OPEN

PRS GLOBAL OPEN

ORIGINAL ARTICLE
Cosmetic

Second Generation Radiofrequency Body Contouring Device: Safety and Efficacy in 300 Local Anesthesia Liposuction Cases

Christopher T. Chia, MD*
Joseph A. Marte, MD*
Derek D. Ulvila, MD†
Spero J. Theodorou, MD*

Background: Suction-assisted lipectomy has undergone significant improvements in technique, outcomes, and safety. The local anesthetic option has an excellent safety profile, and energy-based modalities such as radiofrequency-assisted liposuction (RFAL) devices were developed to enhance soft-tissue contraction. The purpose of this study was to report a single center's experience with two surgeons using the second-generation RFAL device compared with the first-generation device in terms of safety and efficacy.

Methods: In total, 300 consecutive operations were performed under local anesthesia. Following tumescent injection, the RFAL device was used to heat the skin and underlying collagen network. Subsequently, areas to be contoured were followed with suction-assisted lipectomy to remove excess fat and fluid.

Results: An estimated 300 operations were performed on 240 patients in 421 anatomic areas. Treated areas included the face, trunk, and extremities. The average maximum temperatures were 38.6°C externally and 65.6°C internally. The average total and fat aspirate volumes were 1264 and 648 mL. There were no major complications or mortalities, and 3 minor complications treated locally.

Conclusions: The data indicated statistically significant lower proportions of major, minor, or cumulative complications compared with the patients who received first-generation RFAL treatment. Major complications were exhibited for 6.25% of the first-generation group and 0% for the second-generation group. The first-generation group exhibited 8.3% minor complications, with 0.7% in the second-generation group. In sum, the data from the second-generation series of RFAL device operations indicate a statistically, as well as clinically, significant reduction in the overall complication rates compared with the first-generation device. *(Plast Reconstr Surg Glob Open 2020;8:e3113; doi: 10.1097/GOX.0000000000003113; Published online 24 September 2020.)*

INTRODUCTION

Body contouring with suction-assisted lipectomy (SAL) remains the first or the second most common[1] aesthetic plastic surgery procedure in the United States. Since its introduction five decades ago,[2] significant improvements in techniques and outcomes as well as safety have been made. Specifically, greater knowledge on fluid dynamics, pharmacokinetics, anesthetic advancements, and technical improvements[3–7] have resulted in reproducible and durable aesthetic results. The incorporation of local anesthetic option in SAL has proved to have an excellent safety profile with other benefits, including faster patient return to normal daily activities[8] and financial advantages to both the practitioner and the patient alike.

Energy-based modalities with SAL include laser,[9] ultrasound,[10,11] mechanical,[12] and radiofrequency devices developed in an effort to improve outcomes such as emulsification of subcutaneous fat, reduced blood loss, and enhanced soft-tissue contraction. Radiofrequency-assisted liposuction (RFAL) was introduced in the early 2000s and consisted of two main platforms: a monopolar point source with grounding pad and a novel asymmetric bipolar configuration that does not require a grounding pad. With the latter device, the energy is delivered between two electrodes: the external one maintaining contact with the skin and the

*From *body SCULPT, Inc., LLC, New York, N.Y.; and †Private Practice, San Francisco, Calif.*

Received for publication June 2, 2020; accepted July 22, 2020.

DOI: 10.1097/GOX.0000000000003113

Disclosures: *Dr. Chia is consultant and stockholder in InMode Corporation. Dr. Theodorou is consultant and stockholder in InMode Corporation. The other authors have no financial interest to declare.*

internal probe within the subcutaneous fat layer. With disparate energy delivery (more internally than externally), separate temperature goals are achievable. Specifically, the dermis and external temperature may be reached at 40°C and higher, while internal temperatures may reach temperatures as high as 70°C. These energy modalities are then often combined with SAL to optimize soft tissue contraction[13,14] in addition to subtractive body contouring.

The purpose of this article is to report a single center's experience with two surgeons using the second generation RFAL device when compared with the safety and efficacy of the first-generation device which preceded it by the same surgeons and at the same practice location. The second-generation device contains several safety features that are absent on the first. We found that the current iteration of the RFAL device when used judiciously is safe and effective in the group of 300 consecutive cases presented, which were all performed under local anesthesia.

MATERIALS AND METHODS

Three hundred consecutive RFAL operations were performed at a single AAAASF (American Association for Accreditation of Ambulatory Surgery Facilities)-accredited operating room by the two senior authors over a period of 40 months in accordance with the guidelines of the Declaration of Helsinki. All procedures were done under local anesthesia with the patient awake throughout the procedure. Following a thorough history and physical with laboratory values obtained when indicated, the patients were given the option of oral medications, including 10 or 20 milligrams of diazepam, 5 milligrams of hydrocodone with 325 milligrams of acetaminophen, and an oral antibiotic (500mg of cephalexin or 400mg of ciprofloxacin). Some patients opted for additional medication with 50% nitrous oxide/50% oxygen delivered by patient demand through a one-way valve (Pro-Nox, Inc.; CAREstream Medical Ltd, Oakville, ON, Canada).

