ORIGINAL ARTICLE

Radiofrequency-Assisted Liposuction Device for Body Contouring: 97 Patients under Local Anesthesia

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Abstract

Background Radiofrequency-assisted liposuction involves the delivery of a controlled amount of energy to treated tissue resulting in fat liquefaction, accompanying hemostasis, and skin tightening. The purpose of this study is to report experience with a larger sample size using the BodyTite™ radiofrequency-assisted liposuction (RFAL) platform, and its first use with local tumescent anesthesia. The Bodytite™ device is currently awaiting FDA approval.

Methods We prospectively included 97 patients who underwent radiofrequency-assisted liposuction under local anesthesia under IRB approval. We treated 144 anatomical areas in 132 operations and collected the following data: age, sex, height, weight, body mass index (BMI), anatomical area of treatment, operative time, amount of tumescent solution used, amount of fat aspirated, amount of kilojoules (kJ) delivered, and the incidence of infections, seromas, adverse effects from medications, and thermal injuries. Patients were asked to complete an online survey assessing the aesthetic outcome and quality of life after treatment with RFAL-assisted liposuction. Three independent plastic surgeons were asked to evaluate photographs of our 6-month postoperative results in comparison to the preoperative photos.

Results The average age and BMI of our study population was 37.6 years and 28.2 kg/m^2, respectively. The study population was 88% female. The mean amount of lidocaine given per treatment session was 32.7 mg/kg (range = 3.8–83.3 mg/kg). The mean amount of tumescent fluid given per anatomical treatment area was 1,575 cc. The average amount of total aspirate across all anatomical treatment areas was 1,050 cc, with an average total aspirate of 1,146 cc per treatment date. The overall incidence of major complications was 6.25% and the incidence of minor complications was 8.3%. Overall patient satisfaction was 82% for the degree of skin tightening and 85% for the body-contouring result with the BodyTite™ device. Three independent plastic surgeons graded the improvement in body contour as good to excellent in 74.5% of patients and the improvement in skin tightening as good to excellent in 58.5% of patients.

Conclusions The BodyTite™ RFAL platform is a safe and effective device for use as an energy-based liposuction technique under local tumescent anesthesia in the awake patient.

Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors at www.springer.com/00266.

Liposuction is the most commonly performed procedure worldwide for excess fat removal [1]. In 2009, a total of 959,787 liposuction cases were performed in the U.S. [1]. The American Society of Plastic Surgeons (ASPS) reported 203,106 cases of liposuction performed in 2010 [2]. Liposuction methods have improved over the years with the use of the tumescent technique for local anesthesia. Klein [12–14] first reported the use of the tumescent technique, eliminating the need for general anesthesia and decreasing overall blood loss associated with large-volume liposuction. Newer technologies such as ultrasound-

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assisted liposuction (UAL), power-assisted liposuction (PAL), and, most recently, laser-assisted liposuction (LAL) modalities have added to the armamentarium of the plastic surgeon specializing in body-contouring procedures. Despite these recent advances and the availability of new technologies, the ideal treatment for fat removal and concomitant skin tightening remains elusive. The benefits of a technique that contracts skin without lengthy incisions are immeasurable [17].

The ideal liposuction device would (1) remove excessive fat easily without compromising the viability of the overlying skin envelope, (2) cause contraction of the soft tissue envelope, (3) have minimal systemic and local complications, (4) be applicable for use on patients under local tumescent anesthesia, and (5) result in minimal bruising and swelling resulting in a shorter postoperative recovery period.

The use of radiofrequency energy was initially reported in the literature as a noninvasive modality [3, 6, 9, 15, 26]. More recently, the use of radiofrequency energy has been described in the form of a new device for liposuction [4, 18, 19]. Radiofrequency-assisted liposuction (RFAL) of the BodyTite[TM] system (Invasix Ltd., Yokneam, Israel) uses a novel bipolar device to deliver a controlled amount of energy resulting in fat liquefaction, improved hemostasis, and skin tightening. The initial study by Blugerman et al. [4] using this RFAL device reported its safe use on 23 subjects. The purposes of this study are to report on experience with a larger sample size using RFAL and, more specifically to describe its first use with local tumescent anesthesia.

Materials and Methods

We prospectively included 97 consecutive patients who underwent RFAL for a total of 132 operations. All of the operations were performed at the surgeons' AAAASF-accredited surgical facility in New York, NY, between April 2009 through August 2010. The study was conducted under a national Institutional Review Board protocol (IRB) (Essex Institutional Review Board, Inc., Lebanon, NJ). The BodyTite[TM] device is currently awaiting FDA approval. All patients provided signed informed consent and IRB study participation forms for their procedures. Inclusion criteria included male and female subjects of age 21–60 years old who presented with excess fat and skin. Exclusion criteria included pregnant females, cancer or history of cancer, liver or kidney failure, hyperlipidemia, HIV, diabetes, recurrent herpes simplex or zoster, scarring in proposed treatment area, presence of a pacemaker or defibrillator, and a history of a blood clotting disorder.

All patients included in the study received 10 mg diazepam, 500 mg cephalexin or ciprofloxacin, and 5/325 mg of hydrocodone/acetaminophen one half hour before the treatment session. The tumescent solution used for the treatment areas included 1,500 mg lidocaine, 10 cc of 8.4% $NaHCO_3$, and 1.5 cc of 0.1% epinephrine in 1 l of lactated Ringer's solution. This was equivalent to 0.15% lidocaine with 1:750,000 concentration epinephrine. Following standard prep and drape with an iodine-based antimicrobial solution, 1% lidocaine with 1:100,000 epinephrine and 0.84% sodium bicarbonate was initially injected using a 30-gauge needle into the proposed incision sites. A 14-gauge needle was used for puncture access. A Stevens tenotomy scissors was then inserted in a spreading fashion for enlargement of the access site. A 14-gauge infiltration cannula (Wells Johnson Corp., Tucson, AZ, USA) was used to deliver the tumescent solution deep to the superficial fascial system (SFS) until appropriate turgor was achieved. The end point for adequate analgesia was achieved by patient feedback. Following the tumescent infiltration stage, sterile ultrasound gel (Aquasonic 100, Parker Laboratories, Inc. Fairfield, NJ, USA) was used to assist the delivery of energy to the tissues treated by decreasing tissue impedance.

