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PUBLICATION INFORMATION

Ruff PG, DiBernardo B, Gentile R, Cohen S, Bharti K, Kortesis B, Shridharani S, et al. A Prospective Multicenter, Evaluator-Blinded Study Evaluating the Safety and Effectiveness of the Renuvion APR Device to Improve the Appearance of Lax Tissue in the Neck and Submental Region. ISAPS 2022.

FINANCIAL & CONTENT DISCLOSURE: This research was funded in whole by Apyx Medical. Dr. Ruff is a consultant and member of the Medical Advisory Board for Apyx Medical. Dr.'s Bharti, Cohen, DiBernardo, Gentile, Kortesis, and Shridharani are consultants for Apyx Medical. At the time of the conduct of the study, Dr. Gentile was also a member of the Medical Advisory Board. The opinions contained herein are those of the authors(s) and do not necessarily represent the official position or policies of Apyx Medical, Inc.

MANUFACTURING DISCLOSURE: Apyx Medical manufactures and owns the Renuvion/J-Plasma technology discussed in this article.

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.

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.

Free Communications

A Prospective, Multicenter, Evaluator-Blinded Study Evaluating the Safety and Effectiveness of the Renuvion APR Device to Improve the Appearance of Lax Tissue in the Neck and Submental Region

Fri, September 23 | Session Hub 01 | Free Paper

Part of:
Free Communications: Non or Minimally Invasive Procedures

Info

Abstract:

Purpose: To demonstrate the safety and effectiveness of the Renuvion APR Device as a percutaneous, minimally invasive aesthetic treatment to improve the appearance of lax tissue in the neck and submental region.

Design: A prospective, pivotal phase, evaluator-blinded study of 65 subjects at 6 US sites who received a single Renuvion treatment.

The bilateral treatment area included the tissue of the neck (to the posterior border of the sternocleidomastoid muscle) and submental area. Treatment was performed through three (3) incisions (2 periauricular and 1 submental) with each incision large enough to allow for gas egress. Treatment was 4-6 treatment passes at 70% power and 1.5 LPM of helium flow with an activation speed of approximately 1-3 cm/s.

Follow-up visits at D1, D7, D14, D30, D90, and D180.

Primary Effectiveness Endpoint was improvement in the appearance of lax tissue in the neck and submental region at D180 determined by 2 of 3 blinded Independent Photographic Reviewers (IPR). Primary Safety Endpoint was the level of pain and discomfort after treatment as reported by the subject on an 11-point Numeric Rating Scale (NRS) through D7.

Findings: Primary effectiveness endpoint met; 82.5% demonstrated improvement at D180 by IPR. Primary safety endpoint met; 96.9% of subjects experienced no pain to moderate pain to D7. Mean NRS scores were 0.9, 2.3, and 0.6 at immediately post-procedure, D1, and D7.

Additional Endpoints: (1) 76.2% demonstrated improvement at D90 by IPR. (2) 92.1% and 85.5% rated improvement (Improved, Much Improved, or Very Much Improved) by Subject GAIS at D90 and D180. (3) 95.2% and 87.1% rated improvement by Investigator GAIS at D90 and D180. (4) At D180, 72.6% of subjects reported being happy with the results of the procedure. 74.2% would recommend the procedure to a friend. 75.8% would consider having the same type of procedure performed on another part of their body. (5) 62.3% demonstrated quantitative improvement of at least 20mm^2 of lift in the neck and submental region at D180. (6) 68.3% demonstrated quantitative improvement in submental volume at D180. (7) Most common events reported: 92.3% edema/swelling, 86.2% temporary sensory nerve changes, 55.4% ecchymosis/bruising, 46.2% erythema, 40.0% crepitus, 24.6% pain/tenderness. (8) Mean NRS scores were 0.3 and 0.2 at D14 and D30.

Summary: The totality of the data demonstrates benefit to subjects in the improvement of the appearance of lax tissue in the neck and submental region. The primary effectiveness endpoint for this study was achieved at 82.5%. The primary safety endpoint was achieved at 96.9%. There were no serious adverse events reported as related to the study device or the study procedure. Further, the adverse events were within the range expected for subdermal treatments in the neck and submental area.

