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FINANCIAL & CONTENT DISCLOSURE: Apyx Medical sponsored this study; however, did not influence the data generated in this study. Sites were selected by availability of complete medical records required to collect study data. Physicians received site payments for their participation in this retrospective study. Dr. Ruff is a medical advisory board member, consultant, and clinical research investigator for Apyx Medical (Clearwater, FL) and receives compensation in the form of Apyx stock and hourly compensation. Dr. Vanek is also a consultant for Apyx Medical. Dr. Nykiel has no financial relationship with Apyx Medical outside of study funding. The opinions contained herein are those of the authors(s) and do not necessarily represent the official position or policies of Apyx Medical, Inc.

MANUFACTURING DISCLOSURE: Apyx Medical manufactures and owns the Renuvion/J-Plasma technology discussed in this article.

INDICATIONS FOR USE & INTENDED USE DISCLOSURES

- 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 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 to be used with compatible electrosurgical generators owned by Apyx Medical (specifically BVX-200H, BVX-200P, APYX-200H, APYX-200P, APYX-RS3, and APYX-JS3).
- Apyx Medical wants to present you with current scientific discourse. Specific usage outside of the cleared indications may not be safe or effective.
- The use of Renuvion with liposuction has not been approved or cleared by the FDA.

RISKS:

- As with all energy devices there are inherent risks associated with its use. Risk associated with the use of the Renuvion APR may include: helium embolism into the surgical site due to inadvertent introduction into the venous or arterial blood supply system, unintended burns (deep or superficial), pneumothorax, temporary or permanent nerve injury, ischemia, fibrosis, infection, pain, discomfort, gas buildup resulting in temporary and transient crepitus or pain, bleeding, hematoma, seroma, subcutaneous induration, pigmentation changes, increased healing time, scarring, asymmetry and/or unacceptable cosmetic result.

As with any procedure, individual results may vary. As with all energy devices there are inherent risks associated with its use, refer to the IFU for further information.

OPEN FORUM

Body Contouring

Adverse Events of Soft Tissue Coagulation Using a Helium-Based Plasma Technology Alone and in Combination With Ultrasound-Assisted Liposuction

Paul G. Ruff, IV, MD, FACS; Paul Vanek, MD; and Matthew Nykiel, MD

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Abstract

Background: Protein denaturation and collagen contraction occur when living tissue is heated to well-defined temperatures. The result is reduced volume and surface area of the heated tissue.

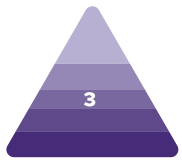
Objectives: To evaluate the adverse events of procedures in which a helium-based plasma technology (HPT) was used with and without ultrasound-assisted liposuction for the coagulation of soft tissue.

Methods: A multicenter retrospective chart review was performed in which patients (n = 192) were divided into 2 groups: one that received only soft tissue coagulation and the other that received both soft tissue coagulation and liposuction. Each of the 2 groups was subdivided into patients with and without adverse events, including seroma. Odds ratios for adverse events were calculated for both demographic and surgical subgroups. Seroma data were analyzed separately.

Results: No serious adverse events were observed. Forty-six (24.0%) patients reported 51 total adverse events. Seroma was the most frequently occurring adverse event with 13 patients (6.8%) reporting 17 (33.3%) events in 12 body areas. In these cases, all areas were treated with both liposuction and soft tissue coagulation. Seroma was not observed in patients receiving soft tissue coagulation alone. Patients aged 61 to 76 years and males were more likely to experience seroma or other adverse event than younger patients or females, respectively.

Conclusions: The use of the HPT for soft tissue coagulation in combination with ultrasound for liposuction is associated with nonserious adverse events. The most frequently occurring adverse event, seroma, was not observed in patients treated with HPT alone.