Following careful marking of the topographic areas to be treated, the treated area was injected with tumescent solution (1000 mg lidocaine per 1000 mL Ringer's Lactate, 10 mL of NaHCO3 and 1.5 mL of 1:1,000 concentration epinephrine) into the subcutaneous adipose layer of the treated area via an access incision made with a 14gauge hollow needle. The internal probe of the bipolar radiofrequency handpiece (BodyTite, InMode Corporation, Lake Forest, Calif.) was then placed into the intermediate subcutaneous adipose layer with the corresponding external probe placed onto the skin covered in a water-based, sterile ultrasonic gel to obtain adequate contact (Fig. 1). The external and internal temperature maximum parameters were then set on the device according to the clinical indications, as determined by the operating surgeon (Fig. 2–11). The RF device was then engaged, liberating electromagnetic radiation in an asymmetric fashion to carefully heat all the soft tissues between the external and internal probes until the desired temperatures were reached on both the skin externally and the collagen/fat layer internally. Once the maximum temperatures were reached for both layers, the heating was sustained for several seconds according to the clinical presentation and the energy deposition process repeated until all treatment zones received the energy as desired. After this was achieved, any areas requiring contouring were treated with standard manual suction-assisted lipectomy (SAL) or power-assisted liposuction (PAL) to remove excess fat and fluid. All access incisions were closed with 5-0 nylon sutures and compression garments were applied to the treated areas for 2–10 days postoperatively.

RESULTS

Two hundred and thirty-two cases (77%) were performed on female patients and 68 cases (23%) on male patients. The ages ranged from 19 to 70 years of age with an average of 42 years. Body mass index (BMI) ranged from 16 to 41.5, with an average BMI of 25.8 During the study period, 240 patients underwent 300 discrete operations and several patients had more than one procedure performed with an average of 1.25 operations per patient. The treatment areas included lower eyelids, cheeks, jowls, neck, upper arms, axillae, bra rolls (midback), flanks, hips, abdomen, male chest, female breast, medial/lateral thighs, and knees, with 421 total anatomical areas treated

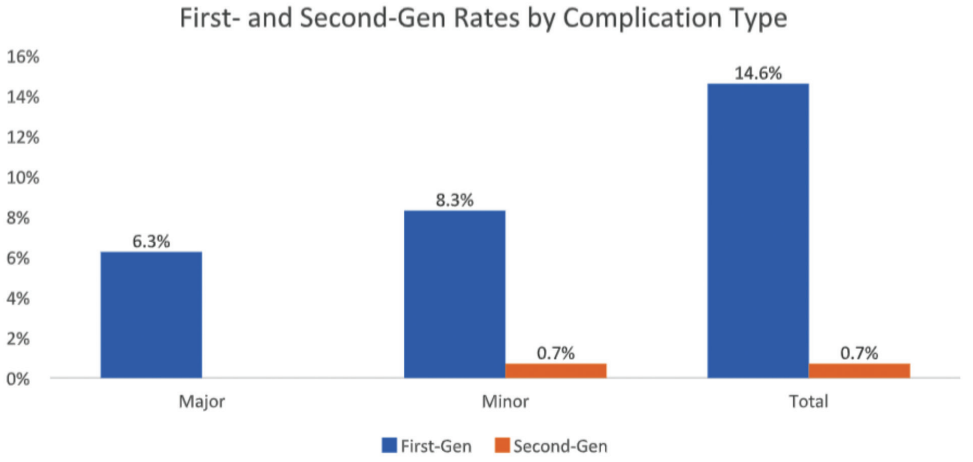

Fig. 1. The percentages of the first-generation and second-generation datasets for the major, minor, and overall complication rates.

Fig. 2. Image of a radiofrequency-assisted liposuction bipolar handpiece (InMode Corporation, Lake Forest, Calif.).

Fig. 3. Image of a radiofrequency-assisted liposuction device platform (InMode Corporation, Lake Forest, Calif.).

(Table 1). The average operating time was 102 minutes with an average tumescent injection volume of 1932 mL. The external and internal temperature maximum ranges were 35–42°C and 50–70°C, respectively (average maximum temperature settings were 38.6 C externally and 65.6 C internally). The average total and fat aspirate volumes were 1264 mL and 648 mL respectively and ranged very widely from 0 to 5300 mL (Table 2). All patients were discharged home following the procedures with a follow up at approximately 1 week and 3 months post-operatively.

