

# A Safety and Feasibility Study of a Novel Radiofrequency-Assisted Liposuction Technique

## **Authors:**

Guillermo Blugerman, M.D.

Diego Schavelzon, M.D.

Malcolm D. Paul, M.D.

*Buenos Aires, Argentina; and California, USA*

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## **Abstract**

**Background:** The feasibility, safety, and efficacy of a novel radiofrequency device for radiofrequency-assisted liposuction were evaluated in various body areas.

**Methods:** From July to December of 2008, 23 subjects underwent radiofrequency-assisted liposuction using the BodyTite system. Information regarding aesthetic results and local and systemic complications was collected immediately after the procedure and at 6- and 12-week follow-up.

**Results:** The mean age of the patients was  $38.8 \pm 12.4$  years, and 87 percent were women. Radiofrequency-assisted liposuction was performed successfully in all cases; volume aspirated per patient was  $2404 \pm 1290$  ml, whereas operative time was  $158 \pm 44$  minutes. All patients underwent liposuction at the hip and low abdominal areas, bilaterally. Body contour improvement was observed postoperatively in all patients and there were no severe systemic or local complications, although postoperative pain was minimal in all patients. Weight and circumference reductions were significant at both 6-week and 3-month follow-up. Skin tightening was judged optimal by the surgeon in all patients.

**Conclusions:** The authors' study suggests that the removal of moderate volumes of fat with concurrent subdermal tissue contraction can be performed safely and effectively with radiofrequency-assisted liposuction. Additional benefits of this technique are excellent patient tolerance and fast recovery time. Nonetheless, a larger sample is required to confirm the authors' results and guarantee the efficacy and safety of the procedure. Direct comparison with traditional liposuction or energy-assisted liposuction techniques may provide some insights to tailor future indications of this novel technique.

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Diego Schavelzon, M.D.  
Malcolm D. Paul, M.D.

Buenos Aires, Argentina; and Irvine,  
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Liposuction has become the most common aesthetic procedure worldwide for excess fat removal.<sup>1</sup> Its relative safety and ease of performance explain its widespread adoption. Over the years, numerous changes and innovations have improved this procedure. First, the dry liposuction technique<sup>2,3</sup> prevailed, but the introduction of tumescent liposuction<sup>4</sup> reduced complications and conveyed better aesthetic results. Still, mechanical liposuction presents several shortcomings: it is time-consuming and results in insufficient skin tightening and the chance of developing multiple systemic and local complications (e.g., infection, fat or blood clot embolism, excessive fluid loss, hemorrhage, damage to the skin or nerves).<sup>1</sup> Newer approaches such as the use of

either power<sup>5</sup> or ultrasound-assisted liposuction<sup>6-8</sup> may lower the side-effect profile but do not show adequate skin tightening. Although several studies have demonstrated good skin tightening with laser-assisted liposuction,<sup>9</sup> it is time-consuming, is not controlled as to the precise application of the energy, and can result in local skin burns.

Recently, noninvasive radiofrequency devices have demonstrated skin tightening during thermal cutaneous treatment<sup>10,11</sup>; however, the impact on high-resistance areas such as the abdomen and thighs was shown to be only mild. The BodyTite

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**Disclosures:** Drs. Blugerman and Schavelzon, to perform the study, received the BodyTite device from Invasix Ltd. In addition, Invasix Ltd. paid part of the study-related expenses. Dr. Paul serves as a consultant to and chairman of the Medical Advisory Board, and has received a stipend from and holds Stock Options in Invasix. Ltd., the manufacturer of Invasix BodyTite.



**Fig. 1.** The radiofrequency device. Note the external and internal electrodes.

system (Invasix Ltd., Yokneam Ilit, Israel) is a novel bipolar device that generates enough radiofrequency energy during liposuction to convey elevated though controlled skin and subdermal temperatures in a precise location, generating fat liquefaction, blood vessel coagulation, and skin tightening. The purpose of this pilot study was to determine

the feasibility and safety of radiofrequency-assisted liposuction.