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: July 11, 2022

ClinicalTrials.gov ID: NCT04146467

Study Identification

Unique Protocol ID:	VP-1902
Brief Title:	Renuvion APR Device to Improve the Appearance of Lax Tissue in the Neck and Submental Region
Official Title:	A Prospective, Multi-Center, Evaluator-Blinded Study Evaluating the Safety and Effectiveness of the Renuvion APR Device to Improve the Appearance of Lax Tissue in the Neck and Submental Region
Secondary IDs:	

Study Status

Record Verification:	July 2022
Overall Status:	Completed
Study Start:	November 26, 2019 [Actual]
Primary Completion:	February 28, 2022 [Actual]
Study Completion:	February 28, 2022 [Actual]

Sponsor/Collaborators

Sponsor:	Apyx Medical
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	Yes

Unapproved/Uncleared Device:	No
Pediatric Postmarket Surveillance:	No
U.S. FDA IND/IDE:	Yes
IND/IDE Information:	FDA Center: CDRH IND/IDE Number: G190152 Serial Number: Has Expanded Access: No
Human Subjects Review:	Board Status: Approved
Data Monitoring:	No
FDA Regulated Intervention:	No

Study Description

Brief Summary:	This is a prospective, multi-center, multi-phase, evaluator-blinded study of subjects undergoing a procedure with the Renuvion APR Device to improve the appearance of lax tissue in the neck and submental region.
Detailed Description:	This is a prospective, multi-center, multi-phase, evaluator-blinded study of subjects undergoing a procedure to improve the appearance of lax tissue in the neck and submental region. All study subjects will be treated with the Renuvion APR Device. Phase I (n=17) of this study will be conducted primarily to provide safety data, however, effectiveness data will also be collected at the above stated timepoints through 6 months post-procedure. Phase II (n=65) of this study is the expansion of the study to a pivotal study.

Conditions

Conditions:	Lax Skin
Keywords:	Submental, Neck

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	N/A
Interventional Study Model:	Sequential Assignment

Number of Arms: 2

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 82 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Study Phase I Subjects will be treated with the Renuvion APR device in the neck and submental region.	Device: Renuvion APR Device The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Experimental: Study Phase II Subjects will be treated with the Renuvion APR device in the neck and submental region.	Device: Renuvion APR Device The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 35 Years

Maximum Age: 65 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

1. Male or female subjects 35-65 years of age (inclusive).
2. Healthy as determined by the investigator examining the subject.
3. Seeking improvement of the appearance of lax tissue in the neck and submental region.
4. Females of childbearing potential who are sexually active must be willing to use an approved method of birth control during study participation.
5. Willing and able to comply with protocol requirements, including obtaining study-required images/photos and assessments, and returning for follow-up visits.
6. Willing to release rights for the use of study photos, including in potential publication.
7. Understands and accepts the obligation not to have significant weight loss or weight gain (≥8 pounds) post the treatment, and for the duration of participation in the study.
8. Willing to abstain from the use of blood thinners (including, but not limited to, Coumadin, NSAIDS, Ibuprofen, vitamin K, other) for 2 weeks (14 days) prior to the procedure.
9. Willing to abstain from smoking, vaping, or the use of e-cigarettes for 1 year prior to and for the entire duration of participation in the study.
10. Willing to abstain from the use of marijuana for 2 weeks prior to and for the duration of participation in the study.
11. Able to read, understand, sign and date the informed consent document (English only).

Exclusion Criteria:

1. Pregnant or lactating.
2. Pregnancy within 12 months prior to screening.
3. Use within 24 hours preceding surgery of ibuprofen, acetaminophen, any other analgesics, anti-inflammatory products, or any products including herbals and supplements that could interfere with the clinical assessments of this study (other than drugs used for anesthesia).
4. Allergy to tumescent anesthetic (lidocaine/epinephrine).
5. Excessive subcutaneous fat in the treatment area (as determined by the treating investigator).
6. Active systemic or local skin disease that may alter wound healing.
7. Significant or uncontrolled medical condition that, in the opinion of the investigator, participation in the study may compromise the patient’s health.
8. Severe solar elastosis.
9. History of autoimmune disease (excluding Hashimoto’s thyroiditis).
10. Known hypersensitivity or adverse reaction to anesthetics.
11. Known susceptibility to keloid formation or hypertrophic scarring.
12. Cancerous or pre-cancerous lesions in the area to be treated.
13. History or current diagnosis of cancer of any type (excluding skin cancer).
14. History of uncontrolled cardiovascular disease (i.e. myocardial infarction, hypertension, hypercholesterolemia, peripheral vascular disease, other).
15. History, or current bleeding disorders (i.e. hemophilia or von Willebrand disease), or anticipated treatment with prescription anticoagulants.
16. Possesses a surgically implanted electronic device (i.e. pacemaker).
17. History of AIDs/HIV.
18. Serious mental health illness such as dementia or schizophrenia; psychiatric hospitalization in the past two years.

