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Body Contouring

# Expansion of Renuvion Application to Areas Beyond the Submental Region: Review and Experience

Cassandra R. Driscoll, MD; Amelia L. Davidson, BS; Matthew N. Marturano, MD; Bill G. Kortesis, MD; and Gaurav Bharti, MD

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## Abstract

**Background:** Minimally invasive and consistent skin redraping following liposuction remains an elusive goal. With the application of Renuvion (Apyx Medical, Clearwater, FL), helium induced cold atmospheric plasma provides coagulation, collagen contraction, and subsequent skin tightening, making this elusive goal attainable.

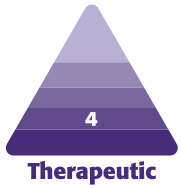
**Objectives:** The objective of this study is to evaluate energy settings, and the safety profile of Renuvion in an effort to achieve optimal cosmesis through the improvement of skin laxity.

**Methods:** A retrospective review at a single site evaluated cases of Renuvion between March 2020 and May 2022. Energy settings, use of concomitant VASER (Solta Medical, Bothwell, WA) liposuction frequency, and adverse events were analyzed.

**Results:** In total, 180 patients were evaluated, of whom 135 (75%) underwent concomitant VASER liposuction. Renuvion was used on the abdomen (47.8%), thighs (45.6%), arms (27.2%), submental region (25%), hip rolls (21.2%), and back (19.4%). Among the entire cohort, there were a total of 24 (13.3%) complications. The complications consisted of 3 (12.5%) hematomas, 1 (4.2%) burn, 6 (25%) persistent skin laxity with 2 returned operating room (OR) treatments, 4 (16.7%) seromas, 9 (37.5%) postoperative lymphedema that self-resolved, and 1 (4.2%) self-limited neuralgia. There were no complications that required an immediate return to the OR.

**Conclusions:** Renuvion utilization with or without VASER has a relatively high complication rate—with minor complications as the most common—relatively safe barring proper patient selection, which can be mitigated with proper patient selection.

## Level of Evidence: 4

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Dr Driscoll is a resident, Department of Plastic and Reconstructive Surgery, Atrium Health at Wake Forest Baptist, Winston-Salem, NC, USA. Ms Davidson is a medical student, Wake Forest School of Medicine, Winston-Salem, NC, USA. Dr Marturano is a surgeon, Department of General Surgery, Atrium Health Carolina Medical Center, Charlotte, NC, USA. Drs Kortesis and Bharti are plastic surgeons in private practice, Charlotte, NC, USA.

**Corresponding Author:**
Ms Amelia Davidson, 425 Vine Street, Winston-Salem, NC 27101.
E-mail: aldavids@wakehealth.edu

In 2022, 25.1 million cosmetic procedures were performed, of which, 23.6 million were minimally invasive.[1] In today's market, there is a large demand for these minimally invasive techniques due to their efficacious nature with the shortest amount of downtime. Previous noninvasive methods have included radiofrequency, laser, and plasma devices for the reduction of facial wrinkles and rhytids by thermal-induced collagen/tissue contraction since the mid-1990s.[2-4] Although there is continued advancement in minimally invasive procedures, skin redraping following tumescent liposuction has remained an elusive goal.

In an effort to resolve skin laxity problems following tumescent liposuction, Renuvion therapy (Apyx Medical, Clearwater, FL) has been developed, which combines helium gas and radiofrequency energy to generate cold atmospheric plasma (CAP). This is delivered subdermally and converted into thermal energy, stimulating collagen contraction and subsequent skin tightening.[5] The coagulation/denaturation temperature of collagen is stated to be a minimum of 66.8°C.[6] Once denatured, collagen rapidly contracts, and fibers shrink to one-third of their overall length.[7] The novelty of Renuvion is its ability to rapidly heat to an optimal temperature of 85°C with rapid heat dissipation, decreasing the amount of bulk tissue and surface skin heating.[8] This limits the adverse effects that can result from the bulk tissue heating, which is commonly seen in other treatment modalities.[9] However, the amount of contraction depends on the temperature and the duration of the treatment. The hotter the temperature, the shorter the amount of treatment time needed for maximal contraction.[10]

To date, the FDA has approved Renuvion for skin redraping of the submental and neck regions. However, within the last few years, Renuvion has been used off-label for a variety of other anatomic locations with a reasonable safety profile. This article aims to examine the current use of Renuvion in the clinical setting to understand its safety in applications to facial, cervical, trunk, and extremity skin laxity.

## METHODS

After IRB approval from Sterling IRB was received, a retrospective review of Renuvion use at a single site between March 2020 and May 2022 was conducted. Written consent was provided, by which the patients agreed to the use and analysis of their data. Energy settings, use of concomitant VASER ultrasonic liposuction (Solta Medical, Bothwell, WA), and adverse events were analyzed. Patients who underwent the use of Renuvion with or without VASER were included.