## PATIENTS AND METHODS

### Study Design

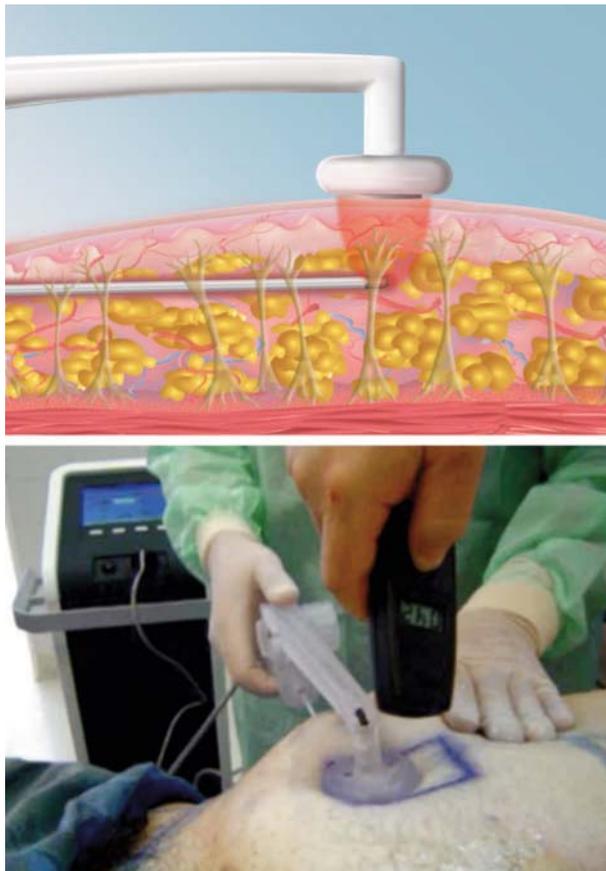
Between July and December of 2008, we prospectively included 23 individuals who underwent radiofrequency-assisted liposuction. These procedures were performed at the surgeons' private clinic (B&S Clinic) in Buenos Aires, Argentina. Our institutional review board approved the study protocol. All participants provided written consent for their procedures.

Inclusion criteria included the following: willingness of the patient to sign the informed consent, men and women aged 18 years or older, presence of excessive fat and loose skin at the abdominal and thigh regions, and cellulite isolated at the posterior or lateral thigh region. Exclusion criteria included the following: prior placement of pacemaker or internal defibrillator; significant systemic illness; pregnancy; recent surgery to the treatment area; disorders affecting the lower abdomen such as Crohn disease, hernia, or acute cervicitis; unsuitability that might make it unsafe for the patients to participate in the study such as body dysmorphic syndrome; and blood dyscrasias.

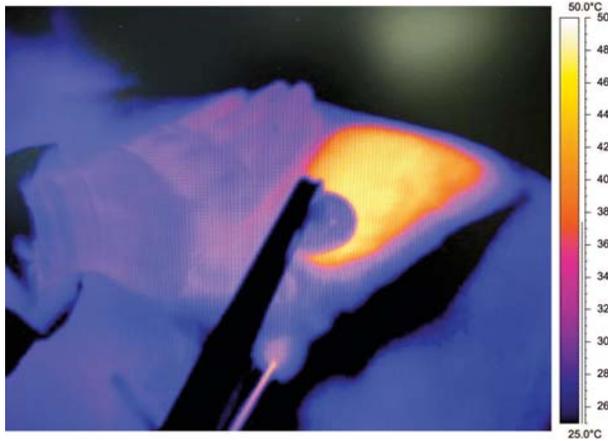
The following data were collected: age, volume aspirated per patient, operative time, and number and type of complications. For this protocol, all patients were seen by a senior surgeon and photographed before surgery and at 6- and 12-week follow-up. During each visit, we further evaluated the degree of skin tightening and the presence of systemic and/or local skin complications.