Two hundred thirty-nine patients underwent 300 operations and there were no mortalities, hospitalizations, or major complications noted. One patient scheduled for a second operation the day after the first patient experienced nausea and vomiting, which was limited and self-resolving. However, the second case was rescheduled and surgery was successfully completed the following week. One case of neck and lower face RFAL had an incidence of temporary weakness of the marginal branch of the mandibular nerve, resulting in an ipsilateral weakness of the depressor anguli oris. This completely resolved after 5 weeks of observation without intervention. The re-operation (touch-up) rate was 1.7% (5 of 300 cases), all of which were for patient desiring further fat removal and none for contour deformities or other technical difficulties.

DISCUSSION

Body contouring with SAL remains the number one or two most common cosmetic procedure performed by plastic surgeons and the most common procedure performed by cosmetic surgeons in the United States.[1] A growing percentage of cases are done using the local anesthetic option in the awake patient as well as a growing number using energy-based options to enhance outcomes by fat emulsification, soft-tissue tightening, or both. The asymmetric bipolar device used in this study is the second-generation device available in the U.S. since 2016, which has several safety features added since the introduction of the device approximately 13 years ago, which provides an excellent safety profile when used by experienced users in the appropriate indications. Many RFAL users report significant soft tissue tightening as a result of the applied energy as well when performed with and with SAL.[13–15] In addition, the local anesthetic option has been proved to be a safe and effective method for body contouring on its own merits, with millions of cases performed over several decades[4,5,8,15,16]

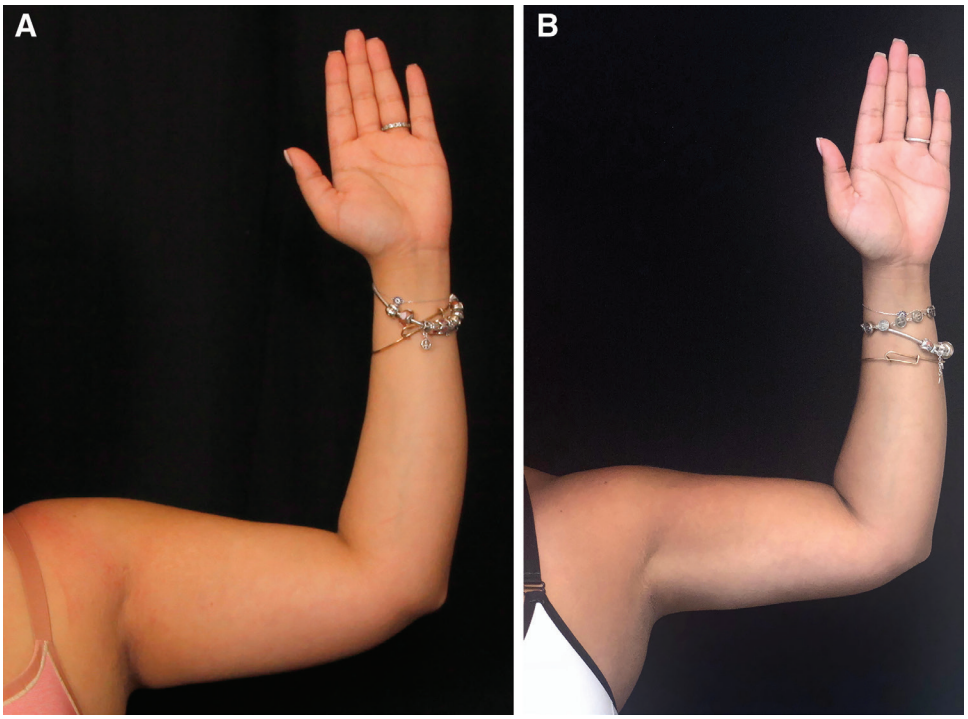

Fig. 4. Radiofrequency-assisted liposuction of 26 year-old woman's bilateral arms under local anesthesia. Total aspirate 2,500 mL with 850mL fat fraction. External temperature maximum setting 38.0 Centigrade and internal temperature maximum setting 65.0 degrees Centigrade. A, preoperative anterior view of left arm. B, one-year postoperative anterior view of left arm.

