

PUBLICATION INFORMATION

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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 Retrospective Study to Evaluate the Efficacy of a Plasma Energy System (Renuvion) in the Management of Skin Laxity to Improve Tightening at the Time of Standard Liposuction of the Arms

Angelo Cuzalina, MD, DDS, Pasquale G. Tolomeo, MD, DDS

Abstract

The aim of this study was to determine the efficacy of cool atmospheric plasma (Renuvion/J-plasma) in promoting skin tightening and soft tissue contouring following liposuction of the upper extremities. The study was a retrospective review of upper extremity liposuction with associated Renuvion therapy performed by the same surgeon. Patients were made aware of Renuvion therapy to assist with skin laxity and offered adjunctive treatment following liposuction. While a majority of patients elected to have Renuvion therapy performed bilaterally, a small subset of patients elected for unilateral treatment. This subset of patients pursued delayed treatment on the control side. The inclusion criteria for the study included patients with moderate fat excess of the upper extremity with associated mild to moderate cutaneous laxity. Exclusion criteria for the study included severe medical comorbidities, body mass index greater than 35 kg/m² and those below the age of 30. The study included 5 female patients between the ages of 46 to 52. The method of treatment was liposuction of the bilateral upper extremities with removal of equal proportions of fat. The recipient site for Renuvion treatment was randomly selected by the study coordinator; the surgeon and clinical staff remained blinded to the selection. Following treatment, the patients were evaluated at 1 week, 6 weeks, and 6 months postoperatively to assess surgical outcomes subjectively. The surgeon and clinical staff were unblinded at the final visit. Patients were evaluated based on subjective criteria and photographic evaluation at each postoperative visit. At the 1-week visit, no significant differences were noted in all subjects. At the 6-week visit, two patients demonstrated improved results to the treatment site when compared with the control site. At the 6-month visit, four out of the five patients demonstrated a significant improvement in contour and laxity at the treatment site when compared with the control site. One patient demonstrated equal results on both treatment and control sites with no major abnormalities. Following the final evaluation, the patients underwent a secondary procedure to the control site with Renuvion to obtain similar results as the recipient site. One patient demonstrated equal results on both test and control sites with no major abnormalities. The use of plasma energy via Renuvion in conjunction with liposuction has demonstrated esthetic results with proposed long-term benefits. The plasma energy device, as an adjuvant therapy, may be beneficial in cases where liposuction alone may not address tissue laxity concerns. Additional studies with a larger sample size, objective criteria, and extended follow-ups are necessary to statistically analyze the results and determine its significance.