The initial treatment goals for the RFAL device included a target skin surface temperature of 38–42°C. This temperature range was chosen as the ideal goal for soft tissue contraction based on previous studies [4, 5, 18, 19]. The power of the device was set between 35 and 40 W. The target temperature, once achieved, was maintained for 1–2 min. The aspiration port of the RFAL device was connected to a standard aspirator (Hercules, Wells Johnson Corp.) set to 15 mmHg of low suction for simultaneous aspiration of liquefied fat. In our experience, the relatively low suction setting assisted in removing the hot emulsion that is released after fat cell destruction. This allowed the operator to focus on skin tightening without significantly altering the contour of the treated area. A PAL® Lipo-Sculptor[TM] (MicroAire[TM], Charlottesville, VA, USA) was then used specifically for body contouring. Drains were placed in all abdominal cases. The drains were removed when the output was 20 cc or less over 24 h.

All patients were instructed to follow an oral hydration protocol postoperatively. This consisted of 500 ml of oral hydration electrolyte solution (Gatorade, Gatorade Co., Chicago, IL, USA) in the office followed by 8 oz. of oral electrolyte solution every hour for the first 8 h after surgery. All patients were questioned the night of the day of surgery and the following morning for any signs of lidocaine toxicity. Patients were specifically questioned about the following: changes in mental status, hyperexcitability, depression, headaches unresolved with medication, visual changes, impaired concentration, tingling of tongue or perioral area, and a metallic taste in the mouth. All patients were instructed to wear post-liposuction compression garments for 6 weeks.

Patients were seen in the office at 1 week, 4 weeks, 3 months, 6 months, and 1 year postoperatively.

The following data were collected for each patient: age, sex, height, weight, body mass index (BMI), anatomic area of treatment, total operative time, amount and concentration of tumescent solution, total amount of fat aspirate, total kJ delivered in each treatment area, the power settings (in W) of the RFAL device, and the goal temperature setting for skin heating (Tmax).

The postoperative data collected included both major and minor complications. Major complications were defined as infections, seromas, adverse effects from medications, and clinically significant burns outside of the port entry sites. Minor complications were defined as periportal burns or end hits from the RFAL device which required no intervention. The postoperative data also included Fitzpatrick skin type and the use of drains. The data were analyzed using SPSS software (SPSS, Inc., Chicago, IL, USA), χ^2 analysis, and Fisher's exact test in order to review the incidence of complications among the different treatment groups. A P value of 0.05 was used to determine statistical significance.

Patients were asked to complete an online survey assessing the aesthetic outcome and quality of life after treatment with RFAL-assisted liposuction. The questions were as follows:

1. What were the most important factors in your decision to have RFAL-assisted liposuction?
2. What was your level of discomfort during the injection of local anesthesia?
3. What was your level of discomfort during the application of heat with the BodyTite™ device?
4. What was your level of discomfort during the fat aspiration portion of the procedure?
5. What was your level of satisfaction with the body-contouring result at 6 months after the procedure?
6. What was your level of satisfaction with the amount of skin tightening at 6 months after the procedure?
7. When did you return to work in the postoperative period?
8. Would you recommend the procedure to someone else?

Three independent plastic surgeons were asked to evaluate photographs of our 6-month postoperative results in comparison to the preoperative photos. They were asked to separately grade the improvement in body contouring and the degree of skin tightening using a 4-point scale: 4 = excellent, 3 = good, 2 = moderate, 1 = poor.

Results

The study population included 97 patients who underwent treatment for a total of 144 anatomical areas in 132 operations. The average age was 37.6 years and the average BMI was 28.2. The majority (93%) of the patients treated had a BMI <35. The study population consisted of 88% females. Further classification by skin type showed that 82% of the population fell into the Fitzpatrick categories 1, 2, and 3. The most commonly treated anatomical areas were the abdomen (43%), flanks (20%), lateral thighs (12%), arms (9%), medial thighs (6%), and back (6%).

In our study, the average number of anatomical areas treated on a given date was 1.4. The 97 patients in the study had an average of 1.5 anatomical areas treated over 16 months. All cases were performed using local anesthesia. Twenty-eight of the 97 patients (28.8%) in the study opted for multiple operations over several dates as opposed to a single operation under local anesthesia with the addition of intravenous sedation. Ten of the 97 (10.3%) patients had treatment over two consecutive days and one patient was treated over three consecutive days.

The average total operative time was 98 min. The mean operative time was highest for treatment of the total thighs (lateral plus medial) at 142.5 min, and a single chest case had an operative time of 150 min. Treatment of the medial thighs had the second longest mean operative time at 117 min. The anatomical areas with the shortest operative times were the flanks at 70.9 min and the back at 73.4 min. The one neck case had an operative time of 35 min. The mean lidocaine dosage by body weight given per operation was 32.7 mg/kg (range = 3.8–83.3 mg/kg). Forty-three of the 132 (33%) operations used lidocaine amounts of more than 35 mg/kg. Upon questioning, one patient reported numbness and tingling of the tip of the tongue on the third day of three consecutive operations. This resolved 6 h postoperatively with no other adverse effects. The mean amount of tumescent fluid given per anatomic area was 1,575 cc. Total thighs (2,200 cc) required the largest amount of tumescent fluid followed by the medial thighs (1,856 cc), chest (1,850 cc), and abdomen (1,806 cc) (Fig. 1).

The average total aspirate volume across all anatomic regions was 1,050 cc. The average total aspirate volume per operation was 1,146 cc. The largest total aspirate volume by anatomical area was for the medial thighs at 1,222 cc. Total thigh (medial and lateral) aspirate volume was second at 1,200 cc and the abdomen was third at 1,193 cc (Fig. 2). The total fat fraction of the aspirate was recorded for each anatomic area treated. The anatomic areas with the largest fat fraction were the lateral thighs at 724 cc, followed by the medial thighs at 716 cc and the abdomen at 657 cc (Fig. 3).

