OPEN FORUM

Body Contouring

Helium Plasma-Driven Radiofrequency for Skin Contraction: Clinical Use, Safety Recommendations, and Results in High-Definition Body Contouring Surgery

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Abstract

Background: For many years, liposuction has remained one of the most-performed cosmetic procedures by plastic surgeons around the world. However, determining the degree of residual skin laxity after evacuation of fat remains a challenge. Renuvion (J-Plasma, Apyx Medical, Clearwater, FL) is a radiofrequency device propelled by helium plasma that generates rapid heating at the subcutaneous layer leading to controlled skin retraction.

Objectives: The authors present the clinical results of their experience with the J-Plasma device in combination with high-definition liposculpture (HDL), while providing some safety recommendations for its use.

Methods: The authors retrospectively collected data from a cohort of patients who underwent HDL in combination with J-Plasma therapy in at least 1 body segment between January 2018 and June 2019 at Dhara Clinic (Bogota, Colombia). Also, 100 patients were randomly selected to complete a satisfaction survey of their results.

Results: The authors evaluated 174 consecutive cases: 149 females (85.6%) and 25 males (14.4%). J-Plasma was performed in addition to HDL alone in 96 cases (55.2%), whereas other aesthetic procedures were performed in addition to J-Plasma and HDL in 78 cases (44.8%). They reported 44% of patients as being "very satisfied" and 41% "partially satisfied."

Conclusions: The helium plasma-based device, J-Plasma, has several unique features that enable surgeons to achieve adequate levels of soft-tissue contraction when used in conjunction with liposuction during High-Def body contouring surgery.

Level of Evidence: 4 (Therapeutic)

Liposuction remains 1 of the top 3 procedures performed by plastic surgeons around the world during the recent decades.[1] Patients request these procedures with the aim of improving body contours while avoiding large incisions and scar burdens. However, one of the most frequent challenges surgeons faced was how to predictably determine the degree of residual skin laxity after liposuction. Even more important is how to maximize skin contraction to appropriately redrape over the newly created underlying soft-tissue contours. Multiple excursions of the cannula during liposuction cause a degree of mechanical trauma, which will stimulate multiple molecular wound-healing cascades. This, coupled with the innate property of dermal elasticity and recoil, leads to tissue contraction and scarring in the treated area. The degree of skin recoil is affected by multiple variables, including the patient's age, medical comorbidities, history of drastic weight fluctuations, the anatomic area of targeted liposuction, history of previous surgical intervention, and the volume aspirated.[2,3]

Advances in modern medical technologies have enabled surgeons to safely combine liposuction with novel skin tightening technologies

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in order to achieve an optimal result. Radiofrequency (RF) is one of the most widely used and effective technologies for both surgical and nonsurgical skin retraction. *Renuvion* (Apyx Medical, Clearwater, FL) has already been approved by the FDA for cutting, coagulation, and ablation of soft tissue. It is an RF device that uses helium plasma (RFHP) to rapidly generate heat at the subcutaneous layer and promote skin retraction in a controlled fashion.[4] The authors aim to present their experience with the system, based on clinical outcomes, and provide safety considerations for its use.

METHODS

Demographics, operative data, and clinical photographs were prospectively collected for a cohort of patients undergoing high-definition liposculpture (HDL) in combination with RFHP therapy in at least 1 body segment. Patients who had surgery between January 2018 and June 2019 at the Dhara Clinic (Bogota, Colombia) were included. Patients utilized as case examples consented to the use of photographs for educational and medical publication purposes. Guidelines set by the Declaration of Helsinki were observed. Written consent was provided, by which the patients agreed to the use and analysis of their data. Exclusion criteria were: patients with ASA risk greater than III and those who endorsed an active smoking status. Standard liposuction protocols and techniques endorsed by the senior surgeons include fat emulsification before HDL. This was performed with the *VASER* device (Bausch Health, Laval, Canada; ultrasound-based adipose emulsification), and lipoaspiration was performed with power-assisted liposuction (PAL) technology through the MicroAire device/system (MicroAire Surgical Instruments, LLC, Charlottesville, VA). The RFHP system was set to the RF mode in all cases. One hundred ($n = 100$) patients were randomly selected and asked to complete a nonvalidated satisfaction survey that consisted of 5 questions: general satisfaction, location of best effect perception, pain, and region affected by pain, and whether the procedure would be performed again. Their responses were graded according to a standard 3-point Likert scale or based on anatomic region.

High Definition Liposculpture and Fat Transfer

This portion of the operation was performed in 3 phases.

1. Infiltration of tumescent solution (1000 mL of saline + 1 mL of epinephrine 1:1000 + 50 cc of 1% lidocaine) in an estimated ratio of infiltration/lipoaspirate of 2:1. Twenty to thirty minutes would elapse before incision, allowing for vasoconstriction.
2. Systematic fat emulsification, utilizing the previously mentioned system, began in the superficial adipose layer and subsequently transitioned to the deep layers. Pulsed and intermittent modes were set to 80% to 90%, depending on patient-specific innate tissue resistance. Emulsification was performed until tactile feedback of the operator noted a complete loss of resistance in the target. Afterwards, PAL was performed with 4.0 and 3.0 mm cannulas connected to the PAL system to increase aspiration efficiency and reduce surgeon fatigue. Thorough liposuction was performed in the deep layer. After de-bulking, a 3.0 mm cannula was used to treat the superficial plane in order to define muscle groups and create the desired athletic appearance.
3. This phase only pertains to patients desiring fat transfer in addition to liposculpting. Fat grafting was performed using a 3.0 mm cannula to deposit fat grafts in small aliquots as the cannula moves in the retrograde motion. Precise placement of the adipose tissue to create shape with 3-dimensional (3D) expansion requires serial passes, multiple tunnels, and at different tissue levels. Subcutaneous and intramuscular planes received fat in multiple fine strokes to ensure small parcels are left rather than large boluses. Bilateral comparison was always performed to ensure symmetry. Further details of the authors' HDL technique are not directly relevant to the focus of this manuscript and have been previously published.[5]

