Body Contouring

Nonexcisional Tissue Tightening: Creating Skin Surface Area Reduction During Abdominal Liposuction by Adding Radiofrequency Heating

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Abstract

Background: Recent publications show that heat-mediated tissue tightening is a promising treatment for the lax abdomen and may provide better long-term outcomes than traditional suction-assisted liposuction (SAL).

Objectives: The author evaluates the degree and duration of skin surface area contraction, as well as the influence of anatomic location of the treatment region on the degree of tissue tightening, in a study comparing SAL alone vs SAL plus radiofrequency-assisted liposuction (RFAL).

Methods: In this prospective, randomized, split abdominal study, 12 consecutive patients were treated with SAL alone on 1 side and with SAL plus RFAL on the other side. Each patient had 4 (3 × 3-cm) squares-2 per treatment type-tattooed in the lower abdominal region (2 on the right and 2 on the left). The surface area of these squares was measured with the Vectra computerized measurement system (Canfield, Inc, Fairfield, New Jersey) at pretreatment, at 6 weeks posttreatment, and at 1 year posttreatment. All measurements were subjected to statistical analysis using predictive analytic software and were evaluated for statistical significance.

Results: In regions treated with SAL alone, there was a 10.4% mean skin surface area contraction at 6 weeks and 8.3% at 1 year posttreatment. The mean skin surface area reduction was 25.8% in regions treated with radiofrequency plus SAL at 6 weeks and at 1 year. The anatomic location of each square (medial vs lateral) did not statistically correlate with more or less tissue tightening.

Conclusions: Radiofrequency-assisted tissue tightening, when applied in conjunction with SAL, is effective in achieving greater skin surface area reduction.

Level of Evidence: 2

Keywords

body contouring, liposuction, tissue tightening, minimally invasive, skin tightening, RFAL, SAL

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Many patients with a desire for abdominal fat reduction and skin tightening decline abdominoplasty because of the long scar, lengthy recovery, and associated morbidity and numbness. While traditional suction-assisted liposuction (SAL) has been reported to offer mild skin tightening, residual skin laxity and superficial contour irregularities can often occur when liposuction is performed in patients with moderate to severe skin laxity and poor skin quality. Physical indicators of a less-than-optimal aesthetic SAL outcome include the presence of a pendulous soft tissue overhang at the suprapubic crease and "rolls" of skin and fat that the patient can easily pull away from the underlying fascia. Massive weight loss patients are especially affected by these problems. These soft tissue laxity issues often go uncorrected with SAL, power-assisted liposuction (PAL), and even ultrasound-assisted liposuction (UAL).¹⁻⁴ Although some degree of skin tightening is observed following SAL, the tightening mechanism is based on

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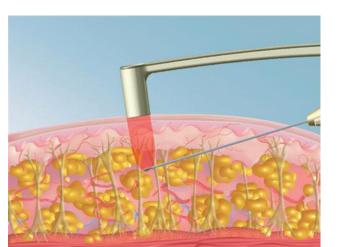


Figure 1. The BodyTite cannula (Invasix, Yokneam, Israel) is inserted into the subcutaneous tissue, while the external thermistor receives and reflects the radiofrequency-generated heat. Reprinted with permission from Invasix.

a nonthermal inflammatory process resulting from subdermal stimulation and elastic contraction of skin, after removing the internal turgor created by excessive adipose tissue. Suction-assisted liposuction skin contraction is limited. While the amount of contraction depends on the inherent skin elasticity, the average amount of surface area reduction achieved with SAL is about 10%.⁵

Patients are increasingly demanding better results and tighter skin from less invasive, nonexcisional procedures with minimal scarring. Certain ethnic groups are especially intolerant of any procedure that leaves a visible scar. The introduction of laser-assisted liposuction (LAL), followed by SAL, has added thermal stimulation to lipocontouring and has shown some ability to cause more skin tightening than SAL alone.^{6,7} DiBernardo⁸ reported mean area soft tissue contraction of 17.2% with LAL followed by SAL compared with a 10.6% skin surface area reduction obtained with SAL alone. Some tightening results were reported after UAL,⁹⁻¹³ but the studies were not randomized, the outcomes were not statistically significant, and the results have not been confirmed in peer-reviewed studies by other investigators.

Radiofrequency-assisted liposuction (RFAL) followed by SAL has been used to treat subcutaneous adipose regions with a combination of soft tissue and skin heating to induce tissue contraction. The BodyTite RFAL device (Invasix, Yokneam, Israel) was introduced in 2008; it consists of a cannula-type probe with a heated tip plus a hollow tube and is capable of performing synchronous heating and aspiration of fat. The internally located cannula tip emits radiofrequency (RF) energy directed toward an external electrode that reflects heat back to the epidermis (Figure 1).

The skin tightening and soft tissue contraction induced by RFAL^{14,15} is due to its effect on the fibroseptal network (FSN). Yoshimura¹⁶ showed that while adipocytes contribute volume to the fatty layer, more than 80% of cells in the region reside in the FSN. Thermal stimulation of the FSN by RF heating has been shown to cause skin surface contraction of up to 45%.¹⁷ In a prospective study reported in 2011,¹⁸ the longevity of RFAL-induced contraction measured with the Vectra computerized measurement system (Canfield Scientific, Inc, Fairfield, New Jersey) averaged 34.5% at 1 year posttreatment.

The purpose of our current institutional review board (IRB)–approved study was to evaluate skin surface area contraction following SAL alone compared with the results following RFAL plus SAL.

METHODS

Study Design and Device

A prospective, randomized study with a 1-year follow-up was designed to analyze and evaluate the degree of skin surface and soft tissue contraction achieved with RFAL plus SAL in comparison to SAL alone. A secondary objective was the comparison of the longevity of skin surface area reduction achieved with RFAL plus SAL vs SAL alone. The significance of the amount of lipoaspirate upon subsequent tissue tightening, the amount of energy used, and the effect of the location of the treatment region were also analyzed.

