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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.

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A Single-site Postmarket Retrospective Chart Review of Subdermal Coagulation Procedures with Renuvion

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Summary: Although tumescent liposuction provides debulking of body areas with excess subcutaneous fat and concurrent skin laxity, the ability to shrink and redrape the skin and soft tissue for added definition has remained an elusive goal. Many modalities employed to facilitate fat removal utilizing light energy, ultrasonic energy, or radiofrequency energy have provided modest skin shrinkage. Apyx Medical's (formerly Bovie Medical) Renuvion (previously branded as J-Plasma) has Food and Drug Administration clearance for the cutting, coagulation, and ablation of soft tissue. The objective of this retrospective chart review was to collect safety and procedural information for patients who have previously undergone liposuction with which Renuvion was used as a tool for subdermal coagulation. All procedures occurred before August 2018. Thirty-two patients were identified (3 male and 29 female). The mean follow-up was 6 months (range, 3–8 months). None of the patients required a revision or secondary procedure suggesting 100% of patients had acceptable final outcomes. No device-related adverse events or complications were noted, suggesting that within this data set, Renuvion's unique cool helium plasma technology can safely be used for skin contraction with or without tumescent liposuction or supplemental modalities used to facilitate fat removal that may otherwise contribute to the skin contraction. *(Plast Reconstr Surg Glob Open 2019;7:e2502; doi: 10.1097/GOX.0000000000002502; Published online 19 November 2019.)*

INTRODUCTION

Multiple technologies have aimed at creating skin tightening to further improve body contouring after liposuction. The debulking of fat with suction-assisted liposuction has been shown to provide approximately 10% shrinkage as a result of a simple deflation effect on the skin envelope and non–thermal inflammation of the fibrocollagenous matrix that in turn generates new blood vessels, collagen, and scar tissue.[1] The application of radiofrequency (RF) energy to the subcutaneous layer has resulted in a surface area reduction at 1 year of about 26% by contracting the dermal collagen fibers.[2] Duncan[2] has proposed that skin laxity that occurs as a loss of binding to underlying fascia and between the deep and superficial fat compartments can be improved by targeting the fibroseptal network (FSN) or interstitial connective tissue. Apyx Medical's Renuvion (Clearwater, FL) cool helium plasma RF technology has been adapted to draw skin closer to underlying fascia via coagulation of the interstitial connective tissue bands. In the Renuvion system, RF energy from an electrosurgical generator unit is delivered to a hand-piece and used to energize an electrode. Helium plasma is generated as helium gas passes over the energized electrode, allowing heat to be applied to tissue in 2 different and distinct ways. The plasma beam provides heat through the ionization and rapid neutralization of helium atoms. A portion of RF energy that passes through the tissue impedance generates a small amount of additional heat, a process known as "Joule heating." In other words, soft-tissue coagulation and contraction are occurring via rapid heating, and rapid cooling by conductive heat transfer to surrounding tissue by unionized helium. With each stroke of the Renuvion device, the RF energy encounters tissue with varying impedance and will continuously change paths of heat transfer. There is minimal depth of thermal effect and prevention of overtreating tissue even with multiple passes while maximizing treatment of untreated tissue. In addition, as electrical

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energy takes the path of least resistance, the user does not need to redirect the hand-piece and tissue is treated in 360°.[3] This is in contrast to "bulk-heating" devices that use a radial pattern of heat from the probe tip which may create "hot spots" resulting in seromas, in surrounding areas with insufficient heating. The generator for the Renuvion device maintains a constant power output regardless of tissue impedance. Tumescence lowers tissue impedance without resisting heating.[1] **(See** Video **1 [online],** which displays the animated Renuvion method of action.) **(See** Video **2 [online],** which displays more animation of the Renuvion method of action.) **(See** Video **3 [online],** which displays real-time use of Renuvion in surgery.)

The primary objective of this retrospective chart review was to collate safety and procedural information on patients who have undergone subdermal coagulation procedures with the Renuvion system. A retrospective chart review was well suited for the latency between skin contraction effect occurring as a biologic healing and exposure to this technology. This review has demonstrated the feasibility of more investigation, adequacy of measured variables, methodologic pitfalls, and clarifies necessary data abstraction.

STUDY DESIGN

A retrospective Electronic Medical Record chart review was conducted to identify patients who had undergone subdermal coagulation procedures with the use of Renuvion from a single surgeon's institution from November 2017 to August 2018. Inclusion criteria included male and female subjects ≥21 years of age who had undergone a liposuction procedure in conjunction with the use of Renuvion as a tool for subdermal coagulation. Institutional review board approval was obtained, and deidentified information was collected on the following patient demographic variables: sex, age, body mass index, and comorbidities. Surgical variables included were as follows: concomitant procedures, aspiration process, intraoperative complications, generator settings (power as percentage, helium flow as liters per minute [lpm]), surgical technique details (number of Renuvion passes), and areas treated. Outcome variables assessed include the following: length of follow-up, postoperative adverse events/complications through follow-up. The sample size was not statistically powered and is a sample size of convenience only. The data were summarized in descriptive measures only.