Level of Evidence: 3



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Thermally induced contraction of collagen through denaturation and coagulation of soft tissue has been used to achieve clinical benefit in ophthalmology,[1] orthopedics,[2] varicose vein ablation,[3] and cosmetic plastic surgery.[4-14] When tissue is heated to a specific temperature, protein denaturation and collagen contraction occur, resulting in a reduction of volume and surface area of the heated tissue.[15-17]

Dr Ruff IV is a cosmetic surgeon in private practice in Washington, DC, USA. Dr Vanek is a cosmetic surgeon in private practice in Mentor, OH, USA. Dr Nykiel is a cosmetic surgeon in private practice in Newport Beach, CA, USA.

Corresponding Author:
Dr Paul G. Ruff IV, 2440 M St NW, Suite #200, Washington, DC 20037, USA.
E-mail: drruff@westendplasticsurgery.com

The use of heat-induced collagen/tissue contraction has been expanded to minimally invasive procedures. When practitioners use laser-assisted lipolysis and radiofrequency (RF)-assisted lipolysis, they combine the removal of subcutaneous fat with soft tissue heating which addresses tissue laxity that often results from fat removal. During treatment, these devices are placed in the same subcutaneous tissue plane as a standard suction-assisted lipolysis cannula. And they deliver thermal energy to coagulate the subcutaneous tissue that includes the fascia and septal connective tissue.[13,18-22] The coagulation of the subcutaneous tissue results in collagen/tissue contraction.[17]

A helium-based plasma technology (HPT; Renuvion, Apyx Medical Corporation, Clearwater, FL) has been introduced for the percutaneous delivery of RF energy and helium plasma for cutting, coagulation, and ablation of soft tissue.[23] The system consists of an electrosurgical generator unit, a handpiece, and a supply of helium gas. RF energy is delivered to the handpiece by the generator and used to energize an electrode. When helium gas is passed over the energized electrode, a helium plasma is generated which allows heat to be applied to tissue in 2 different and distinct ways. First, heat is generated by the actual production of the plasma beam itself through the ionization and rapid neutralization of the helium atoms. Second, since plasmas are good electrical conductors, a portion of the RF energy passes from the electrode to the patient and heats tissue by passing current through the resistance of the tissue, a process known as Joule heating.[23,24]

The purpose of this retrospective study was to evaluate the adverse events of procedures in which the HPT was used with and without ultrasound-assisted liposuction (UAL) (VASER, 2018 Solta Medical, Bausch Health Companies Inc., Laval, QC, Canada) for the coagulation of soft tissue. The use of UAL throughout the text implies an evacuation by traditional liposuction.

METHODS

The study was a 3-site, retrospective chart review. Patients were treated according to 3 protocols: (1) both HPT and UAL in specific body areas (n = 160), (2) HPT alone in body areas (n = 21), and (3) both HPT and UAL in some body areas and HPT alone in other body areas (n =11). In this study, evacuation was not performed after HPT. Treated areas were of the upper body (lower face, neck, infra-axillary, scapular rolls, arms, breasts [male and female], abdomen) and lower body (mons, buttocks, hips, love handles, thighs [inner, outer, anterior, posterior], and lower legs). The mean follow-up time was 3 months (range 1 day to 15 months).

Table 1. Handpieces Used in the Study

HPT handpiece	Percentage of patients
15 cm	23 (n = 44)
27 cm	66 (n = 126)
33 cm	2 (n = 4)
Unknown	9 (n = 18)
Total	100% (n = 192)

HPT, helium-based plasma technology.

Patients

Patients (n = 192, 164 females, 28 males) aged 21 to 76 years of age (47.8 ± 11.9, mean ± SD) and BMI 17.4 to 47.7 kg/m^2 (24.3 ± 6.8, median ± interquartile range [third quartile minus first quartile]) were enrolled in the IRB-approved study. The investigations were carried out following the rules of the Declaration of Helsinki of 1975, revised in 2013. A waiver of Informed Consent and Health Insurance Portability and Accountability Act (HIPAA) Authorization was obtained from Sterling Institutional Review Board (Atlanta, GA) for each patient. Patients <21 years of age who had not undergone the procedures described were excluded.