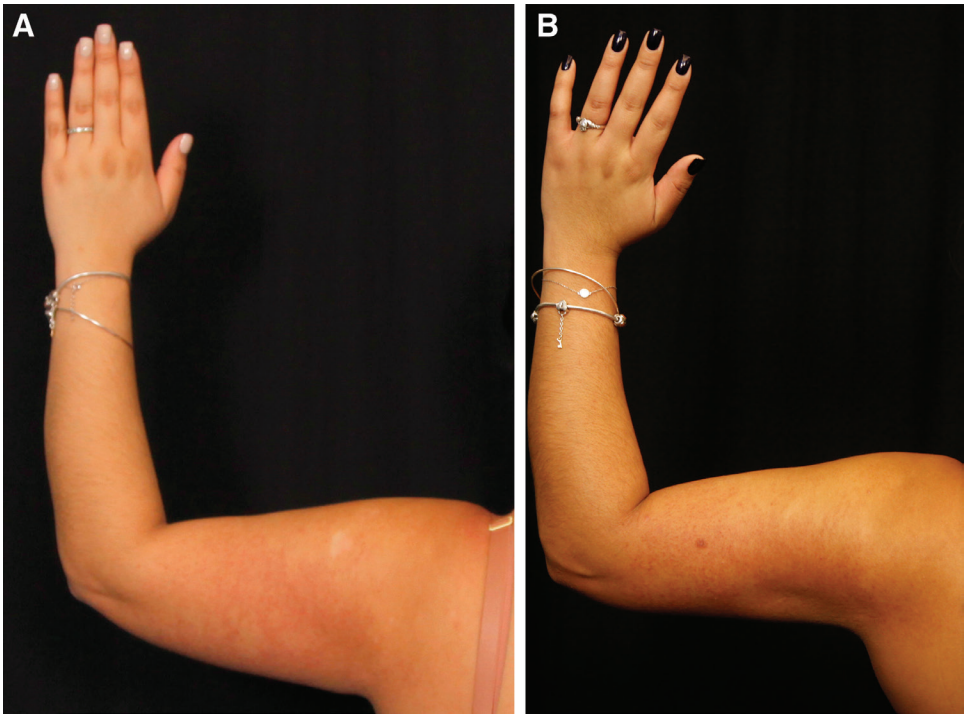

Fig. 5. Radiofrequency-assisted liposuction of 26 year-old woman's bilateral arms under local anesthesia. Total aspirate 2,500 mL with 850mL fat fraction. External temperature maximum setting 38.0 Centigrade and internal temperature maximum setting 65.0 degrees Centigrade. A, preoperative posterior view of left arm. B, one-year postoperative posterior view of left arm.

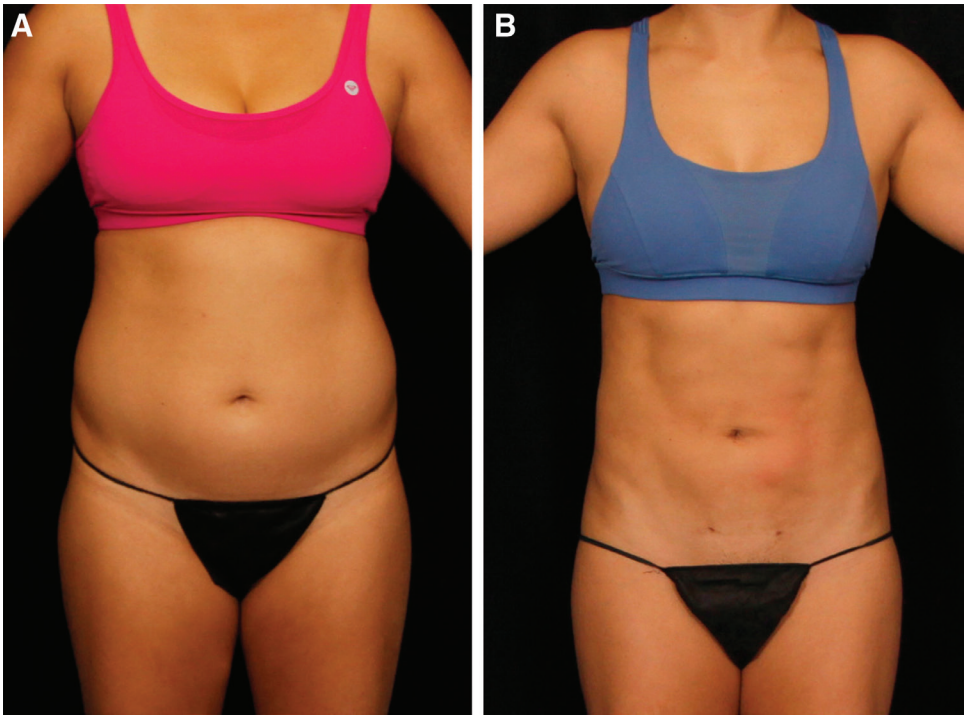

Fig. 6. Radiofrequency-assisted liposuction of 39 year-old woman's abdomen and bilateral flanks. Total aspirate 3,800 mL with 1,600 mL fat fraction. External temperature maximum setting 39.5 degrees Centigrade and internal temperature maximum setting 68 degrees Centigrade. A, preoperative anterior view. B, one-year postoperative anterior view.