### Skin Tightening Assessment

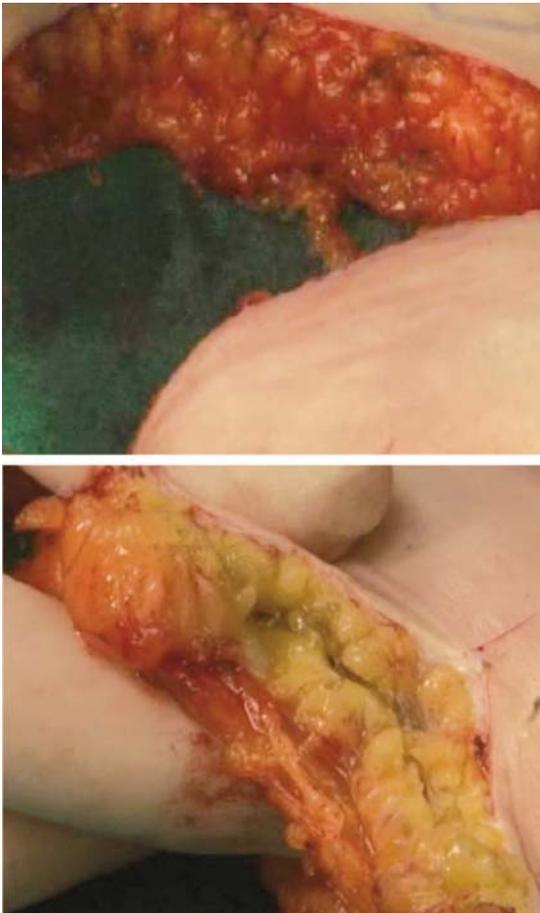
We measured linear skin contraction over the curved skin surface in the treated area (using a



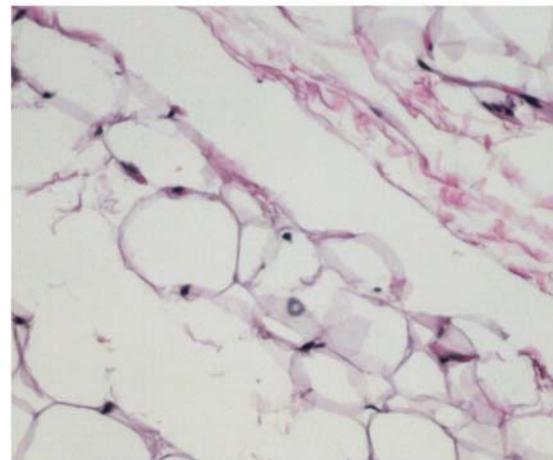
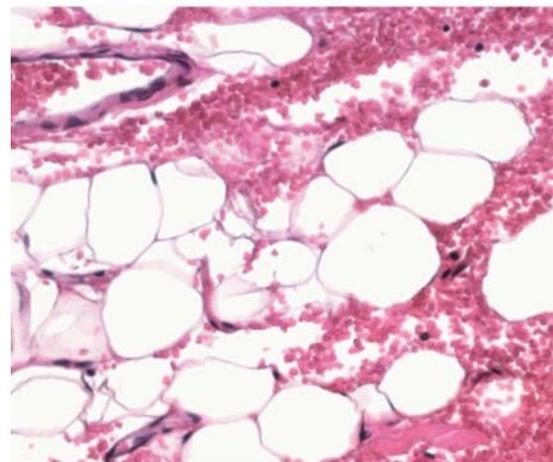
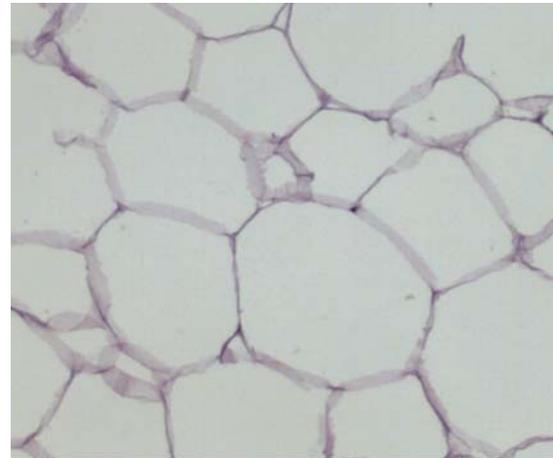
**Fig. 2.** (Above) Schematic drawing of how radiofrequency energy flows from the internal to the external electrodes. (Below) The device being used.



