White Paper

# HELIUM PLASMA VERSUS RADIOFREQUENCY FOR ENERGY-ENHANCED LIPOSUCTION: A PROSPECTIVE SINGLE-BLIND PILOT STUDY

**Michael Kluska, DO, FAACS, FACOS, Sam Nasseri, MD and Vladim Bobrovnikov, MD**
**Southern Surgical Arts, Chattanooga, TN**

## Introduction

At one time, patients looking for fat reduction and tissue contraction were limited to liposuction and surgical procedures, such as abdominoplasty.[1,2] Limitations to these procedures included residual laxity, contour abnormalities, long scars, and prolonged recovery time. Driven by patient demand for less discomfort and scarring, shorter recovery times and improved cosmetic outcomes, a number of less invasive energy-based technologies have become available,[3] including radiofrequency.[4] These devices apply various forms of energy to heat the dermis and subcutaneous tissues, cause immediate collagen denaturation and contraction, and subsequent neocollagenesis resulting in further overall tissue contraction.[5,6,7,8,9,10]

Renuvion® cosmetic technology developed by Apyx™ Medical is a recent addition to minimally invasive procedures. The Renuvion system combines helium plasma and radiofrequency energy and has been cleared for cutting, coagulation and ablation of soft tissue. Helium plasma achieves soft tissue contraction by briefly heating tissue to temperatures of 85°C[11] resulting in rapid tissue contraction with maximum contraction in less than a tenth of a second.[5,6,7,8,9] The following wound-healing response provides additional tissue contraction by stimulating neocollagenesis and tissue remodeling.[12-14]


**Figure 1. 15cm Renuvion APR Handpiece**

Using these high temperatures, maximum contraction can be achieved using shorter treatment times and allows tissue surrounding the treatment site to remain cooler. For example, a treatment time of ≥152 seconds is required for significant contraction to occur at ~65°C. In contrast, a temperature of 85°C can reduce treatment time to 0.044 seconds (i.e., ~3,500 times faster).[5,6,7,8,9]

The objective of this prospective, single-blind, pilot-study was to compare outcomes following Renuvion and bipolar radiofrequency therapy for tissue contraction and improved liposuction results.

## Methods

Study participants (*N*=10) were healthy, nonsmoking adults seeking treatment to contract tissue on the inner thigh, midback or arms. Enrolled subjects had no contraindications to surgery and had not undergone prior tissue contraction procedures.

Treatment with the Renuvion technology was applied to one side and bipolar radiofrequency to the contralateral side. All procedures were performed under general anesthesia, using the same volumes of tumescent fluid and lipoaspirate removal per treatment modality in each patient. Clinical evaluation consisted of physical exam, digital images, and a subject questionnaire at 24 hours, 10 days, 4 weeks, 12 weeks and 24 weeks post-procedure. The questionnaire included a series of questions regarding pain, swelling, bruising and paresthesia rated on a scale from 1 (least severe) to 10 (most severe) and regarding cosmetic appearance and overall satisfaction on a scale of 1 (least satisfied) to 10 (most satisfied).

## Results

Enrolled subjects had a mean (SD) age of 40.5 (6.4) years (range, 35 to 52 years) and a mean BMI 27.1 (3.87) kg/m$^2$ (range, 21 to 33.4 kg/m$^2$).

Liposuction was followed by treatment with the Renuvion® technology or bipolar radiofrequency. Treated body areas (*N*=10) included medial thighs (n=7), arms (n=2) and mid-back rolls (n=1). Renuvion settings were 80% power, 1.5-2.5 LPM and six passes. Bipolar radiofrequency settings were 40°C/70°C, mean 27.92 KJ (range 20.7 – 34.8, SD 5.3).

Among anatomical areas treated with the Renuvion technology, body area measurements decreased 3.2% at 3 months (n=7) and 6.5% at 6 months (n=8). Among areas treated with bipolar radiofrequency, body area measurements decreased 2.3% at 3 months (n=7) and 4.2% at 6 months (n=8). Treatment outcomes are shown in Figures 2-8.

