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CONFLICT OF INTEREST: Dr. Sterodimas is a Medical Advisory Board (MAB) member and consultant for Apyx Medical and has received stock options for his participation in the MAB, research grants, and hourly compensation for consulting activities. Dr. Nicaretta is consultant for Apyx Medical.

INDICATIONS FOR USE & INTENDED USE DISCLOSURES:

The Renuvion system has received clearance for the delivery of radiofrequency energy and/or helium plasma where coagulation/contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue. It has not been cleared for use in any specific body area except for in the neck and submental region.

- 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.

OPEN FORUM

Cosmetic Medicine

Preliminary Report

A Prospective Study on Helium-Based Plasma Radiofrequency for Minimally Invasive Breast Lift Scarless Mastopexy

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Abstract

Background: Although mastopexy addresses breast ptosis, not all patients are willing or able to undergo surgery. Helium plasma radiofrequency (RF) is a minimally invasive alternative to traditional excisional breast lift surgery for mild-to-moderate breast ptosis.

Objectives: To assess the efficacy and safety of helium plasma RF for minimally invasive mastopexy.

Methods: In this single-center prospective study, 15 patients were treated with helium plasma RF. Before and after photographs were assessed by blinded review 180 days postprocedure. Morphometric analysis and evaluations using investigator- and patient-assessed Global Aesthetic Improvement Scales (I-GAIS and P-GAIS, respectively) were carried out on posttreatment Days 30, 90, and 180. On Day 180, patients completed a satisfaction questionnaire and the Breast-Q scale.

Results: At Day 180, the independent photographic review success rate was 73% (11/15). There was improvement in suprasternal notch to nipple distance (−1.2 ± 0.7 cm), midclavicular line to nipple distance (−0.9 ± 0.7 cm), and vertical distance from the suprasternal notch to the lowest point on the base (−1.5 ± 1.0 cm). Morphometric measurement appeared to improve over time, as did improvements in P-GAIS and I-GAIS. All patients (15/15) reported less sagging, higher appearance of breasts on the chest, improved nipple placement, more youthful-appearing breasts, and improved confidence and quality of life on the Breast-Q. There were no adverse events or pain reported during the procedure or follow-ups.

Conclusions: This study suggests that helium plasma RF is a well-tolerated and effective minimally invasive option for patients seeking an alternative to traditional breast lift surgery.

Level of Evidence: 5 (Therapeutic)

Breast ptosis commonly occurs in females, because of normal aging, weight loss, pregnancy, and breastfeeding.[1] Surgical breast lift (mastopexy) can be used to reposition the breast back higher on the chest wall, thereby restoring breast position, shape, and contour; however, the risks associated with surgery, including scarring and downtime, have led to increased patient interest in less invasive options. Helium plasma radiofrequency (RF; Renuvion, Apyx Medical, Clearwater, FL) coagulates subcutaneous fascia and septal connective tissues through the application of heat generated by helium plasma and RF. Because the device is passed through the subcutaneous tissues, target tissue is rapidly and directly heated to >85 °C, causing protein coagulation within 0.04 s[2] and predictable contraction and tightening of the overlying skin.[3,4] The rapid rate of heating and the constant movement of the device handpiece with each treatment stroke permit efficient treatment of larger areas, leading to rapid cooling of the treated area and minimal elevation of the external surface temperature (≤3.6 °C).[2] For patients who are interested in breast lifting without augmentation, helium plasma RF represents a viable, less invasive treatment option. A breast lift with helium plasma RF

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requires only 3 small incisions per side, and thus carries a far lower risk of scarring and is associated with less downtime than traditional surgical lifting. With this technique, the breast gland is elevated by coagulating the subcutaneous tissue surrounding it, which tightens the surrounding skin and effectively repositions the breast gland higher on the chest wall. In the current study, the capacity of the procedure to provide lift and to improve ptosis was evaluated. In addition, multiple patient-reported outcomes were assessed. Because helium plasma RF is not a surgical equivalent, these measures are important for gaining a better understanding of patient perceptions and satisfaction regarding the outcomes of this minimally invasive procedure. This understanding is essential for setting realistic expectations and optimizing patient selection for those who prioritize minimal recovery time, reduced scarring, and overall comfort, while still achieving noticeable improvements.