**Fig. 3.** Experimental use of radiofrequency-assisted liposuction showing uniform heating assessed by infrared camera.



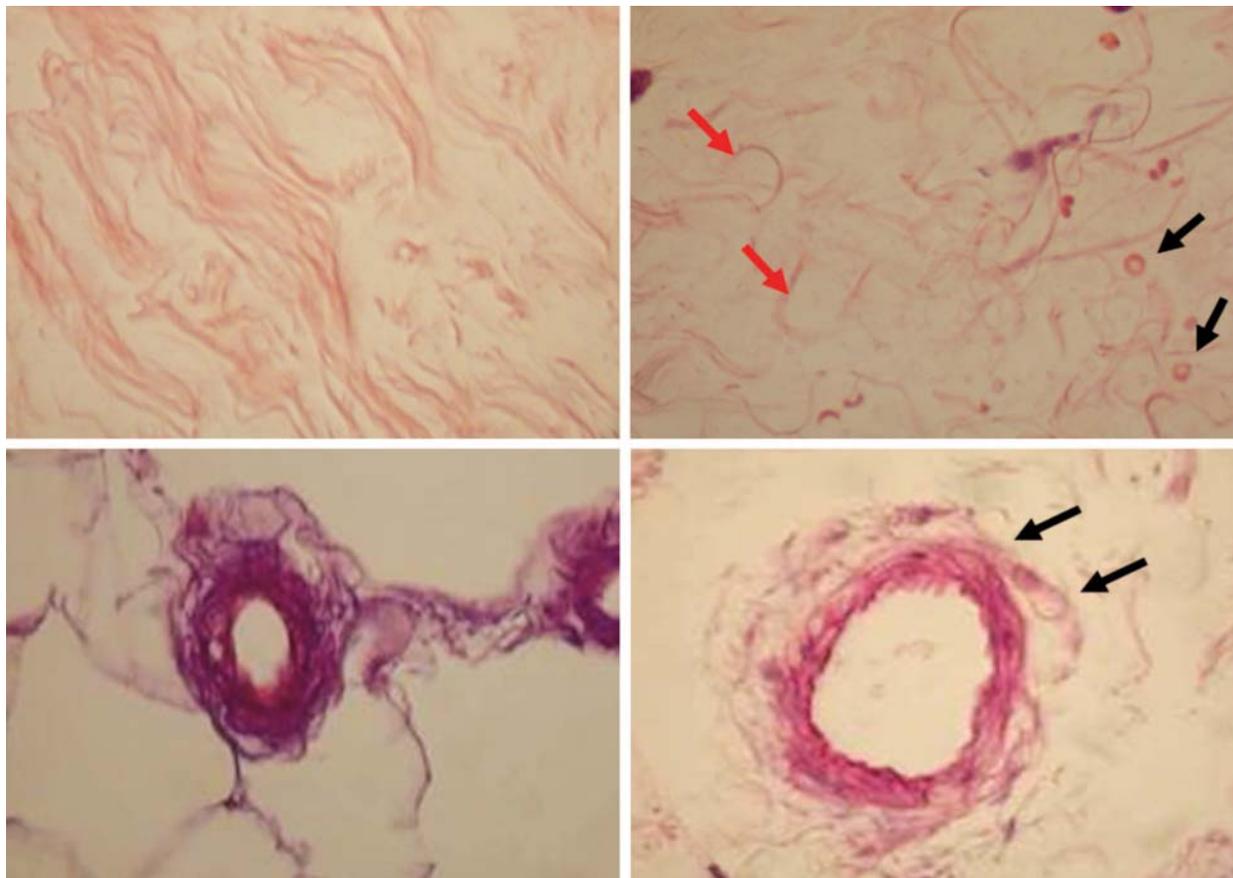
**Fig. 4.** Macroscopic subdermal samples before (*above*) and after (*right*) radiofrequency-assisted liposuction. See the absence of bleeding after radiofrequency-assisted liposuction resulting from blood vessel coagulation.



