A double-blind, prospective, clinical, surgical, histopathological and ultrasound study comparing the effectiveness and safety of liposuction performed using Laserlipolysis and Internal Ultrasound Lipoplasty method.

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ABSTRACT

A clinical and instrumental study was carried out to determine the effects of laserlipolysis as compared to the Internal Ultrasonic Liposuction procedure. The study was aimed at determining the performance of these devices in patients with localized adiposity in the saddle bags. The study had a prospective, longitudinal, and double-blind design. A group of female patients with localized adiposity in the saddle bags was investigated. Liposuction was performed in all patients: laserlipolysis was applied on one side, and the internal ultrasound procedure was applied on the other side. Pictures were taken from all patients before the procedure, and 1, 6, and 21 days after the procedure. All patients were clinically evaluated before the liposuction procedure, and then 1, 6, and 21 days after the procedure. Histopathological studies were performed in all patients; bilateral fat biopsy specimens were collected before and after the procedure. A bilateral ultrasound study (7.5-10 Mhz variable frequency) was conducted in all patients before the liposuction, and 30 days after the procedure. As this was a double-blind study, neither the team performing the ultrasound nor the team performing the histopathological studies nor the patients, knew what device the surgical team had used on each side. The study was conducted in patients with localized adiposity. The surgical team applied laserlipolysis on one side and treated the remaining side with internal ultrasound. In every case, the laserlipolysis and the internal ultrasound procedures were applied for the same length of time. The surgical team made a bilateral aspiration with a syringe and a 2mm-microcannula, with a maximum of 200cc of emulsion in both sides. Prior to liposuction and after superwet-tumescent anesthesia, fat tissue samples were collected from both sides (left and right). Then, after performing liposuction, samples were collected again from both sides. From a clinical point of view results showed, to physician and patients, an improvement in signs (localized adiposity) in both sides, however, the side treated with laserlipolysis showed fewer side effects (no pain, small bruising, and little edema) than the other side. The ultrasound studies showed similar fat tissue results bilaterally. The histopathological study showed a better effect on the adipose tissue in the laser treated side. From a surgical point of view, the laserlipolysis technique is easier to perform, and scars are smaller as compared to those caused by internal ultrasound.

KEYWORDS: liposuction, laser-lysis, ultrasound, adipocytolysis


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DISCLOSURES

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INTRODUCTION

Many treatments have been proposed for the bitronchanteric localized adiposity (saddle bags, culotte de cheval), invasive and non-invasive treatments, some with obscure scientific support, and others backed by strong marketing campaigns.

We know that adipose tissue buildsups in those areas respond to genetic, hormonal, and circulatory factors, and that isolated non-invasive treatments cannot achieve great therapeutic results.

Liposuction has solved this problem to some extent, (into a comprehensive treatment) but today patients demand medical-surgical treatments the least aggressive as possible, with the smallest amount of side effects (pain, edema, swelling, hematomas, ecchymosis), and “with guaranteed results” in terms of skin retraction and harmonious and smooth skin surface.

The efforts in the search for alternatives and new tools are aimed mainly at reducing downtime, decreasing the surgeon’s operating effort, reducing bleeding, reducing side effects and promoting skin tightening.

Within this context, there are two assisted liposuction equipments: the Vaser™ Ultrasound Liposculpture equipment, and the YG Nd Laserlipolysis “Smartlipo™” equipment.

Both equipments have changed Liposculpture, used by well-trained physicians who follow the Lipoplasty safety guidelines. In this prospective, double-blind, research study, liposculpture was performed in the external thigh areas, only in the areas of greater adipose tissue buildup. One side was treated with VASER™, and the opposite area was treated with SMARTLIP™.

Patients have been informed on both techniques and have consented their use for treatment, but they were unaware of which technique had been applied on either side. The ultrasound diagnosis team and the histopathology team were unaware of which technique had been applied on either area.