METHODS

Study Design

This single-center prospective study enrolled female patients aged 18 to 75 years who were scheduled to undergo a single treatment with helium plasma RF (Renuvion, Apyx Medical) for minimally invasive breast lift. Eligible patients were either Class I or Class II as per the American Society of Anesthesiologists Physical Status Classification System, had breast ptosis Grade II or Grade III as per the Eyck et al's Rainbow Scale for Assessing Breast Ptosis[5] (Supplemental Table 1), and had breast cup size A or B.[6] Patients with a history of prior surgery in the breast area (eg, implants, skin tightening, and reduction) or a history of keloid scarring were excluded. Follow-up visits occurred on postprocedure Days 30, 90, and 180, with images taken at each visit. Patient and investigator assessments were conducted on Days 30, 90, and 180.

Study Outcomes

The primary outcome of this study was improvement in breast laxity at 180 days, evaluated by 3 independent, blinded reviewers who assessed baseline and posttreatment photographs. Reviewers were tasked with identifying the posttreatment images from a set of images arranged in random order, including both pre- and posttreatment photographs. Success was defined as the correct identification of the posttreatment image by at least 2 of the 3 reviewers. Improvement was similarly assessed at 90 days using the same method by the independent reviewers.

Additional key endpoints included bilateral change in classification on the Rainbow Scale for Assessing Breast Ptosis[5] (Grades I-V, with Grade I = no breast ptosis and Grade V = extreme breast ptosis) from baseline to Day 180. Morphometric breast measurements were recorded on Days 30, 90, and 180.[7] Measurements were taken by hand with a tape measure by the same person at each visit. Changes in measurements were then calculated from baseline and averaged for each breast.

Both investigator- and patient-assessed Global Aesthetic Improvement Scale (I-GAIS and P-GAIS, respectively) ratings were obtained at posttreatment Days 30, 90, and 180. Possible ratings include "very much improved," "much improved," "improved," "no change," "much worse," and "very much worse." Additionally, patients completed the Breast-Q version 2.0 augmentation module scale[8] at baseline and 180 days. They were instructed, "With your breasts in mind, in the past week, how often have you felt: [question; eg, "Confident in your clothes?"]." Responses were on a 5-point scale from 1 (none of the time) to 5 (all of the time). A patient satisfaction questionnaire (PSQ) was also administered at 180 days postprocedure to assess overall satisfaction with the treatment.

Safety

Safety outcomes included monitoring for adverse events (AEs) and expected treatment effects (ETEs) throughout the study period. ETEs included discomfort/pain, edema, erythema, ecchymosis, hypoesthesia, temporary sensory nerve injury (touch sensitivity, itching, and temporary numbness/tingling), transient migratory firmness, and temporary and/or transient crepitus. All ETEs were defined as being mild to moderate in severity and were expected to have a typical maximum duration. Pain levels for the entire treated area were recorded during treatment and at all follow-up visits using the 11-point numeric rating scale (scale of 0-10, where 0 represents best/no pain and 10 represents the worst possible pain). In addition, study patients were instructed to report all complications experienced following the study procedure to the site personnel as soon as they occurred or were observed.

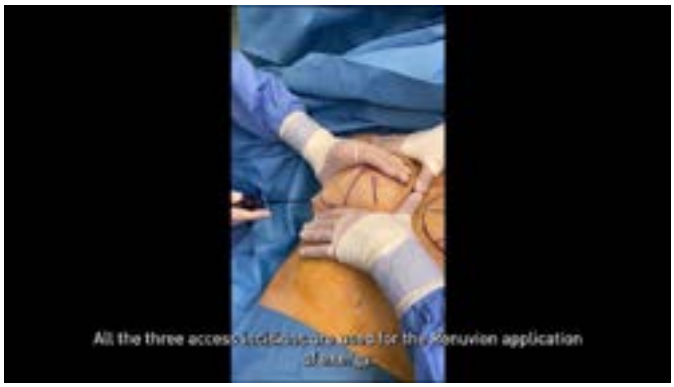
This study was approved by the Ethics Committee for the Metropolitan General Hospital, Athens, Greece. All patients provided consent for treatment and for the review and publication of their images. All procedures were conducted in accordance with the ethical standards of the institutional research committee, the 1964 Declaration of Helsinki and its later amendments, or comparable ethical standards. The study was conducted between November 2022 and April 2024. Helium plasma RF is cleared by the US FDA for use in coagulation and contraction of subcutaneous soft tissue, aesthetic body contouring, and improvement of the appearance of loose skin in the neck and submental region.[9]

Procedure and Technique

All patients were treated under sedation, with most receiving 1.5 g cefuroxime, 4 mg dexamethasone, 2 mg midazolam, 0.05 mg fentanyl, 10 mg metoclopramine, 40 mg omeprazole, 8 mg ondansetron, 1 g paracetamol, 40 mg parecoxib, and 300 mg 1% propofol. The treatment area was first infiltrated (250 mL tumescent solution contained 1 mg of adrenaline and 50 mL 2% xylocaine and 200 N/S 0.9%). Three incisions were made per breast. The first incision was made at the lateral border of the inframammary fold, and the second and third incisions were made at 6 and 12 o'clock, respectively.