Treatment Devices

As stated earlier, HPT consists of an electrosurgical generator unit, handpiece, and supply of helium gas. RF energy delivered to 1 of 2 handpieces (15 or 27 cm) by the generator is used to energize an electrode. When helium gas is passed over the energized electrode, helium plasma is produced which allows heat to be applied to soft tissue beneath the dermis.

The UAL is a third-generation ultrasound device for liposuction.[25-27] The device uses small-diameter probes with grooves at the tip for efficient fragmentation and emulsification of fat.[28] In this study, the infiltrate for all patients was a mixture of lidocaine (2%, 50 mL) and epinephrine (1 mg/mL, 1:1000, 0.50 mL). Emulsified fluids/tissues were aspirated and recorded for each patient. Estimated total blood loss ranged from <20 to 200 mL. Pre-tunneling was performed before the use of the HPT device with the UAL cannula, with or without power (cannula only). Handpieces and probes used in the present study are presented in Tables 1 and 2. A 4-mm double Mercedes cannula was used in 37 patients.

HPT settings (power, helium flow rate) ranged from 40% to 100% and 1.5 to 4.0 liters per minute, respectively. Patients received 2 to 11 passes per treatment session using either a 15- or 27-cm handpiece. UAL settings (power, number of grooves of probe) ranged from 30 to 100 and from 2 to 5, respectively. In addition to soft tissue coagulation and liposuction, many patients had other procedures

Table 2. Probes Used in the Study

UAL probe size	Percentage of patients
3 groove, 2.2-mm probe	0.6 (n = 1)
5 groove, 2.7-mm probe	1 (n = 2)
2.7-mm probe (grooves unknown)	0.6 (n = 1)
3 groove, 2.9-mm probe	4 (n = 7)
2.9-mm probe (grooves unknown)	0.6 (n = 1)
2 groove, 3.7-mm probe	0.6 (n = 1)
3 groove, 3.7-mm probe	7 (n = 12)
5 groove, 3.7-mm probe	63 (n = 107)
8 groove, 3.7-mm probe	0.6 (n = 1)
3.7-mm probe (grooves unknown)	1 (n = 2)
Unknown	21 (n = 36)
Total	100% (n = 171)

UAL, ultrasound-assisted liposuction.

performed such as fat grafting (n = 48), fat injection (n = 42), resurfacing (n = 12), scar revision (n = 11), mastopexy (n = 8), blepharoplasty (n = 8), fat transfer (n = 8), abdominoplasty (n = 6), mammoplasty (n = 5), breast reduction (n = 5), and panniculectomy (n = 5).

Data Analysis

Retrospective data were tabulated on a spreadsheet and patients were divided into 2 groups: one that received only soft tissue coagulation and the other that received both soft tissue coagulation and liposuction. Each of the 2 groups was subdivided into patients with and without adverse events, including seroma. Seroma was analyzed separately.

To compare the 2 subgroups, odds ratios were calculated. For example, we compared the odds of a male experiencing seroma after treatment with the odds of a female having seroma after treatment. In the present study, the odds ratio was 1.35 (see Results), males to females, indicating that males were 1.35 more likely to experience seroma than females. For total adverse events, odds ratios were calculated for both demographic and surgical subgroups.

RESULTS

The mean patient follow-up post-treatment was 3 months (range 1 day to 15 months) postprocedure. No serious adverse events were observed. Forty-six (24.0%) patients reported 51 adverse events (Table 3).

Table 3. Distribution of Adverse Events

Adverse event	No. of patients	No. of events
Blepharitis	1	1
Blood in urine	1	1
Bruising	1	1
Conjunctival edema	1	1
Delayed healing	3	3
Drainage	1	1
Ectropion	1	1
Edema	2	2
Epidermal lysis	2	2
Epiphora	1	1
Erythema	1	1
Fibrosis	2	2
Fullness	2	2
Indentation (small)	1	1
Infected sutures	1	1
Inferior dehiscence	1	1
Lagophthalmos	1	1
Nodule	1	1
Open wound	1	2
Photophobia	1	1
Right capsular contraction	1	1
Seroma	13	17
Skin blister	1	1
Skin dehiscence	1	1
Subcutaneous gas	1	1
Swelling	3	3

Seroma

Seroma was the most frequently occurring adverse event with 13 patients (6.8%) reporting 17 (33.3%) events. In these cases, all areas were treated with both UAL and HPT.