The study cohort comprised 12 patients (11 women and 1 man) who presented for abdominal lipocontouring. Twelve consecutive patients who appeared requesting reduction of abdominal fat thickness were chosen for this study. Inclusion criteria included mild to moderate subcutaneous fat in the abdominal region, with associated mild to moderate skin laxity. Exclusion criteria included pregnancy or breast feeding, obesity, severe skin laxity, significant chronic illness, smoking, and inability to complete all postoperative appointments. The treatment types were randomized to the right or left lower abdomen; RFAL plus SAL was performed on 1 side, while SAL alone was performed on the opposite side.

An objective, reproducible set of measurements was performed using 3-dimensional (3D) photographs taken with the Vectra system, and calculations were performed using Canfield software. No subjective measurements were used in this study. All measurements were verified and subjected to a standardized paired t test by an independent statistician (Table 1).

Pretreatment, two 3×3 -cm² zones were tattooed on each side of each patient's abdomen. The distribution of squares was linear, with 1 square in the lateral aspect of each lower abdominal quadrant (both right and left) and 1 in the medial aspect of each lower abdominal quadrant (both right and left) (Figure 2). Preoperative Vectra 3D photographs were taken of the tattooed surface, and measurement of the skin surface area within the tattooed sites was performed using the Canfield system (Figures 3 and 4). The BodyTite liposuction device used in this study consists of an RF-generating console that drives an applicator with a hollow, silicone-coated cannula (with RF emitted from the tip) and an external electrode that moves along the surface

Table 1. Surface Area Lower Abdomen

| Patient No. | 1pre | 2pre | 3pre | 4pre | 1@6 | 2@6 | 3@6 | 4@6 | 1/y | 2/у | 3/у | 4/y |
|-------------------------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 1 | 8.36 | 8.39 | 8.06 | 8.83 | 7.56 | 7.49 | 8.10 | 8.69 | 5.82 | 6.77 | 7.87 | 8.81 |
| Change, cm ² | | | | | 0.8 | 0.9 | +.04 | 0.14 | 2.54 | 1.62 | 0.19 | 0.02 |
| % | | | | | 9.57 | 10.73 | +0.5 | 1.59 | 30.38 | 19.31 | 2.36 | 0.23 |
| 2 | 9.69 | 10.31 | 9.31 | 9.18 | 8.07 | 7.83 | 8.94 | 8.83 | 6.17 | 6.89 | 8.43 | 8.13 |
| Change, cm ² | | | | | 1.62 | 2.48 | 0.37 | 0.35 | 3.52 | 3.42 | 0.88 | 1.05 |
| % | | | | | 16.72 | 24.05 | 3.97 | 3.81 | 36.33 | 33.17 | 9.45 | 11.44 |
| 3 | 9.23 | 9.13 | 9.20 | 8.61 | 6.86 | 7.26 | 8.91 | 8.50 | 5.03 | 6.10 | 8.35 | 8.47 |
| Change, cm ² | | | | | 2.37 | 1.87 | 0.29 | 0.11 | 4.2 | 3.03 | 0.85 | 0.14 |
| % | | | | | 25.68 | 20.48 | 3.15 | 1.27 | 45.5 | 33.19 | 9.24 | 1.63 |
| 4 | 9.78 | 10.11 | 10.47 | 9.92 | 7.58 | 7.23 | 8.35 | 8.52 | 6.74 | 6.53 | 9.01 | 8.78 |
| Change, cm ² | | | | | 2.2 | 2.88 | 2.12 | 1.4 | 3.04 | 3.58 | 1.46 | 1.14 |
| % | | | | | 22.49 | 28.49 | 20.25 | 14.11 | 31.08 | 35.41 | 13.94 | 11.49 |
| 5 | 9.35 | 9.01 | 9.98 | 10.02 | 6.99 | 5.63 | 7.89 | 8.84 | 6.58 | 5.52 | 8.49 | 8.79 |
| Change, cm ² | | | | | 2.36 | 3.38 | 2.09 | 1.18 | 2.77 | 3.49 | 1.49 | 1.23 |
| % | | | | | 25.24 | 37.51 | 20.94 | 11.78 | 29.63 | 38.73 | 14.93 | 12.28 |
| 6 | 9.27 | 8.98 | 9.46 | 9.43 | 6.48 | 3.90 | 6.82 | 6.08 | 5.91 | 3.75 | 7.83 | 7.35 |
| Change, cm ² | | | | | 2.79 | 5.08 | 2.64 | 3.35 | 3.36 | 5.23 | 1.63 | 2.08 |
| % | | | | | 30.1 | 56.57 | 27.91 | 35.52 | 36.25 | 58.24 | 17.23 | 22.06 |
| 7 | 9.75 | 9.53 | 10.13 | 9.26 | 8.19 | 8.25 | 10.12 | 9.14 | 6.97 | 6.58 | 10.01 | 9.55 |
| Change, cm ² | | | | | 1.56 | 1.28 | 0.01 | 0.12 | 2.78 | 2.95 | 0.12 | +0.29 |
| % | | | | | 16.0 | 13.43 | 0.10 | 1.30 | 28.51 | 30.95 | 1.18 | +3.13 |
| 8 | 8.84 | 9.40 | 8.98 | 9.28 | 6.25 | 5.95 | 7.98 | 8.75 | 5.63 | 5.27 | 8.11 | 8.98 |
| Change, cm ² | | | | | 2.59 | 3.45 | 1.0 | 0.53 | 3.21 | 4.13 | 0.87 | 0.3 |
| % | | | | | 29.30 | 36.7 | 11.14 | 5.71 | 36.31 | 43.94 | 9.69 | 3.23 |
| 9 | 9.04 | 9.11 | 9.45 | 9.07 | 7.44 | 7.11 | 8.26 | 8.43 | 6.05 | 5.45 | 8.64 | 8.57 |
| Change, cm ² | | | | | 1.6 | 2.0 | 1.19 | 0.64 | 2.99 | 3.66 | 0.81 | 0.5 |
| % | | | | | 17.7 | 21.95 | 9.45 | 7.06 | 33.08 | 40.18 | 8.57 | 5.51 |
| 10 | 9.31 | 9.27 | 9.40 | 9.55 | 6.72 | 6.98 | 8.35 | 8.13 | 5.98 | 5.37 | 8.55 | 8.38 |
| Change, cm ² | | | | | 2.59 | 2.29 | 1.05 | 1.42 | 3.33 | 3.9 | 0.85 | 1.17 |
| % | | | | | 27.82 | 24.7 | 11.17 | 14.87 | 35.77 | 42.07 | 9.04 | 12.25 |
| 11 | 9.34 | 9.76 | 9.01 | 8.93 | 6.73 | 7.02 | 7.99 | 8.41 | 5.88 | 6.14 | 8.07 | 8.37 |
| Change, cm ² | | | | | 2.61 | 2.74 | 1.02 | 0.52 | 3.46 | 3.62 | 0.94 | 0.56 |
| % | | | | | 27.94 | 28.07 | 11.32 | 5.82 | 37.04 | 37.09 | 10.43 | 6.27 |
| 12 | 9.48 | 9.25 | 9.37 | 9.61 | 6.77 | 5.84 | 8.38 | 8.02 | 5.96 | 5.41 | 8.44 | 8.78 |
| Change, cm ² | | | | | 2.71 | 3.41 | 0.99 | 1.59 | 3.52 | 3.84 | 0.93 | 0.83 |
| % | | 1 | | İ | 28.59 | 36.86 | 10.57 | 16.54 | 37.13 | 41.51 | 9.92 | 8.64 |