Video. Watch now at http://academic.oup.com/asjopenforum/article-lookup/doi/10.1093/asjof/ojae118

Radiofrequency Helium Plasma Application

After liposuction and fat transfer portions of the operation are completed, the cannula of the *RFHP* handpiece is inserted through the same port sites. The device is activated once the cannula is fully inserted and resides in the subdermal plane of the region to be treated. It is slowly extracted at a speed of 1.5 cm/s. Each complete extraction of the cannula constitutes 1 cycle.[3,5] Each region is treated with multiple cycles in both surface and deep planes. Surgeons can also use the transcutaneous light intensity emitted from the cannula tip as visual confirmation of treatment depth (Video). The total number of cycles in a given area is directly proportional to the thickness of the flap. Although 3 to 4 cycles are recommended for most areas, some with greater thickness (>3 cm) 5 to 7 cycles must be performed to achieve the desired result (Figure 1). However, we found that performing >7 cycles is considered to be counterproductive and may increase the risk of thermal injury/complications.[3] Attention is paid to avoid performing *RFHP* in recipient areas of fat graft. Similar to liposuction techniques, multiple tunnels are created in order to communicate the treated zones, allowing helium gas to easily diffuse and find an outlet (multiple port access/exit). As an extra safety measure, we manually extract the residual gas by manual external manipulation, directing it to the closest port instead of suctioning it with a cannula. This maneuver may improve patient comfort and minimize the amount of residual posttreatment subcutaneous crepitus.

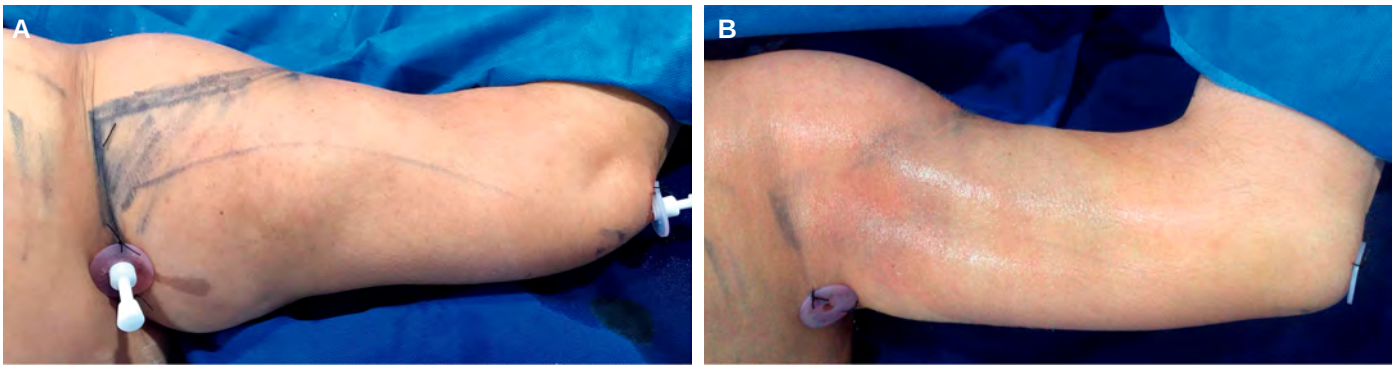

Figure 1. Before (A) and after (B) completion of several cycles of Renuvion. The change in skin laxity is improved immediately (B) on a 40-year-old female.

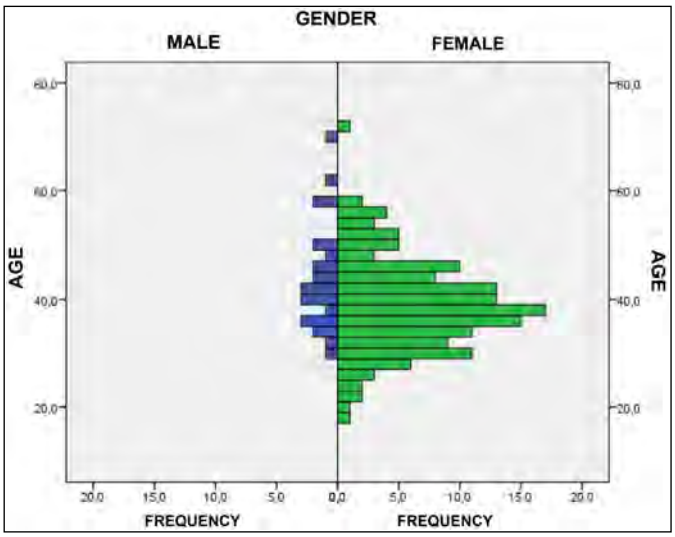

Figure 2. Demographic distribution according to gender.

Table 1. Demographic and Clinical Characteristics

Characteristics	Total $n = 174$ (100%)	Females $n = 149$ (85.6%)	Males $n = 25$ (14.4%)	*P*-value
Age (years), mean ± SD	39.4 ± 9.1	38.7 ± 8.8	43.4 ± 9.8	.014[a]
Weight (kg), mean ± SD	67.9 ± 12.4	64.8 ± 8.9	86.7 ± 14.0	≤.001[a]
Height (m), mean ± SD	1.66 ± 0.8	1.64 ± 0.1	1.77 ± 0.1	≤.001[a]
Preoperative Hb, mean ± SD	14.0 ± 1.1	14.0 ± 1.0	15.0 ± 1	≤.001[a]
Postoperative Hb, mean ± SD	10.9 ± 1.2	10.7 ± 1.1	11.9 ± 1.3	.005[a]
Preoperative Hct, mean ± SD	41.9 ± 4.1	41.3 ± 3.9	45.8 ± 2.6	≤.001[a]
Postoperative Hct, mean ± SD	32.3 ± 3.2	32.0 ± 3.1	35.2 ± 3.4	.007[a]

Hb, hemoglobin; Hct, hematocrit; SD, standard deviation.[a]Statistically significant results.