The BodyTite™ device delivers radiofrequency energy that is converted into heat. This energy is quantitated as kilojoules (kJ). The mean amount of energy delivered was 44 kJ per operation. The energy delivered per anatomic area

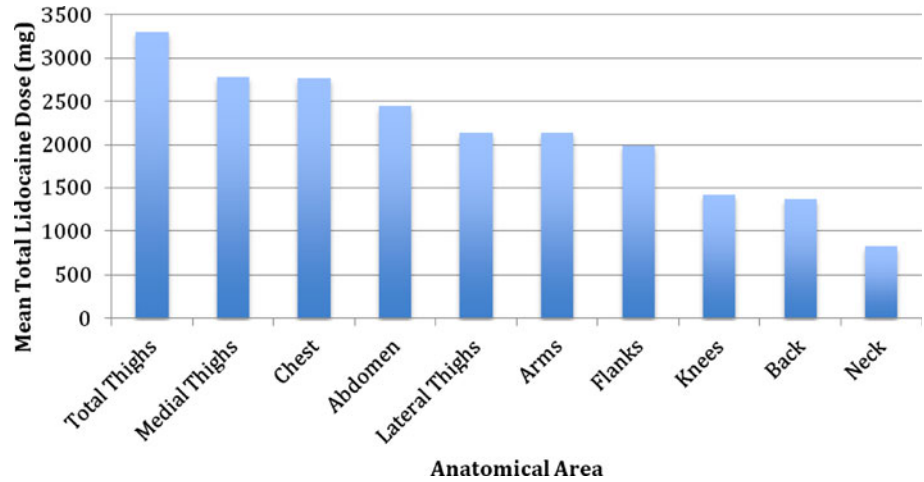**Fig. 1** Mean total lidocaine
dose by anatomical area

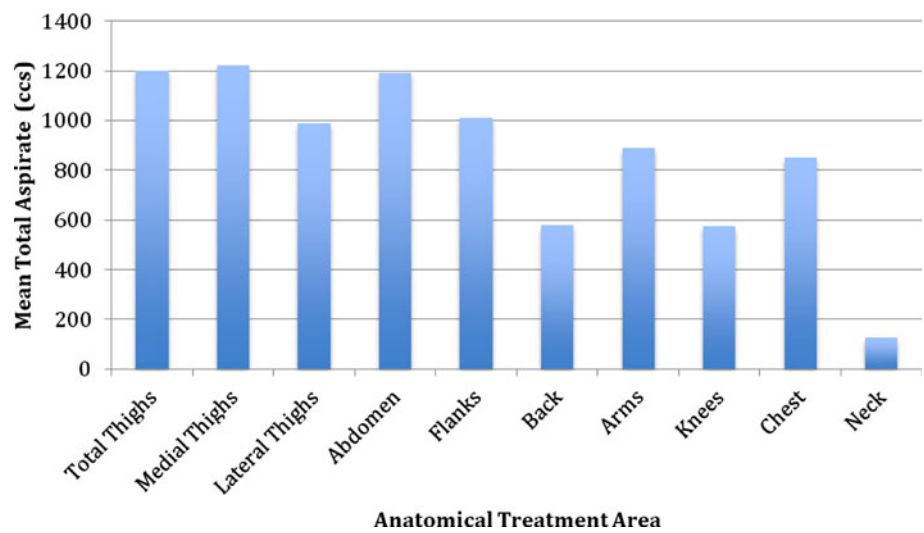**Fig. 2** Mean total aspirate by
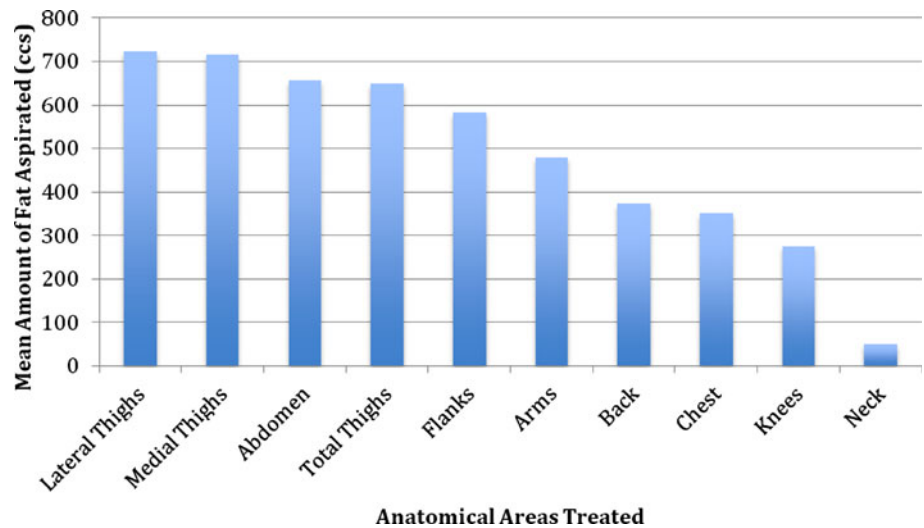anatomical treatment area

Fig. 3 Mean amount of fat
aspirated by anatomical
treatment area

varied. The anatomical areas that received the highest
amount of energy were the chest region at 66 kJ followed by
the medial thighs at 54 kJ. The anatomical areas requiring
the lowest amount of energy were the neck (2.1 kJ) and the

flanks (24 kJ) (Fig. 4). Thirty-seven of 144 (25.8%) of the
areas treated had drains placed at the time of surgery.

No deaths or hospitalizations were reported in this ser-
ies. Minor complications were defined as periportal burns

Fig. 4 The mean kJ delivered by the BodyTite device by anatomical areas treated
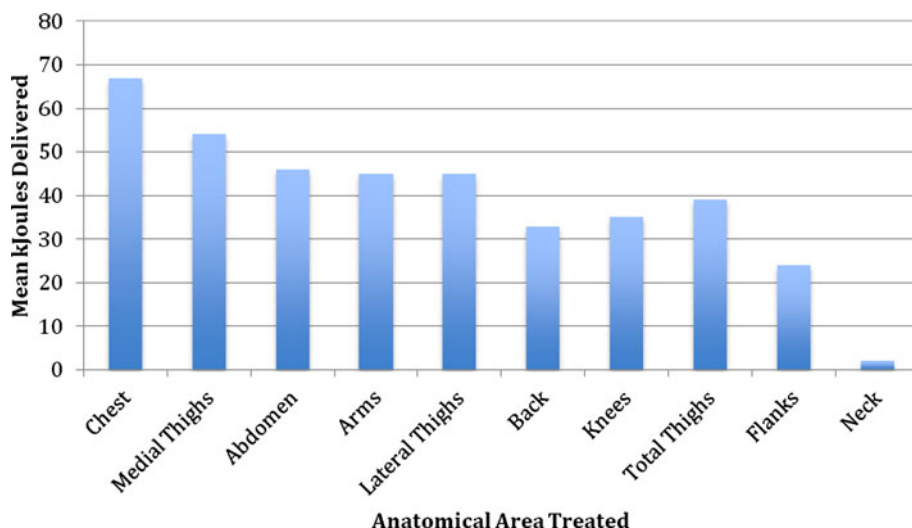
or end hits from the RFAL device which required no intervention. Major complications were defined as infections, seromas, adverse effects from medications, or clinically significant burns outside of the entry sites requiring intervention. The overall incidence of major complications was 6.25% and the incidence of minor complications was 8.3 %. The overall complication rate was 14.6 % (Table 1). The incidence of complications was not statistically significantly different among the anatomical areas treated (Pearson χ^2, $P = 0.21$).