Patients considered eligible were those above 18 years of age, a maximum BMI of 35, and of nonsmoker status. Patients were ineligible if they had prior liposuction, energy, or energy liposuction in the desired area. Renuvion was performed by board-certified or board eligible plastic surgeons in combination with additional cosmetic plastic surgery procedures. Postoperatively, most patients were followed for 23 h of observation with Jackson-Pratt (JP) drains and fluid maintenance. Closed suction drains (17 Fr) were almost always used when indicated. Patients were followed for 12 to 18 months to assess for complications or persistent skin laxity.

During this procedure, the surgeon uses the liposuction porthole to be applied to the same area as VASER. The Renuvion device is kept in a neutral position and placed at a speed within of 1 to 3 cm/s; strokes are kept 2 to 3 cm apart. Time spent in each location depends on relative skin thickness, although each area adds an average of 15 min of operating time. This results in very precise and predictable effects, while minimizing collateral damage to the surrounding healthy tissue.

Data analysis was conducted on 290 procedures. In demographic data, averages and percentages were provided for most demographic variables. For VASER variables, medians and interquartile range (IQR) were presented due to nonnormality of the data.

These procedures were additionally analyzed through logistic regression as predictors of complications. Variables of interest included BMI, smoking status, hypertension, application of VASER liposuction, body area of application, and Renuvion settings. Patients who received multiple procedures were represented in each body area. Body areas that were conducted bilaterally were averaged so that each patient was only counted once. Odds ratios were pulled from the regression results in the context of all other variables.

All data were analyzed by GraphPad Prism software (Version 9.4.1 (458)) (Boston, MA).

## RESULTS

In all, there were a total of 180 patients reviewed over the 26-month period (Table 1). Most patients were female (male:female ratio of 8.5) with an average age of 45 years (±9.8 years 95% CI). One hundred and thirty-five (75%) of them underwent VASER liposuction prior to the use of Renuvion; concurrent use of VASER liposuction did not increase complication rates (15% with VASER vs 10%, $P = .32$). Table 1 displays the anatomic location of Renuvion. The majority of use included the abdomen (27.9%) and thighs (20%), followed by arms (14.1%), submental (12.8%), hip rolls (12.8%), and back (12.4%). Thirty-nine patients ($n = 39$) had multiple anatomical areas treated with Renuvion during the operation.

There were a total of 24 complications (13.3%), with hip rolls comprising the anatomic area with the highest

**Table 1.** Demographics of Patients Receiving Renuvion

| Variable | Represented patient population (*n*, % of total) |
|---|---|
| Total no. of patients | 180 |
| Total no. of procedures | 290 |
| Gender, male/female | 19 (10.6%)/161 (89.4%) |
| Age | 45.4 ± 9.8 |
| BMI | 26.3 ± 4.2 |
| Atrial fib | 3 (1.7%) |
| Active smoker | 13 (7.2%) |
| Hypertension | 28 (15.6%) |
| Diabetes Mellitus, Type 2 | 3 (1.7%) |
| Body area | |
| Abdomen | 81 (27.9%) |
| Arms | 41 (14.1%) |
| Back | 36 (12.4%) |
| Suprailiac | 37 (12.8%) |
| Thighs | 58 (20%) |
| Submental | 37 (12.8%) |
| VASER | 135 (75%) |

incidence of complications at 16.2%. Postoperative lymphedema was the most common complication, occurring in 9 patients (5%) and self-resolving in all instances. This was followed by persistent skin laxity at 3.3%. Three (1.6%) patients experienced hematomas, 1 (0.5%) a localized burn, 1 (0.5%) self-limited neuralgia, and 4 (2.2%) seromas. The burn was not a result of the device within the body, but resulted from activating the device at the skin opening site before entering the subdermal space. None of these complications required immediate operative intervention. Seromas were drained in the clinic without recurrence. Two patients with persistent skin laxity at 1 year had operative intervention: 1 with excision and 1 with repeat Renuvion. Both had resolution of symptoms.

Table 2 includes the average Renuvion settings specific to each anatomical treatment site. Sixty-seven patients (77.9%) had their abdomens treated. The average settings of the abdomen, with a median (IQR), were a power of 80% W (80%-90%) with median flow rate 2 L/min (2-2 L/min) and a median energy (IQR) 10 kJ (6.5-14.5 kJ) used as points of comparison for logistic regression. Power settings were highest, at 90 W (80%-90%), among those who were treated in the back and hip region, whereas the submental region had the lowest power settings at 70 W (70%-70%) and the lowest total energy delivered, 3 kJ.

**Table 2.** Average Settings Used by Body Area

| Body area | % Power Avg. (IQR) | Helium flow Avg. (IQR) | Total kJ Avg. (IQR) |
|---|---|---|---|
| Abdomen | 80 (80-90) | 2 (2-2) | 10.5 (6.5-14.5) |
| Arms | 80 (70-80) | 1.5 (1.5-2) | 10 (7.05-14) |
| Back | 90 (80-90) | 2 (2-2) | 10 (8-15) |
| Hip rolls | 90 (80-90) | 2 (2-2) | 10 (8-12.9) |
| Thighs | 80 (80-80) | 2 (1.5-2) | 10 (6-11) |
| Submental | 70 (70-70) | 1.5 (1-1.5) | 3 (2-4) |

IQR, interquartile range.