**Fig. 5.** Microscopic subdermal fat samples: (*above*) untreated fat, (*center*) after power-assisted liposuction, and (*below*) after radiofrequency-assisted liposuction. After radiofrequency-assisted liposuction, channels in the fat tissue are observed surrounded by disrupted fat cells.

flexible ruler, the distance between two points; i.e., incision ports and anatomical landmarks over the body surface such as the navel). There were

three distance comparisons per patient, before surgery and at 6- and 12-week follow-up. The percentage of contraction was calculated at 6 and 12 weeks.



**Fig. 6.** Histologic samples showing baseline collagen structure (*left*) and its changes with radiofrequency-assisted liposuction (*right*). (*Above, right*) Note fragmentation of collagen fibers (*red arrows*) and extravasation of red blood cells (*black arrows*) after radiofrequency-assisted liposuction. Subdermal blood vessels are surrounded by extracellular matrix at baseline, and detachment from the extracellular matrix is observed after radiofrequency-assisted liposuction (*below, right*) (*black arrows*).

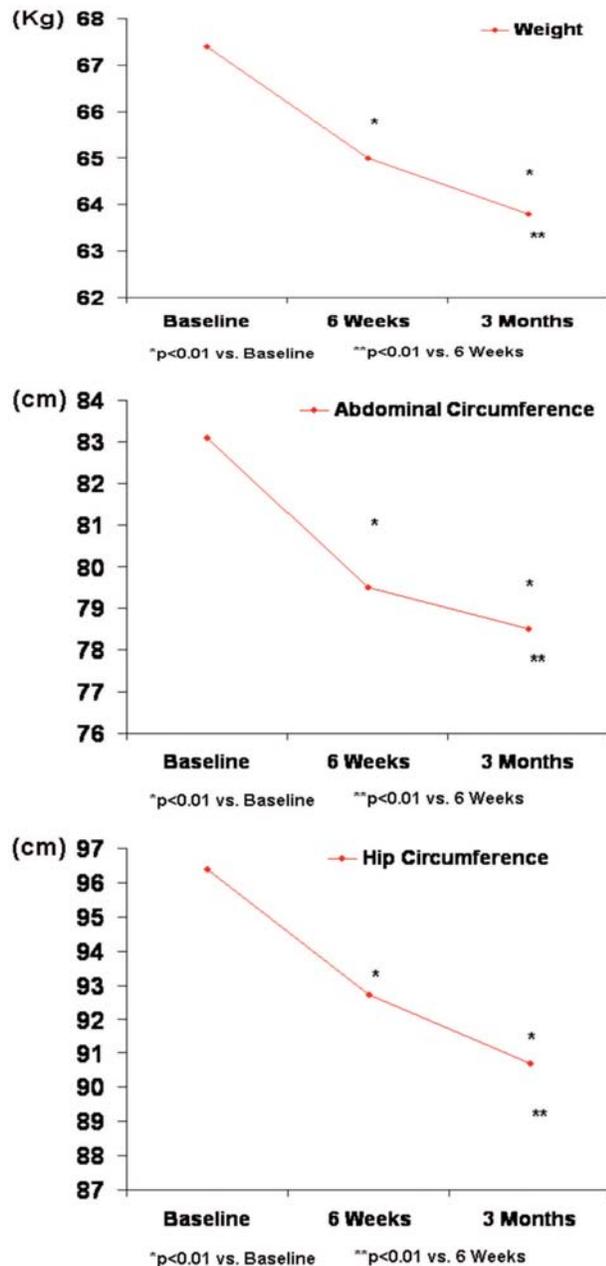
### Device

Radiofrequency energy is electrical energy delivered in the form of high-frequency electrical current applied to the tissue to create a thermal effect. Radiofrequency-assisted liposuction dissolves fat cells, creating small channels in the fatty tissue. In addition, radiofrequency-assisted liposuction triggers immediate contraction of the collagen fibers and subdermal remodeling (i.e., neocollagenesis).<sup>12–15</sup> The BodyTite system is composed of a bipolar radiofrequency handpiece and computer device. The handpiece has an internal electrode and an external electrode (Fig. 1). The internal electrode is coated with polytetrafluoroethylene for the entire length of the cannula except for the very tip of the electrode where the energy is delivered. The external electrode closes the radiofrequency current loop by receiving the energy through the skin and has an imbedded thermal sensor to measure the skin temperature (Fig. 2). The amount of energy delivered to the fat in watts, the limit of skin temperature in degrees, and high and

low limits of impedance are determined by the surgeon on a user-friendly liquid crystal display screen. All parameters are controlled in a closed-loop system to prevent excessive heating of fat and/or dermis. Therefore, the apparatus enables quick and precise control of delivered radiofrequency energy, treatment depth, and skin temperature. The device provides rapid thermal effect, causing significant blood vessel and fat coagulation (Fig. 3) and allowing close surveillance of temperature and energy parameters. The latter translates into uniform heating of skin and subcutaneous layer (Figs. 4 and 5) and limited tissue trauma.