The incidence of complications was 20% in patients with a BMI >35, and 14.6% in patients with a BMI ≤35.

The incidence of complications in those patients with a BMI >35 was not statistically significantly different than those with a BMI ≤35 (Fisher's exact test, $P = 0.63$).

The incidence of complications in patients with Fitzpatrick skin type 1, 2, or 3 was not statistically significant when compared with complications in patients with Fitzpatrick skin type 4, 5, or 6 (Fisher's exact test, $P = 0.575$). The incidence of complications in the first 72 anatomical areas treated was not statistically significantly different than the incidence of complications in our second 72 anatomical areas treated (Fisher's exact test, $P = 0.35$).

Ninety-seven percent of the patients in the study were asked to complete the online survey; there was a 60% response rate at the 6-month follow-up. Eighty-three percent of the respondents were female. The questions and answers were as follows:

1. What were the most important factors in your decision to have RFAL-assisted liposuction (can choose more than 1)?

   52% the ability to have the procedure under local anesthesia
   46% the ability to return to work quickly
   87% the degree of skin tightening with the BodyTite™ device

2. What was your level of discomfort during the injection of local anesthesia?

   43% no discomfort
   39% minimal discomfort
   13% moderate discomfort
   4% significant discomfort

3. What was your level of discomfort during the application of heat with the BodyTite™ device?

   33% no discomfort

Table 1 The incidence of complications by anatomical area

	Total complications [N (%)]	Major [N (%)]	Minor [N (%)]
Abdomen (62)	12 (19.4)	5 (8.1)	7 (11.3)
Arms (13)	1 (7.7)	0 (0)	1 (7.7)
Back (9)	0 (0)	0 (0)	0 (0)
Chest (1)	1 (100)	1 (100)	0 (0)
Flanks (29)	3 (10.3)	2 (6.9)	1 (3.4)
Knees (2)	1 (50)	1 (50)	0 (0)
Lateral thighs (17)	2 (11.8)	0 (0)	2 (11.8)
Medial thighs (8)	1 (12.5)	0 (0)	1 (12.5)
Neck (1)	0 (0)	0 (0)	0 (0)
Thighs (2)	0 (0)	0 (0)	0 (0)
Totals (144)	21 (14.6)	9 (6.25)	12 (8.3)

Minor complications were defined as end hits and periportal burns that required no intervention. Major complications were defined as infection, seroma, adverse effects from medications, or a clinically significant burn outside of the port entry sites. The complications are listed as both incidence (in %) and number (N) of complications. The total number of cases for each anatomical area is in parenthesis next to area name

56% minimal discomfort
11% moderate discomfort
0% significant discomfort

4. What was your level of discomfort during the fat aspiration portion of the procedure?

   44% no discomfort
   41% minimal discomfort
   11% moderate discomfort
   3% significant discomfort

5. What was your level of satisfaction with the body-contouring result at 6 months after the procedure?

   33% extremely satisfied
   22% very satisfied
   30% satisfied
   15% not satisfied

6. What was your level of satisfaction with the amount of skin tightening at 6 months after the procedure?

   11% extremely satisfied
   41% very satisfied
   30% satisfied
   18% not satisfied

7. When did you return to work in the postoperative period?

   7% same day
   67% 1–3 days
   19% 4–6 days
   0% 7–9 days
   7% over 9 days

8. Would you recommend the procedure to someone else?

   70% definitely
   19% probably
   11% not likely

The results of the independent plastic surgeons' evaluations for improvement in body contouring were as follows: 5.5% excellent, 69% good, 24% moderate, and 1.5% poor. The results of the evaluations for the degree of skin tightening were as follows: 7.5% excellent, 51% good, 37.5% moderate, and 4% poor.

Discussion

The purpose of this study was to report our experience in using the BodyTite™ RFAL device in the largest reported series to date. The BodyTite™ device is currently awaiting FDA approval. All previous studies to date reported the use of general anesthesia with the BodyTite™ device [4, 18, 19]. This is the first study that used RFAL with local anesthesia in an accredited outpatient office operating facility (AAAASF). Blugerman et al. [4] reported the safety and feasibility of using the RFAL device with general anesthesia in 23 patients treated in the hip and lower abdominal areas. They reported the use of the device as safe with optimal skin tightening as judged by the surgeon. Despite their claims of safety, they pointed out the need for a larger patient sample size. Mulholland and Paul [4, 18, 19] reported on a series of 20 patients with 40 treatment areas and noted the advantages of RFAL included the ability to heat a significant volume of tissue quickly and uniformly with significant contraction and retraction of adipose and dermal tissue.

The average operating time by treatment area is greater with the BodyTite™ device than traditional liposuction. These findings are consistent with the greater time required for both anesthetizing and treating areas with the RFAL device under local anesthesia. Treatment of the thighs and chest required the longest average operating time. The authors believe the greater sensitivity of the thigh and chest areas contributed to the longer time required to adequately anesthetize the awake patient.

The mean amount of tumescent fluid injected into an anatomical area was 1,575 cc, while the mean amount of total aspirate volume from a given anatomical area was 1,050 cc. When determining these figures per operation (irrespective of the number of areas treated), the numbers are slightly higher at 1,719 cc of tumescent fluid injected and 1,146 cc of total aspirate. These smaller volumes of tumescent fluid injected allowed the use of a higher concentration of lidocaine (1,500 mg) per liter of tumescent fluid. In comparison to standard liposuction under general anesthesia, we treated fewer areas and the aspirate volumes were smaller. These numbers also point out that treatment of this patient population with an average BMI of 28.2 involved smaller-volume treatments. We have found that smaller-volume treatments are also better tolerated by patients under local anesthesia.

The total lidocaine doses required for adequate anesthesia of each anatomical area did vary by region. We believe this is a function of two different variables: the innate sensitivity of an anatomical area and the overall surface area of the area to be treated. The largest lidocaine dose per anatomic area was for the total thighs (medial and lateral) followed by medial thighs. The medial thighs required a larger total dose of lidocaine because of the combination of their larger surface area with higher sensitivity. This is corroborated by Klein [14] who pointed out the different volumes of tumescent fluid required in various anatomical regions.

