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Body Contouring

Safety of Helium-based Plasma Technology for Coagulation of Soft Tissue: A Retrospective Review

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Abstract

Background: The subdermal application of energy using a helium-based plasma radiofrequency (RF) device has been shown to improve skin laxity. Helium-based plasma RF technology (Renuvion; Apyx Medical, Clearwater, FL) utilizes RF to ionize helium into an electrically conductive plasma capable of coagulating and contracting soft tissue with high precision and minimal thermal spread. This study provides information on the early use of the new generation of electrosurgical generator (APYX-RS3) containing a feature that allows for quantification of the amount of energy delivered to tissue during treatments.

Objectives: To collate procedure details, treatment settings, and safety data in patients treated with a helium-based plasma device for soft tissue coagulation.

Methods: A retrospective review was conducted of patients aged ≥ 18 years who underwent treatment with a helium-based plasma RF device (Renuvion) for soft tissue coagulation. Demographic data, procedure details, and adverse events were collected.

Results: Chart review identified 47 patients with an average age of 45 years and an average BMI of 25.8 kg/m^2. The amount of energy (J) delivered per treatment area was greatest for abdomen, buttocks, and thighs, with an average of 13.7 kJ, 13.5 kJ, and 10.6 kJ, respectively. No serious, unexpected, or device-related AEs were reported.

Conclusions: The use of the generator that quantifies the energy (joules) being applied during the procedure allows the provider to understand and optimize their energy usage. While further research is needed to establish the safety and efficacy of the device for skin tightening, this study provides important information regarding energy application.

Level of Evidence: 4

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The practice of applying heat to tissue using cauters has been prevalent for thousands of years as an invaluable method of controlling hemorrhage. Continuous improvements to these methods led to the development of the basic concepts of electrosurgery we know today, and these electrosurgical instruments are used in almost every surgical procedure performed worldwide.[1] Since the 1990s, radiofrequency (RF), laser, and plasma devices have been advocated to heat and cause collagen to contract.[2–7] Between 60°C and just

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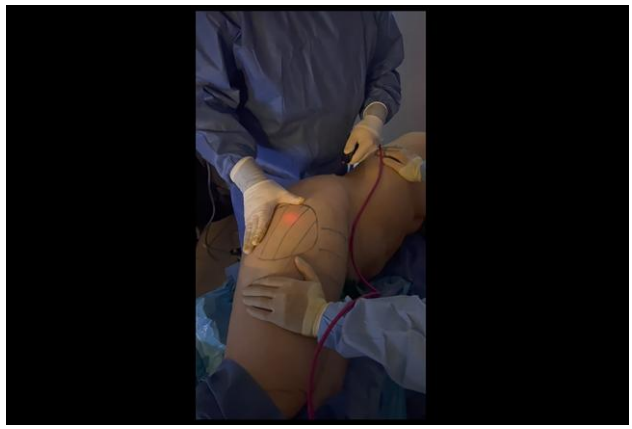
below 100°C, protein denaturation leading to coagulation occurs, as well as dehydration, as the cells lose water through the thermally damaged cellular wall. If temperatures reach 85°C for approximately 0.08 seconds, this is long enough to achieve maximal contraction.[8] As the temperature rises above 100°C, this intracellular water turns into steam, and the tissue cells begin to vaporize. At temperatures of 200°C or more, organic molecules are broken down through carbonization leaving behind carbon molecules that give a black and/or brown appearance to the treated tissue.[1]

Understanding these heat effects of RF energy on cells and tissue can allow the predictable changes to be used to accomplish beneficial therapeutic results. For instance, protein denaturation leading to soft tissue coagulation is one of the most versatile and widely utilized tissue effects. The coagulation/denaturation temperature of collagen is conventionally stated to be 66.8°C.[9] Once denatured, collagen rapidly contracts to one-third of their overall length.[10] This contraction results in a reduction of volume and surface area of the heated tissue. The majority of the soft tissue contraction is due to the effects the helium plasma energy have on the fibral septal network, so maximizing the energy flow could expedite the contraction process.