Total Adverse Events

Table 4 presents that among patients treated with both HPT and UAL, those aged 61 to 76 years were more likely to experience an adverse event than patients aged 20 to 60 years (odds ratio 3.10). The same was true for males

Table 4. Distribution of Patients Treated With Helium Plasma Technology (HPT) and Ultrasound-Assisted Liposuction (UAL), With and Without Adverse Events

Variable	No. of patients			Percent with AE	Odds ratio[a]
	No AE	AE	Total		
Demographic					
Age (yrs.)					
20-60	121	27	148	18.2	3.10 (1.22-7.89)
61-76	13	9	22	40.9	
BMI (kg/m^2)					
17.0-30.0	24	8	32	25.0	1.48
≥30.1	102	23	125	18.4	(0.600-3.66)
Gender					
Female	117	26	143	18.2	2.65 (1.10-6.38)
Male	17	10	27	37.0	
Surgical					
Procedure time (min)					
100-300	93	16	109	14.7	1.66 (0.60-4-66)
<100	21	6	27	22.2	
Handpiece (cm)					
27	95	20	115	17.4	2.59 (1.12-6.04)
15	22	12	34	35.3	
Power setting (UAL)					
40-70	119	26	145	17.9	7.63 (1.87-30.89)
>70	3	5	8	62.5	
No. of grooves[a]					
3	15	8	23	34.8	2.46 (0.94-6.47)
5	97	21	118	17.8	
Power setting (HPT)					
60-80	97	24	121	19.8	1.45 (0.61-3.48)
>80	23	7	30	23.3	
Helium flow rate (liters/minute)					
1.5-3.0	93	29	122	23.8	2.10(0.704-6.23)
>3.0	27	4	31	12.9	
No. of passes					
3-6	90	24	114	21.1	1.07 (0.30-3.80)
<3 or >6	12	3	15	20.0	

[a]Odds ratio (95% confidence limits). AE, adverse event.

vs females (odds ratio 2.65). BMI data (odds ratio = 1.48) suggest that patients with BMI ≥ 30.1 were somewhat more likely to experience an adverse event than those with lower BMIs.

Seroma was not observed in patients whose body areas were treated with HPT alone. Adverse events in patients treated with HPT alone (4/21, 19%) were limited to a small indentation in the submental area (n = 1), post-inflammatory fibrosis (n = 2), and delayed healing (n = 1). Patients aged 61 to 76 years (odds ratio = 1.35) were somewhat more likely to experience seroma than patients aged 20 to 60 years. The same was true for males vs females (odds ratio = 1.35). BMI (odds ratio = 1.058) had less influence on the odds of seroma. Seroma was observed in patients whose treated body areas included the abdomen, hips, love handles, thighs, infra-axillary areas, lower face and neck, scapular rolls, and breasts (male and female).

Among surgical variables, the power setting of the UAL had the greatest effect on the odds of experiencing

an adverse event. Patients treated with a UAL power setting greater than 70% (62.5% of patients) were 7.63 times as likely to have an adverse event than those treated at the 40% to 70% power setting range. Odds ratios for other surgical variables were much lower (1.07 to 2.59).

Total adverse events varied considerably with body areas treated. Among lower body areas, 100% of patients treated on the mons (n = 3) experienced adverse events while none of the buttocks-treated patients (n = 13) had adverse events. Less than 20% of patients treated in other areas of the lower body had adverse events. On the upper body, 48% of patients treated in the infra-axillary area had adverse events. In the remaining body areas, the percentage of patients with adverse events ranged from 12.5% to 33.3%.

DISCUSSION

The results show that adverse events in this study are associated with age, UAL setting, and body area treated. The most frequently occurring adverse event was seroma which was observed only in patients treated with both HPT and UAL procedures. In the authors' experience, seroma is more likely to develop with the delivery of more ultrasonic energy from the UAL device. Clinical examples of outcomes are shown in Figures 1 and 2, and the technique is shown in the Video.