Patients with concomitant procedures at differing anatomic areas were at 2.57 odds of developing a complication. For each L/min of helium flow rate increase in helium flow over 2, the odds that a patient will experience a complication are 24-fold. Each increase in BMI by 1 (over the average of 26.3) increases the odds of developing a complication by 19.5%. Those with hypertension had 4.9 times higher odds of developing a complication than patients without hypertension. Patients over a BMI of 32 have the highest rate of complications, at 24%, although this was not significantly higher ($P = .102$). A combination with the lowest level of complications is patients who are younger in age, nonsmoking status, standard helium flow, and application to the submental area with VASER liposuction (Table 3).

## DISCUSSION

The market for minimally invasive procedures is growing, and applications of CAP such as Renuvion will continue to evolve. There remains a paucity of literature regarding safe and effective settings for various anatomic regions of the body. Current FDA approval for Renuvion application to neck and submental regions does not comment on its power, helium, or total energy settings (DICE of FDA, 2022). Renuvion's current application is limited to only patients with concomitant VASER liposuction in the submental region due to the potential risk of burns.[11,12] Several studies have instead remarked on its continued safety in larger sample sizes.[13,14] In this context, our paper aims to report complication rates and settings used in a single practice to help bring discussion into its continued use and application to areas outside of the submental region.

The CAP utilized in this review has 3 modifiable settings that can alter the way in which energy is delivered: power, helium flow rate, and overall energy. The overall energy delivered is typically determined by clinical judgment

**Table 3.** Logistic Regression for Variables Related to Complication Risk

| Variable | Estimate | Standard error | *P*-value | Odds ratio |
|---|---|---|---|---|
| Age | −0.04771 | 0.01978 | .0159 | 0.9534 |
| BMI | −0.02033 | 0.04663 | .6629 | 0.9799 |
| Smoking | −0.1127 | 0.6982 | .8718 | 0.8934 |
| Hypertension | 0.01248 | 0.5074 | .9804 | 1.013 |
| VASER | −0.2852 | 0.4823 | .5543 | 0.7519 |
| Body area | | | | |
| Back | −0.2945 | 0.6367 | .6437 | 0.7449 |
| Submental | −1.757 | 0.9439 | .0627 | 0.1726 |
| Thighs | 0.1589 | 0.4966 | .7490 | 1.172 |
| Hip rolls | 0.1112 | 0.5643 | .8438 | 1.118 |
| Arms | −0.2848 | 0.6040 | .6373 | 0.7522 |
| % Power | −0.01974 | 0.01796 | .2717 | 0.9805 |
| Helium flow | −1.520 | 0.7227 | .0354 | 0.2187 |
| Total kJ | 0.05200 | 0.03756 | .5543 | 0.2817 |

as to the appearance of the anatomic area being resurfaced, whereas the power and helium flow rate are set variables chosen by the surgeon at the initiation of the procedure. The increase in helium flow rate significantly increased the complication profile and should be done with caution and careful consideration (operating room = 24). Tweaking these variables occurs through a trial-and-error process. Of note, power settings above 80% and flow rates outside of 1.5 to 3.0 L/min have not been evaluated for safety.

The current state of the Renuvion application is not without risk. Although self-limiting, postoperative hematoma and localized lymphedema occur at decently high rates (1.6% and 5%). Patient selection can help provide a higher margin of safety. Specifically, patients with increased BMI and hypertension may be at a higher postoperative risk. Hypertension, in particular, is noted to be associated with hematoma formation in soft-tissue procedures.[15,16] Although no complications experienced in this study required reoperation, seromas and hematoma risk should be discussed with great emphasis with these patients.

Limitations of this study include its retrospective nature and small sample size. There are no control groups in this study, aside from the exclusion criteria, which limits the number of conclusions drawn from the safety profiles calculated from this patient cohort. Fine-tuning will continue to occur, and it is our hope that this paper provides valuable insight into ongoing for Renuvion utilization.

## CONCLUSIONS

This article specifies the overall safety profile of Renuvion with optimized patient selection and recommended settings for specific anatomic locations, due to its relatively high complication rate. Albeit minor complications, it is crucial to give patients an understanding of what their risk will be. As innovations continue to prosper in minimally invasive techniques, the need for device application research is imperative for safe and effective use, and reports of its use from high-volume facilities should be shared.

### Disclosures

Drs Bharti and Kortesis are consultants for the company and receive financial compensation in this role from Renuvion (Apyx Medical, Clearwater, FL). These individuals were not a part of the data analysis or representation, although they did review this manuscript for its results. The authors have no financial, personal, or entrepreneurial ties to the company and products involved in this project.

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