Certain incisions in the dependent position are routinely left open for egress of lymphatic drainage and any residual gas. Blake drains (ETHICON, Inc., Johnson & Johnson, New Brunswick, NJ) are placed in the subcutaneous space for additional drainage. The remaining incisions are sutured with inverting deep dermal sutures. At the conclusion of the operation, garments and foam are placed immediately, and the patients are transferred to a monitored recovery room as they emerge from anesthesia. We routinely use mild compression stockings for deep vein thrombosis prevention in the early postoperative period and up to 7 days after surgery. Antibiotic prophylaxis is with Cefazolin 1 g administered 30 min before incisions; Ondansetron 8 mg, Diclofenac 75 mg, and Tramadol 50 mg are also administered to all patients during the procedure. Patients also receive Pregabalin 75 mg qd in the immediate postoperative period.

RESULTS

A total of 174 consecutive cases were evaluated: 149 females (85.6%) and 25 males (14.4%; Figure 2). Patients were operated on by the senior surgeons at the same center (Dhara Clinic): senior author A.E.H. operated on 63% ($n = 110$) patients and the remainder, 36% ($n = 64$) patients were operated on by author L.C.C. The mean age in females was 38.7 years (range, 29.9-47.5 years) and 43.4 years in males (range, 33.6-52.2 years). The mean weight in females and males was 64.8 and 86.7 kg, respectively. The mean height in females and males was 1.64 and 1.77 m, respectively. Mean follow-up was 7.5 months (range, 2-24 months).

There was a statistically significant difference in age, height, weight, and bleeding between genders. Males experienced a greater blood loss, calculated by preoperative and postoperative blood draws (Table 1). In 96 cases (55.2%), *RFHP* and HDL were performed alone, whereas in 78 cases (44.8%), ancillary aesthetic procedures were performed in addition to *RFHP* and HDL. These procedures include mammoplasty, umbilicoplasty, abdominoplasty, etc (Table 2). *RFHP* was applied in a single anatomic area in approximately one-third of patients (34%, $n = 59$; Table 3). It was mostly utilized in the arms (41.4%) and legs (73.9%; Table 4).

The satisfaction survey was conducted with 100 randomized patients (Table 5): 44% of patients reported being “very satisfied,” 41% answered “partially satisfied,” and 15% remained “unsatisfied.” The body segments perceived as most effective were the arms (31.1%) and the abdomen (30.1%). Severe pain, defined as 8 out of 10 pain in the Verbal Numerical Rating Scale, was reported in 48.5% of the

Table 2. Aesthetic Procedure Performed

Type of procedure	Total	Females	Males
Renuvion and liposuction, *n* (%)	96 (55.2)	73 (49.0)	23 (92.0)
Renuvion, liposuction, and other procedures, *n* (%)	78 (44.8)	76 (51.0)	2 (8.0)

Table 3. Number of Body Segments in Which Renuvion was Performed

No. of body segments	Total	Females	Males
One, *n* (%)	59 (34.3)	50 (29.1)	9 (5.2)
Two, *n* (%)	44 (25.6)	38 (22.1)	6 (3.5)
Three, *n* (%)	23 (13.4)	22 (12.8)	1 (0.6)
Four, *n* (%)	7 (4.1)	7 (4.1)	0 (0)
Five, *n* (%)	2 (1.2)	2 (1.2)	0 (0)

Table 4. Body Segment in Which Renuvion was Performed

Body segment	Total	Females	Males	*P*-value
Arms, *n* (%)	72 (41.4)	69 (46.3)	3 (12.0)	.001[a]
Legs, *n* (%)	66 (37.9)	64 (43.0)	2 (8.0)	.001[a]
Back, *n* (%)	29 (16.7)	28 (18.8)	1 (4.0)	.066
Neck, *n* (%)	36 (20.7)	27 (18.1)	9 (36.0)	.041[a]
Abdomen, *n* (%)	69 (39.7)	57 (38.3)	12 (48.0)	.357
Pectorals, *n* (%)	2 (1.1)	0 (0)	2 (8.0)	.001[a]
Buttocks, *n* (%)	8 (4.6)	8 (5.4)	0 (0)	.236
Waist, *n* (%)	4 (2.3)	2 (1.3)	2 (8.0)	.040[a]
Axila, *n* (%)	5 (2.9)	4 (2.7)	1 (4.0)	.716
Knees, *n* (%)	3 (1.7)	3 (2.0)	0 (0)	.474
Trunk, *n* (%)	17 (9.8)	14 (9.4)	3 (12.0)	.685

[a]Statistically significant results.

Table 5. Satisfaction Survey Results

Questions	Answers options	Total	Males	Females
		n (%)	*n* (%)	*n* (%)
1. How satisfied are you with the result obtained by the Renuvion in skin tightening?	Very satisfied	44 (44.0)	10 (76.9)	34 (39.1)
	Partially satisfied	41 (41.0)	3 (23.1)	38 (43.7)
	Not satisfied at all	15 (15.0)	0 (0)	15 (17.2)
2. Which body segment do you think the device was effective on?	Arms	32 (31.1)	3 (20.0)	29 (33.0)
	Abdomen	31 (30.1)	6 (40.7)	25 (28.4)
	Back	19 (18.4)	2 (13.3)	17 (19.3)
	Neck	7 (6.8)	4 (26.7)	3 (3.4)
	Thighs	14 (13.6)	0 (0.0)	14 (15.9)
3. How much pain did you feel at the Renuvion application sites?	None	8 (7.9)	1 (7.7)	7 (8.0)
	Moderate	44 (43.6)	9 (69.2)	35 (39.8)
	Severe	49 (48.5)	3 (23.1)	46 (52.3)
4. In which body segment did it hurt the most?	Arms	35 (47.3)	0 (0.0)	35 (53.0)
	Abdomen	15 (20.3)	1 (12.5)	14 (21.2)
	Back	4 (5.4)	2 (25.0)	2 (3.0)
	Neck	7 (9.5)	3 (37.5)	4 (6.1)
	Thighs	10 (13.5)	0 (0.0)	10 (15.2)
	Pectorals and arms	1 (1.4)	1 (12.5)	0 (0.0)
	Trunk	2 (2.7)	1 (12.5)	1 (1.5)
5. Would you undergo the procedure again?	Yes	58 (58.6)	10 (17.3)	48 (82.7)
	No	41 (41.4)	3 (7.4)	38 (92.6)

