different body unities is established, including the documentation of the thickness of fat in the abdomen and upper body, as well of muscular mass.

For body contouring liposuction procedures, we utilize the routine VASER®, as long as the protocol surgical indications are identical, without any exceptions. We begin with the patient in orthostatic position and the first delimited anatomic marks are the areas in which we plan to remove 100% of the lamellar layer of subcutaneous cellular tissue. Then the rectus abdominis muscles are identified, as well as the anteriorsuperior iliac crests and the inguinal ligaments. Not less important, in the lateral and posterior anatomy, the gluteus Maximus muscles topography is delimited, as well as the sacral concavity and the transition between the upper and lower back, following the sintopia of the lumbosacral fascia (Figure 6).

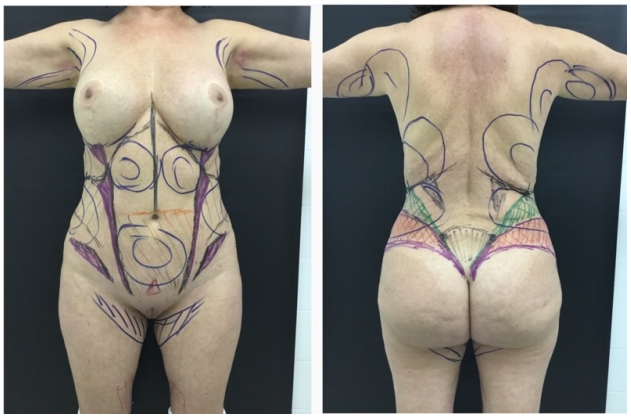

Figure 6: Blue: Deep extraction markings, Black: Strategic anatomic point markings, Purple: Transition areas of superficial relief, Green: Total extraction of lamellar layer region and partial extraction of areolar compartment, Red: Alert areas to avoid excessive resection.

Operatory technique

The preparation of the patient in a surgical centre begins by the anesthetic act, in which we have the preference for general anesthesia. That is followed by the preparation of the long-term urinary catheterization, intermittent venous compression equipment and stockings for the lower limbs, and the body warming system.

We standardize the operatory act in three stages: Infiltration, emulsification and suction.

Positioning

We begin by positioning the patient in ventral decubitus, with wide exposure of the anatomical units and, after finishing this stage, we change the positioning to dorsal decubitus. In both positions, we make strategic portals in camouflage areas (Back: intergluteal groove and in posterior axillary fold topography. Abdomen: On the pubic area, umbilical scar, infra-mammary topography and in anterior axillary topography). After the infiltration these access receive protectors ("skin-ports") for the sliding of the probes, avoiding adjacent thermal lesions (Figure 7).

Figure 7: Patient in dorsal decubitus with safety portals in the pubic area, upper edge of umbilical scar and infra mammary folds (prorings).

Infiltration

We use the super humid technique of infiltration for the superficial region as well as for the deep region. The routine volume used is 1:1 (infiltrated volume/aspirated volume), with a solution of heated saline solution and epinephrine- 1 ampoule for each 1000 ml of saline solution. The solution is inserted through the previously made portals. We also call the attention for the necessity of maintaining the adjacent area humid during the surgical stages with saline solution, for better dissipation of thermal energy generated by the device and by the friction.

Emulsification

The introduction of the probes follows the manual movement practiced in traditional liposuction, that is, the movement of excursion "back and forth", without applying force, feeling the device crossing by the tissues. This process begins by the lamellar layer and ends at the areolar compartment.

The recommended duration of VASER®, according to the manufacturer's instruction, is of about 1 minute for each 100 ml of infiltrated solution, generating the sensation of "loss of resistance". Areas with higher concentration of adipose tissue can be approached with a larger diameter probe, and with 80% of the equipment's potency in a continuum mode. However, in less dense areas, such as the waist, it is recommended smaller probes, of 2.9 mm, with 3 rings (higher lateral energy dispersion) and equipment potency up to 60%, on a pulsation mode.