Seroma has been described as a subcutaneous exudate fluid.[25] Its formation has been attributed to disruptions of vascular and lymphatic vessels, the creation of dead space, shearing forces between flap and fascia, and inflammation.[25-27] Sforza et al suggest that since the main cause of seroma is inflammation, seroma will always form to some degree in any surgical procedure.[25] They further suggest that the volume of seroma may be reduced by minimizing both lymphatic trauma and the creation of dead space.

Other groups have attributed seroma formation to procedures involving the use of heat and the resulting tissue destruction. Ozdogan et al compared the use of scalpel vs electrocautery dissection on wound complications and pro-inflammatory cytokine levels in patients undergoing modified radical mastectomy.[28] Their study showed that (1) electrocautery resulted in less bleeding and total drain output but a higher rate of seroma formation and (2) electrocautery dissection increased pro-inflammatory cytokine response in wound fluid. They suggested that these effects indicated aggravated inflammation and a greater potential for tissue damage.

This is supported by the 647-patient study of Rousseau et al who reported a higher rate of seromas in abdominoplasty patients treated with Bovie dissection as opposed to scalpel dissection.[29] Swanson who, in their prospective study of 551 cases of liposuction and abdominoplasty performed alone and in combination, reported that electrocautery produced an internal burn, inciting an inflammatory response and leading to capillary permeability, fluid extravasation, and seroma formation.[30]

In a later study, Swanson reported that seromas occur more frequently in mastectomy patients treated with electrocautery than with scalpel dissection, and that limiting undermining reduces the risk of seromas because electrodissection is reduced, resulting in less internal burn injury.[31] Danilla et al, in their study of complications associated with high-definition liposculpture, suggested that postoperative seroma in their study may be due to aggressive liposuction in high-definition areas, transection of the fibrous septum in the superficial fat layer, damage to the lymphatic system during liposuction, and heat produced by energy-based liposuction.[32]

If the HPT has the potential for causing seromas by damaging or ablating lymphatics within the treatment zone, it was not demonstrated in the present study. Our absence of HPT-induced seroma may be due to the rapid cooling of tissue surrounding the HPT treatment site after RF energy application, and that soft tissue coagulation and contraction occur without heating the full thickness of the dermis. As indicated earlier, the low current RF energy results in a minimal depth of thermal effect and prevention of over-treating tissue when performing multiple passes. There is no internal tissue burn, undermining, or dead space, all of which have been associated with seroma formation.[25-27,30,31] Woodworth et al suggested that seroma formation is a result of surgical disruption of lymphatics and capillaries with ensuing leakage of fluid into the dead space created by surgical dissection.[26] If this is true, then IPT does not damage lymphatics and capillaries during treatment.

Seroma is a known and expected risk of UAL and has been associated with UAL procedures.[32-37] Reported rates of seroma range from 0% to 29.9% in studies with up to 1772 patients. In the present study, seroma was noted in 6.8% of 192 patients, which compares with the average rate in the aforementioned studies, 6.9%, in 3968 total patients.

Collectively, the data of both the present study and previous reports confirm that increased energy delivered to tissue by the UAL is associated with increased seroma rates. This is demonstrated in our data with higher UAL power settings greater than 70% resulting in higher incidence of seroma. The authors, therefore, suggest that practitioners use lower power settings or fewer passes, when multiple energy sources are being used for pre-tunneling and aspiration before heat application via plasma on the same tissue, to minimize the likelihood of seroma. Age and body area treated should also be considered.