19. Chronic hypoxia or dependence on supplemental oxygen.
20. Participation in any other investigational study within 30 days prior to consent.
21. Any surgical or transdermal neck/submental aesthetic procedures or plans to undergo any other aesthetic procedure during study participation. Such procedures include, but are not limited to, submentoplasty, liposuction, ultrasound, cryolipolysis, radiofrequency, and laser.
22. History of or current injury to the head and neck or any area of the body being treated as a part of this study.
23. Presence of more than mild platysmal banding as per the Geister, et al Validated Assessment Scale for Platysmal Bands.
24. Subject requiring removal of adipose tissue prior index procedure.
25. A family member of the investigator or sponsor; an employee of the investigator or sponsor.
26. Subject who, in the opinion of the investigator, is not an appropriate candidate for the study.

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IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Documents

Study Protocol
Document Date: December 16, 2020
Uploaded: 04/29/2022 20:19

Study Results

Participant Flow

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Overall Study

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Started	17	65
Completed	17	62
Not Completed	0	3
Adverse Event	0	1
Lost to Follow-up	0	2

Baseline Characteristics

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Baseline Measures

		Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II	Total
Overall Number of Participants		17	65	82
Age, Customized Mean (Standard Deviation) Unit of measure: years	Number Analyzed	17 participants	65 participants	82 participants
Average Age		58.5 (4.0)	55.9 (6.3)	56.4 (5.9)
Age, Customized Median (Inter-Quartile Range) Unit of measure: years	Number Analyzed	17 participants	65 participants	82 participants
Median Age		59 (56 to 62)	57.0 (51 to 61)	57.0 (53 to 61.8)

		Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II	Total
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	17 participants	65 participants	82 participants
	Female	16 94.12%	59 90.77%	75 91.46%
	Male	1 5.88%	6 9.23%	7 8.54%
Race/Ethnicity, Customized Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	17 participants	65 participants	82 participants
[Not specified]	Asian	1 5.88%	1 1.54%	2 2.44%
	Hispanic or Latino	1 5.88%	3 4.62%	4 4.88%
	White	14 82.35%	61 93.85%	75 91.46%
	Other: Greek Spanish	1 5.88%	0 0%	1 1.22%
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	17 participants	65 participants	82 participants
United States		17	65	82
Body Mass Index (BMI) Mean (Standard Deviation) Unit of measure: kg/m^2	Number Analyzed	17 participants	65 participants	82 participants
		36.49 (4.1)	25.4 (4.9)	25.5 (4.7)

		Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II	Total
Body Mass Index (BMI)	Number Analyzed	17 participants	65 participants	82 participants
Median (Inter-Quartile Range) Unit of measure: kg/m^2		25.5 (22.6 to 28.3)	24.7 (22.8 to 27.0)	24.8 (22.7 to 27.6)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Day 180 Number of Participants With Improvement Measured By Independent Photographic Review
Measure Description	Improvement in the appearance of lax tissue in the neck and submental region at 6 months as determined by qualitative 2D photography assessment by blinded Independent Photographic Reviewers. Three experienced, blinded photographic reviewers performed a qualitative analysis/review of the pre-treatment and post-treatment sets of images of each subject in a blinded and randomized order. Each blinded reviewer chose which image was the post-treatment image. Success was correct post-treatment image selection by at least 2 of the 3 reviewers. The percentage of subjects with a correct post-treatment image selection was calculated.
Time Frame	180-Day

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed	7	63
Day 180 Number of Participants With Improvement Measured By Independent Photographic Review Measure Type: Count of Participants Unit of measure: participants	6 85.71%	52 82.54%

Statistical Analysis 1 for Day 180 Number of Participants With Improvement Measured By Independent Photographic Review

Statistical Analysis Overview	Comparison Group Selection	Sub-Dermal Neck Renuvion APR Device - Study Phase II
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