With the second generation device in particular, the addition of the internal temperature real-time monitoring with the existing external thermistor expands both the safety profile as well as the efficacy of the RFAL instrument. The heating of the subcutaneous collagen network in particular recruits what is termed the fibroseptal network (FSN), which provides the contraction of the treated areas in three dimensions with neocollagenesis over time and thermal contraction[13,14,17–18] in the relative near term. In addition, an additional safety feature known as temperature surge protection (TSP) further enables the practitioner to achieve efficacious temperatures without exceeding the maximally set parameters and avoiding burns. TSP works by continuously monitoring not only the temperatures internally and externally real-time many times per second, but analyzing the *rate* of rise of temperature so that dangerous temperature spikes are avoided before they can cause a thermal injury. For example, if the device senses that an area being treated is rising in temperature too quickly, it will stop the flow of energy automatically, alert the user, and require him or her to re-start the machine via the foot pedal before treatment resumes.

In this study of 300 consecutive patients who had undergone RFAL under local anesthesia of over a dozen different anatomical regions, there were two burns observed compared to nine in a smaller sample size in the first-generation device study presented previously.[15] The one case of nausea was attributed to the patient's sensitivity to hydrocodone especially when dehydrated and with an empty stomach one day postoperatively following a flanks RFAL case. She fully resolved and had the second abdominal RFAL procedure performed without incident a few weeks later. We routinely separate cases of large treatment areas when the anticipated lidocaine load would significantly exceed the 35mg lidocaine per kilogram body weight maximum widely accepted by plastic surgeons.

The temporary unilateral neuropraxia of the marginal branch of the mandibular nerve resulting in paralysis of the ipsilateral *depressor anguli oris* also fully resolved with observation after 38 days. This was consistent with a Grade I neuropraxia and no intervention except time was needed for fully recovery of function. This is a recognized complication of contouring of the neck and lower third of the face, especially with SAL even in the absence of an energy modality. Although it cannot be known with absolute certainty, it is postulated that either the relatively tight soft tissue envelope following approximately 250–350 mL of tumescent injected near the area and/or mechanical contact with the liposuction cannula resulted in the temporary neuropraxia. Now, less tumescent is used in our practice, and a specific "no fly" zone near the probably course of the nerve is marked and avoided from manipulation. The neuropraxia rate is at or below published rates with liposuction alone with one citation having a 0.5% rate in 987 cases.[19] We have seen similar rates with SAL alone, SAL plus laser assistance, and SAL with ultrasound assistance.

The wide range in operating time, tumescent fluid infiltrated and aspirate removed reflects the flexibility with

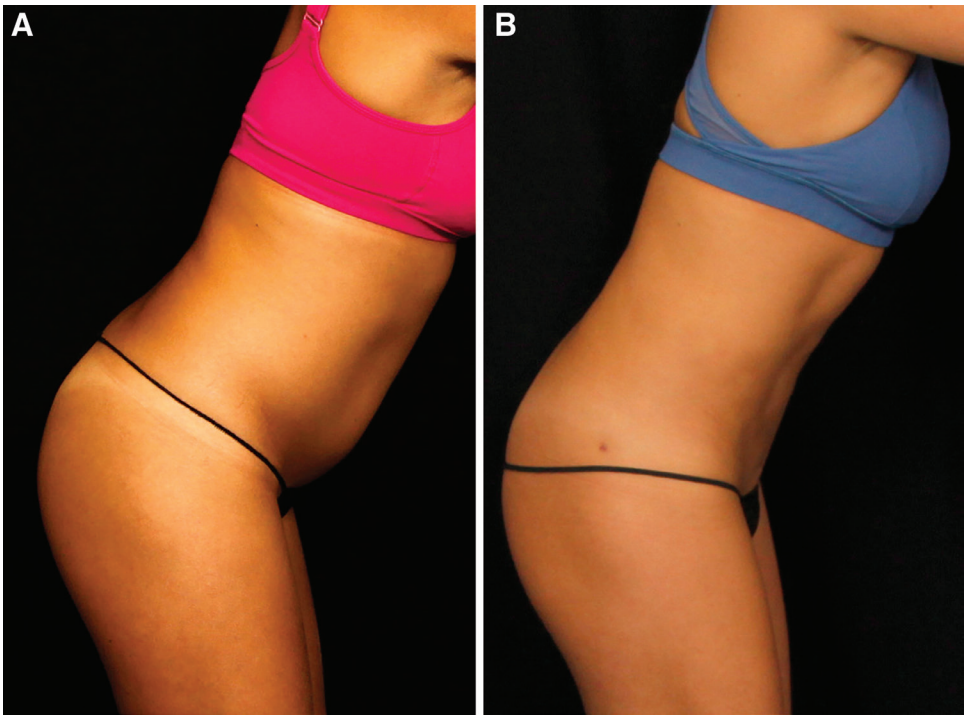

Fig. 7. Radiofrequency-assisted liposuction of 39 year-old woman's abdomen and bilateral flanks. Total aspirate 3,800 mL with 1,600 mL fat fraction. External temperature maximum setting 39.5 degrees Centigrade and internal temperature maximum setting 68 degrees Centigrade. A, preoperative flexed right lateral view. B, one-year postoperative flexed right lateral view.