### Surgical Steps

Before the procedure, all subjects were adequately marked in the standing position. When first using this technology, conservative settings are encouraged; that is, a maximum power of 35 to 40 W, skin temperature of 40°C, and low- and high-impedance settings of 40 and 600  $\Omega$ .



**Fig. 7.** Graphs showing changes in weight and abdominal and hip circumferences at 6-week and 3-month follow-up.

As the internal electrode is coated with polytetrafluoroethylene, port protectors are not required, unlike the requirement for skin port protection when performing ultrasound-assisted liposuction. Therefore, access incisions are only 3 mm (the diameter of the internal cannula).

To guarantee safe and efficient liposuction, radiofrequency energy requires an optimal degree of tumescence of the soft tissue. This can be accomplished rapidly by using an infusion pump. The ratio of infusate used to aspirate was in the

range of 2:1 to 3:1. Waiting at least 15 to 20 minutes for the maximum vasoconstriction effect of the epinephrine significantly diminishes blood loss. Skin lubrication with a sterile gel is critical for the radiofrequency energy to penetrate the skin.

The handheld device can be adjusted such that the internal electrode can be positioned in the deeper fat. The thickness of the fat layer can be determined by pinching the skin and fat, and dividing the thickness in half to determine the depth of placement of the internal electrode. Once the internal electrode is placed, a spring mechanism allows the external probe to contact the skin surface. The closed-loop feedback provided by the device emits an audible tone while the energy is being delivered and a different tone when the skin temperature is approaching the target value. The preset power, cut-off temperature, and impedance limits allow for the safe application of energy. The system automatically limits radiofrequency power when skin temperature limits are being approached, and will maintain and not exceed the preset levels.

First, energy is delivered to the deeper fat in zones (25- to 35-mm depth) and maintained to allow uniform heating of the deep fat (Fig. 3). This maneuver will coagulate the blood vessels (diminishing blood loss, ecchymosis, and resultant discomfort) and dissolve the fat (Fig. 4).

The internal probe is then moved to approximately 10 to 15 mm below the skin surface. The energy is delivered until the skin temperature of 42°C is reached and maintained for 2 minutes, or 2 kJ. The procedure covers a skin surface area of 15 × 10 cm. After the procedure, the handpiece is moved to another zone, and the procedure is repeated.