The superficial use of VASER® is executed with a 2.9 mm probe, with 3 rings and always on the pulsation mode. This stage is the one responsible for the retraction of the skin, compensating in areas of myofascial flaccidity, specially the hypogastry. The duration of the stage of emulsification is a period of approximately 30 minutes to 45 minutes in each decubitus, according to our daily practice (Table 3).

Density	Volume	Probe	Model	Frequency
Soft	Medium-large	3.7 mm (3 rings)	Continuum	70-80
Soft	Small	2.9 mm (3 rings) or 3.7 mm (2 rings)	Continuum or Pulsation	70-80
Slightly Fibrous	Medium-large	3.7 mm (2 rings)	Continuum	80-90
Slightly Fibrous	Small	2.9 mm (3 rings) or 3.7 mm (1 ring)	Continuum	80-90
Very fibrous	Medium-large	3.7 mm (2 rings) or 3.7 mm (1 ring)	Continuum	80-90
Very fibrous	Small	2.9 mm (3 rings)	Continuum	80-90

Table 3: Probes of the VASER® system.

Liposuction

Lamellar layer

The suction of fat follows the conventional technique of tissue collection, that is, "in fan" and with a "flat hand", feeling the movement of the cannula. There is minimum resistance, having in mind that the tissue density is sensibly diminished by the emulsification. The cannulas used had the diameter of 3.0 mm, 3.7 mm and 4 mm. The suction of adipose tissue is always initialized by the deep layer with cannulas of a larger diameter (3.7 mm and 4 mm).

Areolar layer

The superficial emulsification and liposuction are performed selectively at the borders of muscle groupings (linea alba, inguinal ligament). Thinner cannulas are fundamental (Figure 8).

Figure 8: Example of liposuction with the approaches of diverse levels of superficial anatomic relief with the extraction of lamellar fat, joint reduction of subcutaneous cellular tissue in areas of tendinous encounters and the adjacent anatomic transitions.

After finishing this stage of liposuction, we introduce the continuum aspiration drain (Porto Vac) in the lumbosacral region and in the upper pubic region.

Post-operative handling

The patients make use of a compression modeling garment and the venous return pump during the whole period of hospitalization. On the second day after the surgery, the patients are submitted to a daily lymphatic drainage, at our own facility, for at least 10 days.

Results

In this retrospective study, we examined the medical records of patients submitted to liposuction with the aid of VASER® in order to analyze the surgical complications found, and then making the comparison with the medical literature available.

The main emphasis was the evaluation of the VASER® device concerning its safety. Data such as the volume of infiltrated and aspirated solution, the mode of the energy used (pulsation or continuum) and the time of application of ultrasound were also collected. Some results will be mentioned in general terms.

The maximum volume did not exceed 4.000 ml in none of the patients. In all of the cases, the supernatant of fat exceeded 80% of the total aspirated volume (Figure 9). In some cases this percentage was over 93%.

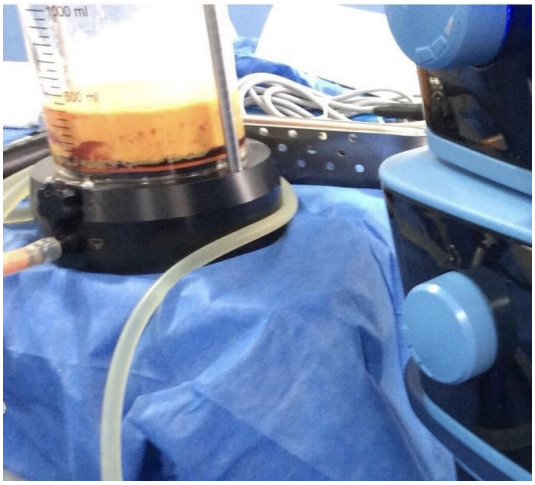

Figure 9: Documentation of the emulsified fat. In our casuistry the supernatant fat exceeds 80% of the total aspirated volume.