It is our experience that the higher concentration of lidocaine in tumescent fluid is a critical part of effectively treating patients with the BodyTite™ device under local anesthesia. The average amount of lidocaine given to a patient per operation was 32.7 mg/kg (range = 3.8–83.3 mg/kg). Klein's original reports of the tumescent technique involved the use of solutions with 500–1,000 mg of lidocaine and 1 mg of epinephrine per liter of tumescent fluid [12–14]. We report the use of a tumescent solution that has 1,500 mg of lidocaine (0.15%) and 1.5 mg of epinephrine per liter of fluid. We attribute the need for these higher concentrations to patient discomfort related to the generation of heat by the RFAL device.

All patients were questioned about signs and symptoms of lidocaine toxicity. In 43 of 132 operations (33%), lidocaine doses exceeded the recommended 35-mg/kg ceiling for tumescent technique [12–14]. There was only one case of suspected lidocaine toxicity involving tingling of the tip of the tongue with no other adverse effects. This patient underwent three operations over three consecutive days. For the first operation (day 1), the lidocaine dose was calculated to be 71.8 mg/kg, for the second operation (day 2) it was 52.8 mg/kg, and for the third and final operation (day 3) it was 14.8 mg/kg. The numbness and tingling of the tip of the tongue was reported on day 3 and resolved 6 h postoperatively with no other adverse effects.

Doses of lidocaine as high as 90 mg/kg have been reported in the literature without any subsequent adverse effects or issues related to lidocaine toxicity [16]. Pitman et al. [20, 21] reported doses as high as 63.8 mg/kg in his series of 142 patients, with the highest serum lidocaine level recorded at 4.2 µg/ml at 12 h. Although we report no adverse events related to these higher concentrations, further studies are needed in order to determine absorption rates and peak serum levels at these higher doses (0.15% lidocaine with 1:750,000 concentration epinephrine). These studies should include measurement of serum lidocaine levels at 3-h intervals to determine the absorption curve of lidocaine with these higher concentration tumescent solutions. Samdal et al. [24] reported that larger doses of dilute lidocaine and epinephrine have characteristically higher and earlier peak concentrations when serum levels were measured. Based on this study and others, we believe that higher concentrations of lidocaine in tumescent fluid are safe, contrary to the current practice guideline of 35 mg/kg [12–14], but, again, it requires further investigation.

The operators (SJT and CTC) noted less bruising in the early postoperative period compared to standard liposuction under general anesthesia. This may be due to (1) less trauma on infiltration due to the slow speed of injection, (2) increased epinephrine dose to 1:750,000, and (3) the coagulative effect of heat generated by the RFAL device.

However, more studies are required to support these claims.

The end point for every area treated was the target skin temperature of 38–42°C, as reported in previous studies [4, 5, 18, 19]. We set our target skin temperature to 38–40°C. We set our Tmax slightly lower in order to decrease the risk of thermal injury (one of our most common complications). In our series of awake patients, we determined that setting the power at 35–40 W, as opposed to 40–50 W mentioned in previous studies, resulted in higher patient tolerance [18, 19]. We have also found that there were fewer incidences of tissue hardening and fat necrosis at the lower power setting of 35–40 W compared to the previous recommendation of a 70-W power setting [19]. We believe that the slower and graduated application of thermal energy to the soft tissue at a lower wattage (35–40 W) with the same target temperature (38–40°C) results in an even distribution of the energy and less focal tissue hardening. Even though it is an imprecise example, we like to use the analogy of a frog placed in boiling water versus a frog placed in water that is gradually heated to a boiling point. Tissue response and patient tolerance, like the frog, respond better to gradual heating (Fig. 5).

Complications

As with traditional liposuction, it is of great importance to always be aware of the location of the tip of the aspirating cannula. This is especially true when the aspirating tip is an energy-generating device like the RFAL handpiece. In order to limit complications from energy delivery, we have classified energy-related injuries into two categories: direct and indirect.

Direct energy-related injuries are the result of direct contact of the treated tissues with the energy-generating device. In the case of the BodyTite™ handpiece, this is the internal electrode. With laser-assisted liposuction, this is the tip of the laser fiber. With ultrasound-assisted liposuction, this is the tip of the ultrasound probe. End hits and periportal burns are direct energy-related injuries. Indirect energy-related injuries are the result of thermal energy dissipation causing an expanded zone of thermal injury beyond that which is in direct contact with the device.

The incidence of minor complications (end hits or periportal burns) across all treatment areas was 8.3%, and none required intervention and eventually resolved. End hits are noted in our complications as minor complications. They are the result of the RFAL device delivering energy to the deep undersurface of the dermis. Newer versions of the BodyTite™ device have an insulated tip that decreases the incidence of end hits. In addition, the incidence of periportal burns can be significantly decreased with liberal application of petroleum-based ointment to the portal site
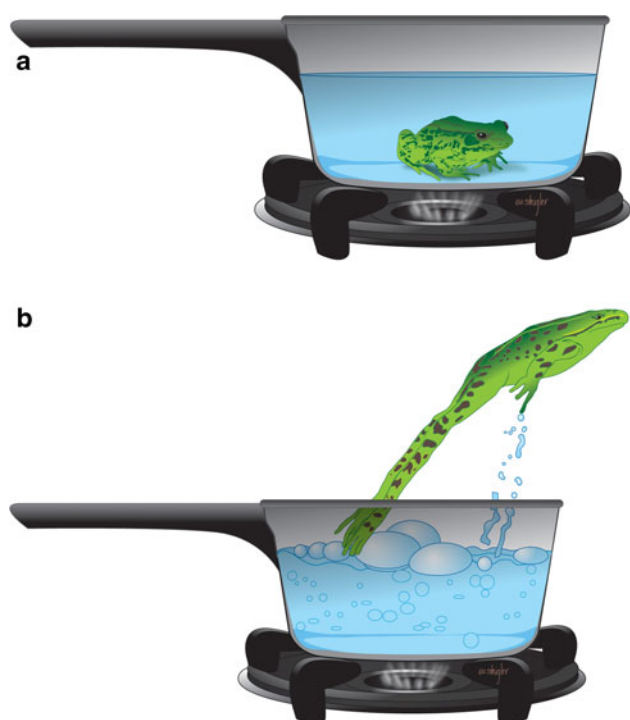
Fig. 5 For tissue response to energy settings we use the analogy of a frog gradually being heated in a pot of water to a target temperature of 100°C (*top* diagram) as opposed to the frog being placed in a pot of boiling water (*bottom* diagram). In the first instance, the frog (tissue response) tolerates the gradual increase in temperature and remains in the pot. In the second instance, the frog (tissue response) jumps out. These diagrams are an analogy for tissue response to higher energy settings (70 W and 38–42°C) used in previous studies with the radio frequency-assisted liposuction (RFAL) device and to the lower energy settings used in this study group (35–40 W and 38–42°C). In our experience, both patient tolerance and tissue response to the energy delivered by the RFAL device are better at the lower energy settings as long as the same target temperature of 38–42°C is achieved