The subdermal application of energy using a helium-based plasma RF device has been shown to improve skin laxity. A helium-based plasma device (Renuvion; Apyx Medical Corporation, Clearwater, FL) has been cleared by the US FDA for cutting, coagulation, and ablation of soft tissue (K191542). On July 15, 2022, 510(k) clearance was received for the use of Renuvion in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region. Helium-based plasma RF technology (Renuvion) utilizes RF to ionize helium into an electrically conductive plasma capable of coagulating and contracting soft tissue with high precision and minimal thermal spread. This use of thermal-induced collagen/tissue contraction has been expanded to minimally invasive procedures. Laser-assisted lipolysis and RF-assisted lipolysis devices have combined the removal of subcutaneous fat with soft tissue heating to reduce the skin laxity that often results from fat volume removal.

Current guidance for the use of this helium-based RF device relies solely on the number of passes administered to the treatment area. A pass being each time the provider uses the handpiece to administer energy to the indicated treatment area. The recommended technique is to use a treatment speed of 1 cm per second at 60%-80% power to produce soft tissue coagulation and contraction without applying unnecessary heat and maintaining temperatures of less than 47°C, which are safe for epidermal application.[2] This would result in patients with skin types I-IV being treated, on average, with 3 passes epidermally.[11,12] Another study found that when undergoing subdermal treatment, patients could be treated with between 2 and 11 passes per treatment session and in conjunction with ultrasound-assisted liposuction without any serious adverse events (AEs) being observed.[13] A clinical example of a patient procedure can be found in the Video 1.



Video 1. Watch now at https://academic.oup.com/asj/article-lookup/doi/10.1093/asjof/ojac081.

This study utilized the APYX-RS3 (Renuvion) electrosurgical generator, which contains a feature that allows for the quantification of the amount of energy delivered to tissue during treatments. The primary objective of this retrospective review was to collate procedure details, treatment settings, and safety data in patients treated with a subdermal helium-based plasma RF device for soft tissue coagulation with or without concurrent procedure(s) utilizing the new generation of the electrosurgical generator unit.

METHODS

A retrospective chart review of procedures performed by the principal investigator (PI) in which a helium driven plasma device was used for the coagulation of soft tissue. This study was conducted with a waiver of consent granted by Sterling IRB. The electronic medical records of a single medical clinic were reviewed to identify eligible subjects. Eligible subjects were males and females aged ≥18 years who underwent a procedure in which a helium-based plasma RF device was used for soft tissue coagulation using the APX-RS3 Generator between February 2020 and December 2020. Patients who are candidates for treatment utilizing Renuvion are those with apparent skin laxity but that do not require excisional surgery to address their skin laxity in the opinion of the investigator. All other patients would not be considered candidates for this procedure, would not be offered this as a treatment option, and therefore would have been excluded from this retrospective study. The helium plasma portion of the generator contains a new feature that allows for quantification of the amount of energy delivered to tissue during treatments. All patients underwent either a combination of suction-assisted

liposuction (SAL) and helium-based plasma RF device or helium-based plasma RF device only (no liposuction). Subjects not meeting these criteria were excluded.

A 1:1 (50 cc of 1% lidocaine +0.5 cc of 1 mg/mL epinephrine [1:1000]) infiltrate mixture was utilized for all treatments. Undermining was performed by cannula in 100% of the patients ($n = 47$). The PI applied the recommended technique of treating 1-1.5 cm of tissue per second with retrograde activation at device settings between 60% and 80% power and within a helium flow rate range of 1.5 liters per minute (LPM) and 3.0 LPM. Passes were radially oriented from the access port site with approximately 2-2.5 cm of distance between each radial pass.

All subjects were required to use compression garments for approximately 23 hours a day for the first week post treatment followed by 18 hours a day for the second week. Drains are not used postoperatively for these procedures. Subjects were seen per site standard of care for posttreatment follow-up (mean 6 months; range 2 weeks to 15 months post procedure).