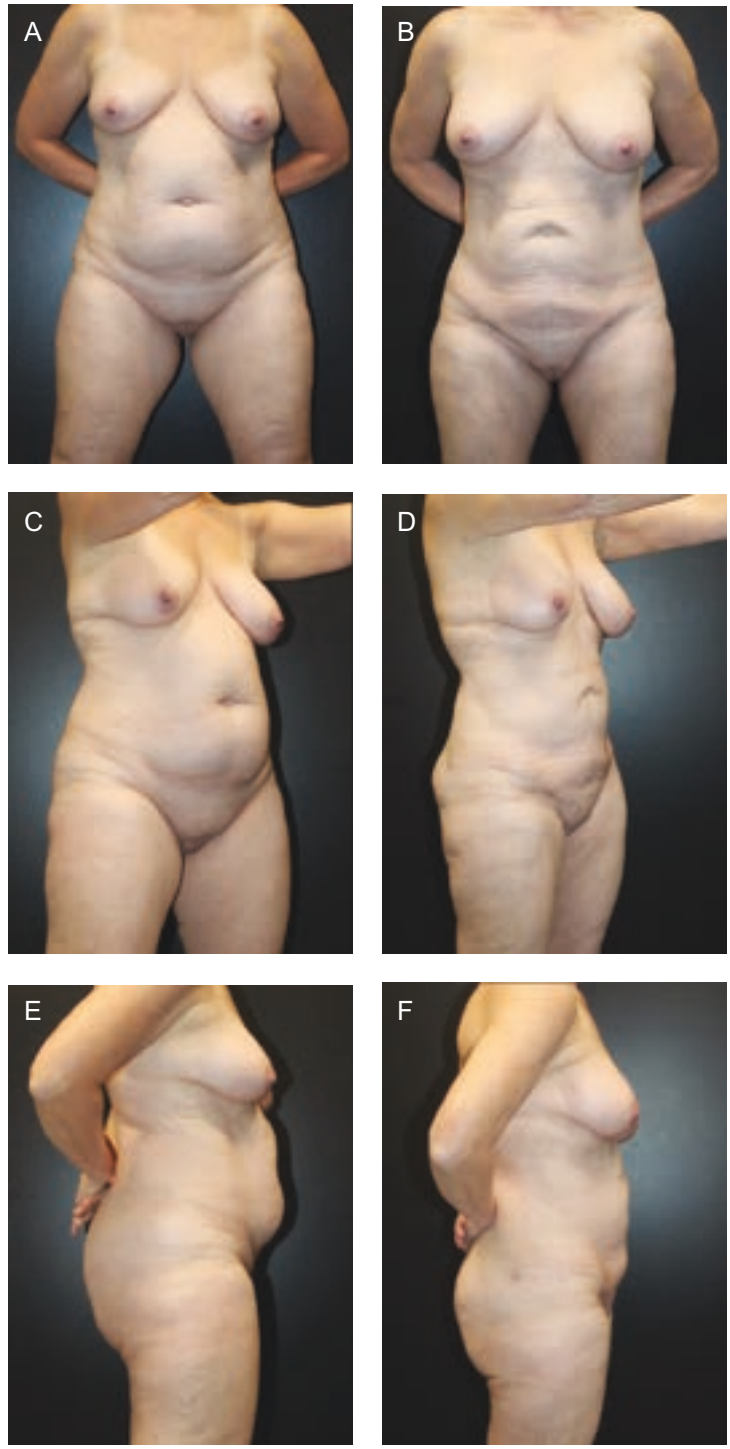


Figure 1. A 51-year-old female who underwent ultrasound-assisted liposuction with helium-based plasma technology on arms, abdomen, flanks, midback, and circumferential thighs: (A, B) front view, preoperative and 8 months postoperative; (C, D) right diagonal view, preoperative and 8 months postoperative; and (E, F) right side view, preoperative and 8 months postoperative. Adverse events were not observed.

The HPT used in the present study is FDA-cleared for the cutting, coagulation, and ablation of soft tissue. The handpiece achieves soft tissue coagulation and contraction by rapidly heating the treatment site to temperatures greater than 85°C for between 0.040 and 0.080 seconds. The tissue surrounding the treatment site remains at much cooler temperatures resulting in rapid cooling after the application of the energy through conductive heat transfer.