patients. Arms (47.3%) were the more painful body segment after *RFHP* and HDL. A majority of patients (58%) responded "yes" when asked whether they would like to have the procedure again in the future. Preoperative and postoperative cases are shown in Figures 3-8.

Complications

In this cohort, 2 cases (1%) demonstrated an overcorrection of skin contraction (defined as a focal area of depression), 1 case (0.6%) of high-pitched/"reedy" voice, 1 case (0.6%) of extended ecchymosis, and 2 cases (1%) of pneumoperitoneum (Table 6). Prolonged and extended ecchymosis occurred in a patient after *RFHP* treatment of the buttocks: the patient presented with painless ecchymosis that extended from the buttocks to the calves, which resolved with serial manual massage and non-steroidal anti-inflammatory drugs (NSAIDS). Duck-like speech was observed in a patient after *RFHP* treatment over the thighs. Twenty-four hours after surgery, the patient presented with a high-pitched voice, which resolved spontaneously by the following day. Two patients presented with skin overcontraction over the abdomen. Serial manual massages coupled with intermittent ultrasound and physical therapy helped reduce the severity and minimize the aesthetic stigmata.

Two patients presented with severe abdominal pain and concerning abdominal physical exam findings in the immediate postoperative period. Abdominal computed tomography scans demonstrated pneumoperitoneum in 1 case and pneumoperitoneum plus pneumomediastinum plus retropneumoperitoneum in the other (Figure 9). *RFHP* therapy was performed in the back, flanks, and abdomen in both of these cases. Of note, one of these patients had an umbilical hernia that was repaired without complication 6 months before the aesthetic body contouring operation. Both patients underwent emergent exploratory laparoscopy procedures

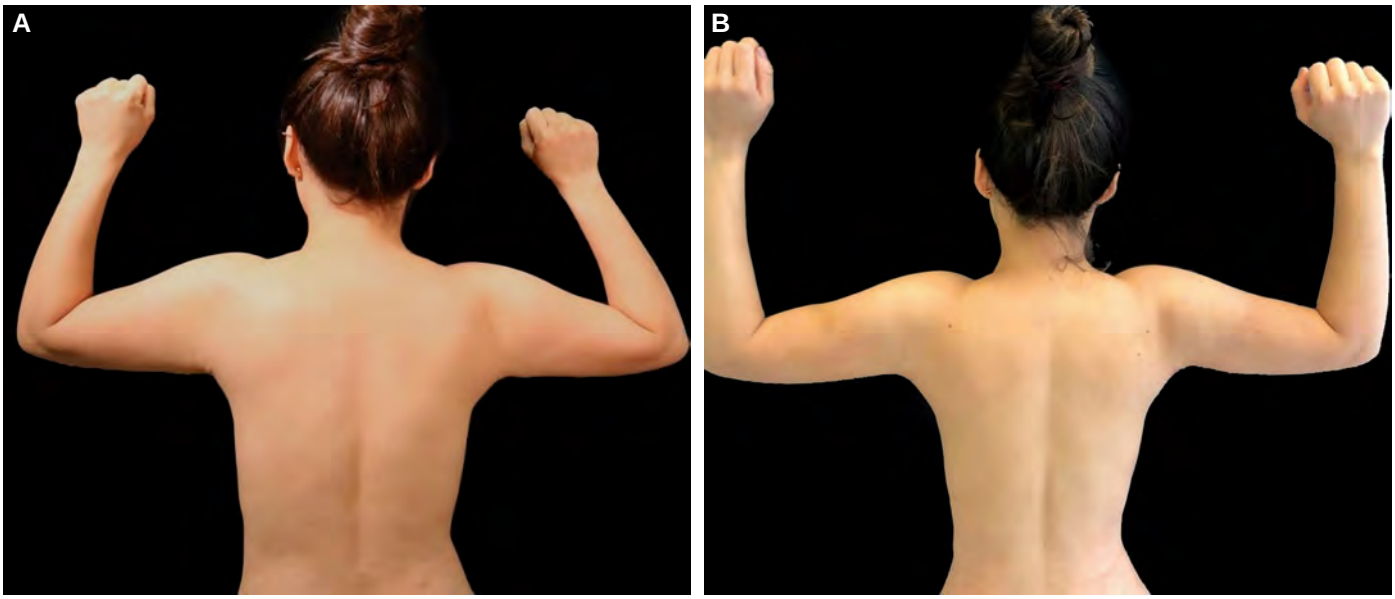

Figure 3. Renuvion therapy in a 35-year-old female. Notice the redundant skin and also laxity in the arms (A) compared with improvements in skin retraction, redraping with an overall toned appearance in the 10-month postoperative photograph (B).

