# **Publication Information**

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**CONFLICT OF INTEREST:** Dr. Barone is a consultant for Apyx Medical and receives compensation for speaking engagements. However, this study & literature were completed independently by Dr. Barone and were not supported by Apyx Medical.

### INDICATIONS FOR USE & INTENDED USE DISCLOSURES:

- 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.

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# Efficacy of Renuvion Helium Plasma to Improve the Appearance of Loose Skin in Patients Undergoing Abdominoplasty After Massive Weight Loss: A Prospective Controlled Randomized Study

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#### Abstract

#### Introduction

Renuvion was the first FDA approved helium plasma device utilized for subdermal tissue heating to reduce skin laxity. The purpose of this study was to demonstrate that the use of Renuvion improves the outcomes, skin quality and reduces the edema faster after lipoabdominoplasty.

#### Materials and Methods

Patients with abdominal skin laxity after a weight loss of at least 20 kg, nonsmokers, without major comorbidities, with a minimum 2-year follow-up and standardized preand postoperative photographs were included in this study. They were randomly divided in two groups: group 1, lipoabdominoplasty alone; group 2, lipoabdominoplasty and Renuvion. Both the patients and two of the authors measuring outcomes were blinded to the treatment methods. Postoperatively, all patients were administered the BODY-Q satisfaction with abdomen and appraisal of excess skin scales. Two independent plastic surgeons reviewed photographs, rating the outcomes on a 1–5 visual analog scale (VAS). Pinch test and ultrasound of the subcutaneous tissue were also performed.

## Results

Seventy–six patients were enrolled, 33 males and 43 females, aged between 20 and 50 years. The BODY–Q satisfaction with abdomen scores were higher in group 2 in the 6-month (p=0.007), 1–year (p=0.021) and 2–year (p=0.024) evaluations. The BODY–Q appraisal of excess skin scores were significantly higher in group 2 in the 6-month (p<0.0001), 1–year (p<0.0001) and 2–year (p<0.0001) postoperative evaluations. The VAS scale reported higher scores in group 2 (p=0.01). Ultrasound at 6 months postoperatively demonstrated lower subcutaneous thickness in group 2 (31 mm  $\pm$  2.8 SD) compared to group 1 (42 mm  $\pm$  1.4 SD) implying a faster edema reabsorption.

## **Conclusions**

Data showed a significantly greater improvement of abdominal skin laxity in patients treated with Renuvion compared to those who underwent lipoabdominoplasty alone. This is the first prospective randomized study about Renuvion and lipoabdominoplasty and could be considered a pilot study.

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