Fig. 6 A depiction of the convexity of the lateral thigh treatment zone in relationship to the straight BodyTite handpiece. Caution needs to be exercised in this type of convex treatment area in order to avoid end hits (direct injury) and a rapid increase in temperature that can lead to possible full-thickness injury of the dermis (indirect injury). The *top* picture points out the area of treatment and the *lower* picture depicts the magnified area of interest. The area in *red* is the zone of caution

and constant movement of the RFAL cannula to avoid energy delivery to the portal area.

The BodyTite™ handpiece has two significant safety features that decrease the incidence of indirect injuries. The first safety feature limits the delivery of energy to the tissues treated between the two electrode probes. The second safety feature is the superior external electrode's ability to also act as a thermostat. This feature shuts off the device at the predetermined selected temperature (38–42°C). Both of these features allow for safer use of the device.

The incidence of major complications (infections, seromas, adverse effects from medications, or clinically significant thermal injuries outside of the entry sites) was 6.25% in total. Of the major complications, there were five seromas requiring drainage in the office. One infection was treated with incision and drainage under local anesthesia in the office and oral antibiotics with complete resolution. Cultures fro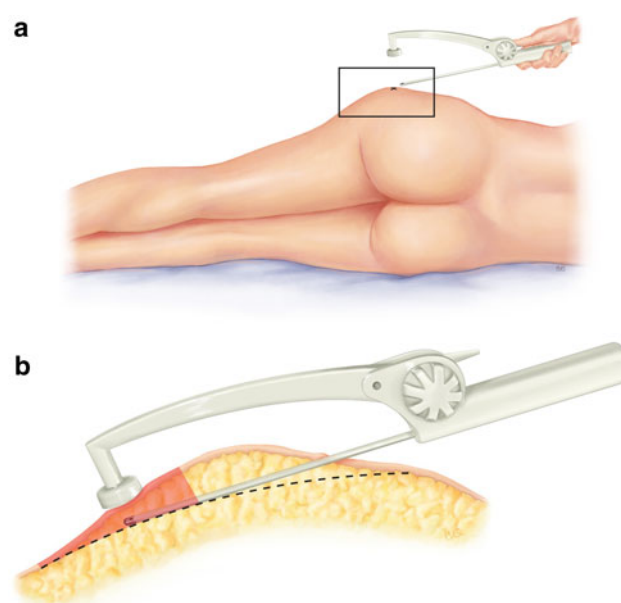m the wound showed no growth. Three 2-cm superficial second-degree burns were treated with local wound care. No excision was necessary for any of the burns. The aesthetic outcome was not affected.

A review of our data reveals that we placed drains in 37/144 (26%) of areas treated, all occurring in the abdomen. Our early experience with treating the abdomen involved the five cases of seromas that were treated in the office. There are two reasons for the high rate of seroma formation in the abdomen: the delivery of energy to the tissue with the RFAL device and the higher propensity for seroma formation in the abdomen. The RFAL device, like an electrocautery, also works by energy delivery to the tissues which may result in more seromas. The use of electrocautery has been associated with higher rates of seroma formation in comparison to sharp dissection and the use of the Harmonic scalpel for abdominoplasties [7, 25]. After this early experience with seromas, we now routinely place 7–10-mm Jackson-Pratt drains intraoperatively in all abdominal RFAL cases. Drains remain in place until the total output is less than 20 cc in a 24-h period. The time the drains remained in place ranged from 5 to 14 days in this study group. No seromas occurred in the abdomen subsequent to implementation of this protocol.

We compared the incidence of complications by anatomical treatment area and found that there was no statistically significant difference among the anatomical areas

treated ($P = 0.21$). However, technical considerations related to the design of the device need to be taken into account when treating convex and concave areas in order to avoid end hits and thermal injury. We found that complications in patients with BMI $\leq$35 versus BMI >35 were not statistically significantly difference between the two groups ($P = 0.63$). Despite the fact that it did not reach statistical significance, the risk of total complications in patients with a BMI >35 was 20% compared to 14.6% in patients with BMI $\leq$35. Overall, BMI does not appear to be a factor in the incidence of complications with RFAL. It is worth noting that 133 of the 143 areas treated were in patients with BMI <35, and our mean BMI was 28.2.

We looked at the risk of complications in patients with Fitzpatrick skin type 1, 2, or 3 versus Fitzpatrick 4, 5, or 6, and found no statistically significant difference in the incidence of complications ($P = 0.575$). Obviously, the patients with higher Fitzpatrick skin type are at higher risk of hyperpigmentation or hypopigmentation after thermal injury.

Fig. 7 Preoperative photo (*left*) and 1-year follow-up photo (*right*) of a 30-year-old female patient whose arms were treated with BodyTite at 35 W and 38°C for a total of 30.2 kJ of energy delivered. A total of 600 cc was aspirated, anterior view


Fig. 8 Preoperative photo (*left*) and 1-year follow-up photo (*right*) of the same 30-year-old female patient in Fig. 7, posterior view

Fig. 9 Preoperative photo (*left*) and 1-year postoperative photo (*right*) of a 30-year-old postpartum female with preoperative central abdominal adiposity and skin changes whose abdomen and flanks were treated with BodyTite at 35 W and 38°C for a total of 48.8 kJ delivered. A total of 2.7 l of lipoaspirate was removed, anterior view