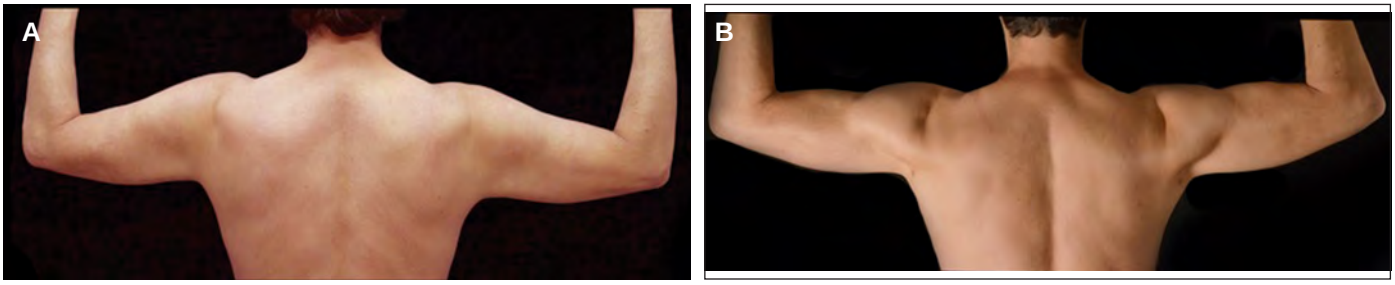

Figure 4. A 37-year-old male who underwent high-definition liposculpture in addition to Renuvion therapy. Observe the skin retraction over the arms, which gives a stronger, more toned appearance and enhanced definition of the muscle groups in the 7-month postoperative photograph (B) compared with those in the preoperative photograph (A).

without evidence of visceral injury. Their abdominal pain improved, and they were discharged from the hospital without additional intervention once they were able to tolerate an oral diet.

DISCUSSION

Liposuction procedures utilizing standard tumescent infiltration protocols have been a safe and reliable option for contour improvement in patients of different ages. It is offered to patients who present with a mild-to-moderate degree of skin laxity before suggesting more invasive excisional procedures that carry a higher scar burden and morbidity.[4] The degree of cutaneous contraction after liposuction relies on patient-specific characteristics and properties contributing to dermal elasticity (amount and quality of collagen and elastin). Traditional liposuction has been shown to reduce the surface area of a treatment zone by only 10% on average,[3] which limits the applicability of this procedure to patients with a moderate degree of skin laxity and elasticity.

Laser-assisted liposuction has been used to achieve fat emulsification as well as small-vessel coagulation. This has a favorable effect on improving skin contractility, thereby expanding the patient population that will attain adequate skin contraction after liposuction. The activated healing process, even at a molecular level, yields increased skin retraction compared with conventional liposuction.[6,7] The authors of an observational study involving 41 patients, who were treated with diode lasers on the face, submentum, arms, abdomen, flanks, breasts, and thighs, reported laser liposuction as a safe procedure to address areas of localized adiposity and cutaneous flaccidity. The latter effect was thought to be secondary to the microscopic effect on collagen, modification by coagulation, thereby reducing the cutaneous surface by 13% to 17% over a period of 3 to 6 months.[6,8,9] Ultrasound-assisted liposuction has been shown to increase skin retraction up to 53% compared with conventional liposuction. An additional benefit is the decreased amount of hematocrit in the lipoaspirate.[10] Moreover, certain studies have found increased patient satisfaction with ultrasound emulsification-assisted HDL compared with conventional techniques, whereas maintaining a natural and athletic outcome in most patients (84%).[11]

The evolution of technology to provide additional skin retraction with liposuction has brought alternative modalities to the market.

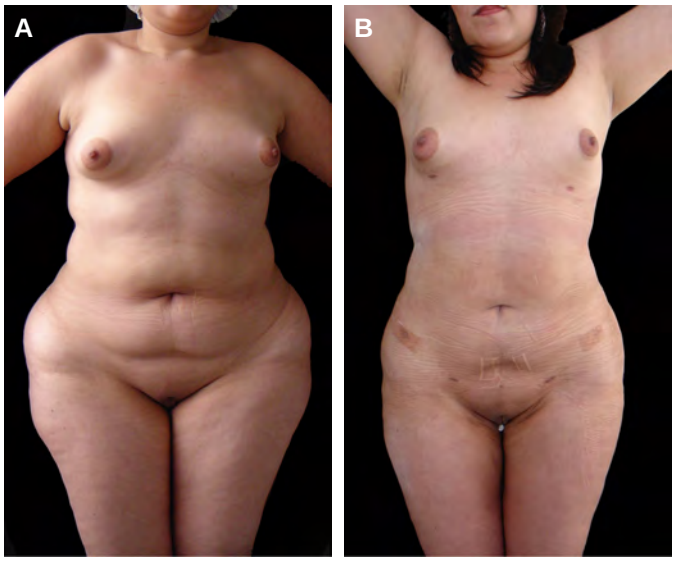

Figure 5. A 38-year-old female who underwent Renuvion therapy and high-definition liposculpture. Excess skin laxity and redundancy generate folds in the abdominal flanks (A). After treatment, an improvement in the general appearance is appreciated in the 6-month postoperative photograph (B).

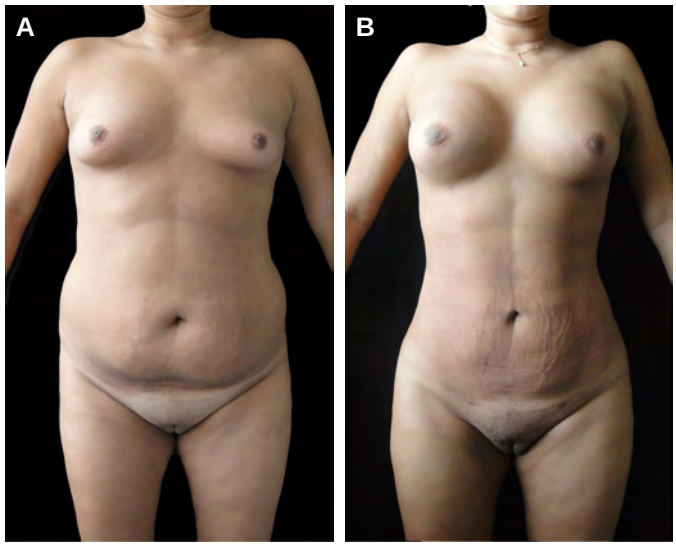

Figure 6. (A) Preoperative photograph of a 32-year-old female before treatment with liposuction and Renuvion. (B) Twelve months postoperative results of the patient after treatment with liposuction and Renuvion.