For the purpose of statistical analysis, square 1 was noted as the most lateral region treated with SAL plus RFAL. Square 2 was designated as the medial region treated with SAL plus RFAL. Square 3 was the most medial region treated with only SAL, and square 4 was the most lateral region treated with only SAL. 1pre indicates measurements of square number 1, taken preoperatively. 1@6 indicates Vectra calculated measurements taken of square 1 at 6 weeks. 1/yr indicates similar computer generated measurements taken at 1 year.



Figure 2. Distribution of measured treatment squares in the lower abdomen.

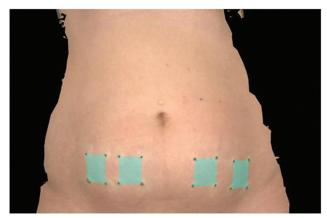


Figure 3. Three-dimensional Vectra (Canfield Scientific, Inc, Fairfield, New Jersey) photograph of tattooed treatment zones on a patient's abdomen. Measurements were taken with the Vectra system pretreatment, after tattoos were placed, at 6 weeks posttreatment, and again at 1 year.

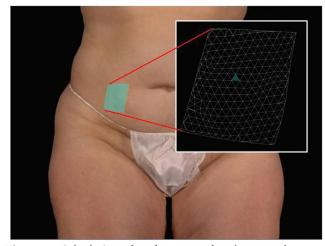


Figure 4. Calculation of surface area of each tattooed region. Because the surface of body parts is curved, the 3-dimensional image is broken down into multiple small triangles, the sum of which are added together to derive the total surface area. Reprinted with permission from Canfield Scientific, Inc (Fairfield, New Jersey).

of the skin. The external electrode receives the ablative RF energy from the internal cannula-electrode, which delivers nonablative transepidermal RF dermal stimulation superficially. The Teflon-coated cannula performs synchronous coagulation and aspiration of the coagulated adipose tissue. The external electrode—in addition to providing nonablative, transepidermal heating of the dermis—also houses temperature thermistors and internal impedance

monitoring sensors linked to an online feedback "cutoff" capability in the console. This allows the surgeon to achieve and maintain therapeutic end points and minimizes the risk of a thermal injury from overheating of adipose tissue and skin. Typically, after injection of tumescent fluid and a modest reduction in the density of subcutaneous fat with SAL, RFAL is applied to achieve the desired thermal and energy end points. During this RFAL phase, approximately 25% of the aspiration is performed. Following the RFAL phase, final contour is achieved with traditional microcannula SAL.

Treatment

All patients were treated under general anesthesia. Tumescent fluid was infiltrated at a 1:1 ratio in the lower abdomen throughout all 4 quadrants. In the lower quadrant randomized on each patient to receive RFAL treatment only, settings were 45 watts, with a maximum epidermal skin temperature of 38°C. Treatment end points in the RFAL-treated regions were warmth to touch, erythema, achievement of the 38°C skin surface temperature sustained for 1 to 2 minutes, and a visible contour flattening prior to aspiration. Radiofrequency heating was performed at multiple levels, from deep to superficial. The transition between levels was determined by decreasing soft tissue resistance and the energy deposited at each level, as well as the observed elevation in skin temperature at each level. Following RFAL heating to the end points at each level and synchronous aspiration, final soft tissue contouring was performed using standard, blunttipped microcannula SAL. The opposite lower quadrant of each patient's abdomen received standard SAL treatment.

Patients were followed up at 1 week, 6 weeks, and 1 year posttreatment. They were instructed to wear compression garments for 6 weeks posttreatment. At 6 weeks and 1 year posttreatment, photographs were taken, including 3D Vectra photography. The Vectra 3D system was used to measure the surface area of each treatment square at each follow-up interval. To better identify numeric trends for each treated region, the most lateral tattooed square treated with RFAL plus SAL was labeled square 1. The medial square treated with RFAL plus SAL was labeled square 2. The medial square treated with SAL alone was labeled square 4.

The percentage of skin surface change was calculated for each numbered square at 6 weeks and at 1 year and analyzed for statistical significance using a paired Student t test. Although our study population was relatively small, if the differences were large, both the number of treated squares and the data would be significant. The data from each of the 48 regions were analyzed.

RESULTS

The average age of the 12 patients in this study was 40.2 years (range, 20-61 years). In this study, all 12 patients

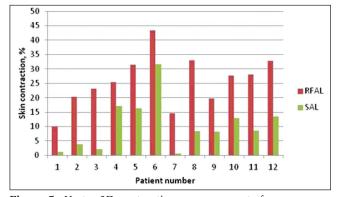


Figure 5. Vectra 3D contraction measurements for radiofrequency-assisted liposuction (RFAL) plus suction-assisted liposuction (SAL) and SAL-only treated regions measured at a 6-week follow-up.