The superior boundary of the treatment area extended from a horizontal line at the superior aspect of the axilla to the midline. The inferior boundary was defined by the inframammary crease (IMC) at the junction of the breast and abdomen. The lateral boundary was the outermost curvature of the breast or a vertical line drawn from the preaxillary line to the IMC. The medial boundary extended to the innermost curvature of the breast, up to 1 cm lateral to the sternal midline.

The procedure was performed in both the intradermal and subdermal planes over the full breast area, without penetrating the breast gland. The helium plasma RF system settings were set between 60% and 70% power, with a helium flow rate of 1.5 L/min. Up to 6 retrograde or 3 antegrade/retrograde passes were performed. Anecdotally, with >6 passes, the risk of induration is increased. Standard postoperative care instructions were provided to all patients. The technique is demonstrated in Video.



Video. Watch now at http://academic.oup.com/asjopenforum/article-lookup/doi/10.1093/asjof/ojaf004

RESULTS

Study Demographics and Procedure Data

A total of 15 female patients were enrolled in the study and completed all study visits through Day 180. The mean age of the patients was 38.0 ± 9.1 years, and the mean BMI at baseline was 21.5 ± 2.4 kg/m^2. All patients were treated with the helium plasma RF system at 70% power with a helium flow rate of 1.5 L/min. Each breast received 6 retrograde passes, with an average total energy delivery of 14.6 ± 3.7 kJ for both breasts. The average total treatment time was 95.7 ± 23.4 min, with an average procedure time for helium plasma RF of 63.3 ± 20.9 min.

Primary Effectiveness Measures

The success rate for independent photographic review (IPR) was 73% (11/15) at Day 180 and 67% (10/15) at Day 90. These rates, while within the expected range for minimally invasive aesthetic procedures, highlight the inherent challenges of conducting blinded photographic reviews. Variability in factors, such as arm position, lighting, camera angle, and image quality, likely contributed to the observed success rates in this study, underscoring the need for mirroring software to aid in photographic consistency in future studies. Figures 1-4 illustrate 2 patients with high outcome measures for all endpoints.

Secondary Effectiveness Measures

Breast morphometric measurements from baseline to the Day 180 follow-up visit showed reductions across several dimensions: suprasternal notch to nipple distance (SSN–N; −1.2 ± 0.7 cm), midclavicular line to nipple distance (MCL–N; −0.9 ± 0.7 cm), vertical distance from the suprasternal notch to the lowest point on the breast base (SSN–base; −1.5 ± 1.0 cm), vertical distance from the suprasternal notch to the IMC (SSN–IMC; −0.8 ± 1.0 cm), and IMC to nipple distance (IMC–N; −0.6 ± 0.5 cm). These reductions indicate tissue contraction and improvement in breast laxity. No significant changes were observed in the nipple-to-nipple distance (N–N) or nipple–areola complex diameter measurements, which was anticipated given that no fat transfer or breast implant procedures were performed. The maximum point of breast projection measured perpendicular to the chest wall increased slightly (0.3 ± 1.2 cm), which indicates a repositioning of the breast gland tissue within the breast capsule, again indicative of improvement. Measurements taken at Days 30, 90, and 180 are presented in Table 1.