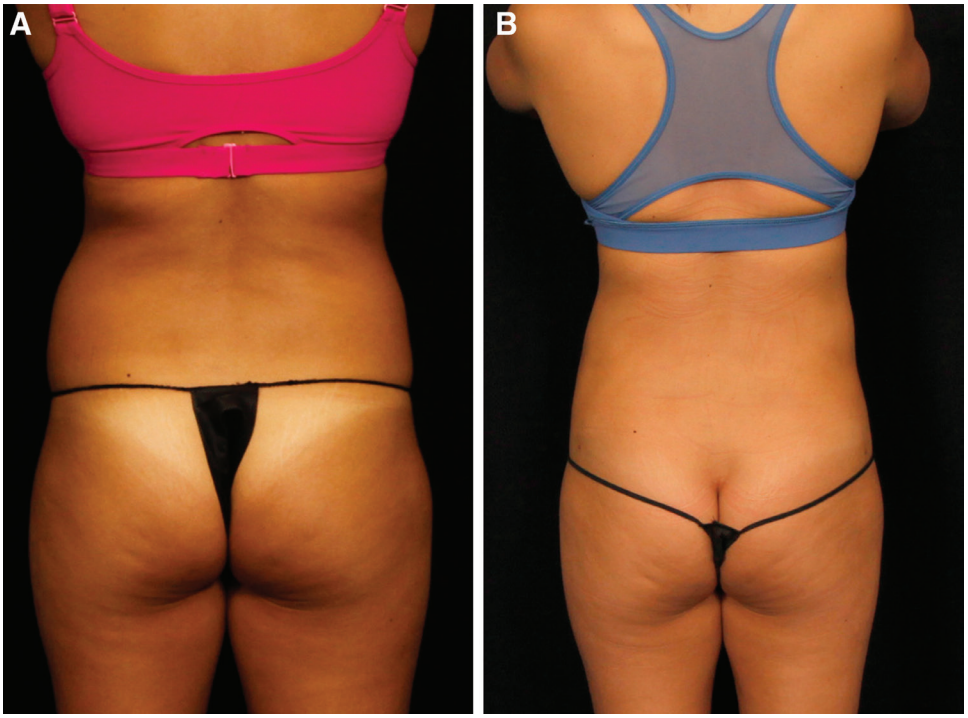

Fig. 8. Radiofrequency-assisted liposuction of 39 year-old woman's abdomen and bilateral flanks. Total aspirate 3,800 mL with 1,600 mL fat fraction. External temperature maximum setting 39.5 degrees Centigrade and internal temperature maximum setting 68 degrees Centigrade. A, preoperative posterior view. B, one-year postoperative posterior view.

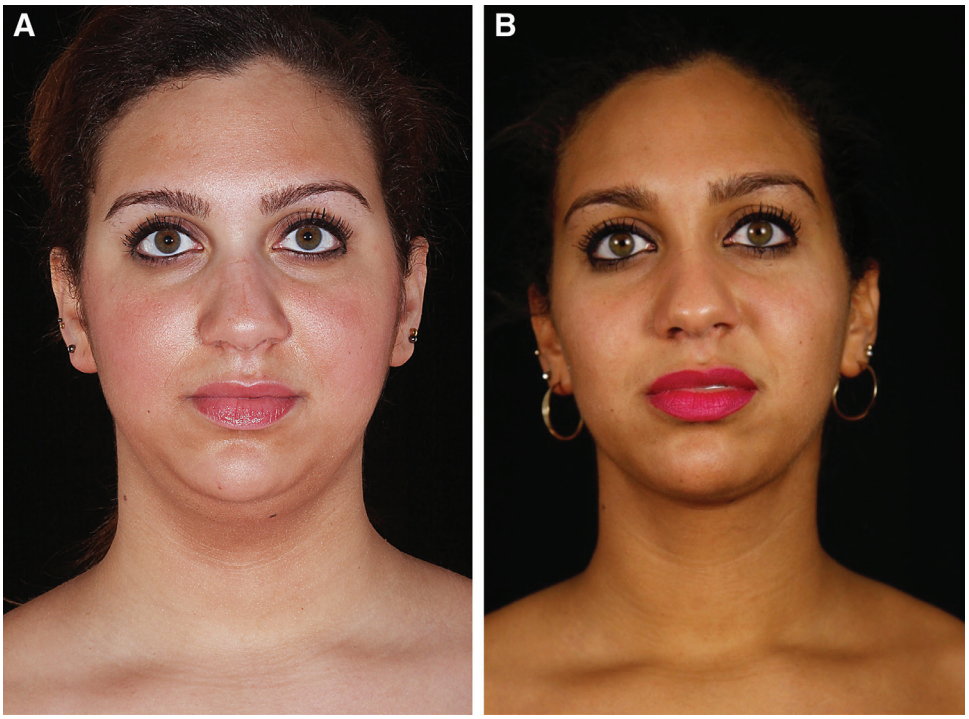

Fig. 9. Radiofrequency-assisted liposuction of neck 28 year-old woman. 250 mL tumescent fluid injection and 75 mL total aspirate and 35 mL fat fraction. Maximum external temperature setting 38.5 degrees Centigrade; maximum internal maximum temperature 68 degrees Centigrade. A, preoperative anterior view. B, one-year postoperative anterior view.