Following the identification of eligible patient charts, study data were de-identified and documented. Demographic data were collected, including sex, age, and BMI. Procedure details were collected, including area of device application, volume of tumescent, cannula size, handpiece size, and volume of aspirate. Treatment settings were collected, including power as percentage, helium flow (L/min), number of device passes, and amount of energy delivered (J). Expected treatment effects (ETEs), AEs, and follow-up period were also recorded. Subject data generated after chart review were then summarized into 18 subsections (Body Areas Treated with Liposuction and Renuvion, Body Areas Treated with Renuvion-Only, Body Areas Treated with Liposuction-Only, Follow-Up Period, Volume of Tumescent for Renuvion Procedures, Average Volume of Tumescent for Renuvion Procedures by Body Area, Cannula Size Used for Undermining, Distribution of Average Power Settings by Body Area, Distribution of Average Helium Setting by Body Area, Distribution of Average Number of Passes by Body Area, Distribution of Average Energy Applied by Body Area, Renuvion Handpieces, Distribution of Handpiece Used by Body Area, Total Aspiration for SAL Procedures in Conjunction with Renuvion, Average Volume of Aspirate for SAL Procedures in Conjunction with Renuvion by Body Area, Summary of Expected Treatment Effects (ETEs) for Areas Treated with Renuvion, Summary of Procedure-Related Adverse Events for Areas Treated with Renuvion, Summary of Procedure-Related Adverse Events for Areas Not Treated with Renuvion).

RESULTS

Chart review identified 47 patients (39 females and 8 males) who underwent a total of 68 treatments with helium-based plasma RF technology. Patients had an average age of 45 years (range, 20-67 years) and an average BMI of 25.8 kg/m^2 (range, 19.7-36.6 kg/m^2). The most common treatment areas were the arms (19.1% of treatments) and the neck (16.2%) followed by the flanks (14.7%), abdomen (11.8%), and upper back (11.8%).

Most patients (38%, $n = 18$) were treated with a volume of tumescent between 1001 cc and 2000 cc, followed by 30% ($n = 14$) of patients treated with a volume of tumescent less than 500 cc. The average volume of tumescent for helium-based plasma RF device treatments by body area was greatest (1275 cc) for the abdomen, followed by the thighs (1257 cc), buttocks (1025 cc), and gynecomastia (900 cc). The average volume of tumescent for helium-based plasma RF device procedures by body area was lowest for the axilla (100 cc), knees (300 cc), and neck (248 cc).

A 3 mm cannula was used for undermining for 60% ($n = 28$) of patients. Of the remaining, undermining was conducted with a 2.4 mm cannula in 19% ($n = 9$) of patients, 19% ($n = 9$) with a 4 mm cannula, and 2% ($n = 1$) were treated with an unknown size cannula. Most patients underwent SAL (92%, 43/47), and four patients (9%) had no liposuction treatment. The majority of patients (62%, $n = 29$) were treated using a 27 cm J-Plasma/Renuvion Precise Handpiece (Renuvion), and the remaining 38% ($n = 18$) were treated using a 15 cm J-Plasma/Renuvion Precise Handpiece (Renuvion).

The average generator settings for all procedures were 70% power (range 60%-80%) and 1.5 LPM of helium flow (range 1.5-2). The distribution of average power setting by body area is greatest at 75% for the arms, buttocks, chest side wall, and gynecomastia, followed by 70% for the abdomen, flanks, knees, thighs, and upper back, and 65% for the axilla and neck. The distribution of average helium settings by body area is 1.5 LPM for all treated areas.

Most body areas were treated with an average number of 6 passes. The exceptions, gynecomastia and axilla were treated with an average of 5 passes, and the neck was treated with an average of 4 passes. The overall average of 9.2 kJ (range 0.6-18 kJ) of energy was applied. The average amount of energy delivered per treatment area was greatest for abdomen (13.7 kJ), buttocks (13.5 kJ), and thighs (10.6 kJ) and lowest for axilla (1.9 kJ), chest side wall (4), and upper back (6.4 kJ) (Table 1).