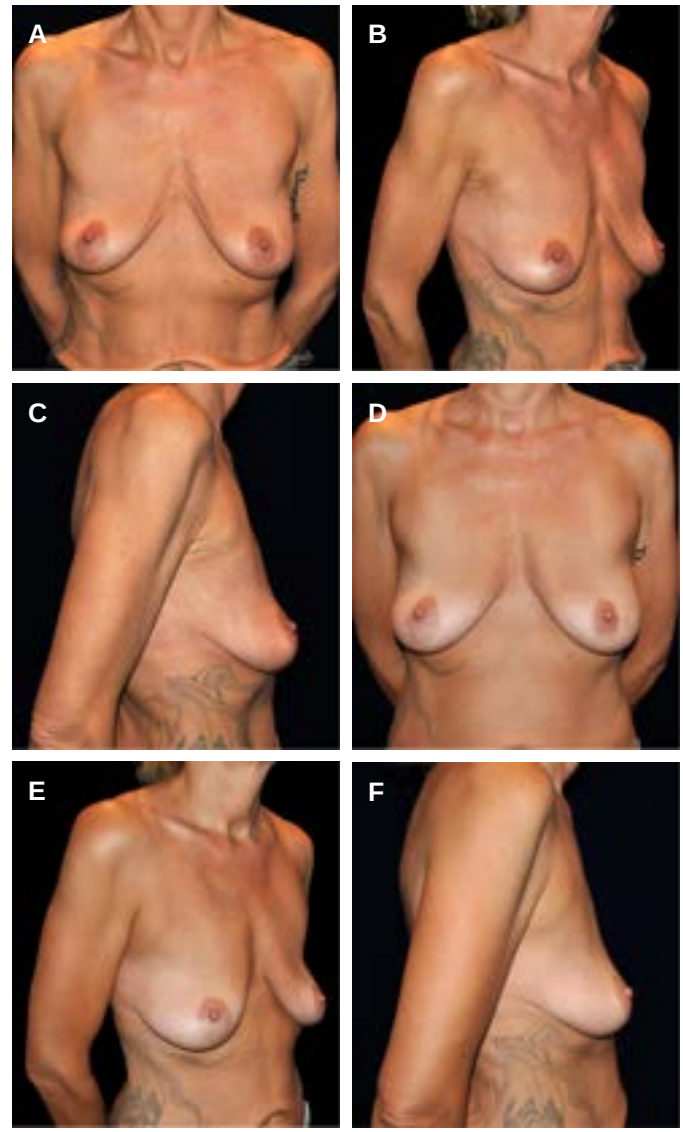


Figure 1. A 49-year-old patient at baseline (A-C) and 180 days following treatment with helium plasma radiofrequency (D-F). The after images were correctly identified by 100% of blinded reviewers; P-GAIS and I-GAIS were "much improved," patient satisfaction questionnaire noted as "very satisfied" with "less sagging breasts," "breasts look higher on chest," "nipple placement is improved," and "breasts appear more youthful."

These morphometric findings are consistent with results on the Rainbow Scale for breast ptosis: at baseline, all patients (15/15) had Grade II (mild) breast ptosis and by Day 180, 40% (6/15) had improved to Grade I (no breast ptosis), whereas the remaining 60% of patients (9/15) remained at Grade II.

Qualitative and Patient-Reported Outcomes

All patients (15/15) reported at least some level of improvement at all time points (Figure 5). At Day 180, 66.7% (10/15) of the patients rated

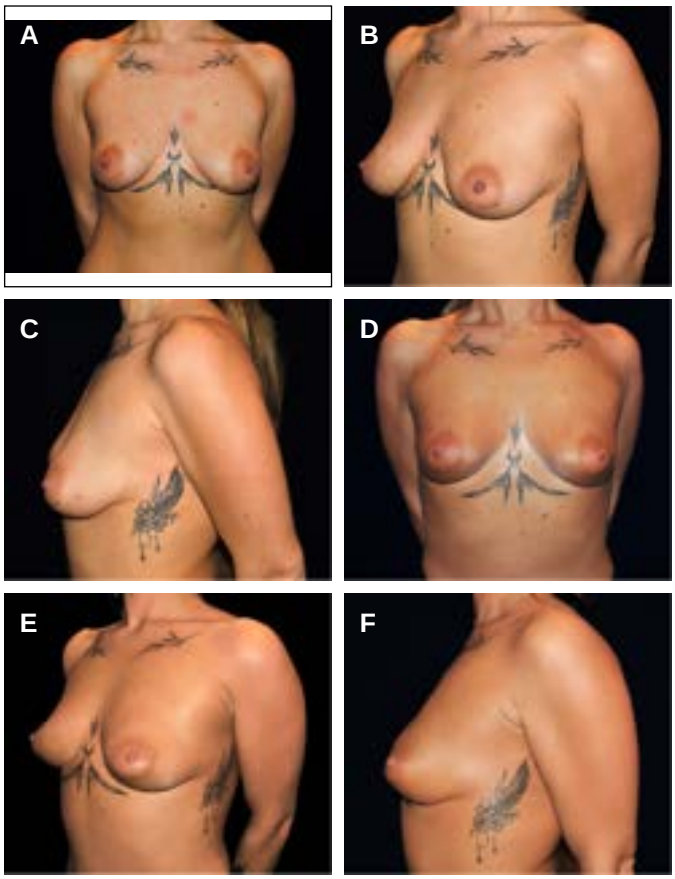


Figure 2. A 28-year-old patient at baseline (A-C) and 180 days following treatment with helium plasma RF (D-F). The after images were correctly identified by two-third of blinded reviewers; P-GAIS and I-GAIS were "very much improved," patient satisfaction questionnaire noted as "very satisfied" with "less sagging breasts," "breasts look higher on chest," "nipple placement is improved," and "breasts appear more youthful." I-GAIS and P-GAIS, investigator- and patient-assessed Global Aesthetic Improvement Scales.