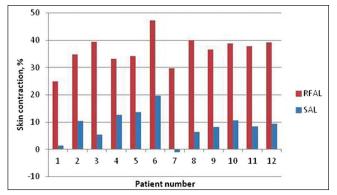


Figure 6. Vectra 3D contraction measurements for radiofrequency-assisted liposuction (RFAL) plus suction-assisted liposuction (SAL) and SAL-only treated sides measured at a 1-year follow-up.

demonstrated contour improvement with both modalities. The amount of RFAL-aspirated fat ranged from 410 to 2200 mL. Average skin surface area reduction in the RFAL/SALtreated regions was 25.8% at 6 weeks (range, 9.6%-56.6%) (Figure 5) and increased to 36.4% at 1 year (range, 19.3%-58.2%; Table 2 and Figure 6). The regions that received SAL treatment only had a wide range of much smaller, but measurable, surface area changes. Skin surface change ranged from an increase of 0.5% to contractions of 35.5% at 6 weeks. The average surface area contraction was 10.4% in the SAL-treated regions at 6 weeks (Figure 6). At 1 year posttreatment, the average change was an 8.26% reduction (range, 3.1% increase to 22.1% contraction), indicating that the initial degree of skin tightening appeared to diminish over time in the SAL control sites (Figure 6). Table 3 shows a full statistical comparison of various treatment end points for both treatment protocols.

Our SAL contraction results were similar to the percent contraction reported by DiBernardo.⁸ At 6 weeks, the average skin contraction on the RFAL/SAL-treated side was 2.5 times greater than on the side where only SAL was performed.

Clinical results are shown in Figures 7 through 11.

Effect of Time

Again, the average amount of skin surface area contraction increased significantly in the regions treated with RFAL plus SAL between the 6-week and 1-year follow-up intervals. In the areas treated with SAL alone, much of the early skin surface area contraction was lost. Adding RFAL to SAL resulted in continuing skin contraction over time, with an average addition of 10.6% over 10.5 months. Every patient exhibited this ongoing improvement in soft tissue contraction in the RFAL treatment region over the 12 months. A mean of 2.1% of the initial skin surface area contraction was lost in the regions treated with SAL alone. Adding RFAL heating to the treatment region induced significant, long-lasting skin surface area contraction. At 6 weeks posttreatment, an additional 15.2% skin surface contraction was noted over the SAL "baseline" in lower abdominal treatment regions. Vectra measurements taken at 1 year showed a much larger difference—28.1% more skin contraction was noted in the RFAL-plus-SAL regions than in the SAL-only areas. While the SAL-treated regions lost some skin contraction with time, the areas treated with RFAL plus SAL continued to show further tightening with little to no residual skin laxity at 1 year (Figure 6; Table 3).

Table 2. Distribution of Measured Treatment Squares in the Lower Abdomen

| | Area 1: RFAL + SAL (Outer) | Area 2: RFAL + SAL (Inner) | Area 3: SAL Alone (Inner) | Area 4: SAL Alone (Outer) | |
|----------------------------------|----------------------------|----------------------------|---------------------------|---------------------------|--|
| At 6 weeks | | | | | |
| Mean reduction, surface area, % | 23.1 | 28.54 | 10.87 | 9.96 | |
| Range of change, surface area, % | -9.57 to -29.3 | -10.73 to 56.57 | +0.5 to -27.91 | -1.27 to -35.52 | |
| At 1 year | | | | | |
| Mean reduction, surface area, % | 34.76 | 37.95 | 8.86 | 7.66 | |
| Range of change, surface area, % | -28.51 to 45.5 | -19.31 to 58.24 | -1.18 to -17.23 | +3.13 to -22.06 | |

RFAL, radiofrequency-assisted liposuction; SAL, suction-assisted liposuction.

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Table 3. Statistical Analysis of Comparative Values

| Comparison | P Value | Statistically Significant? |
|--|-----------|----------------------------|
| Surface area reduction | | |
| RF plus SAL vs SAL alone at 0-6 weeks (combined areas 1 and 2 vs combined areas 3 and 4) | .00000102 | Yes, less than .05 |
| RF plus SAL vs SAL alone at 6 weeks to 1 year (combined areas 1 and 2 vs combined areas 3 and 4) | .00000013 | Yes, less than .05 |
| RF plus SAL vs SAL alone at 0 to 12 months (combined areas 1 and 2 vs combined areas 3 and 4) | .00000203 | Yes, less than .05 |
| Time | | |
| SAL alone 0 to 6 weeks vs SAL alone 6 weeks to 1 year | .0053 | Yes, less than .05 |
| RF plus SAL 0 to 6 weeks vs RF plus SAL 6 weeks to 1 year | .00263 | Yes, less than .05 |
| RF plus SAL at 6 weeks vs RF plus SAL at 1 year | .01728 | Yes, less than .05 |
| SAL only at 6 weeks vs SAL alone at 1 year | .00000267 | Yes, less than .05 |
| Anatomic location | | |
| RF lateral vs RF medial at 6 weeks | .1118 | No, greater than .05 |
| RF lateral vs RF medial at 1 year | .1653 | No, greater than .05 |
| SAL lateral vs SAL medial at 6 weeks | .420 | No, greater than .05 |
| SAL lateral vs SAL medial at 1 year | .1657 | No, greater than .05 |

RF, radiofrequency; SAL, suction-assisted liposuction.

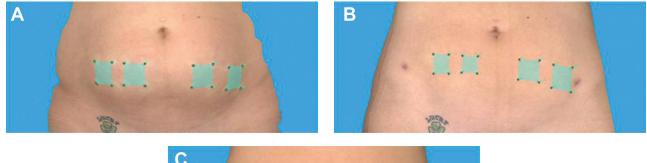




Figure 7. (A) This 21-year-old woman presented for treatment of her pannus. She is shown pretreatment, with tattoos in place. (B) Six weeks after treatment on the right side with radiofrequency (RF) plus suction-assisted liposuction (SAL) and on the left side with SAL alone. Surface area reduction is visibly greater on the RF plus SAL side. (C) One year posttreatment, the side treated with SAL plus RFAL maintained more skin surface area reduction than the left (SAL-only) side.