When comparing the average energy applied by body area of female patients to male patients, the abdomen and neck have similar average energy applied outputs despite differences between the average BMIs. Female patients who had their abdomen treated ($n = 6$) had an average BMI of 24.6 (range 20.3-28.3), and the average energy applied was 14.5 kJ (range 9.2-18 kJ) with a SD of 3.8 (Table 2). Male patients who had their abdomen treated ($n = 2$) had an average BMI of 29.1 (range 27.8-30.4), and the average energy applied was 14.8 kJ (range 12.7-17 kJ) with a SD of 3.1 (Table 3). Female patients who had their

Table 1. Distribution of Average Energy Applied by Body Area

Body area	Average (kJ)	Range (kJ)
Abdomen ($n = 8$)	13.7	7.8-18
Buttocks ($n = 2$)	13.5	12-15
Thighs ($n = 7$)	10.6	6.7-15.5
Flanks ($n = 10$)	9.6	3.2-17
Gynecomastia ($n = 2$)	7.5	6.1-9
Arms ($n = 13$)	7.4	3.2-12.5
Knees ($n = 2$)	7.3	6.3-8.4
Neck ($n = 11$)	7.1	3.2-8.7
Upper back ($n = 8$)	6.4	4.3-10
Chest side wall ($n = 1$)	4	NA
Axilla ($n = 4$)	1.9	0.6-4

Table 2. Demographics and Distribution of Average Energy Applied by Body Area: Female

Body area	Average BMI	Average energy applied (kJ)	Standard deviation
Abdomen ($n = 6$)	24.6 (range: 20.3-28.3)	14.5 (range: 9.2-18.0)	3.8
Arms ($n = 12$)	26.4 (range: 20.3-36.6)	11.0 (range: 5.7-16.0)	3.5
Axilla ($n = 3$)	25.5 (range: 22.4-29.9)	2.5 (range: 1.0-4.0)	2.1
Breast ($n = 1$)	22.4	3.0	NA
Buttocks ($n = 2$)	24.2 (range: 23.8-24.6)	13.5 (range: 12.0-15.0)	2.1
Flanks ($n = 8$)	25.6 (range: 20.3-32.0)	8.7 (range: 3.1-12.5)	3.0
Knees ($n = 2$)	24.6 (range:20.6-28.6)	7.3 (range: 6.3-8.4)	1.5
Neck ($n = 7$)	23.1 (range: 20.3-26.1)	7.0 (range: 3.2-8.4)	1.9
Thighs ($n = 7$)	24.5 (range: 19.7-28.6)	10.6 (range: 6.7-15.5)	3.0
Upper back ($n = 9$)	24.8 (range: 20.3-29.5)	6.4 (range: 4.3-10.0)	1.7

neck treated ($n = 7$) had an average BMI of 23.1 (range 20.3-26.1), and the average energy applied was 7.0 kJ (range 3.2-8.4 kJ) with a SD of 1.9 (Table 2). Male patients who had their neck treated ($n = 4$) had an average BMI of 28.3 (range 22.9-30.4) and the average energy applied was 7.3 (range 6.0-17.0) with a SD of 1.1 (Table 3).

No serious, unexpected, or device-related AEs were reported. Of the 213 total events reported, 190 were ETEs, 23 were deemed procedure related, 20 were anesthesia-related nausea, and 1 was related to a concomitant procedure that did not utilize treatment with the helium-based plasma RF device (Table 4). The remaining 2 AEs were related to known side-effects of the procedure and both resolved within 10 days of the treatment date and had no lasting effects on the patients (Table 5). ETEs are any typical treatment side-effect of the Apyx Plasma RF handpiece of mild to moderate severity and lasting up to a typical maximum duration, whereas an AE is any new problem, or the exacerbation of an existing problem,

Table 3. Demographics and Distribution of Average Energy Applied by Body Area: Male