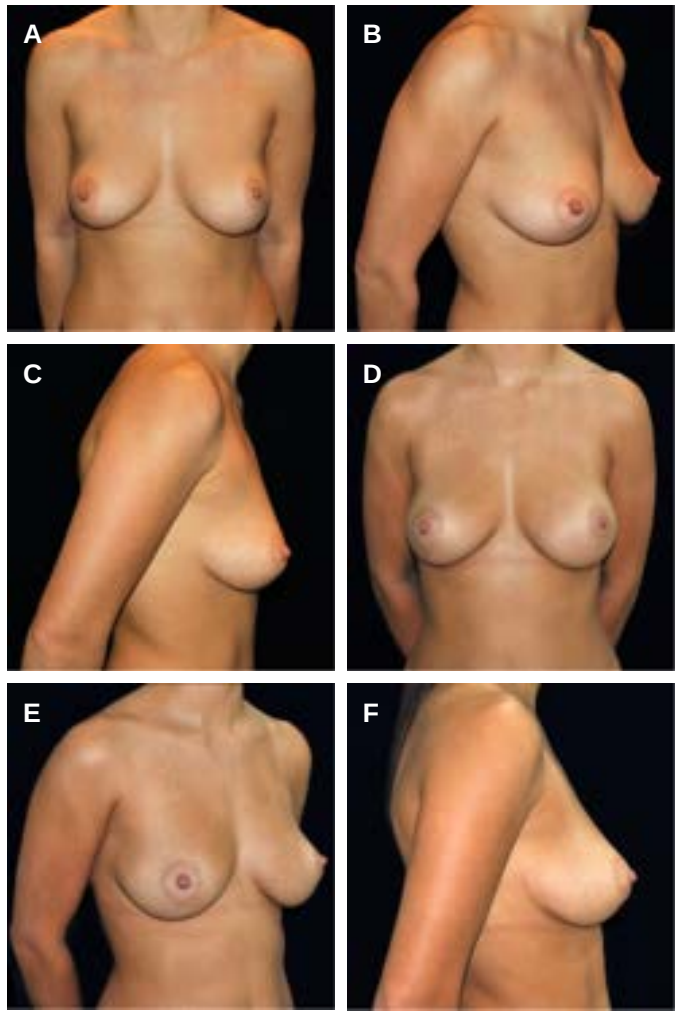


Figure 3. A 22-year-old patient at baseline (A-C) and 180 days following treatment with helium plasma radiofrequency (D-F). The after images were correctly identified by 100% of blinded reviewers. P-GAIS and I-GAIS were "very much improved," patient satisfaction questionnaire noted as "very satisfied" with "less sagging breasts," "breasts look higher on chest," "nipple placement is improved," and "breasts appear more youthful." I-GAIS and P-GAIS, investigator- and patient-assessed Global Aesthetic Improvement Scales.

themselves as "very much improved," whereas 33.3% (5/15) rated themselves as "much improved." Investigator assessments mirrored these findings, with 66.7% (10/15) of patients rated as "very much improved" and 33.3% (5/15) as "much improved" at Day 180. Both investigator- and patient-reported measures showed an increasing trend in perceived improvement over time, with a growing proportion of patients classified as "very much improved" from Day 30 to Day 180.

Across all domains of the Breast-Q scale, mean patient scores demonstrated improvement (Figure 6). The most significant changes were seen in areas related to body confidence and self-perception, including feeling "sexy when unclothed" (mean change, 1.9), "confident sexually about how your breasts look when unclothed" (mean change, 1.9), "confident about your body" (mean change, 1.5), "confident in your clothes" (mean change, 1.4), and "accepting of your body" (mean change, 1.2). All Breast-Q domains with a change in mean score ≥1 point are shown in Figure 6.

These findings are consistent with PSQ results, whereby Day 180, all patients (15/15) reported noticeable improvement in their breast appearance, specifically citing less sagging (15/15), a higher breast position on the chest (15/15), improved nipple placement (15/15), and a more youthful overall appearance of the breasts (15/15). Furthermore, all patients (15/15) indicated that they would recommend the procedure to friends and family.

Safety Outcomes

Across all time points, the average pain score reported for the entire treated region was zero, with no pain reported during treatment or at follow-up visits. No ETEs or AEs were reported in this study.