Fig. 10. Radiofrequency-assisted liposuction of neck 28 year-old woman. 250 mL tumescent fluid injection and 75 mL total aspirate and 35 mL fat fraction. Maximum external temperature setting 38.5 degrees Centigrade; maximum internal maximum temperature 68 degrees Centigrade. A, preoperative lateral view. B, one-year postoperative lateral view.

which RFAL may be incorporated into a body contouring regimen. For example, the excellent analegesia achieved allows the surgeon to perform concomitant aesthetic procedures simultaneously with RFAL. Autologous fat transfer, non-invasive skin treatments, scar revisions, and the like were commonly performed in conjunction with RFAL with excellent patient compliance and comfort while not contributing significantly to morbidity as reflected by the data.

A series of tests were conducted to determine if the proportion of complications for the second generation of the RFAL device was lower compared with that for the first generation of the RFAL device. The Chi-Square test for comparing a pre-specified proportion with an observed proportion was employed. For these tests, the first-generation results[15] were input as the expected proportions, while the observed proportions represented the second-generation results reported in this study. Three tests were conducted to compare the second-generation device to the first-generation device: 1) proportion of major complications, 2) proportion of minor complications, and 3) proportion of all complications (thus, the cumulative proportion of major and minor complications).

All three tests indicated that second generation participants demonstrated statistically significant lower proportions of major, minor, or cumulative complications compared with the patients who received first generation RFAL treatment. Major complications were exhibited for 6.25% of the first-generation group, while 0% (n = 0) of the second-generation group exhibited major complications. (Table 3). As previously mentioned, this difference was statistically significant (z-statistic = 5.30, p <.001, 95% LL CI = 0%, 95& UL CI = 0.9%); this demonstrates a complete decrease in the change. Moreover, the first-generation group exhibited 8.3% of minor complications, while 0.70% of the second-generation group of patients did so. This difference was statistically significant (z-statistic =5.65, p <.001, 95% LL CI =.14%, 95& UL CI = 2.10%); this demonstrates a 91.5% decrease in change. Given that the major and minor complication test differences were significant, it is no surprise that the cumulative test results were also significant. Overall, the first-generation group exhibited 14.6% rate of any complications, while 0.70% of the second-generation group of patients did so. This difference was statistically significant (z-statistic =8.10, p <.001, 95% LL CI =.14%, 95& UL CI = 2.10%); this demonstrates a 95.2% decrease in change.

CONCLUSIONS

A limitation of the study was that this was a retrospective study with data reviewed from prior cases. Some cases did not have liposuction as an indication but were included, since the charts were for all consecutive cases utilizing the radiofrequency platform to maintain consistency. While all patients returned for at least one follow up, longer term data for all patients were not possible (although the focus of this paper is for safety and efficacy and all included parameters for chart review were complete). At the time of writing the manuscript, four patients were lost to follow-up due to unknown consequences of the worldwide COVID-19 pandemic.

In sum, the data from the second-generation series of RFAL device operations indicate a statistically, as well as clinically, significant reduction in the overall complication rates compared with the first-generation device data. Moreover, the first- and second-generation device data were collected from the same two surgeons at the same, single practice location eight years apart. Thus, surgeon and location differences were not possible confounding

Table 1. Anatomical Areas Treated

Anatomical Area	Cases
Abdomen	95
Arms	40
Axilla	25
Bra roll	17
Breast	4
Cheeks	3
Chest	18
Eyelids	1
Flanks	89
Hip	7
Jowls	23
Knees	12
Mons pubis	6
Nasolabial folds	1
Neck	50
Pre sacrum	4
Thighs	25
Tibia	1
Total	421

Table 2. Patient and Operating Case Data

	Low	High	Average
Age, y	19	70	42
Body mass index	16	41.5	25.8
Tumescent injected, mL	20	6000	1932
Total aspirate, mL	0	5300	1264
Fat aspirate, mL	0	4100	648
Operating time, min	15	300	102
Total energy, kJ	0.6	90	20.2
External temperature, °C	35	42	38.6
Internal temperature, °C	50	70	65.6
No. operations per patient	1	4	1.25

Table 3. Complications by Anatomical Area and Series (First-generation versus Second-generation Devices)