Body area	Average BMI	Average energy applied (kJ)	Standard deviation
Abdomen ($n=2$)	29.1 (range: 27.8-30.4)	14.8 (range: 12.7-17.0)	3.1
Arms ($n=1$)	26.5	17.0	NA
Flanks ($n=2$)	29.1 (range: 27.8-30.4)	13.0 (range: 9.0-17.0)	5.7
Gynecomastia ($n=2$)	30.3 (range: 30.1-30.4)	7.5 (range: 6.1-9.0)	2.1
Neck ($n=4$)	28.3 (range: 22.9-30.4)	7.3 (range: 6.0-17.0)	1.1

Table 4. Summary of Expected Treatment Effects for Areas Treated With Renuvion (Apyx Medical Corporation, Clearwater, FL)

Expected treatment effect	No. of ETEs reported ($n=190$)	No. of subjects reporting ETE ($n=47$)
Discomfort/pain/ tenderness	$n=47$ (24.7%)	$n=47$
Ecchymosis/bruising	$n=47$ (24.7%)	$n=47$
Edema/swelling	$n=47$ (24.7%)	$n=47$
Erythema	$n=3$ (1.2%)	$n=3$
Temporary reduction of nerve sensation	$n=47$ (24.7%)	$n=47$

ETE, expected treatment effect.

experienced by the subject while enrolled in the study whether considered device-related by the investigator or not. ETEs reported were discomfort/pain/tenderness ($n=47$), ecchymosis/bruising ($n=47$), edema/swelling ($n=47$), erythema ($n=3$), and temporary reduction of sensory nerve sensation ($n=47$). Procedure-related AEs reported for areas treated with Renuvion were nausea ($n=20$), motor nerve injury ($n=1$), and subcutaneous induration ($n=1$). Procedure-related AEs reported for areas not treated with Renuvion were abscess/infection ($n=1$).

DISCUSSION

Based on the literature, by gaining an understanding of the heat effects of RF energy on cells and tissue can allow the predictable changes to be used to accomplish beneficial therapeutic results. Most commercially available RF devices work on a principle of bulk tissue heating where the subdermal temperature around 65°C is maintained across the entire volume of tissue.[2] Although the bulk tissue heating

Table 5. Summary of Procedure-Related Adverse Events Treated With Renuvion (Apyx Medical Corporation, Clearwater, FL)

Adverse event	No. of AEs reported ($n=22$)	No. of subjects reporting AE ($n=22$)
Nausea[a]	$n=20$ (90%)	$n=20$ (90%)
Motor nerve injury	$n=1$ (5%)	$n=1$ (5%)
Subcutaneous induration	$n=1$ (5%)	$n=1$ (5%)

AE, adverse event. [a]Anesthesia-related.

has been found to result in soft tissue contraction, the process (heating the tissue to 65°C for a minimum of 120 seconds) can be time consuming and potentially harmful to the epidermis if heat conduction causes temperatures to surpass safe levels.[14] This process is not conducive to a surgical procedure where timing is important.

Helium plasma devices heat tissue differently by bringing the treatment location to temperatures of 85°C or more for approximately 0.08 seconds, achieving maximal contraction but maintaining cooler temperatures in the surrounding tissue.[2] Previous research has shown that helium plasma device settings between 60% and 80% power produce soft tissue coagulation and contraction because it rapidly heats the treatment site to 85°C or greater. This process expedites the treatment from what it was, but it still requires the surgeon to treat the area at 1 cm per second which can be tedious and take up a lot of time. This highlighting the need for further standardization of this energy application within parameters deemed safe to expedite the process and see more consistent outcomes.

To our knowledge, this is the first report to describe energy dose (kJ) per treatment area as a metric for administering helium-based plasma technology in clinical practice. The ability to quantify energy applied during a treatment allows the provider to better understand and, therefore, optimize their energy usage during treatment by adjusting their technique to improve the efficiency of the device. This quantification could also provide an additional safety component to treatment. By studying how much energy is applied to the various body areas in practice and then tracking the AEs, ETEs, and/or absence thereof, that result, you could reduce the possibility of damaging the treated area. With this report and further research on energy dose administered during helium-based plasma RF treatments, there is a potential for standardization by body area treated. The standardization of energy doses could help guide the development of effective treatment protocols and lead to achieving consistent outcomes.