DISCUSSION

Overall, the findings of this study suggest that helium plasma RF may serve as a viable alternative to excisional breast lift for patients seeking a less invasive option. The 73% (11/15) success rate for IPR at

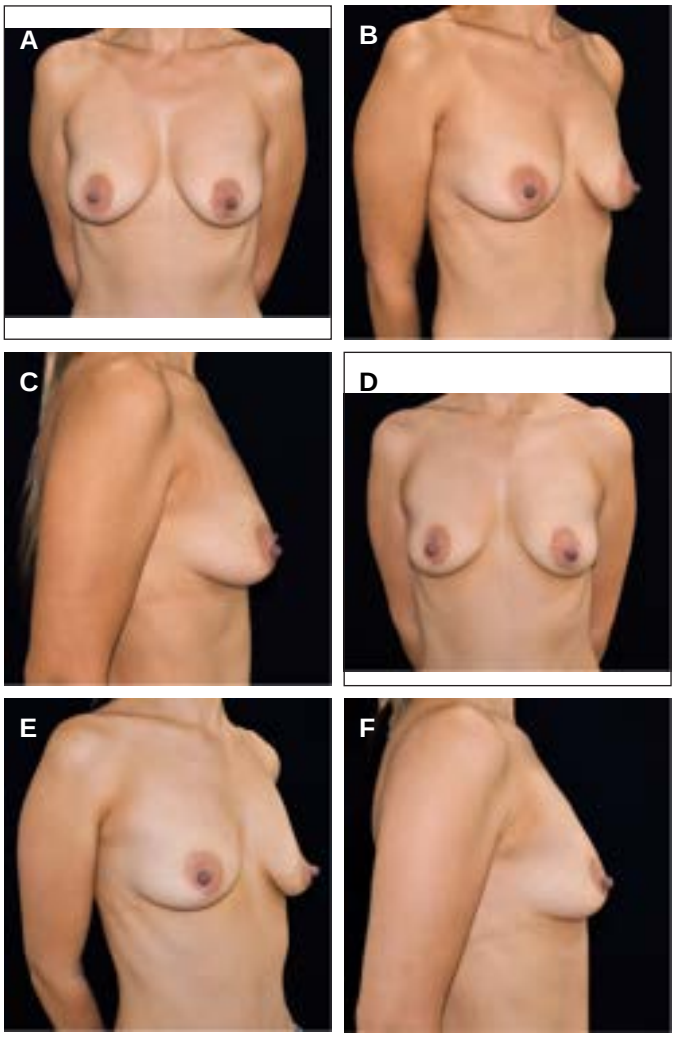


Figure 4. A 41-year-old patient at baseline (A-C) and 180 days following treatment with helium plasma RF (D-F). The after images were correctly identified by two-third of blinded reviewers. P-GAIS and I-GAIS were "much improved" and "very much improved," respectively, and the patient satisfaction questionnaire noted as "very satisfied" with "less sagging breasts," "breasts look higher on chest," "nipple placement is improved," and "breasts appear more youthful." I-GAIS and P-GAIS, investigator- and patient-assessed Global Aesthetic Improvement Scales.

Day 180, combined with the improved morphometric measures—specifically, reductions in SSN–N (−1.2 ± 0.7 cm), SSN–base (−1.5 ± 1.0 cm), and MCL–N (−0.9 ± 0.7 cm) distances—indicates a moderate treatment effect consistent with a successful minimally invasive intervention. Moreover, the changes in morphometric measures were accompanied by an improvement from Grade II on the Rainbow Scale for breast ptosis (mild breast ptosis) to Grade I (no breast ptosis) for 40% (6/15) of patients. This modest rate of single-grade improvement is attributed to baseline classification of all patients as Grade II, where the only measurable improvement would be the complete elimination of ptosis. Such a result may not be achievable for all patients with a minimally invasive procedure, particularly those with larger breasts, thereby limiting the detectability of improvement using this scale. Future studies could benefit from including a broader patient population or a more sensitive measurement tool to better assess the treatment effect on ptosis. In the authors' experience, helium plasma RF is most useful in a subset of patients with small breasts requiring mild lift; hence, the enrollment criteria of B-cup or smaller. A larger sample size could be used to address differential effects based on breast size.