MATERIALS AND METHODS

The experimental study had a prospective, longitudinal, and double-blind design. A group of 6 female patients with localized adiposity in the saddle bags was investigated. Each patient was assessed through clinical, iconographic and instrumental non-invasive methods (ultrasound) at the beginning of the trial. For each patient, histopathological studies of the saddle bags fat were performed, both before surgery and immediately after it (both sides, different containers).

Inclusion criteria: presence of localized adiposity in the external thigh; female patients; aged between 20 and 30 years; and interested in participating in the trial.

Exclusion criteria: undergoing any non-surgical treatment in the 30-day period prior
to trial (including patients treated with liposuction); menstrual cycle alterations; use of oral contraceptive medication; endocrinology signs or symptoms; undergoing any endocrinology treatment; metabolic disorders (diabetes); pregnancy or breastfeeding; history of cardiac, renal and/or liver disorders; and obesity.

Four observer teams carried out the different studies independently.
- Team I performed the clinical–iconographic studies and responsible for patient distribution, and scheduling
- Team II performed the echographic–ultrasound studies
- Team III performed the histopathology studies
- Team IV performed surgery.

Anesthesia

Local anesthesia was used with a formulation for tumescent local anesthesia, containing 600 mg lidocaine, 1 mg adrenaline and 5 cc Na bicarbonate in 1000cc of sterile saline solution.

The anesthesia was injected with a 60cc syringe; 300cc were injected in the area to be treated with laser lipolysis, and 500cc were injected in the area to be treated with internal ultrasound.

All patients were monitored by the anesthetist, and a conscious sedation was used.

History of UAL (Ultrasonic assisted liposuction)

Qualitative and quantitative studies were performed to examine the differences between the UAL devices, the power delivered controlled by the surgeon, as well as the clinical outcomes.

Surgical complications due to the use of excessive ultrasound energy during lipoplasty were observed; old ultrasound devices (UAL) used cannulas that required high levels of ultrasound energy for fat fragmentation, and the use of excessive ultrasound energy can produce internal cavity formation that leads to seroma or even pseudobursa formation, or delayed swelling resolution.

Also prolonged tissue indurations, painful dysesthesias, and sensory changes have been reported.

Vaser™

This system is a breakthrough in the use of ultrasonic technology for liposuction procedure.

Sound Surgical Technologies was the developers of a Vaser™ device.

This new ultrasound surgical system, has a smaller diameter, solid probes (2.9 mm – 3.7 mm) with grooves near the tip to increase fragmentation efficacy.

The grooved probe designed redistributes the ultrasound energy, transferring some of the vibration energy from the front of the tip to a region just proximal to the tip.

Because the efficacy of the fragmentation/emulsification process has been im-
proved by the use of the grooved design, probes of smaller diameter can be used to achieve rapid and effective fragmentation (Fig. 1).

The ultrasound power delivered to tissues is directly related to probe diameter.

Probes of smaller diameters deliver less energy to tissues, but still achieve the desired fragmentation and emulsification because of the grooves at the tip, resulting in higher efficiency.

The Vaser™ mode (delivery of pulsed ultrasonic energy) reduces the applied power still further while maintaining efficiency.

The efficacy of the probe design is critical for the delivery of low power levels.

The 2.9 mm-diameter probes achieve further reductions in applied power with very high fragmentation efficacy.

**Laserlipolysis (Smartlipo™)**

The laserlipolysis produces an adipocytolytic activity with adipocyte rupture, reduction of fat cell number, small vessel coagulation and collagen neoformation using a Nd YAG laser, using a wavelength of 1.064 nm, energy of 150 milijoules mJ, a frequency of 40 Hz, and a potency of 6 W, and 100 microsecond pulse. This laser also features a helium-neon (HeNe) red aiming beam. The HeNe beam can be seen through the skin, allowing the surgeon to identify target areas.