The results of this study show that, although various body areas were treated, most of the helium-based plasma technology treatments performed (60.3%) were done so at

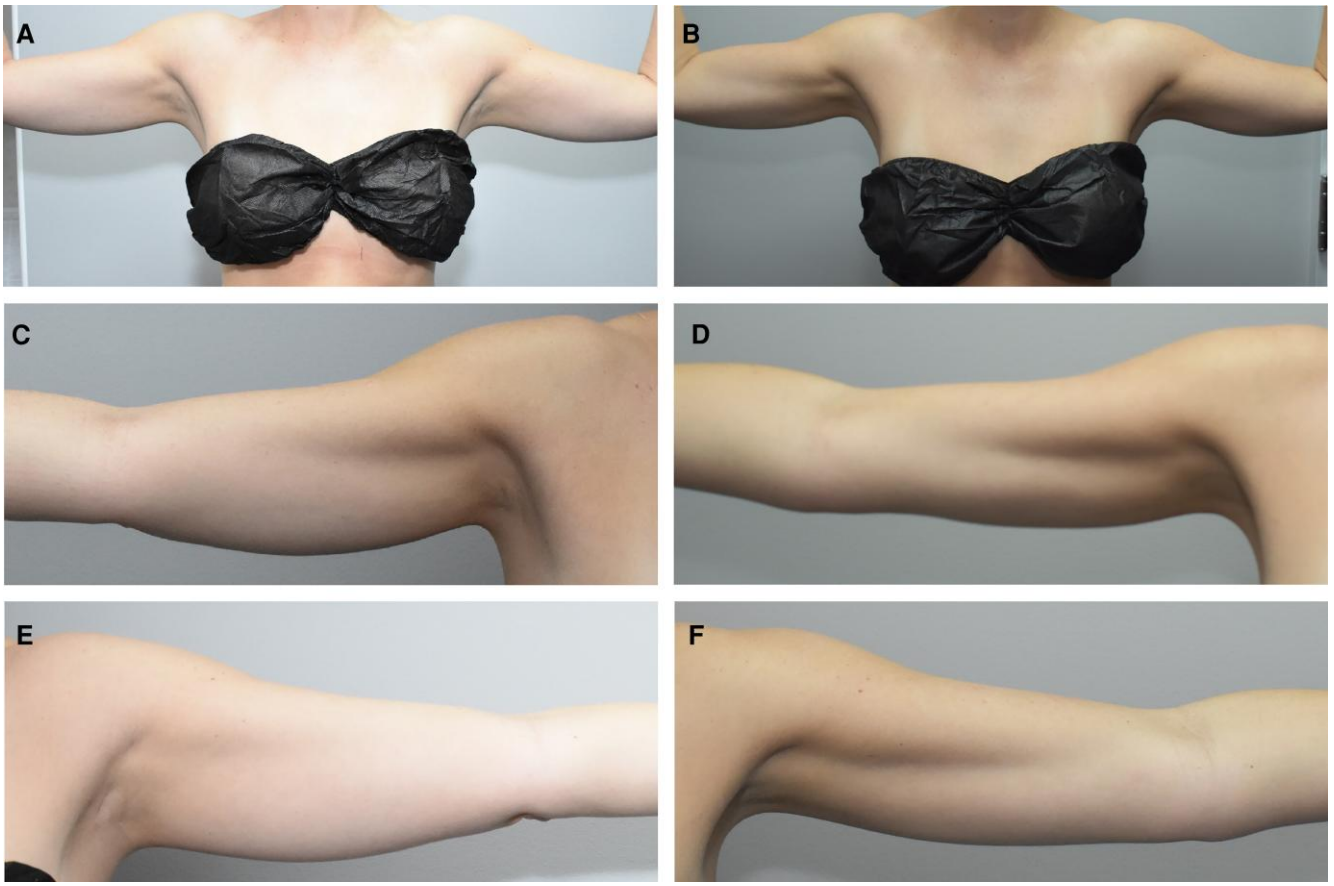


Figure 1. A 35-year-old female patient who presented with a chief complaint of excess fat and laxity of the bilateral upper arms, who underwent liposuction with Renuvion/J-Plasma (Apyx Medical, Clearwater, FL) to the bilateral upper arms. Photos taken (A, C, E) prior to the procedure and (B, D, F) at 7 months postoperative.