The use of RF systems for skin rejuvenation became popular in the early 1990s with noninvasive devices (*Thermage*—Solta Medical International Inc, Hayward, CA) used for skin texture improvement and tightness. RF-assisted liposuction (RFAL) was first described in 2008 with a bipolar device called *BodyTite* (InMode, Lake Forest, CA): Designed as an internal cannula that emits radial waves to an external electrode that in turn reflects heat to the epidermis. Later, a monopolar system for soft-tissue coagulation (*Thermi*—Celling Biosciences, Austin, TX) was introduced in 2012.[5] Subsequently, an updated version of the bipolar system harnessing the benefits of setting independent internal and external temperature cutoffs with real-time actual temperature monitoring was released in 2012. Studies using this particular device report a significant improvement in skin retraction while optimizing safety.[5,12]

RFAL demonstrated a significant contracture advantage on skin and soft tissue compared with traditional liposuction. Studies utilizing the *this adjunct technology* have reported a 35% increase in skin tightening after 1 year, compared with the 8% reported with conventional liposuction.[5] RFAL in combination with helium gas (J-Plasma system, Apyx Medical, Clearwater, FL) has achieved comparable results with fewer adverse effects, compared with their counterpart technologies using laser and argon.[12] Helium gas is found in the air and is a colorless, odorless, tasteless, nontoxic, inert, and monoatomic gas. The simple molecular structure of helium (2 electrons) allows ionization with minimal energy requirements. Thus, it allows for a controllable, stable, and precise flow of thermal energy.[12]

The RFHP device was introduced in 2016 as a helium-based system for subcutaneous coagulation, first used in laparoscopic procedures for general surgery, urology, and gynecology. It has shown significant advantages for endometriosis management, preventing vaginal dehiscence in gynecological procedures, treating and preventing intraabdominal adhesions, and managing chronic pelvic pain by treating localized tissue without damaging the surrounding healthy tissue.[13-16] It consists of an electrosurgical generator, a handpiece, and a helium tank. RF energy is provided by the generator to the handpiece that terminates in an electrode. When helium gas passes through this electrode, helium plasma is generated. This allows for precise delivery of thermal energy to soft tissues adjacent to the electrode. It was introduced to the field of plastic surgery for the treatment of skin laxity on its own or as an adjunct to liposuction procedures.[3]

Both RF devices stimulate collagen contraction through exposure to high temperatures. Small fragments of collagen are rapidly heated to 85 °C with fractionated energy. These high temperatures lead to the denaturation of proteins and the triple helix structure. As a result, the length of its fibers is reduced by 40% to 50%.[3,17] High temperatures will also stimulate innate tissue repair mechanisms (before reaching the threshold of necrosis) by neocollagenesis. Activated fibroblasts modify the underlying skin structure and produce retraction secondary to tissue hyperthermia.[18] As temperature rises, the metabolic process gradually increases as well. When external temperature reaches 45 °C, the dermal collagen structure has already begun to change. Above 45 °C, there is a conformational change in proteins, and cell death may occur. Denaturation of the proteins, coagulation, and contraction of collagen fibers occur at internal temperatures of 60 to 79 °C.[19] Although tissues are dissected and "destroyed" by evaporation of water and fluids at 90 to 100 °C, temperatures of 100 °C and higher produce tissue carbonization.[19]

The RFHP device can reach temperatures >85 °C in 0.040 to 0.080 s, which produces immediate tissue contraction because of its coagulation effect, whereas keeping tissues at intermediate proximity at lower temperatures compared with other devices/systems that create a larger 3D area of thermal injury. Therefore, it minimizes the risk of skin injuries (blisters and burns).[20] RFAL systems are capable of fat-cell dissolution by establishing tunnels within the adipose layer. It also causes dermal and subcutaneous as contraction and stimulates neocollagenesis with subdermal tissue remodeling. Studies have found that this results in a 36% skin contraction per area, 1 year after treatment. In addition, it has been safely tested in patients after massive weight loss, improving skin contour and