2. Primary Outcome Measure:

Measure Title	Subject Reported Pain - None to Moderate

Measure Description	The primary safety endpoint is the level of pain and discomfort after treatment as reported by the subject on an 11-point Numeric Rating Scale (NRS) through the 7-day follow-up visit where 0 is no pain and 10 is the most pain. Pain scores are classified as scores of 0 being no pain, 1 – 5 is minor pain, 6 – 7 is moderate pain, and 8 – 10 is severe pain. The primary safety objective is to demonstrate that the proportion of subjects with none-to- moderate pain exceeds the performance goal (PG). The performance goal is 55%.
Time Frame	Day 7

Analysis Population Description

Phase I: 17 total participants started Phase I. 4 participants missed their Day 7 follow-up visit due to COVID-19 office closures and/or restrictions. Therefore, Day 7 data for Subject Reported Pain was only analyzed for 13 participants.

Phase II: 65 participants started Phase 2. 1 participant exited the study prior to Day 7 follow-up visit. Therefore, Day 7 data for Subject Reported Pain was only analyzed for 64 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	Subjects treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed	13	64
Subject Reported Pain - None to Moderate Measure Type: Count of Participants Unit of measure: participants	13 100%	62 96.88%

3. Other Pre-specified Outcome Measure:

Measure Title	Day 90 Number of Participants With Improvement Measured By Independent Photographic Review
Measure Description	Change in the appearance of lax tissue in the neck and submental region at 90-days as determined by qualitative 2D photography assessment by blinded Independent Photographic Reviewers. Three experienced, blinded photographic reviewers performed a qualitative analysis/review of the pre-treatment and post-treatment sets of images of each subject in a blinded and randomized order. Each blinded reviewer chose which image was the post-treatment image. Success was correct post-treatment image selection by at least 2 of the 3 reviewers. The percentage of subjects with a correct post-treatment image selection was calculated.
Time Frame	90-Day

Analysis Population Description

Phase I: 17 total participants started Phase I. 7 participants missed their D90 images due to COVID-19 office closures and/or restrictions. Therefore, D90 Independent Photographic Review data was only available for 10 participants.

Phase II: 65 total participants started Phase 2. 1 participant exited the study prior to D90 visit and 1 participant was lost to follow-up prior to D90 Follow-up visit. Therefore, Day 90 Independent Photographic Review data was only available for 63 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed	10	63
Day 90 Number of Participants With Improvement Measured By Independent Photographic Review Measure Type: Count of Participants Unit of measure: participants	8 80%	48 76.19%

Statistical Analysis 1 for Day 90 Number of Participants With Improvement Measured By Independent Photographic Review

Statistical Analysis Overview	Comparison Group Selection	Sub-Dermal Neck Renuvion APR Device - Study Phase II
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0004
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

4. Other Pre-specified Outcome Measure:

Measure Title	Subject Modified Global Aesthetic Improvement Scale (GAIS)
Measure Description	Subject Modified GAIS: Very Much Improved, Much Improved, Improved, No Change, Worse, Much Worse, Very Much Worse
Time Frame	90-Day

Analysis Population Description

Phase I: 17 total participants started Phase I. 1 participant missed their D90 Modified GAIS due to COVID-19 office closures and/or restrictions. Therefore, D90 Subject Modified GAIS data was only available for 16 participants.

Phase II: 65 total participants started Phase 2. 1 participant exited the study prior to D90 visit and 1 participant was lost to follow-up prior to D90 Follow-up visit. Therefore, Day 90 Subject Modified GAIS data was only available for 63 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

		Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed		16	63
Subject Modified Global Aesthetic Improvement Scale (GAIS) Measure Type: Count of Participants Unit of measure: participants	Very Much Improved	0 0%	7 11.11%
	Much Improved	7 43.75%	18 28.57%
	Improved	5 31.25%	33 52.38%
	No Change	3 18.75%	3 4.76%
	Worse	0 0%	1 1.59%
	Much Worse	0 0%	1 1.59%
	Very Much Worse	1 6.25%	0 0%

5. Other Pre-specified Outcome Measure:

Measure Title	Subject Modified Global Aesthetic Improvement Scale (GAIS)
Measure Description	Subject Modified GAIS: Very Much Improved, Much Improved, Improved, No Change, Worse, Much Worse, Very Much Worse

Time Frame	180-Day

Analysis Population Description

Phase-II discrepancy is due to 1 subject exited due to an AE during treatment and 2 subject lost to follow-up prior to Day 180 visit. Which brought the numbers to: Phase-II 62