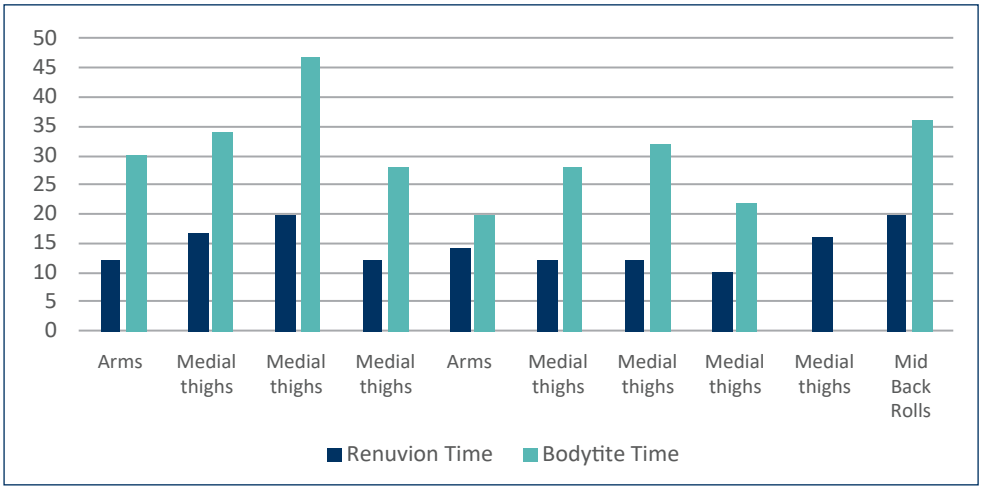


**Figure 2. Treatment Time**
Treatment times were generally 50% shorter for the Renuvion®-treated areas.

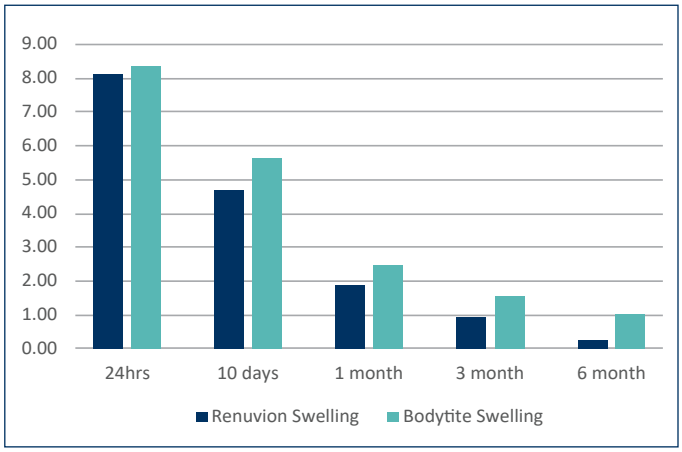


**Figure 3. Swelling**
The extent of swelling was similar for both procedures during the first 24 hours post-procedure but tended to improve more quickly on areas treated with Renuvion.

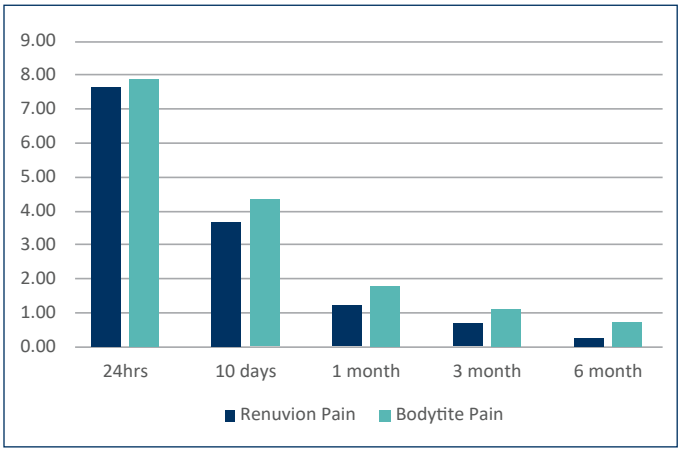


**Figure 4. Pain Scores**
Pain scores were similar for both procedures during the first 24 hours post-procedure but tended to improve more quickly on areas treated with Renuvion.