Table 1. Average Changes in Morphometric Measurements

Measurement	Day 30 ($n = 15$) (cm)	Day 90 ($n = 15$) (cm)	Day 180 ($n = 15$) (cm)
SSN–N	−0.7 ± 0.5	−0.9 ± 0.5	−1.2 ± 0.7
IMC–N	−0.3 ± 0.5	−0.6 ± 0.6	−0.6 ± 0.5
MCL–N	−0.7 ± 0.5	−0.8 ± 0.6	−0.9 ± 0.7
NAC	−0.1 ± 0.4	−0.1 ± 0.5	0.1 ± 0.4
PROJ	−0.2 ± 1.2	0.0 ± 1.2	0.3 ± 1.2
N–N	−0.3 ± 1.0	−0.3 ± 1.1	0.0 ± 1.1
SSN–IMC	−0.5 ± 0.6	−0.7 ± 0.8	−0.8 ± 1.0
SSN–base	−0.9 ± 0.8	−1.1 ± 0.8	−1.5 ± 1.0

IMC, inframammary crease; MCL, midclavicular line; N, nipple; NAC, nipple–areola complex diameter; PROJ, maximum point of breast projection measured perpendicular to the chest wall; SSN, suprasternal notch.

Helium plasma RF was well tolerated by the study population, with no pain reported during the procedure or at any of the follow-up time points and with minimal risk of AEs or ETEs. The absence of reported ETEs is likely because of the first follow-up visit occurring at 30 days, after the window within which most ETEs would typically manifest and resolve without intervention. Importantly, the minimal number of small incisions needed for breast lift with helium plasma RF substantially reduces the risk of scarring compared with traditional surgical methods.

Although RF treatments have been explored in combination with liposlysis for breast contouring, there is emerging evidence specifically documenting the effectiveness of RF for nonsurgical mastopexy. Unger et al reported that RF-assisted lipolysis using a bipolar RF device (InMode) can effectively improve mild-to-moderate breast ptosis, demonstrating high levels of patient satisfaction and improvements in morphometric measurements.[10] These findings align with the present study's results, supporting the potential of RF-based treatments for breast contouring. However, Swanson's 2022 systematic review of subsurface RF treatments, including InMode and Thermi devices, offers a contrasting perspective, because there is limited evidence supporting the efficacy and safety of subsurface RF treatments compared with traditional surgical methods.[11] In this systematic review, RF treatments did not appear to consistently demonstrate effectiveness in treating breast ptosis and are associated with several complications, such as prolonged swelling, numbness, and the occurrence of induration, nodules, and seromas. Considering the unique mechanism of helium plasma RF—which combines RF energy with helium plasma to achieve instantaneous tissue heating rather than relying on bulk heating—the data presented here, showing no AEs along with high levels of satisfaction and reported improvement, are important for supporting use in clinical practice.

Notably, the authors' helium plasma RF procedure in the breast evolved since this study was initiated. Greater improvements were observed by the authors when treating the breast tissue at multiple depths, including both superficial intradermal and deeper subdermal