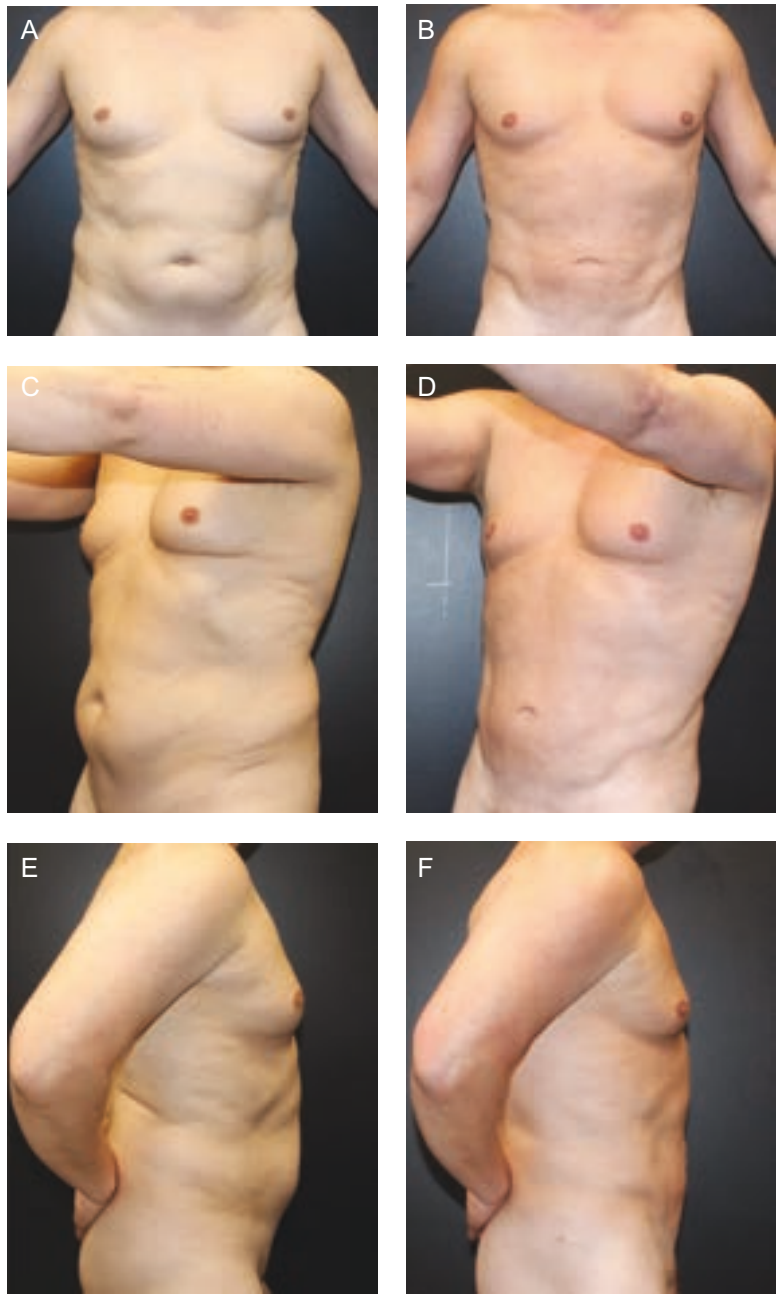
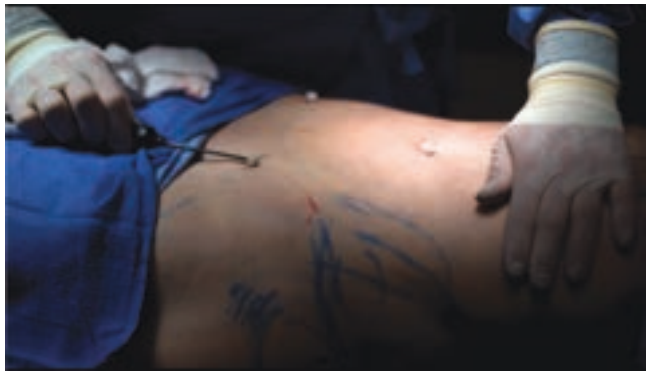


Figure 2. A 51-year-old male who underwent ultrasound-assisted liposuction with helium-based plasma technology on abdomen, flanks, chest, and circumferential thighs: (A, B) front view, preoperative and one year postoperative; (C, D) left diagonal view, preoperative and one year postoperative; and (E, F) right side view, preoperative and one year postoperative. Adverse events were not observed.