Effect of Treatment Region

Mean values showed that the medial treatment regions had a higher rate of skin contraction than the lateral regions. The more central the location—probably due to the area having more fat—the more surface area reduction was noted. However, the difference was small, and when subjected to a paired t test, statistical significance was not achieved. However, the trend was noted for both treatment modalities. At 6 weeks, there was a mean of 5.4% more skin tightening in the medial RFAL-plus-SAL treatment

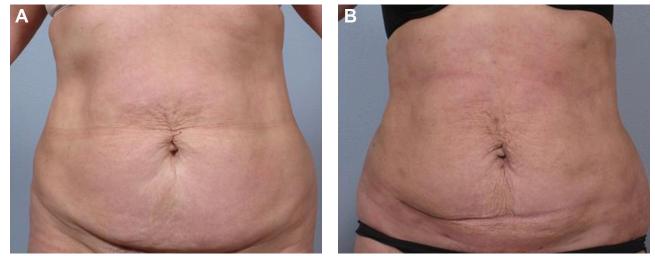


Figure 8. (A) This 53-year old woman presented with a complaint of a loose, flaccid abdomen with excess fat and a suprapubic overhang. An abdominoplasty was recommended, but she declined. (B) Six weeks after treatment on the right side with suction-assisted liposuction (SAL) alone and on the left side with radiofrequency-assisted liposuction plus SAL. Improvement of the pendulous overhang is visible on both sides.

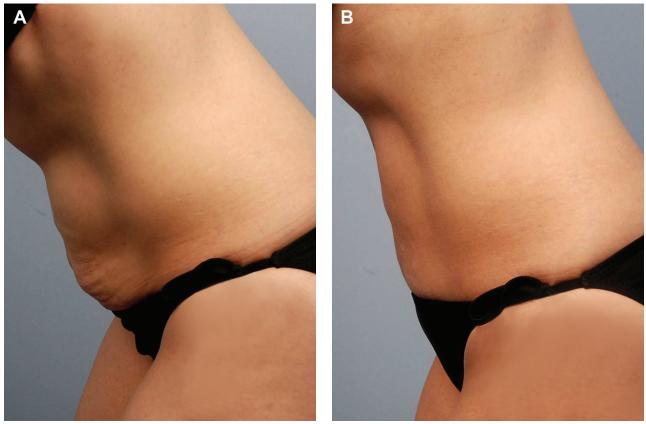


Figure 9. (A) This 48-year-old woman presented with postpartum deformity; the loose, flaccid pannus was her chief complaint. (B) Two months following radiofrequency-assisted liposuction in all abdominal regions, the patient's abdominal tissue has reattached to her underlying fascia. Note that this woman was not a study patient, and photographs were provided by Stephen Mulholland, MD.

region than the lateral. At 1 year, these areas showed a 3.19% difference. In the SAL-only areas, there was a dif-

ference of 0.9% at 6 weeks, with the medial region showing more surface area reduction than the lateral. At 1 year,

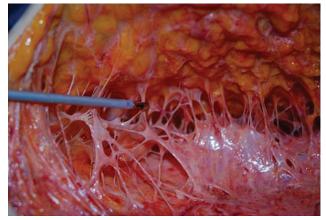


Figure 10. Adipose stromal fibers make up the fibroseptal network, which is targeted by the radiofrequency-powered BodyTite cannula (Invasix, Yokneam, Israel).

SAL-only medial regions showed more skin contraction than the lateral regions by an average of 1.2%.

Effect of Amount of Energy Deployed

Although both treatment types showed a wide range of differences in the degree of skin contraction, it would be logical to assume that the increase in the degree of skin surface area reduction in the RFAL-treated areas could be attributed to the addition of heat to the skin and underlying septal network in the subcutaneous fat. Therefore, we evaluated the amount of RF energy used in each patient quadrant. Patient 8 had the least surface area reduction in the RFAL-treated regions, and patient 6 had the most. For the patient with the least response, 22.7 kJ were used, while 22.5 kJ were used for the patient with the greatest response. Kilojoule usage ranged from 14.23 for the patient who weighed the least to 24.9 kJ for the heaviest patient. Statistical analysis of total energy compared with the amount of skin surface area contraction showed no correlation.

Effect of Amount of Fat Aspirated

There was no statistical correlation between the amount of overall lipoaspirate and skin surface area reduction in the tattooed treatment zones. The amount of fat removed from within the tattooed regions was not separately measured. Future studies of this effect may be warranted.

Complications

No patient experienced hematoma, infection, or seroma following treatment. No patient was burned. Two had nodularity persisting after 1 year. No patient underwent a revision of the treatment region, and no patient noted dissatisfaction with the outcome with either treatment protocol.

DISCUSSION

Many devices, including energy-assisted liposuction systems, claim to induce skin tightening, tissue tightening, and skin contraction.¹⁹⁻²² Although most of these findings

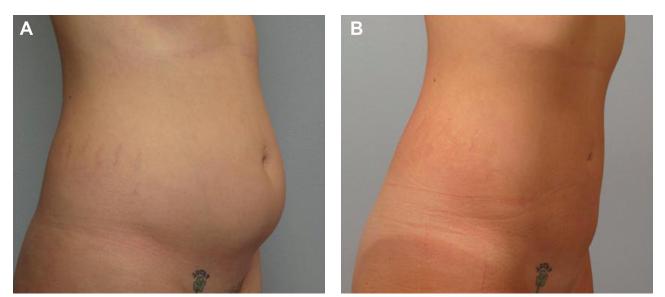


Figure 11. (A) This 21-year-old woman presented with lower abdominal lipodystrophy and striae after a 20-lb weight loss. (B) One year after treatment with radiofrequency-assisted liposuction plus suction-assisted liposuction (SAL) to the right abdomen and SAL alone on the left.

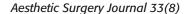




Figure 12. This image illustrates treating a patient with striae. The right side was treated with suction-assisted liposuction (SAL) plus radiofrequency-assisted liposuction; the left was treated with SAL alone. The increased soft tissue contraction on the right causes even more buckling of the skin than SAL alone does.

are published in peer-reviewed articles, these claims lack the rigor of scientific analysis through randomized trials employing validated, objective instruments to measure soft tissue contraction. Measurements such as circumferential reduction are prone to a wide degree of interobserver variability and are not well regarded as reliable, reproducible measurements of soft tissue contraction. While histological sections of skin and hypodermis can show cell wall disruption of adipocytes and collagenesis in the treatment region, biopsies cannot measure the degree of skin tightening seen over a broad surface area.