Both laser beams are conducted through a 300-micron optical fiber that is inserted in a 1 mm-stainless steel microcannula. (Fig. 2)

This technique is a useful tool for the treatment of small localized adiposities and fat tissue irregularities, in healthy patients, weighting close-to-ideal weights (BMI <25).
A microcannula is introduced through small incisions with the 300 um-optical fiber, advancing and retreating within the fat tissue at different depth levels. These movements are facilitated by the laser itself. The distal portion of the optical fiber is extended approximately 2mm beyond the distal end of the cannula.

In contact with fat tissue, the low-power laser beam (maximum 6 W) produces an effect known as “selective photo-hyperthermia”. When the light energy strikes an adipocyte, it is transformed into heat. Temperature increase causes the rupture of the capsules that surround fat cells (photothermic activity), releasing an oily substance contained in the cells.

In the sequence of effects produced by the laser, the liquefactive necrosis or cellular lysis is the last effect of the extreme thermal damage to the irradiated adipose tissue.

The subsequent tissue liquefaction, further facilitates eventual aspiration.

This oily solution produced by laserlipolysis together with the fat cell residues remain spread over the treated area, and are then drained. Drainage is performed with a 2 mm cannula, through one or two holes, with a 60 cc syringe. The rectilinear cannula is inserted at different depth levels to reach all fat tissue layers (superficial and medium).

The laser activity is controlled through a panel that shows the amount of energy (Joules) delivered in the area.

After extracting the emulsion (200 cc in each area), a slightly compressive bandage, analgesia and generic treatments are indicated. In general, the procedures are performed in an outpatient basis, and patients can return to their daily activities as early as the first day after the procedure.

Manual lymphdrainage is performed in the first week after the procedure.

**Team I (clinical- iconographic studies)**

The patient’s medical history recorded including the following data:

- Personal details and history: age, pregnancies, surgeries, history of cardiac, renal and/or liver disorders, food and/or drug allergies, menstrual cycle, use of hormonal medication, date of withdrawal of previous cosmetic and/or physiotherapeutic treatments
- Present patient disease: arterial tension, description of symptoms (heaviness, pain, cramps, tingling sensation in lower limbs) and signs (edema, superficial and deep tenderness) associated to EFP (edematous fibrous panniculopathy), body weight, BMI (body mass index), and evolution of the disease.
- Iconographic images from area of treatment, saddle bags and lower limbs

After the liposuction procedure from a clinical point of view, the following should be highlighted (Table 1), (Fig. 3,4,5):

- Good clinical-aesthetical evolution on
TABLE 1.

<table>
<thead>
<tr>
<th>Day 6</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>3 left</td>
<td>2 left</td>
<td>6 left</td>
<td>4 left</td>
<td>3 left</td>
<td>8 left</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>x 3 days</td>
<td>0</td>
<td>x 3 days</td>
<td>x 1 day</td>
<td>x 2 day</td>
<td>2 days</td>
</tr>
<tr>
<td>Swelling</td>
<td>+left</td>
<td>+left</td>
<td>+left</td>
<td>left</td>
<td>left</td>
<td>left</td>
</tr>
<tr>
<td>Bruising</td>
<td>small R</td>
<td>left</td>
<td>left</td>
<td>left</td>
<td>left</td>
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</tr>
<tr>
<td>Itching</td>
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<td>left</td>
<td>none</td>
</tr>
<tr>
<td>Surgical date</td>
<td>28/09</td>
<td>27/09</td>
<td>27/09</td>
<td>28/09</td>
<td>28/09</td>
<td>27/09</td>
</tr>
</tbody>
</table>

FIGURE 3. Right side

Left side

FIGURE 4. Right side

Left side
both sides.

- Greater number of side effects on the left side (hematomas and pain).
- Good skin retraction in the buttocks area, even though the procedure was performed on the external thigh.
- Lack of pain in the right area. (between 1-10 maximum)

**Team II (echography–ultrasound)**

a) Ultrasound studies of the subcutaneous cell tissue were performed in 6 patients, in standing position. The areas were localized by taking the anterosuperior iliac spine and the middle third of the thigh as reference. The areas were centered perpendicularly, at a certain distance from that imaginary line, in order for the measurements to be repeatable in time.