Among the patients analyzed in this study, 71 (93.42%) did not presented undesirable post-operative events referring to the liposuction with the aid of VASER®. Five cases (6.57%) presented outcomes according to the numbers evidenced on the chart below (Table 4).

Complications	Number of patients	Percentages
Prolonged edema	1	1.31%
Lesion caused by the insertion	1	1.31%
Hyperpigmentation	2	2.64%
Epidermal lesion	1	1.31%
Cellulite	0	0.00%
Anesthetic complications	0	0.00%
Fibrosis	0	0.00%
Sensibility alteration	0	0.00%
Seroma	0	0.00%
TOTAL	5	6.57%

Table 4: Post-operative complication outcomes.

The events of hyperpigmentation and thermal lesion caused by the portal insertion occurred to the same patient. The rest of the complications occurred to different patients. The transmission of ultrasonic energy to the tissues may cause lesions on the site of insertion of the portals or terminal damage due to keeping the probes in a stationary position for too long or, as in our case, by the wearing of the "skin port". Excision and suture were performed [18].

There also was the occurrence of a flank epidermal lesion after the use of VASER®. The patient showed progressive improvement after intense care of the dressing on the lesion area. The dyschromia (hypo or hyperpigmentation of the skin) with the use of ultrasonic devices have reports in the literature [18-20]. The hyperpigmentation may occur due to the liberation of hemosiderina and its deposit, generating coloration alterations, or the use of modeling garments which compressed inadequately the tissues; state possibly related to the physiopathology of this complication. The two patients that were affected in our casuistry had complete remission after compression release.

There was no occurrence of seroma in our study. There was only a case of prolonged edema (1.31%) which was solved with the intensification of the conservative therapy. We credit the low percentage found in our casuistry to the standardizing of lymphatic drainages and the systematic use of vacuum drains (Figure 10).

Infiltration of 300 ml of saline solution by side, using the 2.9 mm probe for 3 minutes and 7 seconds on the right and for 3 minutes and 20 seconds on the left. It was used 70% of the potency in pulsation mode. Total aspirated volume of 520 ml (90% of emulsified adipose tissue).

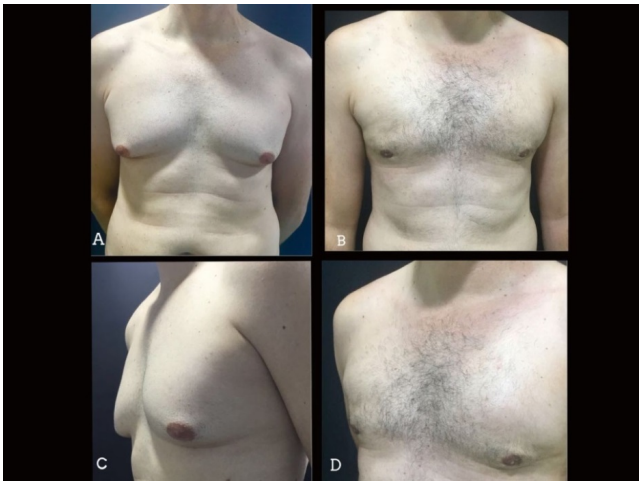

Figure 10: A and C: Photographic pre-operative documentation of 48-year-old male with gynecomastia. B and D: Photographic post-operative documentation after 8 weeks from the surgical treatment of ultrasonic-assisted liposuction aided by VASER®.

Discussion

In the performed study, 76 patients were submitted to ultrasonic liposuction aided by VASER® for the treatment of lipodystrophy. The results indicate that the emulsification of subcutaneous cellular tissue through the pulsation and continuum modes of ultrasound was shown efficient and safe. The aspirated material contained more than 80% of supernatant fat, reaching 93% in some cases. The blood losses were not relevant, having in mind that the characteristics of the aspirated infranatant fluids were tiny and, by association, no clinic handling by depletion was performed. These findings corroborate with the comparative study performed by Garcia which concludes that the use of ultrasonic devices of third generation generate 20% less blood loss when compared to other techniques [21].