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

		Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed		17	62
Subject Modified Global Aesthetic Improvement Scale (GAIS) Measure Type: Count of Participants Unit of measure: participants	Very Much Improved	4 23.53%	12 19.35%
	Much Improved	5 29.41%	17 27.42%
	Improved	3 17.65%	24 38.71%
	No Change	3 17.65%	7 11.29%
	Worse	1 5.88%	2 3.23%
	Much Worse	0 0%	0 0%
	Very Much Worse	1 5.88%	0 0%

6. Other Pre-specified Outcome Measure:

Measure Title	Investigator Modified Global Aesthetics Improvement Scale (GAIS)
Measure Description	Investigator Modified GAIS:Very Much Improved, Much Improved, Improved, No Change, Worse, Much Worse, Very Much Worse
Time Frame	90-Day

Analysis Population Description

Phase I: 17 total participants started Phase I. 2 participants completed virtual visits and 1 participant missed their D90 visit due to COVID-19 office closures and/or restrictions. Therefore, D90 Investigator GAIS data was only available for 14 participants.

Phase II: 65 total participants started Phase 2. 1 participant exited the study prior to D90 visit and 1 participant was lost to follow-up prior to D90 visit. Therefore, Day 90 Investigator GAIS data was only available for 63 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

		Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed		14	63
Investigator Modified Global Aesthetics Improvement Scale (GAIS)	Very Much Improved	0 0%	8 12.7%
	Much Improved	3 21.43%	19 30.16%
	Improved	8 57.14%	33 52.38%

		Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Measure Type: Count of Participants Unit of measure: participants	No Change	2 14.29%	3 4.76%
	Worse	1 7.14%	0 0%
	Much Worse	0 0%	0 0%
	Very Much Worse	0 0%	0 0%

7. Other Pre-specified Outcome Measure:

Measure Title	Investigator Modified Global Aesthetic Improvement Scale (GAIS)
Measure Description	Investigator Modified GAIS: Very Much Improved, Much Improved, Improved, No Change, Worse, Much Worse, Very Much Worse
Time Frame	180-Day

Analysis Population Description

Phase-II discrepancy is due to 1 subject exited due to an AE during treatment and 2 subject lost to follow-up prior to Day 180 visit. Which brought the numbers to: Phase-II 62

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

		Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed		17	62
Investigator Modified Global Aesthetic Improvement Scale (GAIS) Measure Type: Count of Participants Unit of measure: participants	Very Much Improved	2 11.76%	8 12.9%
	Much Improved	6 35.29%	19 30.65%
	Improved	5 29.41%	27 43.55%
	No Change	3 17.65%	6 9.68%
	Worse	1 5.88%	2 3.23%
	Much Worse	0 0%	0 0%
	Very Much Worse	0 0%	0 0%

8. Other Pre-specified Outcome Measure:

Measure Title	Day 180 Patient Satisfaction Questionnaire (PSQ) of Procedure
Measure Description	At 180 days post procedure, the subject's satisfaction with the procedure was assessed using a Patient Satisfaction Questionnaire. Questions were YES or NO questions pertaining to satisfaction with study treatment, observations of improvement, and considerations for recommendation.
Time Frame	180-Day

Analysis Population Description

Phase II: 65 total participants started Phase 2. 1 participant exited the study prior to D180 visit and 2 participants was lost to follow-up prior to D180 Follow-up visit. Therefore, Day 180 Patient Satisfaction Questionnaire data was only available for 62 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed	17	62
Day 180 Patient Satisfaction Questionnaire (PSQ) of Procedure Measure Type: Count of Participants Unit of measure: participants		
Number of Subjects that Answered YES to Happy With Results of Procedure	12 70.59%	47 75.81%
Number of Subjects that Answered YES to More Jawline Definition	NA [1]	39 62.9%
Number of Subjects that Answered YES to Reduction in Jowls	NA [1]	20 32.26%
Number of Subjects that Answered YES to Improvement in Skin Texture in Treatment Area	NA [1]	20 32.26%
Number of Subjects that Answered YES to Reduction in the Area Under the Chin	NA [1]	41 66.13%
Number of Subjects that Answered YES to Reduction of Lines & Wrinkles in the Treatment Area	NA [1]	21 33.87%
Number of Subjects that Answered YES to Other Changes	NA [1]	10 16.13%
Number of Subjects that Answered YES to Would Recommend Procedure to a Friend	12 70.59%	46 74.19%
Number of Subjects that Answered YES to Would Consider Having the Procedure on Another Body Area	11 64.71%	47 75.81%