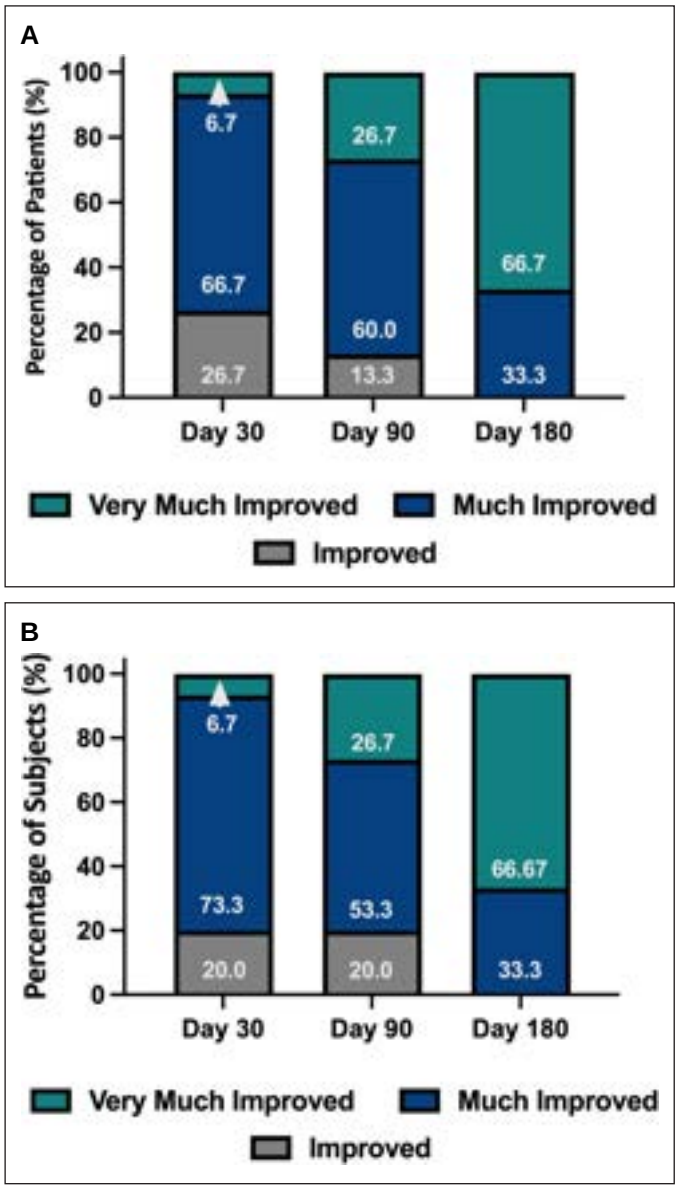


Figure 5. Investigator-assessed Global Aesthetic Improvement Scale ratings (A) and patient-assessed Global Aesthetic Improvement Scale ratings (B).

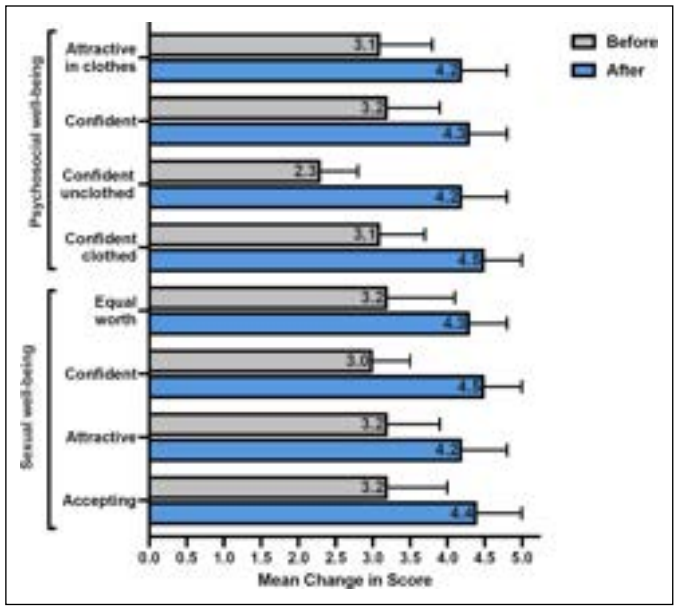


Figure 6. Mean change in Breast-Q score. Patients were asked, "With your breasts in mind, in the past week, how often have you felt: [question]." Possible responses were "none of the time" (1 point), "a little of the time" (2 points), "some of the time" (3 points), "most of the time" (4 points), or "all of the time" (5 points).

planes. In the authors' experience, contracting tissue across multiple layers provides a higher degree of lift and improved breast shape. For properly selected patients with realistic expectations and goals that do not require excisional surgery, helium plasma RF presents an effective and satisfying alternative. Unlike surgical methods that rely on excision, the improvements achieved with helium plasma RF are because of contraction across the treated area and are achieved with a very few number of small incisions. Furthermore, the larger treatment surface area also has improved skin quality.

Limitations of this study include the small sample size and inconsistencies in clinical photography, in particular arm and body positioning and variations in camera angle, which impacted IPR evaluation. Furthermore, the ptosis scale used was not sufficiently sensitive to capture improvement in this limited population. The results are subtle and are not easily captured with clinical photography, and incorporating additional objective measures such as cytometry or ultrasound assessment of skin thickness could provide valuable complementary data to the successful patient-reported outcomes and morphometric measures presented here. In addition, it will be important to characterize longer term duration as well as any long-term effects on the breast parenchyma, especially if these impact imaging. This is particularly important, given the potential for some positive bias stemming from patient and photographic reviewer participation in the study, a challenge in any aesthetic study. Although helium plasma RF was well tolerated and associated with no pain during the procedure or at any of the follow-up time points, and with minimal risk of AEs or ETEs, the absence of reported ETEs is likely because of the first follow-up visit being at 30 days, after the window within which most ETEs would have occurred and resolved without intervention. More frequent follow-up following the procedure may shed some light on the incidence of mild ETEs that may occur. Future research could also explore the use of helium plasma RF devices in combination with fat transfer or augmentation, offering a broader range of treatment options for patients, including tightening lax breast tissue and providing additional volume for those who desire it.

CONCLUSIONS

This study suggests that helium plasma RF could be considered as an alternative to excisional breast lift for patients who wish to avoid surgery and its associated scarring, downtime, and risks. Helium plasma RF shows a subtle but meaningful effect on breast appearance, with all patients reporting high levels of improvement and satisfaction and noted improvement in quality of life. Patients tolerated the procedure well, with no pain or AEs/ETEs reported during the procedure or at follow-up visits.

Supplemental Material

This article contains supplemental material located online at https://doi.org/10.1093/asjof/ojaf004.

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Disclosures

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