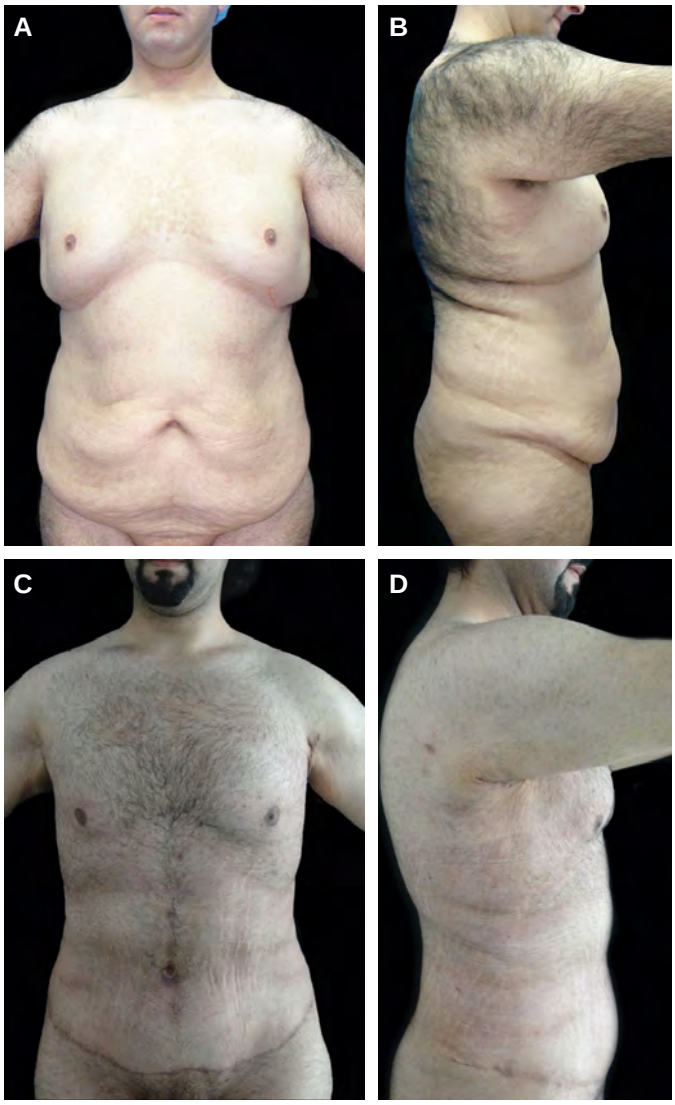

Figure 7. (A) Preoperative photographs of a 39-year-old male patient: (A) frontal and (B) lateral. On clinical examination, the patient has a significant degree of skin laxity. Ten months postoperative photographs of the patient after liposuction, abdominoplasty, and Renuvion: (C) frontal and (D) lateral. This combination of treatments achieved the appropriate amount of skin retraction for a natural and aesthetically pleasing appearance.

contraction.[21,22] RFAL systems may offer a safe alternative, or even complementary benefits to invasive procedures such as excisional body contouring surgeries.[22]

RFHP may be used alone or after liposuction. In our study, it was applied after HDL and, in some cases, after HDL in combination with other procedures (eg, abdominoplasty). The application of *RFHP* after liposuction has shown better results by reducing the surface area of the skin: some studies have shown an area reduction of 28.5% with RF with liposuction, compared with 10.3% for regions treated with liposuction alone after 6 weeks postoperatively, and a 34.5% reduction in skin surface area compared with an 8.3% reduction after 1 year of treatment, respectively.[5]

Ideal patients for RFHP treatments are those with regional lipodystrophy who also present with mild-to-moderate skin laxity in the lower third of the face, neck, arms, back, some areas of the chest, abdomen and flanks, thighs, and knees. Patients with first- and second-degree mammary ptoses may also benefit from targeted superior pole skin retraction.[23] It has also been indicated for postbariatric patients when the need for skin contraction is estimated to be <33%. The postoperative pain is an important factor to be considered, because 48.5% of patients reported pain as severe after these treatments. Hence, an optimal perioperative analgesic regimen should be considered; we advise to administering pregabalin 75 mg qd during 5 preoperative days, including the day of surgery and during the first postoperative week, to address the neuropathic postsurgical pain. Despite the pain, a majority of patients (58.6%) were willing to undergo the procedure again, probably because of the satisfactory aesthetic results achieved with this system and the decrease in skin laxity. When asked specifically, the improvement of skin quality/contraction in most patients was reported in the satisfaction survey where 44% of patients were very satisfied and 41% were partially satisfied.

RFHP therapy is generally considered a safe procedure when performed in conjunction with HDL. Our study reported complications in 6 cases (3.4%). Two of them described as gas diffusion into the peritoneal cavity required a second surgical intervention (negative exploration) without evidence of major organ damage. The potential morbidity of a second surgical procedure is not insignificant. A case report for these 2 complications has been submitted separately for open access consultation and caution surgeons to counsel patients accordingly. The patient with a temporary postoperative high-pitched, “reedy” voice may also be attributed to hematogenous helium gas diffusion into the lungs. After evaluation by the anesthesiology team, they believe that it was unlikely to be a sequela of vocal cord irritation from the endotracheal tube. The main contraindications for *RFHP* treatment are pregnancy and lactation, the presence of ulcers and/or unrelated wounds in the region to be treated, medical comorbidities with wound-healing implications (poorly controlled diabetes mellitus, vascular insufficiency, oxygen dependence, autoimmune diseases), severe skin hyperlaxity, poor skin quality of the region to be treated, severe local scarring, unrealistic expectations, and abdominal wall/chest wall defects (eg, previous abdominal or thoracic surgeries, hernias, etc).[3]

Another feature of the *RFHP* system is its 360° effect on the soft tissue, and the electrode is in contact with minimal propagation of thermal injury.[24] These features give the system several advantages in terms of safety and tissue protection:[25]

1. Quickly reaches local temperatures of 85 °C (0.040-0.080 s).
2. The surrounding tissue remains at low temperatures (protective).
3. Energy is concentrated in the subdermal plane, immediately contracting the soft tissue without affecting the superficial dermis, minimizing the risk of superficial burns.
4. 360° dispersion of energy within the tissue, preventing the need of redistribution by the surgeon.
5. Prevention of tissue overtreatment because of the shallow thermal effect of low-current RF energy when performing multiple cycles.

After reviewing our findings and outcomes, we list a number of safety recommendations and considerations for *RFHP* treatments:

1. Keep flow below 2.5 L.
2. Continuously evacuate the gas in each region in-between cycles.
3. Connect internal pathways between 2 outlet ports.
4. Leave 2 or more entry/exit incisions per treated site.