75% power, with a helium flow rate of 1.5 LPM and with 6 passes completed. Compared to the helium flow rate and number of passes, the power setting (range 60%-80%) and energy applied (range 0.6 kJ-18 kJ) are less consistent across the various body areas and subjects being treated. Further research focused on the individual body areas being treated and/or with a larger subject pool per body area being treated with helium-based plasma RF technology could lead to a body area specific standardization of treatment protocols.

The helium-based plasma RF device that was utilized in this study uses a low current RF energy which results in minimal depth of thermal effect and prevents the tissue from being over-treated when performing multiple passes. The APYX-RS3 electrosurgical generator that was utilized in this study allows for the quantification of the amount of energy delivered to the tissue. These factors add to the number of controlled variables a physician has and the amount of information a physician has access to while performing a treatment using a helium-based plasma RF device. The ability to control or predict variables and/or changes in variables during treatment could benefit results.

Furthermore, the results of this study show that there were no helium-based plasma RF device–related AEs when used for treating skin laxity regardless of body area. The results also showed that despite the increase in average energy applied to different body areas, the abdomen (13.7 kJ) and the neck (7.1) for instance, there was no increase in the number of AEs between these body areas. The ETEs and AEs that were unrelated to the helium-based plasma RF device, but were related to the procedure, anesthesia, or a concomitant procedure all resolved and had no lasting effects on the patients. The ability to continue performing treatment using helium-based plasma RF technology without causing lasting harm to patients is pertinent for this research to continue as well.

This retrospective study was limited by the amount of information available at a single site at the time of this chart review. Patient satisfaction, quantitative data of the reduction of skin laxity, and quantitative data of energy administered per body surface area were not captured and