[1] Data not collected in Study Phase I

9. Other Pre-specified Outcome Measure:

Measure Title	Quantitative Improvement in Overall Lift of the Neck and Submental Area
Measure Description	Quantitative improvement in overall lift of the neck and submental area as determine by quantitative assessment based on 2D photography with Canfield Vectra system analysis. Fixed landmarks on the subject's face were used.
Time Frame	180-Day

Analysis Population Description

Phase II: 65 total participants started Phase 2. 1 participant exited the study prior to D180 visit, 1 participant completed a virtual visit, and 2 participants were lost to follow-up prior to D180 Follow-up visit. Therefore, Day 180 Quantitative Improvement data was only available for 61 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed	0	61

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Quantitative Improvement in Overall Lift of the Neck and Submental Area Measure Type: Count of Participants Unit of measure: participants	---	38 62.3%

10. Other Pre-specified Outcome Measure:

Measure Title	Quantitative Improvement in Submental Volume
Measure Description	Quantitative improvement in submental volume at 180 days as determined by quantitative assessment based on 3D photography with Canfield Vectra system analysis.
Time Frame	180-Day

Analysis Population Description

Phase II: 65 total participants started Phase 2. 1 participant exited the study prior to D180 visit, 2 participants were lost to follow-up prior to D180 visit, 1 participant completed a virtual visit for D180 and did not have photographs for volume assessment, and 1 subject had poor image quality that resulted in the inability to assess volume change. Therefore, Day 180 Quantitative Improvement in Submental Volume was only available for 60 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed	0	60
Quantitative Improvement in Submental Volume Measure Type: Count of Participants Unit of measure: participants	---	41 68.33%

11. Other Pre-specified Outcome Measure:

Measure Title	Average Pain at Day 7 Reported by Subject
Measure Description	Level of pain and discomfort after treatment as reported by the subject on a 11-point Numeric Rating Scale where 0 is "No Pain" and 10 is "Worst Possible Pain"
Time Frame	7-Day

Analysis Population Description

Phase I: 17 total participants started Phase I. 4 participants missed their D7 follow-up visit due to COVID-19 office closures and/or restrictions. Therefore, D7 Average Pain data was only available for 13 participants.

Phase II: 65 total participants started Phase 2. 1 participant exited the study prior to D7 visit . Therefore, Day 7 Average Pain data was only available for 64 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed	13	64
Average Pain at Day 7 Reported by Subject Mean (Standard Deviation) Unit of measure: score on a scale	1.23 (1.24)	0.6 (1.2)

Statistical Analysis 1 for Average Pain at Day 7 Reported by Subject

Statistical Analysis Overview	Comparison Group Selection	Sub-Dermal Neck Renuvion APR Device - Study Phase II
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

12. Other Pre-specified Outcome Measure:

Measure Title	Median Pain Reported by Subject at Day 7
Measure Description	Level of pain and discomfort after treatment as reported by the subject on a 11-point Numeric Rating Scale where 0 is "No Pain" and 10 is "Worst Possible Pain"
Time Frame	7-Day

Analysis Population Description

Phase I: 17 total participants started Phase I. 4 participants missed their D7 follow-up visit due to COVID-19 office closures and/or restrictions. Therefore, D7 Median Pain data was only available for 13 participants.

Phase II: 65 total participants started Phase 2. 1 participant exited the study prior to D7 visit . Therefore, Day 7 Median Pain data was only available for 64 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed	13	64
Median Pain Reported by Subject at Day 7 Median (Inter-Quartile Range) Unit of measure: score on a scale	1.0 (0 to 3)	0.0 (0 to 1)

13. Other Pre-specified Outcome Measure:

Measure Title	Average Pain Reported by Subject at Day 30

Measure Description	Level of pain and discomfort after treatment as reported by the subject on a 11-point Numeric Rating Scale where 0 is "No Pain" and 10 is "Worst Possible Pain"
Time Frame	30-Day

Analysis Population Description

Phase I: 17 total participants started Phase I. 2 participants missed their D30 follow-up visit due to COVID-19 office closures and/or restrictions. Therefore, D30 Average Pain data was only available for 15 participants.