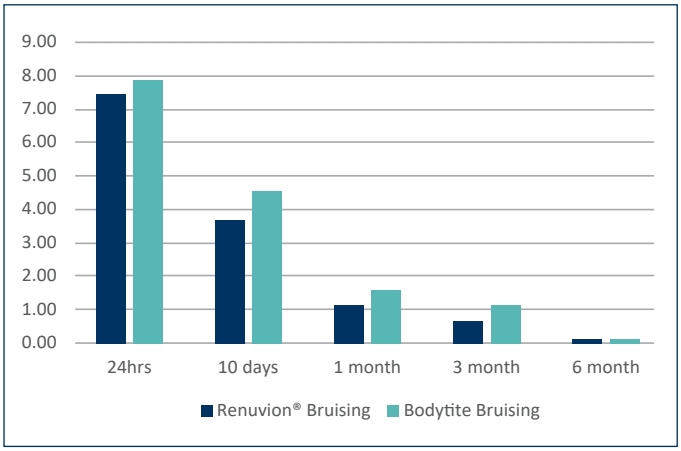


**Figure 5. Bruising**
Bruising tended to be more severe on areas treated with bipolar radiofrequency.

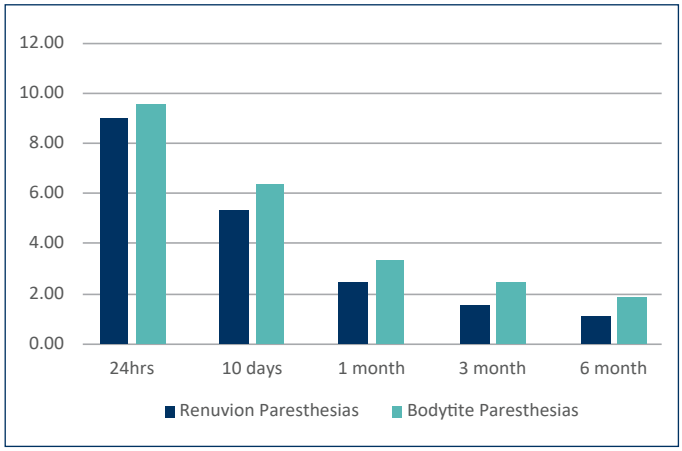


**Figure 6. Paresthesia**
Less paresthesia was reported on areas treated with Renuvion.

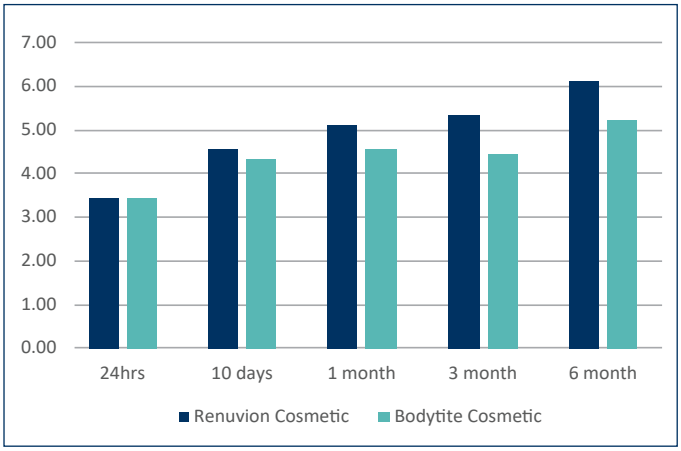


**Figure 7. Cosmetic Appearance**
Cosmetic appearance of treated areas was similar during the initial 24 hours post-treatment but continued to improve during the following 6 months on Renuvion-treated areas.

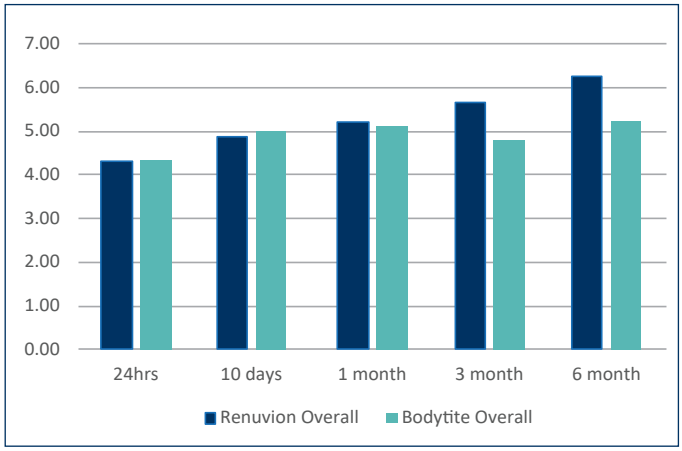


**Figure 8. Overall Satisfaction**
Overall subject satisfaction was substantially higher for areas treated with Renuvion at 3- and 6-months post-treatment.