A standard manual cannula or Power-assisted Liposuction Device (MicroAire Surgical Instruments LLC, Charlottesville, Va.) is used to aspirate the liquefied fat. The aspirate has the appearance of a milkshake, as opposed to the traditional aspiration of clumps of fat seen with traditional liposuction.

The most recent handpiece prototype features a hollow cannula, thereby allowing for simultaneous coagulation of blood vessels, lipolysis, uniform subdermal heating (producing skin retraction), and aspiration of the dissolved fat—avoiding a second step. Interestingly, unlike other devices, the narrow cannula diameter of 3 mm has been maintained in this probe. It is appealing to both surgeons and patients that tiny skin-access incisions and no port protectors are required.

During postoperative care, we leave the incision opened. All patients wear compression garments around the clock continuously for 3 weeks and at

night only for an additional 3 weeks (or longer, if there are any areas of soft-tissue thickening).

### RESULTS

A total of 23 patients underwent successful radiofrequency-assisted liposuction. Mean age was  $38.8 \pm 12.4$  years (range, 19 to 59 years), and 87 percent were women. None of the patients had undergone any previous treatments for fat reduction. Mean volume aspirated per patient was  $2404 \pm 1290$  ml (range, 400 to 6400 ml), and operative time was  $158 \pm 44$  minutes. Body contour improvement was observed postoperatively in all patients. There were no deaths, severe arrhythmias, deep vein thrombosis, major bleedings, or any other severe adverse event. No patient required rehospitalization. Furthermore, there were no burns, deforming scars, hematoma, or seromas, and postoperative pain was minimal in all patients.

### Histologic Studies

Macroscopic and histologic assessment was carried out on tissues aspirated from the subjects immediately after radiofrequency-assisted liposuction. Significant findings following radiofrequency-assisted liposuction included the coagulation of small blood vessels in the fatty tissue (Fig. 6, *above, right*); rupture and fragmentation of adiposities; and development of fatty channels (Fig. 6, *above, right*), collagen fragmentation, edema, and disarray (Fig. 6).

### Clinical Follow-Up

Twenty-two of 23 patients (96 percent) returned for a clinical visit at 6 weeks and 16 (70 percent) completed the 3-month follow-up. Weight and circumference reductions were significant at both 6-week and 3-month follow-up (Fig. 7). By visual estimation, skin tightening was judged to be optimal by the surgeon in all patients (Figs. 8 through 11). At least three measurements were made for each



**Fig. 8.** A male patient underwent radiofrequency-assisted liposuction to the lower abdomen.



**Fig. 9.** A male patient underwent radiofrequency-assisted liposuction to both hips.



**Fig. 10.** A female patient underwent radiofrequency-assisted liposuction to both hips.

patient between three points to increase the statistical significance of the data. Measurements showed significant linear contraction at 6 weeks (13.9 percent) and also at 12 weeks (24.3 percent) ( $p < 0.001$  for both). All patients demonstrated some level of skin tightening, which varied from 9 to 42 percent. No patient reported discomfort at 6- or 12-week follow-up and no permanent adverse skin effects were seen. At 1 year, no patients required or asked for a new liposuction procedure.

### Complementary Studies

We performed magnetic resonance imaging before and 3 months after radiofrequency-assisted liposuction in five patients (Fig. 12). The postoperative image shows significant reduction of the subcutaneous fat tissue in the treated areas, with signals of remaining edema expressing the persistence of the reparatory process 90 days after the procedure.