Fig. 10 Preoperative photo (*left*) and 1-year postoperative photo (*right*) of the same 30-year-old postpartum female in Fig. 9, lateral view
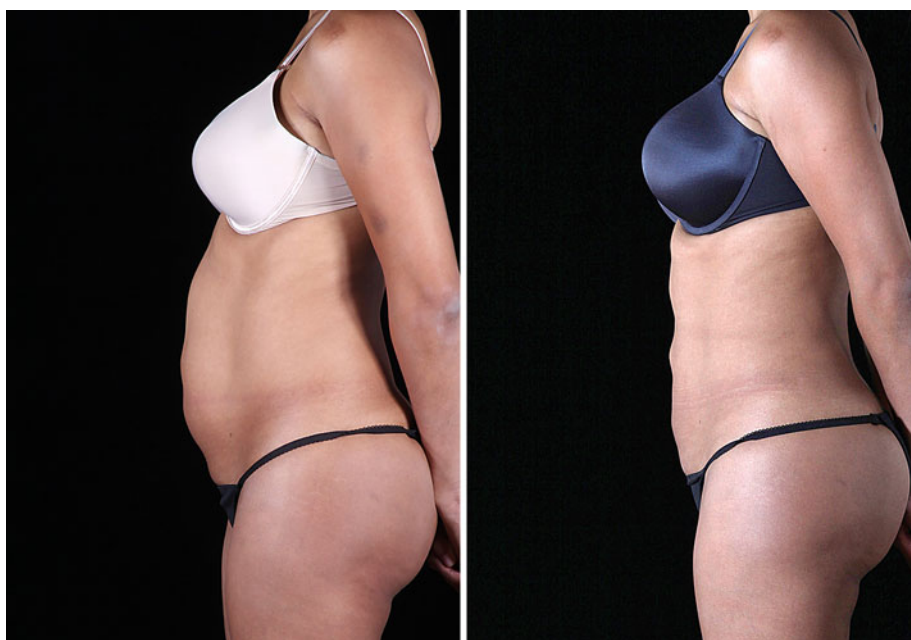
In addition, we looked at the risk of complications in the first 72 anatomical areas treated versus the second 72 anatomical areas treated to determine if there was a learning curve in the use of the device. There was no statistically significant difference between these two groups, although the odds ratio for the second group was 0.59, indicating that they were less likely to develop complications. Based on the odds ratio and our clinical experience, we found that RFAL with the BodyTite™ device does have a learning curve, even though these statistical findings fail to point that out. Figure 6 demonstrates one of the

areas requiring operator caution when using the Body-Tite™ device.

Although the purpose of this study was not to evaluate skin tightening, we believe that most of the tightening occurs at the subdermal tissue level, as hypothesized in other studies [10, 19]. Superficial liposuction is perhaps the best nonenergy-based traditional liposuction technique with which to compare the RFAL technique using the BodyTite™ device. This is due to the claims that superficial liposuction causes tightening of the dermis. However, it is a well-known fact that superficial liposuction has an

Fig. 11 Preoperative photo (*left*) and 1-year follow-up photo (*right*) of a 40-year-old female with massive weight loss who was treated with BodyTite at 35 W and 38°C for a total of 40 kJ delivered to the medial and lateral thighs. The abdomen and flanks were also treated. A total of 1 l of lipoaspirate was removed from bilateral thighs, anterior-view

Fig. 12 Preoperative photo (*left*) and 1-year postoperative photo (*right*) of the same 40-year-old female with massive weight loss as in Fig. 11, posterior view

increased risk of contour deformities. Our overall incidence of complications is comparable to that of a recent study of 2,398 cases of superficial liposuction that reported a 8.6% complication rate compared to our 6.25% major complication rate [11]. Our rate of seromas (3.5%) was higher than this larger study group, which reported a rate of 2.25% [11]. The rate of complications for traditional liposuction has been reported as less than 2% [8, 18, 22].

Obviously, the incidence of second-degree burns is unique to the use of an energy-assisted liposuction device compared to traditional or power-assisted liposuction. It is important to note that established devices such as UAL have comparable thermal injury rates [23]. As Mulholland points out in his study, the linear contraction observed at 6 months with the BodyTite™ device is much more significant than reported with any other technology and varied from 12.7 to 47%, depending on patient and treatment variables [19]. Considering the above findings, we believe that the additional risk inherent with the BodyTite™ device, i.e., thermal injury, is justified by its ability to

Fig. 13 Preoperative photo (*left*) and 13-month follow-up photo (*right*) of a 41-year-old female who was treated with BodyTite at 70 W and 40°C for a total of 103.8 kJ delivered to the abdomen, back, and flanks. A total of 3.5 l of lipoaspirate was removed. The patient lost 40 lb. between the preoperative and postoperative photos, anterior view
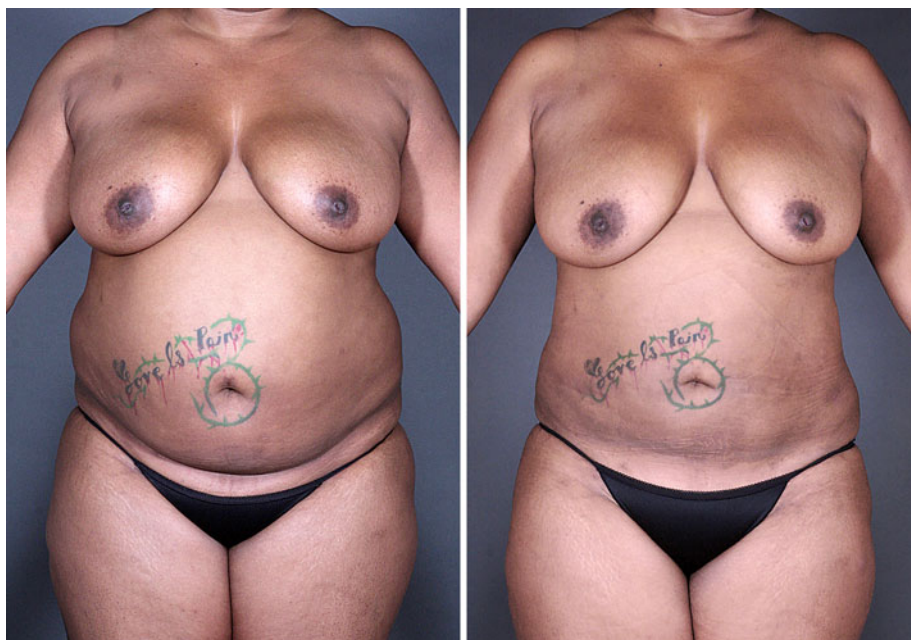

Fig. 14 Preoperative photo (*left*) and 13-month follow-up photo (*right*) of the same 41-year-old female as in Fig. 13, posterior view

uniformly contract the soft tissue envelope without causing contour deformities (Figs. 7, 8, 9, 10, 11, 12, 13, 14).