## Conclusion

The results of this pilot study indicate the use of helium plasma is associated with less pain, bruising, paresthesia and swelling. Coupled with superior improvement in cosmetic appearance and tissue contraction in key anatomical areas, overall patient satisfaction with Renuvion was 20% greater after 6-months when compared to the bipolar radiofrequency configuration. With treatment time consistently 50% faster than bipolar radiofrequency, Renuvion technology allows for significantly less operative time and anesthesia while yielding superior results at lower operative costs. Study limitations included small sample size and several patients lost to follow-up.

## General & Financial Disclosures

- This study was supported by an unrestricted educational grant provided by Apyx™ Medical. Dr. Kluska is a paid consultant for Apyx Medical.

- The opinions contained herein are those of the author and represent experiences/outcomes with his medical practice and may not necessarily represent the official regulatory position or policies of Apyx™ Medical, Inc.

## Risks

Risk associated with the use of Renuvion® may include: unintended burns (deep or superficial), pneumothorax, scars, temporary or permanent nerve injury, pain, ischemia, fibrosis, discomfort, gas buildup resulting in temporary and transient crepitus or pain, bleeding, infection, hematoma, seroma, subcutaneous induration, pigmentation changes, increased healing time, unsatisfactory scarring, asymmetry and/or unacceptable cosmetic result. There may be additional risks associated with the use of other devices along with Renuvion and there may be an increased risk for patients who have undergone prior surgical or aesthetic procedures in the treatment area. 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.

## Intended Use Disclosures

- The Renuvion system is intended to be used for the delivery of radiofrequency energy and/or a helium gas plasma for electrosurgical cutting, coagulation and ablation of soft tissue during open surgical procedures.
- The Renuvion Apyx Plasma/RF Handpiece (Renuvion APR HP) is intended to be used with compatible electrosurgical generators 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 HP is a sterile, single use electrosurgical (monopolar) device intended to be used in conjunction with compatible generators for the percutaneous delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue.
- Renuvion/J-Plasma® has received a general clearance and has not been determined to be safe or effective for use in any specific indication or anatomical location.
- Apyx Medical does not promote its general clearance products for any specific surgical specialty or subspecialty.

## References


1. Gutowski KA. Evidence-based medicine: abdominoplasty. Plast Reconstr Surg. 2018;141:286-299e.
2. Collins PS, Moyer KE. Evidence-based practice in liposuction. Ann Plast Surg. 2018;80:S403-405.
3. Afrooz PN, Pozner JN, DiBernardo BE. Noninvasive and minimally invasive techniques in body contouring. Clin Plast Surg. 2014;41:789-804.
4. Elsaie ML. Cutaneous remodeling and photorejuvenation using radiofrequency devices. Indian J Dermatol. 2009;54:201–205.
5. Feldman LS, et al. (eds). The SAGES Manual on the Fundamental Use of Surgical Energy (FUSE), ISBN 978-1-4614-2073-6.
6. Chen SS, Wright NT, Humphrey JD. Heat-induced changes in the mechanics of a collagenous tissue: isothermal free shrinkage. Journal of Biomechanical Engineering 1997:109:372-378.
7. McDonald MB. Conductive Keratoplasty: A Radiofrequency-based Technique for the Correction of Hyperopia. Trans Am Ophthalmol Soc 2005;103:512-536.
8. Chen SS, Humphrey JD. Heat-induced changes in the mechanics of a collagenous tissue: pseudoelastic behavior at 37° C. J Biomech 1998;31:211-216.
9. Wright NT, Humphrey JD. Denaturation of collagen during heating: An irreversible rate process. Annu Rev Biomed Eng; 2002;4:109-128.
10. Duncan, DE. Nonexcisional Tissue Tightening: Creating Skin Surface Area Reduction During Abdominal Liposuction by Adding Radiofrequency Heating. Aesthetic Surgery Journal. 2013;33(8) 1154-1166.
11. Gentile RD. Renuvion/J-Plasma for subdermal skin tightening facial contouring and skin rejuvenation of the face and neck. Facial Plast Surg Clin North Am. 2019;27:273-29
12. Sadick N. Tissue tightening technologies: fact or fiction. Aesthet Surg J. 2008;28:180-188.
13. Fabi SG. Noninvasive skin tightening: focus on new ultrasound techniques. Clin Cosmet Investig Dermatol. 2015;8:47-52.
14. Souren JM, Ponec M, van Wijk R. Contraction of collagen by human fibroblasts and keratinocytes. In Vitro Cell Dev Biol. 1989;25:1039-1045.