The perimeter of the examined thigh was measured passing over the area to be studied.

A new ultrasound assessment was performed with the same equipment (Voluson 7.5-10 Mhz) and by the same operator, 30 days after the procedure.

**Case 1**

The initial study in the first patient was made on 10-Sept-07. Heterogeneous subcutaneous cell tissue, 47 mm -thick in the right thigh and 45 mm -thick in the left thigh was observed (Fig. 6).

In the post-lipo study performed on 01-Nov-07, a 10-12 mm -thick solid hyperecho- genic area was observed on both sides at 10 mm-depth, which could correspond to adipose tissue replacement by scar tissue. This area was more evident on the right side (Fig. 7).

**Case 3**

The initial study on 12-Sept-07 showed a heterogeneous subcutaneous cell tissue (53 mm -thick in the right thigh, and 55 mm -thick in the left thigh) (Fig. 8).
**FIGURE 6.** Case 1. Pre Left side

**FIGURE 7.** Case 1. Post Left side

**FIGURE 8.** Case 3. Pre Right side
In the post-lipo study performed on 24-Oct-07 (25 days after the procedure), a clearly hyperecogenic area was observed (10 mm beneath the epidermis and 10-12 mm-thick) similar on both sides (Fig. 9).

**Team III (histopathology)**

Histopathology samples were identified using patient name, “pre-lipo” or “post-lipo” labels, and “right side” or “left side” labels.

Biopsy specimens of subcutaneous cell tissue (24 samples) (Table 2)

**TABLE 2.**

<table>
<thead>
<tr>
<th>Patient</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. (ml)</td>
<td>20</td>
<td>18</td>
<td>15</td>
<td>15</td>
<td>12</td>
<td>17</td>
</tr>
<tr>
<td>B. (ml)</td>
<td>15</td>
<td>15</td>
<td>14</td>
<td>13</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>C. (ml)</td>
<td>25</td>
<td>17.5</td>
<td>20</td>
<td>14</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>D. (ml)</td>
<td>15</td>
<td>15</td>
<td>14</td>
<td>17</td>
<td>13</td>
<td>16</td>
</tr>
</tbody>
</table>

A: Prior to liposculpture, external right thigh
B: Prior to liposculpture, external left thigh
C: Post-liposculpture, external right thigh
D: Post-liposculpture, external left thigh

Histological technique

Sample fixation in formol, inclusion in paraffin, and staining with hematoxilyn-eosin.

Macroscopic examination: liquefied adipose tissue.

Samples A and B

The sections show subcutaneous cell tissue with varying degrees of mucinosis, interstitial edema, and proliferation of blood and lymphatic vessels with varying degrees of microangiopathies (grade 1 and 2, according to Handelsman).

There is fibrous thickening of the interlobar connective septa and inflammatory perivascular and interstitial infiltrates (Fig. 10,11,12,13).
Diagnosis: Edematous-fibrosclerotic pan-niculopathy\textsuperscript{15}

Samples C and D

The sections show varying degrees of subcutaneous cell tissue damage.

There is reversible (hydropic, balloon-like degeneration)\textsuperscript{16} and irreversible (fat necrosis with lipogranuloma formation in severe cases) cell damage.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{fig10}
\caption{Microangiophaty degree 3}
\end{figure}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{fig11}
\caption{Interstitial edema and vascular proliferation (HE x400)}
\end{figure}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{fig12}
\caption{Adipose tissue pre}
\end{figure}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{fig13}
\caption{Adipose tissue pre}
\end{figure}

In this 6 cases (12 biopsies), there was a higher effect of fat cellular lysis (20%) in the right side, post-liposculpture (Fig. 14,15,16,17,18,19,20,21) (Table 3).

**RESULTS**

From a clinical point of view, all patients expressed their satisfaction at the medical-aesthetical results on both sides.