## DISCUSSION

Liposuction has become a very popular aesthetic surgical procedure.<sup>1</sup> Nonetheless, standard mechanical liposuction requires attention to multiple technical details; it does not guarantee optimal skin tightening and can result in a variety of medical and cosmetic complications. In the quest to obtain better results with liposuction, several energy-assisted liposuction techniques have been attempted<sup>5,8,9,16,17</sup>; however, none of them has gained a great deal of popularity because of their inherent limitations. The ideal lipoplasty technique should be one that is user

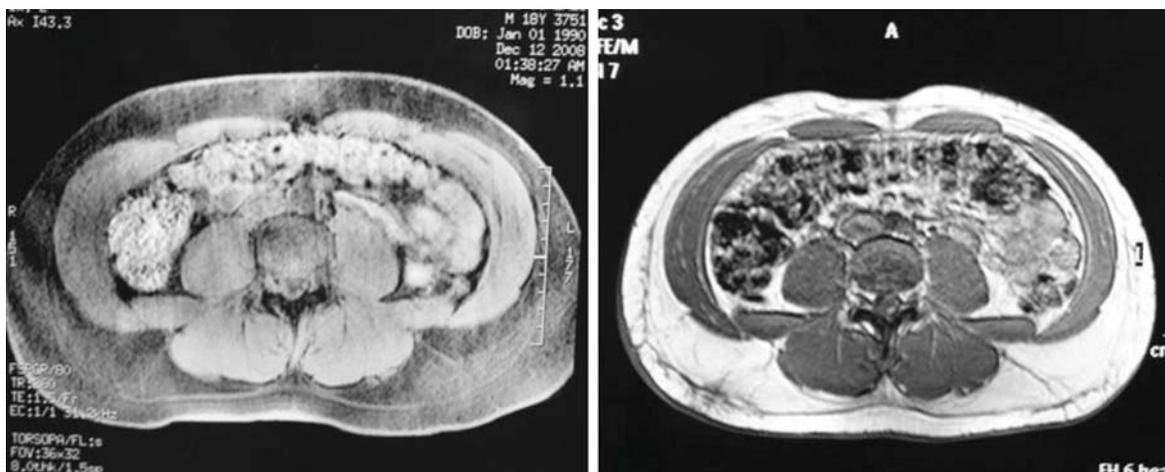
friendly and can be performed fairly quickly but that allows simultaneous subdermal fat liquefaction and blood vessel coagulation in a uniform manner, thus limiting patient swelling, bruising, and discomfort. In this study, we describe our experience with radiofrequency-assisted liposuction. We have treated 23 patients, with no systemic or local complications. Aesthetic results in our series were deemed satisfactory by the surgical team and by all participants. Skin tightening was judged optimal in all patients. Objective assessment of skin tightening by measuring sequential changes in length between two points confirmed our subjective appraisal. As previously mentioned, radiofrequency-assisted liposuction generates heat fast at the skin and in the subdermal fat in a controlled and uniform manner, which translates into subdermal fat liquefaction and blood vessel coagulation at the treated area. Radiofrequency-assisted liposuction leads to minimum tissue trauma in addition to adequate skin tightening, which constitutes an advantage when compared with energy-assisted or tumescent liposuction.

## CONCLUSIONS

The present study results suggest that removal of moderate volumes of fat with concurrent subdermal tissue contraction is feasible, safe, and effective with radiofrequency-assisted liposuction. Additional benefits of this technique are excellent patient tolerance and fast recovery time. Nonetheless, a larger sample size is required to confirm our results and guarantee the efficacy and safety of



**Fig. 11.** A female patient underwent radiofrequency-assisted liposuction to the lower abdomen.



**Fig. 12.** Magnetic resonance imaging of the abdomen before and 3 months after radiofrequency-assisted liposuction, respectively, showing significant reduction of the abdominal fat thickness and mild edema. Note the indentation of the midabdominal line at 3-month follow-up, which was absent prior to the procedure.

the technique. Direct comparison with tumescent liposuction or energy-assisted liposuction techniques may provide some insights to tailor future indications of this novel technique.

**Guillermo Blugerman, M.D.**

Clínica B&S de Excelencia en Cirugía Plástica  
Laprida 1579  
Buenos Aires 1124, Argentina  
blugerman@ciudad.com.ar

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