Anatomical Area	Series I			Series II		
	Major	Minor	Total	Major	Minor	Total
Abdomen	5	7	12	0	0	0
Arms	0	1	1	0	1*	1
Back	0	0	0	0	0	0
Chest	1	0	1	0	0	0
Flanks	2	1	3	0	1*	1
Knees	1	0	1	0	0	0
Lateral thighs	0	2	2	0	0	0
Medial thighs	0	1	1	0	0	0
Neck	0	0	0	0	1†	1
Total	9	12	21	0	3	3
Total areas	144	144	144	421	421	421
Percentage	6.25	8.3	14.6	0	0.7	0.7

*Minor burn, arms; resolved with local care.
†Temporary neuropraxia, unilateral marginal branch of mandibular nerve; self-resolved.

variables. We found in this group of patients that the second generation bipolar RFAL device used in a variety of anatomical regions under local anesthesia can be done safely and effectively with a very low complication rate and faster return to daily activities than traditional methods of SAL and anesthesia techniques. The addition of two safety features in the current iteration (with three in total) provides the surgeon excellent feedback as to the progress of the treatment as it is occurring real-time as well as intervening (ie, shutting off) in certain instances automatically, where the clinical scenario may result in a complication even before the practitioner is able to determine it.

Christopher T. Chia, MD
128 Central Park South
New York, NY 10019
E-mail: christophertchia@gmail.com

REFERENCES

1. American Society of Plastic Surgeons. *Report of the 2018 Plastic Surgery Statistics*. 2019. Arlington Heights, Ill.: ASPS.
2. Illouz YG. Body contouring by lipolysis: a 5-year experience with over 3000 cases. *Plast Reconstr Surg*. 1983;72:591–597.
3. Bitar G, Mullis W, Jacobs W, et al. Safety and efficacy of office-based surgery with monitored anesthesia care/sedation in 4778 consecutive plastic surgery procedures. *Plast Reconstr Surg*. 2003;111:150–156; discussion 157.
4. Boeni R. Safety of tumescent liposuction under local anesthesia in a series of 4,380 patients. *Dermatology*. 2011;222:278–281.
5. Klein JA. The tumescent technique for liposuction surgery. *Am J Cosm Surg*. 1987;4:263–267.
6. Klein JA. Tumescent technique for regional anesthesia permits lidocaine doses of 35 mg/kg for liposuction. *J Dermatol Surg Oncol*. 1990;16:248–263.
7. Brown SA, Lipschitz AH, Kenkel JM, et al. Pharmacokinetics and safety of epinephrine use in liposuction. *Plast Reconstr Surg*. 2004;114:756–763; discussion 764.
8. Chia CT, Theodorou SJ. 1,000 consecutive cases of laser-assisted liposuction and suction-assisted lipectomy managed with local anesthesia. *Aesthetic Plast Surg*. 2012;36:795–802.
9. DiBernardo BE. Randomized, blinded split abdomen study evaluating skin shrinkage and skin tightening in laser-assisted liposuction versus liposuction control. *Aesthet Surg J*. 2010;30:593–602.
10. Graf R, Auersvald A, Damasio RC, et al. Ultrasound-assisted liposuction: an analysis of 348 cases. *Aesthetic Plast Surg*. 2003;27:146–153.
11. Rohrich RJ, Beran SJ, Kenkel JM, et al. Extending the role of liposuction in body contouring with ultrasound-assisted liposuction. *Plast Reconstr Surg*. 1998;101:1090–1102; discussion 1117.
12. Fodor PB. Power-assisted lipoplasty versus traditional suction-assisted lipoplasty: comparative evaluation and analysis of output. *Aesthetic Plast Surg*. 2005;29:127.
13. Paul M, Mulholland RS. A new approach for adipose tissue treatment and body contouring using radiofrequency-assisted liposuction. *Aesthetic Plast Surg*. 2009;33:687–694.
14. Duncan DI. Nonexcisional tissue tightening: creating skin surface area reduction during abdominal liposuction by adding radiofrequency heating. *Aesthetic Surg J*. 2013;33:1154–1166.
15. Theodorou SJ, Paresi RJ, Chia CT. Radiofrequency-assisted liposuction device for body contouring: 97 patients under local anesthesia. *Aesthetic Plast Surg*. 2012;36:767–779.
16. Klein JA. Tumescent technique for local anesthesia improves safety in large-volume liposuction. *Plast Reconstr Surg*. 1993;92:1085–1098; discussion 1099–1100.
17. Hantash BM, Ubeid AA, Chang H, et al. Bipolar fractional radiofrequency treatment induces neoelastogenesis and neocollagenesis. *Lasers Surg Med*. 2009;41:1–9.
18. Sadick N. Tissue tightening technologies: fact or fiction. *Aesthet Surg J*. 2008;28:180–188.
19. Habbema L, Tang JC, Sattler G, et al. Liposuction of the neck: low incidence of nerve injury and other complications in 987 patients. *J Drugs Dermatol*. 2018;17:30–34.