Focused delivery of energy on immediate heating of the fibroseptal network results in immediate soft tissue coagulation and contraction without heating the full thickness of the dermis. Since the electrical energy takes the flow of least resistance, the user can perform 360° treatment without having to redirect the flow of energy. The power output of the electrosurgical generator permits unencumbered delivery of power regardless of tissue impedance. The low current RF energy results in minimal depth of thermal effect and prevention of over-treating tissue when performing multiple passes.

Regarding the thermodynamics of living tissue as it relates to the HPT device, Ruff recently quantified and compared the thermal effects of the helium/RF system to a temperature-controlled RF system in a porcine model.[38] The aim was to determine if the percutaneous application



Video. Watch now at http://academic.oup.com/asjopenforum/article-lookup/doi/10.1093/asjof/ojac064

of plasma/RF energy in the subcutaneous space is a safe procedure.

On March 14, 2022, the US FDA published a safety communication related to the use of the Renuvion/J-Plasma device by Apyx Medical for certain aesthetic procedures intended to improve the appearance of the skin through dermal resurfacing or procedures under the skin for the purpose of skin tightening. On June 2, 2022, the FDA published an update to the initial release announcing the clearance of the Renuvion Dermal Handpiece for dermal resurfacing procedures for the treatment of moderate to severe wrinkles and rhytides. In July 2022, the FDA published another update to the safety communication, communicating FDA clearance for the Renuvion APR handpiece for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region.[39]

For the plasma/RF system, energy was applied both in a stationary and a dynamic mode using a 60% and 80% setting. For the temperature-controlled RF system, both a high and low energy/temperature setting (50°C and 75°C) was used. The depth of thermal effects was evaluated histologically for both modalities.

The histological data suggested that the percutaneous application of plasma/RF energy led to the formation of ablative and thermocoagulated zones. No obvious difference in average and maximum depth of the thermal injury was observed between the 2 treatment modalities. An average 54.3% increase in the depth of the thermal effect was observed in the fibroseptal network when increasing generator power settings, and no such effect was observed in the reticular dermis. There were no apparent differences between stationary and dynamic treatments except for a tendency of increased thermal effect in the reticular dermis with the stationary mode at the higher energy setting. For both devices, the depth of thermal effect was higher in the reticular dermis than in the fibroseptal network. The author concluded that the thermal effect of the plasma/RF did not differ significantly from that of the monopolar RF system, suggesting that the percutaneous application of plasma/RF energy in the subcutaneous space is a safe procedure.

Our encouraging results justify prospective randomized controlled trials in which patients are treated with both procedures, alone and in combination, with careful attention paid to age, the effects of "stacking" multiple energy sources, power settings, and areas treated to minimize tissue damage. Additional studies would also include the mean filtration, aspiration, and application times for HPT and UAL. Limitations of this study include its retrospective design, lack of randomization with several devices, data availability during chart review, and difficulties in contour assessment and irregularity review due to the 3-month mean follow-up.

CONCLUSIONS

The use of the HPT for soft tissue coagulation in combination with ultrasound for liposuction is associated with nonserious adverse events. The most frequently occurring adverse event, seroma, was not observed in patients treated with HPT alone.

Supplemental Material

This article contains supplemental material located online at www.asjopenforum.com.

Acknowledgments

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Disclosures

Physicians received site payments for their participation in this retrospective study. Dr Ruff is a medical advisory board member, consultant, and clinical research investigator for Apyx Medical (Clearwater, FL) and receives compensation in the form of Apyx stock and hourly compensation. Dr Vanek is also a consultant for Apyx Medical. Dr Nykiel has no financial relationship with Apyx Medical outside of study funding.

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