Phase II: 65 total participants started Phase 2. 1 participant exited the study prior to D30 visit and1 participant was lost to follow-up prior to D30 visit. Therefore, Day 30 Average Pain data was only available for 63 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed	15	63
Average Pain Reported by Subject at Day 30 Mean (Standard Deviation) Unit of measure: score on a scale	1.33 (2.66)	0.2 (0.5)

14. Other Pre-specified Outcome Measure:

Measure Title	Median Pain Reported by Subject at Day 30
Measure Description	Level of pain and discomfort after treatment as reported by the subject on a 11-point Numeric Rating Scale where 0 is "No Pain" and 10 is "Worst Possible Pain"
Time Frame	30-Day

Analysis Population Description

Phase I: 17 total participants started Phase I. 2 participants missed their D30 follow-up visit due to COVID-19 office closures and/or restrictions. Therefore, D30 Median Pain data was only available for 15 participants.

Phase II: 65 total participants started Phase 2. 1 participant exited the study prior to D30 visit and1 participant was lost to follow-up prior to D30 visit. Therefore, Day 30 Median Pain data was only available for 63 participants.

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

Measured Values

	Sub-Dermal Neck Renuvion APR Device - Study Phase I	Sub-Dermal Neck Renuvion APR Device - Study Phase II
Overall Number of Participants Analyzed	15	63
Median Pain Reported by Subject at Day 30 Median (Inter-Quartile Range) Unit of measure: score on a scale	0 (0 to 9)	0.0 (0 to 0)

Reported Adverse Events

Time Frame	Through 6 month follow-up visit for all enrolled subjects
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Sub-Dermal Neck Renuvion APR Device - Study Phase II	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.
Sub-Dermal Neck Renuvion APR Device - Study Phase I	All subjects will be treated with the Renuvion APR device. Renuvion APR Device: The Renuvion APR Handpiece 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation. The Renuvion APR Handpiece has a non-extendable electrode to generate helium plasma.

All-Cause Mortality

	Sub-Dermal Neck Renuvion APR Device - Study Phase II		Sub-Dermal Neck Renuvion APR Device - Study Phase I	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total All-Cause Mortality	0/65 (0%)		0/17 (0%)	

Serious Adverse Events

	Sub-Dermal Neck Renuvion APR Device - Study Phase II		Sub-Dermal Neck Renuvion APR Device - Study Phase I	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	3/65 (4.62%)		0/17 (0%)	
Gastrointestinal disorders				
Lower GI Bleed [1] *	1/65 (1.54%)	1	0/17 (0%)	0
General disorders				
Acute Appendicitis [1] *	1/65 (1.54%)	1	0/17 (0%)	0
Renal and urinary disorders				
Kidney Stone [1] *	1/65 (1.54%)	1	0/17 (0%)	0

* Indicates events were collected by non-systematic methods.

[1] Not related to device or procedure.

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Sub-Dermal Neck Renuvion APR Device - Study Phase II		Sub-Dermal Neck Renuvion APR Device - Study Phase I	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	62/65 (95.38%)		16/17 (94.12%)	
Nervous system disorders				
Temporary motor nerve Injury (nerve weakness, muscle atrophy, twitching, and paralysis) *	4/65 (6.15%)		1/17 (5.88%)	
Skin and subcutaneous tissue disorders				
Crepitus [1] *	27/65 (41.54%)		3/17 (17.65%)	
Ecchymosis/ bruising [1] *	36/65 (55.38%)		10/17 (58.82%)	
Edema/Swelling [1] *	60/65 (92.31%)		14/17 (82.35%)	
Erythema [1] *	32/65 (49.23%)		3/17 (17.65%)	

	Sub-Dermal Neck Renuvion APR Device - Study Phase II		Sub-Dermal Neck Renuvion APR Device - Study Phase I	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Nodules/subcutaneous lumps (migratory firmness) [1] *	8/65 (12.31%)		6/17 (35.29%)	
Pain/tenderness [1] *	16/65 (24.62%)		5/17 (29.41%)	
Pruritus/itching (not related to nerve injury) *	4/65 (6.15%)		0/17 (0%)	
Temporary sensory nerve injury (loss of sensation) [1] *	57/65 (87.69%)		5/17 (29.41%)	

* Indicates events were collected by non-systematic methods.

[1] Expected Treatment Effect

Limitations and Caveats

Limitations of this study was the pandemic that occurred in the middle of the study and caused study visits to be more challenging for all subjects enrolled.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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