All patients (100%) expressed lack of pain on
FIGURE 14. H&E x 400 Lipofagic granuloma, right side

FIGURE 15. H&E x 400 Lipogranuloms, right side

FIGURE 16. H&E x 400 Incipient Lipofagy, left side

FIGURE 17. H&E x 400 Intracellular edema (hydropic degeneration- reversible cellular injury) Left side

FIGURE 18. H&E x 400 Foam cells (macrophages with fat inside) sign of destruction of the fat cells, right side +++

FIGURE 19. H&E x 400 6 Foamy Cells (right side +++
the right side treated; and 100% of patients experienced pain on the left side, ranging from 5/10 in the first 72 hours post-treatment to 3/10 in the subsequent 10 days.

80% of patients showed ecchymosis, small hematomas and a sensation of induration on the left side. 40% of patients showed few ecchymosis on the right side.

Patients experienced no symptoms post-lipo on their right sides, and showed good aesthetic results in both sides.

The ultrasound study, shows a similarity in adipose tissue alterations after de procedure on both sides. There is a marked action of both techniques to improve skin tightness and to tense tissues. Likewise, both techniques have a proved adipocytolytic activity on fat tissue (fat thickness reduction).

The histopathological study shows adipose tissue on clinically evident localized adiposity, with some edematous-fibrosclerotic panniculopathy aspects, and that the adipocytolytic activity (destruction and/or fat cellular lysis) predominates in the right area treated.

The ultrasound (UAL) and laserlipolysis techniques when performed by well-trained Liposculpture specialists produce very effective results and a significant cosmetic improvement. However must be highlighted that the use of Laserlipolysis (Smartlipo™), generates imperceptible skin scars and UAL Vaser™ generates larger scars due to the use of the skin protector that is needed for the placement of the ultrasound probe (Fig. 22,23).

**COMMENTS**

This is a prospective research study in 6 patients with clinical localized adiposity in the saddle bags.

All patients underwent liposuction with UAL Vaser™ on the left side using 60% of
the energy for 15 minutes and Laserlipolysis Smartlipo™ on the right side using a total of 3500 Jules.

All patients in the area treated with Ultrasound assisted liposuction (left side) showed bruising, pain and a hard sensation.

None of the patients experienced pain and a hard sensation in the areas treated with laserlipolysis (right side). Scars were larger on the side treated with
Smartlipo™ produce smaller and imperceptible scars (right side).
The results of the ultrasound studies show that both devices have a strong effect on fat tissue and skin retraction.\(^\text{17}\)

The histopathology studies showed a more aggressive activity on the fat tissue (fat cellular lysis) on the sides treated with laserlipolysis compared to the areas treated with UAL internal ultrasound.

The aesthetic results on both sides were good in all patients, with good skin retraction (Fig. 24, 25).

**CONCLUSIONS**

The purpose of this study was to observe the activity of two medical equipment for the treatment of small localized adiposity area, comparing their actions, determining which could produce less side effect to patients and shorter recovery downtime.

Today, in lipoplasty, patients demand good skin retraction, no skin irregularities, good body contour, and short post-surgery recovery.

The histopathology report indicated that localized adiposity\(^\text{18}\) do not exist alone; they are always related to microcirculatory, lymphatic and extracellular matrix alterations\(^\text{19}\) (PEFE Panniculopathy Edematous Fibrous Sclerotic). Therefore, a complete treatment for a localized adiposity and lipodistrophy, has to be included besides liposuction, a comprehensive therapeutic plan: skin care, oral medication, carboxytherapy and manual lymphatic drainage.

Smartlipo™ Laserlipolysis accomplishes the reduction of fat tissue in minor localized adiposity with less side effects. The thermal damage on the adipose tissue produced by the Nd YAG laser (1064 nm) promoted better hemostasis, better wound healing, and less surgical trauma.

The decrease in tissue trauma is likely to be associated with the laser-induced coagulation of small vessels in fat tissue, the adequate infiltration of the anesthetic solution, and the possibility of using smaller-caliber cannulas. Internal laserlipolysis with 1064 nm Nd YAG laser has proven to be a safe and effective method.
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