Jewell, Fodor and de Souza Pinto made a revision of the literature including statistical analysis of surgical complications related to liposuction [11]. There were selected 93 articles of which 14 allowed statistic evaluation. It was obtained an average of 13.5% of undesired events in the studied literature. In our casuistry we obtained 6.57% of post-operative complications, so endorsing the safety of this technology.

Rohrich et al. [17] pursued to evaluate the experience with the usage of ultrasonic devices in liposuction in which 114 consecutive patients were analyzed [13]. In their sample, five complications were found: one case of disestesia, that the author believes was the consequence of the excessively prolonged use of the device; three cases of abdominal seroma (which presented the need of aspiration and compression); and one case of thermal lesion in the cannula insertion site, probably in consequence of inappropriate technical conduction. The author emphasizes the necessity of keeping the environment humid and the constant movement of the cannula. These are also positive statistics if compared to the traditional context. The author relates the complications to the learning curve [22].

Varun and Milind through a broad literature revision about post-operative problems in liposuction showed a rate of 18.7% of cutaneous hyperpigmentation on the manipulated areas [16]. They affirm that the main cause would be the inadequate approach to the areolar layer with consequent lesion of the subcutaneous plexus. In our study, we found 2.64% of events of this nature. The low incidence of this mishap is an important point for analysis, considering that on these surgeries in 92.1% of the cases we approach at least one anatomic unity of the areolar layer with the adipose emulsification and the consequent liposuction. The low amount of negative events in superficial liposuctions is the finding that calls more attention in terms of safety, once conventional liposuction has as established technical foundations for the deep manipulation of adipose tissue in a humid environment, leaving as suggested protection the thickness of approximately one centimeter of tissue, to prevent contour irregularities and/or surface devitalization.

Vanek and Nagy [23,24]. made a study multi-centric and randomized, comparing the traditional liposuction and the ultrasonic method in contra lateral anatomic regions in the same patient. Feminine patients from 20 years to 48 years old.

Increase on tissue retraction occurred in 53% by cc aspirated when VASER® was used. Characterizing the study with an index of statistic significance and making it clinically relevant [25].

Based on these premises of superior cutaneous retraction and the manipulation of the areolar layer without tissue devitalization, it was made possible a higher muscular definition in patients with propitious physical characteristics. We agree with this premise, although we have a subjective contextualization. It is important to point out that when performing techniques that pursue a better definition of the compartments than the surgical steps, in this context, they increase and simultaneously the precepts of basic safety such as the utilization of adequate probes, selection of pulsating or intermittent dispersion of energy, super humid superficial or deep infiltration, and lamellar aspiration with posterior areolar collection are fundamental (Figure 11).

Figure 11: A: Photographic postoperative documentation immediately after the surgery of 32-year-old female submitted to Vaser-assisted liposuction in the abdominal region, flanks and back with deep approach in the whole circumference, and superficial as well as deep manipulation in the muscle intersection areas. B, C and D: "pinch test" with different thicknesses, according to the surgical plan.

Hoyos and Millard [2] affirm that the Vaser technology make the surgeon apt to indicate techniques of superficial lipoplast. The ultrasonic devices of first and second generation are associated to severe burnings and necrosis when dispersed their energy on the surface, routine that was practically annulled with the advent of the technological third generation, concept that was evidently displayed in our study [26-30].

Conclusion

The medical literature, as well as our analysis, demonstrate that the employment of VASER® in liposuction procedures to improve the body contouring present itself as a safe approach with low percentage of complications.

The potential mishaps of the employment of an ultrasonic device, such as the superheating, which causes tissue ischemia/necrosis, are majorly credited to inadequate use of the device. It is of fundamental importance the standardizing of care related to the insertion of portals, utilization of the adequate infiltrating solution and the use of the device for the adequate period and in the adequate areas. Therefore VASER® is a potentially safe tool for the performance of body contouring plastic surgery.

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Conflicts of Interest

No Conflicts of interest. The patients were informed about using their pictures in the paper.

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