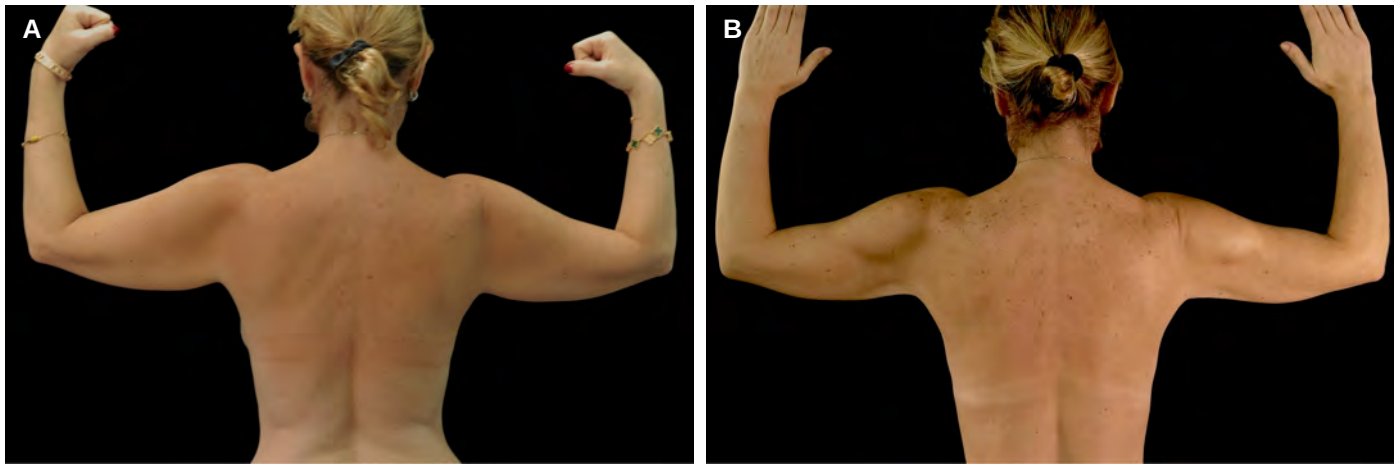

Figure 8. (A) Preoperative photograph of a 39-year-old female before the treatment of Renuvion and liposuction in arms. Notice the skin redundancy, especially in the axillary fold. (B) Seventh-month postoperative photograph demonstrating significant improvement in axillary fold skin redundancy after liposuction and Renuvion treatment.

Table 6. Complications Depending on Which Body Segment Renuvion was Used

Body segment	Complication ($n = 6$; 3.5%)	Resolution
Buttocks	Extend ecchymosis ($n = 1$, 0.6%)	Local measures
Thighs	Reedy voice ($n = 1$, 0.6%)	Spontaneous
Abdomen	Helium diffusion to peritoneal cavity ($n = 1$, 0.6%)	Laparoscopy
Abdomen	Skin overcorrection ($n = 2$, 1.2%)	Local measures
Back	Helium diffusion to retroperitoneum ($n = 1$, 0.6%)	Laparoscopy

5. Thorough preoperative evaluation for the presence of hernias and/or other anomalous communications to deeper organs (abdominal and/or thoracic scars).
6. Maintain postoperative compression (use of girdles) 4 to 6 weeks after surgery.
7. Leave at least 1 port site open for each treated region to allow for passive egress of gas.
8. Select patients with mild-to-moderate skin laxity with realistic expectations.
9. Pregabalin 75 mg qd during 5 preoperative days (including the surgery day) and during the first postoperative week.

The limitations of this study are mainly the sample size and especially the lack of an objective tool to measure skin retraction. The isolated contribution of skin retraction secondary to the *RFHP* device cannot be accurately assessed, because liposuction was performed in addition to this treatment modality in all cases. Prospective studies with objective measurements to accurately assess the degree of skin contraction, skin tightening therapies performed in isolation, the presence of control groups, and a bigger sample size need to be conducted to support our findings.[26] Unfortunately, it would be unethical to treat 1 body part or 1 side of the body with various treatments to determine the degree of skin contraction each modality is capable of achieving. Patient satisfaction, a high degree of safety margin, and the aesthetic appearance of various treated areas once patients have healed are the ultimate endpoints. Surgeons evaluate numerous variables (Fitzpatrick skin type, subcutaneous thickness, amount of lipoaspirate evacuated, history of previous treatments, and desired aesthetic outcome) when determining the amount of energy that can be

Figure 9. A 2-dimensional, representative image extracted from an abdominal computed tomography scan performed to diagnose pneumoperitoneum in one of the patients who complained of severe abdominal pain and worrisome examination findings after Renuvion treatment. In addition to free air in the abdominal cavity, gas/free air was present in the retroperitoneal space. It has also partially dissected the suprarenal fascia (green arrow).

safely applied to a certain area in order to improve skin laxity and optimize aesthetic results.[27] It would not be possible to standardize and control for all of these variables in a clinical setting.

CONCLUSIONS

The *RFHP* system has several features that make it an efficient and effective device for achieving a degree of soft-tissue contraction. It is difficult to ascertain the amount of skin contraction that is because of each component of the procedure—thermal energy generated from the PAL and/or laser-assisted liposuction and the innate dermal contraction after 3D subcutaneous fat debulking. However, clinical results suggest a synergistic effect in body contouring surgery. *RFHP* is considered a popular ancillary treatment to liposuction to further address skin flaccidity in the appropriately selected patient population. Although quite uncommon, the potential for significant morbidity, such as pneumoperitoneum and pneumomediastinum, after *RFHP* treatment warrants additional investigation. Additionally, the use of *RFHP* in conjunction with HDL increases postoperative pain. We found that patient discomfort in the recovery period was one of the main reasons patients would not recommend undergoing the procedure again. Further comparative studies need to be performed to support this association.

Disclosures

Dr. Hoyos was an unpaid consultant and speaker for the product development team of Sound Surgical Technologies system and Cannulas (now: VASER 2018 Solta Medical—Bausch Health Companies Inc., Laval, Canada) up to May 2013. He receives royalties for the liposuction kits named after him. Dr Dayan receives royalties from Thieme (Leipzig, Germany) and is a consultant/investigator for InMode (Irvine, CA). The other authors have no conflicts of interest.

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- *The Renuvion® APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma where coagulation/contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue.*
- *The Renuvion APR Handpiece is intended for the coagulation of subcutaneous soft tissues following liposuction for aesthetic body contouring.*
- *The Renuvion APR Handpiece is indicated for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region.*
- *The Renuvion APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma for cutting , coagulation and ablation of soft tissue during open surgical procedures.*
- *The Renuvion APR Handpiece is intended to be used with compatible electrosurgical generators owned by Apyx Medical.*