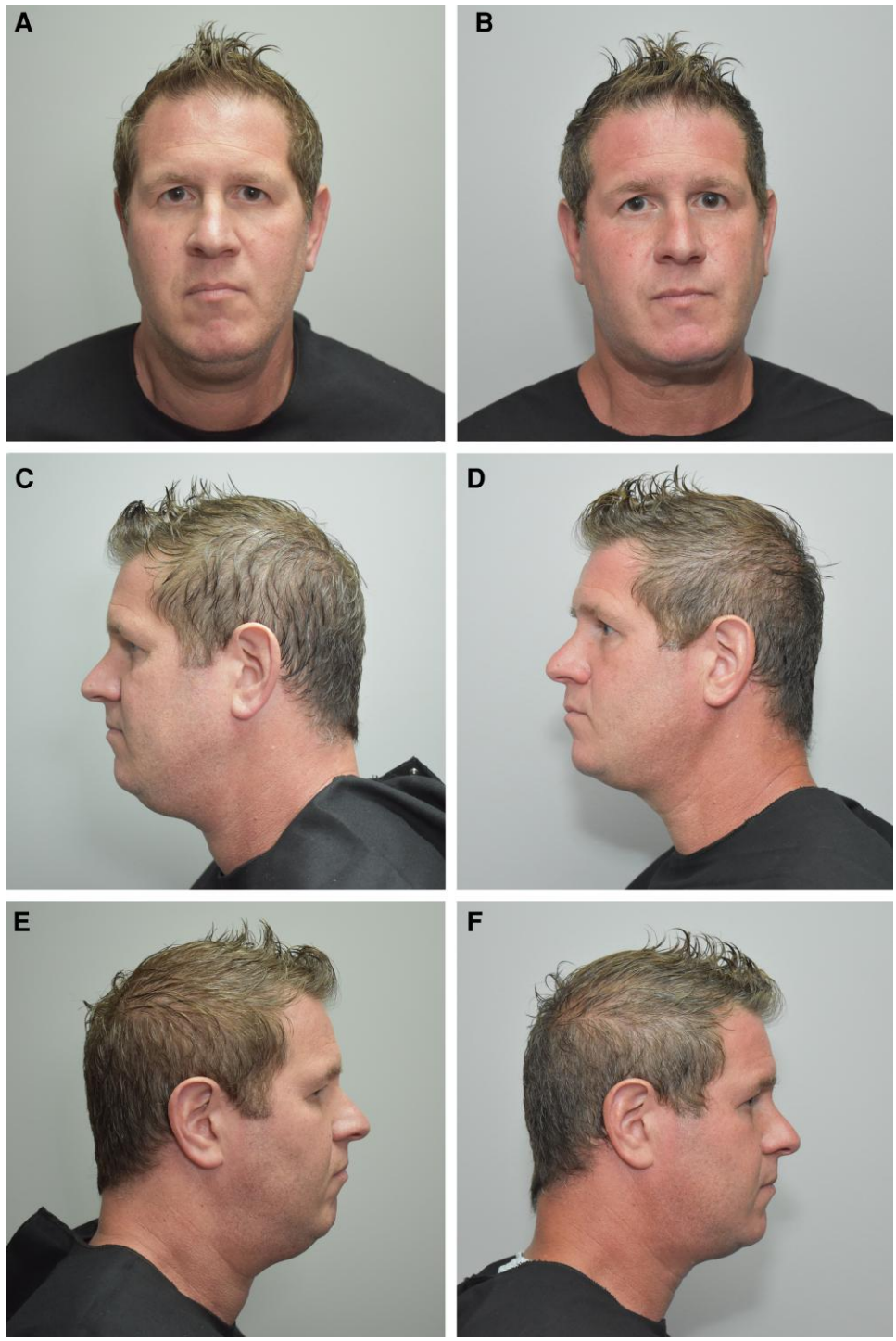


Figure 2. A 53-year-old male patient who presented with a chief complaint of submental fullness and laxity, who underwent liposuction of submental chin and bilateral jawline, and Renuvion/J-Plasma (Apyx Medical, Clearwater, FL) to bilateral neck and jawline. Photos taken (A, C, E) prior to the procedure and (B, D, F) at 6 months postoperative.

therefore are not represented in the results of this retrospective study. This study is also limited by the small sample size as it was conducted at a single site within a single surgeon's patient population.

Although the results of this study are beneficial in furthering guidance for the safe and effective use of helium-based plasma RF technology, additional research is required. Prospective, multicenter research with a larger sample size would address

the limitations and weaknesses seen in this retrospective chart review and would be beneficial to determine the amount of energy required, when treating with the Renuvion handpiece, to obtain effective results safely. Clinical examples of patient outcomes can be found in Figures 1 and 2.

CONCLUSIONS

In the author's opinion, when compared to a nonenergy-based suction-assisted lipectomy technique, liposuction in conjunction with HPRF leads to improved clinical outcomes, increased skin tightening, dermal thickening, and skin quality improvement. The primary surgeon finds that the heat-based contraction effect is superior to stand alone scarification which occurs with traditional liposuction modalities included power assisted liposuction. Finally, the primary surgeon notes that patients who traditionally would have been deemed necessary to undergo a secondary skin excisional procedure often requires a less aggressive excisional approach, or no skin excision at all.

Preliminary evidence from this study indicates that helium-based plasma RF technology is well-tolerated and unaccompanied by AEs when used for treating skin laxity in various regions of the body. This knowledge accompanied with the standardization of energy doses could help guide the development of effective treatment protocols and, ultimately, may be important for achieving consistent outcomes. Further research and formal clinical studies are needed to establish the safety and efficacy of helium-based plasma RF devices for skin tightening and to inform best practice guidelines.

Supplemental Material

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

Disclosures

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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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.*