Several articles in the plastic surgery literature have demonstrated clinical improvement with apparent skin tightening in localized treatment regions with LAL and RFAL, 23,24 but only DiBernardo²⁵ compared the degree of skin contraction when treating the abdomen with LAL plus SAL versus SAL alone. McBean and Katz²⁰ measured skin surface area reduction with LAL but did not directly compare it with SAL-treated regions as a control. In DiBernardo's study, the surface area of the tattooed squares was measured before treatment and again at 1 month and 3 months posttreatment. The author noted that the skin surface area reduction ratio of LAL to SAL improved over time. This finding of thermally stimulated soft tissue contraction was mirrored in our study. In DiBernardo's study, there was a wide range of skin surface area change, from a 9% to 28% reduction in the 1-month LAL-plus-SAL group and a 6% to 27% reduction in the SAL-alone group. At 3 months, the range of values was 7% to 25% in the LAL-plus-SAL group and 2% to 23% in the SAL-alone group. Both groups appeared to lose some degree of initial skin contraction over time. Average surface area reduction noted by DiBernardo was 22% (LAL/SAL) versus 18% (SAL) at 1 month and 17% (LAL/SAL) versus 13% (SAL) at 3 months.

McBean and Katz²⁰ measured skin surface area reduction with LAL but did not directly compare it with SALtreated regions as a control. In their study, they calculated a 17% skin surface area reduction with LAL plus SAL compared with a "negligible" degree of skin contraction with SAL alone.26 Estimates of the degree of long-term, aesthetically acceptable skin surface reduction with SAL alone ranges from negligible to 13%, although experts in superficial liposuction techniques claim a larger percentage (C. Mendieta, personal communication, September 2011). A definitive and widely accepted value of skin surface area contraction with SAL alone remains elusive, as techniques vary greatly among practitioners. Proponents of superficial liposuction speculate that by injuring the superficial FSN in the subdermal space and removing volumetric distention immediately below the dermis, centripetal skin contraction and accommodation of the skin is forced. Paul and Mulholland²⁷ note that if the balance between FSN contraction and subdermal heating is not maintained, an irregular skin surface can result. This is especially important to remember when treating patients with striae or damaged skin (Figure 12).

Tissue recruitment plays a major role in lipocontouring of the abdominal region, and it is an expected consequence of heat-mediated tissue tightening. As the fibroseptal bands draw together, some shifting of the relative positions of subcutaneous tissue and overlying skin occurs. The skin surface accommodates the contraction of the underling subcutaneous tissue. Subcutaneous tissue contraction is not easily measured. We tattooed the skin surface because it is the only means of visible measurement.

There is less controversy about the value of adding heat to the tissue before or after SAL, as many studies validate the effect of heat on skin and adipose tissue.^{28,29} The septal network remaining after tumescent infusion and SAL is depicted in Figure 10. By performing approximately 50% to 60% of the SAL prior to heating, some of the insulating adipose tissue is removed, and the exposed collagenous tissue of the FSN responds more rapidly and strongly to RFAL heating. However, this is not the current standard practice. With this alteration in protocol, no burns or other complications were noted. The amount of SAL was not extensive. Some SAL was performed prior to heating to reduce the amount of insulation provided by fat. This exposed the fibroseptal bands to heat, creating more visible and measurable tissue tightening. Theoretically, burns might be more likely, but with skin temperature monitoring using the external thermistor, the skin temperature is closely monitored, and burns can be avoided.

Immediately after application of the RFAL device to the septal network and overlying skin, visible contraction of the fibers is evident. In vivo studies on soft tissue contraction showed that RFAL-induced temperatures of 69°C applied to the septofascial network can result in a mean 33% contraction, compared with less impressive contraction when the RF thermal stimulus was applied to the dermis or directly to the fat.²⁷ The effect of LAL and RFAL on soft tissue contraction is heat mediated; RF is a more efficient and conductive form of thermal stimulation.³⁰

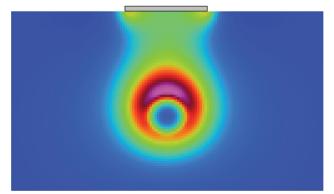


Figure 13. Directional thermal containment in the BodyTite device, as measured by a thermal camera, shows the heat source as the cannula tip, which has been positioned within the subcutaneous fat. Heat is directed specifically towards the external thermistor. There is no nondirectional diffusion noted within the tissue. Reprinted with permission from Invasix (Yokneam, Israel).

The distribution of heat during RFAL or LAL is also important. To maintain smooth, multilevel tissue contraction, multiple levels of thermal stimulation, from deep to superficial, should be performed, rather than just the 2 levels of thermal stimulation currently suggested by LAL experts. Following tumescent infusion, SAL is performed to better expose the collagenous FSN to heat. Deep treatment can create a reattachment of the flaccid pannus to the deep fascia (Figure 9). Too much heating or uncontrolled thermal stimulation at the deep fascial level can increase the risk of seroma, so it is important to keep the RFAL cannula moving to deposit modest levels of thermal energy and avoid exceeding the FSN contraction temperatures of 69°C. The operator should then move to sequentially more superficial levels and treat multiple areas of the broad surface. Midlevel RFAL heating is performed at about the level of Scarpa's fascia. The response to heating of fascia is more rapid than that of the FSN, so less heating time is spent at this location. The supra-Scarpa region is heated, and then the subdermal region is heated. If a significant section of skin surface area reduction is needed, 2 shorter sessions of superficial heating with a maximum external skin temperature of 38°C is safer and will reduce the risk of thermal skin injury.