In terms of patient satisfaction, 82–85% of patients were satisfied with the body contouring and skin-tightening effects of RFAL. Eighty-nine percent of patients reported they would definitely or probably recommend RFAL treatment to someone else. When asked about the discomfort related to the procedure itself, the majority of patients reported none to minimal discomfort for all aspects of the treatment (72–89%). The improvement in the body contour was good to excellent in 74.5% of the areas treated,

and the degree of skin tightening was good to excellent in 58.5% of patients treated, according to independent evaluators.

In our opinion, the ideal candidate for BodyTite™ treatment is a patient with moderate to severe skin laxity without irreversible damage to the dermis or presence of striae. In addition, a moderate amount of adiposity is necessary to allow for subdermal contraction to occur. Previous studies of RFAL have demonstrated that the mechanism by which the subdermal contraction occurs is simultaneous heating of the septal connective tissue and

aspiration of the fat in the subcutaneous space [19]. The absence of fat in the subcutaneous space decreases the effectiveness of this mechanism which results in less contraction. This is corroborated by our clinical observations. Further confirmation of these findings would require direct histological comparison between tissues treated with conventional liposuction versus RFAL.

Conclusions

The BodyTite^{TM} RFAL device is safe and effective for energy-based liposuction with local tumescent anesthesia in the awake patient. Higher lidocaine concentrations are required for effective analgesia when performing this procedure due to the delivery of higher energy by the device to the tissues. Further studies on lidocaine absorption levels would be beneficial to practitioners utilizing these higher concentrations. BodyTite^{TM} is highly effective as a low- to moderate-volume liposuction device in an outpatient setting under local anesthesia. The observed complication rates associated with RFAL are justified by its ability to uniformly contract the soft tissue envelope without skin resection resulting in lengthy incisions. We believe that the BodyTite^{TM} device is a promising alternative to current excisional techniques in the field of body contouring in the properly selected patient.

References

1. American Academy of Cosmetic Surgery (2010) 2009 procedural census. AACS, Chicago
2. American Society of Plastic Surgeons (2010) Report of the 2010 plastic surgery statistics. ASPS, Arlington Heights
3. Basil MH, Ubeid AA, Chang H, Kafi R, Renton B (2008) Bipolar fractional radiofrequency treatment induces neoelastosis and neocollagenasis. Lasers Surg Med 41:1–9
4. Blugerman G, Schavelson D, Paul MD (2010) A safety and feasibility study of a novel radiofrequency-assisted liposuction technique. Plast Reconstr Surg 125:998–1006
5. DiBernardo B (2009) Evaluation of tissue thermal effects from 1064/1320-nm laser-assisted lipolysis and its clinical implications. J Cosmet Laser Ther 11:62–69
6. Emilia del Pino M, Rosado RH, Alejandro A, Guzman G, Arguelles D, Rodriguez C, Rosado GM (2006) Effect of controlled volumetric tissue heating with radiofrequency on cellulite and the subcutaneous tissue of the buttocks. J Drugs Dermatol 5(8): 714–722
7. Fang RC, Lin SJ, Mustoe TA (2010) Abdominoplasty flap elevation in a more superficial plane: decreasing the need for drains. Plast Reconstr Surg 125(2):677–682
8. Grazer FM, de Jong RH (2000) Fatal outcomes from liposuction: census survey of cosmetic surgeons. Plast Reconstr Surg 105: 436–446
9. Hsu T, Kaminer MS (2003) The use of nonablative radiofrequency technology to tighten the lower face and neck. Semin Cutan Med Surg 22(2):115–123
10. Kenkel JM (2009) Evaluation of skin tightening after laser-assisted liposuction, commentary. Aesthet Surg J 29(5):407–408
11. Kim YH, Cha SM, Shenthilkumar N, Hwang WJ (2011) Analysis of post-operative complications for superficial liposuction: a review of 2,398 cases. Plast Reconstr Surg 127(2):863–871
12. Klein JA (1990) The tumescent technique; anesthesia and modified liposuction technique. Dermatol Clin 8(3):425–437
13. Klein JA (1990) Tumescent technique for regional anesthesia permits lidocaine doses of 35 mg/kg for liposuction: peak plasma lidocaine levels are diminished and delayed 12 hours. J Dermatol Surg Oncol 16:248–263
14. Klein JA (1993) Tumescent technique for local anesthesia improves safety in large-volume liposuction. Plast Reconstr Surg 92(6):1085–1098
15. Lack E, Rachel J, D'Andrea L, Corres J (2005) Relationship of energy settings and impedance in different anatomic areas using a radiofrequency device. Dermatol Surg 31:1668–1670
16. Lillis PJ (1988) Liposuction surgery under local anesthesia: limited blood loss and minimal lidocaine absorption. J Dermatol Surg Oncol 14:1145–1148
17. Matarasso A (2011) Discussion: analysis of postoperative complications for superficial liposuction: a review of 2398 cases. Plast Reconstr Surg 127(2):872–873
18. Paul M, Mulholland RS (2009) A new approach for adipose tissue treatment and body contouring using radiofrequency-assisted liposuction. Aesthet Plast Surg 33(5):687–694
19. Paul M, Blugerman G, Kreindel M, Mulholland RS (2010) Three-dimensional radiofrequency tissue tightening: a proposed mechanism and applications for body contouring. Aesthet Plast Surg 35(1):87–95
20. Pitman GH (1993) Liposuction and aesthetic surgery. Quality Medical Publishing, St. Louis
21. Pitman GH, Aker JS, Tripp ZD (1996) Tumescent liposuction: a surgeon's perspective. Clin Plast Surg 23(4):633–645
22. Rohrich RJ, Beran SJ (1999) Is liposuction safe? Plast Reconstr Surg 104:819–822
23. Rohrich RJ, Beran SJ, Kenkel J, Adams WP, DiSpaltro F (1998) Extending the role of liposuction in body contouring with ultrasound-assisted liposuction. Plast Reconstr Surg 101(4):1090–1102
24. Samdal F, Amland PF, Bugge JF (1994) Plasma lidocaine levels during suction-assisted lipectomy using large doses of dilute lidocaine with epinephrine. Plast Reconstr Surg 93:1217–1223
25. Stoff A, Reichenberger MA, Richter DF (2007) Comparing the ultrasonically activated scalpel (Harmonic) with high-frequency electrocautery for postoperative serous drainage in massive weight loss surgery. Plast Reconstr Surg 120:1092–1093
26. Zelickson BD, Kist D, Bernstein E, Brown DB, Ksenzenko S, Burns J, Kilmer S, Mehregan D, Pope K (2004) Histological and ultrastructural evaluation of the effects of a radiofrequency-based non-ablative dermal remodeling device. Arch Dermatol 140: 204–209