RESULTS

Mean patient follow-up was 6 months (range, 3–8 months) postprocedure. There were 29 female (90.6%) and 3 male (9.4%) subjects with a mean age of 48 years and a mean body mass index of 27.5 (range, 19.7–38.6). An internal ultrasound (VASER, Solta Medical, Bothell, WA)-assisted liposuction was employed in all patients. Areas of the body treated include neck, arms, female breast, abdomen, hips or love handles, scapular rolls, infra-axillary, buttocks, outer thigh, inner thigh, and lower legs (Fig. 1). The distribution of Renuvion settings and number of passes is given in Table 1. No intraoperative complications occurred, and of the 32 patients, no serious, unexpected, or device-related adverse events were noted.

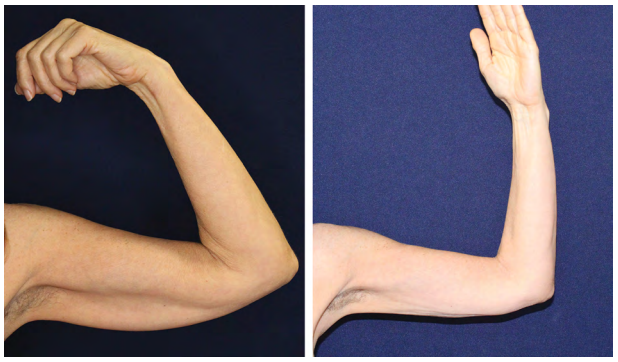

Fig. 1. Example of patient results. A 61 year old woman, 5.5 months postoperatively, demonstrates long lasting soft tissue contraction after VASER liposuction (2.5 minutes, 60% amplitude, continuous energy, 5 ring probe) with 125 cc aspirate, followed by Renuvion subdermal coagulation (50% power, 4 lpm, 6 passes).

DISCUSSION

One of the most conspicuous signs of aging, skin laxity has been characterized by weakening of the FSN between muscle and skin and by the loss of dermal elastic recoil.[4] Several technologies including laser, ultrasound, and RF have demonstrated some skin tightening after liposuction beyond the normal deflation that accompanies the removal of fat and beyond the non–thermal skin contraction that accompanies subdermal inflammatory stimulation by the cannulas.[2] Of these, RF has been shown to provide the greatest contraction, as stromal collagen is heated quickly to 85°C causing a reduction of fiber length of 40%–50%.[1] The mechanisms of action for percutaneous and subcutaneous RF devices include the generation of heat through tissue resistance within the dermis and fat that results in neocollagenesis, elastin and dermal matrix remodeling, and mild adipocyte loss.[4] The contraction of the FSN by deeper application of cool helium plasma RF technology is felt to be an additional mechanism that results in additional body contouring by soft-tissue contraction. In a preclinical study, the use of a Forward-Looking Infrared Radiometer system to monitor surface temperatures directly under the Renuvion hand-piece, and adjacent tissue, suggested that the fatty layers are disrupted and skin is drawn closer to the underlying fascia. Internal and external tissue temperatures were monitored in porcine studies utilizing tumescent liposuction before treatment with the Renuvion device. They demonstrated maximum soft-tissue coagulation and contraction, with

Table 1. Renuvion Settings

Power (%)	Helium Flow	No. Passes	No. Patients
50	4	6	2
60	2	6	8
60	4	6	18
80	2	6	1
80	2	8	3

adjacent tissue cooling and tissue heat transfer, thereby obviating the need for constant temperature monitoring.[3]

As with all retrospective chart reviews, limitations exist in the data collection. These include use of a single-site, small sample size, collection of variables not routinely captured in the patients' records (eg, separation of lipoaspirate volumes of fat from tumescence), and depth of the passes was not quantified.

CONCLUSIONS

In this surgeon's practice, Apyx Medical's Renuvion system appears to be safe and effective in the short term with limited side effect profile. The body of evidence on the use of Renuvion is limited because of the nascence of the technology; however, the use of Renuvion is promising in plastic and cosmetic surgery and is grounded in established principles for enhanced body contouring. The efficacy of this new modality in areas that have been previously treated with this or other skin tightening techniques may shed some light on the limits of skin contraction that can be achieved. This review provides clinically relevant data, serves as a framework for future prospective studies including formal assessment of patient satisfaction, and guides the development and applications of this unique technology.

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