Protection from risk of thermal injury is an integral part of the BodyTite system's mechanism of action. An internal cannula-electrode with an RF current flowing up to the external electrode provides thermal containment (Figure 13), along with constant monitoring of internal tissue impedance and external epidermal temperature. The synchronous aspiration of the coagulated deep adipose tissue removes very hot, liquefied tissue from the adipose compartment while continuing to heat the FSN. The heat generated by the internal probe is directed superficially toward the external electrode, and the thermal containment between the 2 RF electrodes ensures safety of deeper structures. Little heat is lost to nondirectional dispersion. When working with RFAL at the superficial level, care must be taken to deliver heat gently and evenly. An external skin surface temperature monitor and impedance monitor is built into the external electrode. The device cuts off RF delivery when the preset safe skin temperature is achieved and will begin to apply energy again when the temperature drops below the set point, allowing the surgeon to safely maintain a constant epidermal and deep tissue temperature. During our study, that temperature

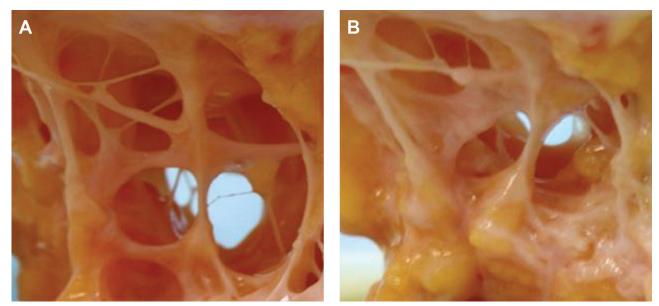


Figure 14. (A) Abdominal tissue treated with suction-assisted liposuction (SAL) alone. (B) Appearance of the same tissue following treatment with radiofrequency heating using the BodyTite device (Invasix, Yokneam, Israel). Note shrinkage of the open regions in all dimensions. Vertical shortening plus contraction in the horizontal and oblique planes is apparent.

Figure 15. (A) This 23-year-old man presented after massive weight loss of 80 pounds. He disliked the bulge and pendulous overhang of his abdomen, which was quite pronounced when the patient was shirtless. (B) One year after treatment with radiofrequency-assisted liposuction plus suction-assisted liposuction (SAL) in the right abdomen and bilateral flanks and SAL alone on the left abdomen.

was set at 38°C to avoid overheating the skin. Other studies have used a skin temperature cutoff of 40 to 42°C.^{31,32}

While the focus of this study was skin surface area contraction, the true target of treatment is the lax FSN above and below Scarpa's fascia. Time spent heating the basal dermis is important, but the degree of heat-mediated dermal tightening that is safely achievable with RFAL or LAL is significantly less than the amount of safe subcutaneous fibrous tightening.³³ The degree of skin contraction is directly dependent on the thermal temperature achieved and the duration of that thermal stimulus, which in turn is reflected in the amount of energy used at the site during treatment. Thermal containment of the RF-generated heat is a safety feature of the BodyTite system. This allows focused treatment of a particular area while protecting the deep and lateral tissues from overheating (Figure 14). Too little energy will result in too little contraction, and too much energy can create an irregular surface as the underlying septal network contracts more than the skin. This effect is mainly seen in patients with very thin skin or patients with striae. Our findings would appear to support Kenkel's theory that most of the skin contraction seen with heat-mediated devices is due to contraction of the underlying septal network.34

While the effects of heat-mediated tissue tightening are helpful in patients with mild to moderate soft tissue and skin laxity, the application is somewhat limited. This treatment is not meant to replace skin excision and redraping when those procedures are clinically indicated. The RF device is a powerful tool, and its use should be undertaken only by those who are trained and recognize the possibility of complications, including burns and seroma. During this study, it became evident that the total amount of energy used may be less important than the location of the heating, thermal end points, and the technique of heating. Multiple levels of adipose tissue heating were performed, from deep to superficial. More energy was used at the superficial than the deep level. This multilayer RFAL heating pattern creates the effect of tightening multiple levels of the FSN, which effectively binds the loose dermal-subcutaneous tissue layer back to the abdominal rectus fascia through the contracted FSN (Figure 10). This heat-mediated contraction of the septal network in the adipose layer is not seen with SAL alone.

Clinical treatment outcomes vary between patients. The 53-year-old woman seen in Figure 8 was advised that she needed an abdominoplasty. She declined, stating that she would only agree to liposuction. Her posttreatment outcome showed a surprising amount of improvement in the pendulousity of her abdomen, both on the left (RFAL-plus-SAL treated) side and the right (SAL-only) side. Tattoos were placed well above the pendulous skin to reduce the risk of confounding variables. Figure 9 (not a study patient) shows the effect of RF assistance in correcting the separation of the skin/fat layer from the underlying fascia. Contraction of the FSN creates a readherence of the tissue to the body framework.

CONCLUSIONS

This prospective, randomized study of a 12-patient cohort was performed to determine the amount of additional skin and soft tissue tightening achieved by adding RFAL to traditional liposuction. The longevity of skin surface area contraction was also evaluated over 1 year. Independent statistical analysis showed a significant difference between RF heating of the tissues plus SAL compared with SAL alone. The regions treated with RFAL plus SAL showed a mean skin surface area reduction of 28.5% versus 10.3% with SAL alone at 6 weeks posttreatment. At 1 year, RFALplus-SAL regions showed a 34.5% surface area reduction, as opposed to an 8.3% contraction in the SAL-only regions. RFAL plus SAL also yielded a significant increase in surface area reduction over time. The SAL regions lost approximately 2% of the original surface area reduction at 1 year.

Heating of the FSN appears to account for the majority of RFAL-induced contraction noted with heating of subcutaneous and dermal tissues when used as an adjunct to SAL (Figure 15). The application of multiple levels of heat can also reattach a loose pannus to the abdominal fascial wall, thereby improving the pendulous character of the tissue. While traditional liposuction removes distended fat and mechanically stimulates the FSN, the addition of heat can create significantly more skin contraction.

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Disclosures

The manufacturer of the BodyTite device (Invasix, Yokneam, Israel) supplied the device, but the author returned it after the study's conclusion. The author received neither money nor honoraria from Invasix, nor does she have any stock shares or other financial interest in the company. The manufacturer had no control over study design, data collection, or authorship of the article.

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REFERENCES

- 1. Hughes CW. Reduction of lipoplasty risks and mortality: an ASAPS survey. *Aesthetic Surg J.* 2001;21:120-125.
- Scuderi N, Paolini G, Grippaudo FR, Tenna S. Comparative evaluation of traditional, ultrasonic, and pneumatic assisted lipoplasty: analysis of local and systemic effects, efficacy, and costs of these methods. *Aesthetic Plast Surg.* 2000;24:395-400.
- Zukowski M, Ash K. Ultrasound-assisted lipoplasty learning curve. *Aesthetic Surg J.* 1998;18:104-110.

- Fodor PB. Body contouring by lipoplasty. In: Goldwyn RM, Cohen MN, eds. *The Unfavorable Result in Plastic Surgery*. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2001:1123-1134.
- Mulholland RS. Advances in RFAL for soft tissue tightening. Paper presented at: IMCAS Asia; July 10-12, 2010; Hong Kong.
- Goldman A, Gotkin RH. Laser assisted lipolysis. Clin Plast Surg. 2009;36(2):241-253.
- Mordon S, Plot E. Laser lipolysis versus traditional liposuction for fat removal. *Expert Rev Med Devices*. 2009;6(6):677-688.
- DiBernardo BE. Randomized, blinded split abdomen study evaluating skin shrinkage and skin tightening in laser-assisted liposuction versus liposuction control. *Aesthetic Surg J.* 2010;30(4):593-602.
- Jewell ML, Fodor PB, De Souza Pinto EB, Al Shammari MA. Clinical application of VASER-assisted lipoplasty: a pilot clinical study. *Aesthetic Surg J.* 2002;22:131-146.
- Vanek PF, Nagy MW. A multi-center, prospective, randomized, single-blind, controlled clinical trial comparing VASER-assisted lipoplasty and suction-assisted lipoplasty. Paper presented at: ASPS Annual Meeting; October 23-27, 2009; Seattle, Washington.
- 11. Troilus C. Ultrasound assisted lipoplasty: is it really safe? *Aesthetic Plast Surg.* 1999;23(5):307-311.
- Grolleau JL, Rouge D, Chavoin JP, Costagliola M. Severe cutaneous necrosis after ultrasound lipolysis: medicolegal aspects and review. *Ann Chir Plast Esthet*. 1997;42: 31-36.
- 13. Gingrass MK. Lipoplasty complications and their prevention. *Clin Plast Surg.* 1999;26:341-354.
- 14. Paul M, Blugerman G, Kreindel M, Mulholland RS. Threedimensional radiofrequency tissue tightening: a proposed mechanism and applications for body contouring. *Aesthetic Plast Surg.* 2011;35(1):87-95.
- 15. Hurwitz D, Smith D. Treatment of overweight patients by radiofrequency-assisted liposuction (RFAL) for aesthetic reshaping and skin tightening. *Aesthetic Plast Surg.* 2012;36(1):62-71.
- Yoshimura K. Composition of adipose layer. Paper presented at: IMCAS Asia; July 12-14, 2009; Bangkok, Thailand.
- 17. Blugerman G, Schavelzon D, Paul M. A safety and feasibility study of a novel radiofrequency-assisted liposuction technique. *Plast Reconstr Surg.* 2010;125:998-1006.
- Duncan D. Achieving excellence in upper arm contouring. Paper presented at: IMCAS; January 8, 2011; Paris, France.
- Collawn SS. Skin tightening with fractional lasers, radiofrequency, Smartlipo. *Annals Plast Surg.* 2010;65(5):526-529.
- McBean J, Katz B. A pilot study of the efficacy of a 1,064 and 1,320 nm sequentially firing Nd:YAG laser device for lipolysis and skin tightening. *Lasers Surg Med*. 2009;41(10):779-784.
- Ichikawa K, Miyasaka M, Tanaka R, Tanino R, Mizukami K, Wakaki M. Histologic evaluation of the pulsed Nd:YAG laser for laser lipolysis. *Lasers Surg Med.* 2005;36:43-46.

- 22. Zelickson BD, Dressel TD. Discussion of laser assisted liposuction. *Lasers Surg Med.* 2009;4(10):709-713.
- 23. Sasaki GH. Quantification of human abdominal tissue tightening and contraction after component treatments with 1064-nm/1320-nm laser-assisted lipolysis: clinical implications. *Aesthetic Surg J.* 2010;30(2):239-245.
- 24. Paul MD. Radiofrequency-assisted liposuction comes of age. *Plast Surg Practice*. February 2009:18-19.
- 25. DiBernardo B. Evaluation of tissue thermal effects from 1064/1320-nm laser-assisted lipolysis and its clinical implications. *J Cosmet Laser Ther.* 2009;11(2):62-69.
- 26. Katz BE. Discussion during body contouring session. Paper presented at: IMCAS; January 6-9, 2011; Paris, France.
- 27. Paul M, Mulholland SR. A new approach for adipose tissue treatment and body contouring using radio-frequency-assisted liposuction. *Aesthetic Plast Surg.* 2009;33(5):687-694.
- 28. Sadick N. Tissue tightening technologies: fact or fiction? *Aesthetic Surg J.* 2008;28(2):180-188.

- 29. Goldman A. Submental Nd:YAG laser-assisted liposuction. *Lasers Surg Med.* 2006;38:181-184.
- Mulholland RS. An in-depth examination of radiofrequency assisted liposuction (RFAL). J Cosmet Surg Med. 2009;4:14–18.
- Ahn DH, Mulholland RS, Duncan DI, Paul MD. Nonexcisional face and neck tightening using a novel subdermal radiofrequency thermo-coagulative device. *J Cosmet Dermatol App.* 2011;1(4):141-146.
- 32. Divaris M, Boisnic S, Branchet M, Paul M. A clinical and histological study of radiofrequency-assisted liposuction (RFAL) mediated skin tightening and cellulite improvement. *J Cosmet Derm Sci App.* 2011;1:36-42.
- 33. Mulholland SR. Radio frequency energy for non-invasive and minimally invasive skin tightening. *Clin Plast Surg.* 2011;38:437-448.
- Kenkel J. Response to evaluation of skin tightening after laser-assisted liposuction. *Aesthet Surg J.* 2009;29(5): 407-408.