ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: September 1, 2026

ClinicalTrials.gov ID: NCT07807085

Study Identification

Unique Protocol ID:	GOO-APPLE-PEPTIDE-001
Brief Title:	Apple Peptide Complex for Post-Surgical and Aesthetic Skin Recovery (APC-SKIN)
Official Title:	Evaluation of the Efficacy of the Breast and Body Apple Peptide Complex in Post-Surgical Recovery and Non-Invasive Aesthetic Treatments in Medical Aesthetic Clinics, Dermatology Practices, and Med Spas
Secondary IDs:	

Study Status

Record Verification:	September 2026
Overall Status:	Completed
Study Start:	January 20, 2021 [Actual]
Primary Completion:	December 4, 2025 [Actual]
Study Completion:	December 29, 2025 [Actual]

Sponsor/Collaborators

Sponsor:	Grow Out Oils Clinical Aromatherapy Company
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Exempt
Data Monitoring:	No

Study Description

Brief Summary:	This clinical study evaluates a topical botanical formulation for supporting skin recovery following invasive and non-invasive aesthetic procedures. These procedures include liposuction, breast augmentation, Brazilian butt lift (BBL),

laser treatments, and micro needling, pregnancy stretch mark and weight loss skin.

The study will assess the effects of the formulation on skin elasticity, hydration, and overall appearance when used as part of post-procedure care under the supervision of licensed medical professionals. Participants will apply the product to treatment areas over a defined study period, and outcomes will be compared to a control group receiving standard care or placebo.

Detailed Description: The investigational product is a topical botanical formulation composed of plant-derived extracts including Pyrus malus (apple) fruit extract, Vanilla planifolia fruit extract, Jasminum officinale (jasmine) flower extract, and Vitis vinifera derivatives. These components are commonly used in dermatologic and cosmetic applications for their antioxidant, emollient, and skin barrier-supporting properties.

The formulation contains fatty acid components, including linoleic acid, which may contribute to maintaining skin hydration and barrier integrity. The product is intended for topical use following invasive and non-invasive aesthetic procedures, including liposuction, breast augmentation, Brazilian butt lift (BBL), laser therapies, and micro needling, pregnancy stretch mark and weight loss skin.

This study is designed as a randomized, interventional clinical trial conducted in medical aesthetic clinics, dermatology practices, and med spa settings. Participants were assigned to either an intervention group receiving the investigational product for standard post-procedure usage for topical skincare use.

Primary outcome measures include assessment of skin elasticity, hydration, and visible skin appearance. Secondary outcomes include time to visible recovery and incidence of adverse skin reactions.

Conditions

Conditions: Skin Barrier to Water Loss
Skin Health
Skin Discoloration
Skin Irritation
Skin Abnormalities
Hyperpigmentation
Hyperpigmentation; Melanin
Stretch Mark
Breast Reconstruction
Breast Augmentation and Breast Reconstruction
Chemotherapy Effects
Lymphatic Abnormalities

Keywords: aesthetic care healing modality
bbl post care treatment
breast augmentation and reconstructive post care treatment
stretch marks
skin hyperpigmentation
skin irritation
skin barrier health
skin discoloration

Study Design

Study Type: Interventional

Primary Purpose:	Supportive Care
Study Phase:	N/A
Interventional Study Model:	Single Group Assignment Participants were randomized into two parallel groups: an intervention group receiving the topical Apple Peptide Complex as part of post-procedural care, and a control group receiving standard post-procedure care. Both groups were monitored over the same study period following invasive and non-invasive aesthetic procedures, including surgical and dermatologic treatments, to evaluate skin recovery outcomes.
Number of Arms:	1
Masking:	None (Open Label) This study was conducted as an open-label trial. Both participants and investigators were aware of the assigned treatment groups due to the nature of the topical intervention and standard care comparison.
Allocation:	N/A
Enrollment:	50 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Apple Peptide Complex Post-Aesthetic Care Protocol Participants receive the Apple Peptide Complex topical formulation as a standardized post-aesthetic care intervention following an invasive or non-invasive aesthetic procedure. The formulation is applied to designated treatment areas according to the study protocol-defined frequency and duration. Participants are evaluated for predefined biomedical and/or health-related outcomes associated with post-procedural recovery and overall cellular repair.	Apple Peptide Complex Post-Aesthetic Care Protocol Participants receive the Apple Peptide Complex topical formulation as a standardized post-aesthetic care intervention following invasive and non-invasive aesthetic procedures. Participants apply the formulation to designated treatment areas according to the protocol-defined frequency, amount, and duration. Outcomes are evaluated to assess the formulation's effects on post-procedural skin recovery and overall cellular repair. Apple Peptide Complex is administered topically as a standardized post-aesthetic care intervention following invasive and non-invasive aesthetic procedures. Participants apply the formulation to designated treatment areas according to protocol-defined instructions regarding frequency and duration. The study evaluates predefined outcomes associated with post-procedural recovery and overall cellular repair.

Outcome Measures

Primary Outcome Measure:

1. Clinician-Graded Visual Skin Evaluation Score
   Clinician assessment of skin surface appearance to monitor reductions in post-procedural redness and dryness. Evaluation is performed using a standard 0 to 4 scale, where 0 indicates no redness/dryness and 4 indicates severe redness/dryness. Unit of Measure: Units on a scale (0 to 4)

   [Time Frame: Baseline, Day 14, and Day 28 post-procedure]
2. Change in Trans epidermal Water Loss (TEWL)
   Evaluation of skin barrier function following daily topical use of the cosmetic Apple Peptide Complex. Data are collected via a tewameter to assess absolute changes in skin moisture retention. Unit of Measure: g/h/m²

   [Time Frame: 28 days post-procedure (with assessments conducted at day 14 and day 28)]
3. Participant Comfort Rating Score

Self-reported participant feedback regarding skin comfort, including soothing sensations and lack of irritation. Scores are recorded using a feedback scale from 0 (extreme discomfort/irritation) to 10 (complete skin comfort/highly soothed). Unit of Measure: Units on a scale (0 to 10)

[Time Frame: Baseline, Day 14, and Day 28 post-procedure]

Secondary Outcome Measure:

4. Presence of Post-Inflammatory Hyperpigmentation (PIH)Description
   Clinical observation of the treated area to identify the development of post-procedural hyperpigmentation. Unit of Measure: Percentage of participants with observed hyperpigmentation.

   [Time Frame: Baseline (pre-procedure), immediately post-procedure, Day 14, and Day 28]
5. Clinician-Graded Skin Desquamation Score
   Assessment of skin flaking or peeling in the treated area using a standard clinical scaling chart. Evaluation is graded on a 0 to 4 scale, where 0 indicates no desquamation and 4 indicates severe desquamation.

   [Time Frame: Baseline (pre-procedure), immediately post-procedure, Day 14, and Day 28]

Other Pre-specified Outcome Measures:

6. Clinician-Rated Skin Erythema Score
   Assessment of skin redness in the treated area using a localized erythema grading scale. Evaluation is graded on a 0 to 3 scale, where 0 indicates no erythema and 3 indicates severe erythema. Unit of Measure: Units on a scale (0 to 3)

   [Time Frame: Baseline (pre-procedure), immediately post-procedure, Day 14, and Day 28]

Eligibility

Minimum Age:	
Maximum Age:	
Sex:	Female
Gender Based:	Yes female
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria:

- Female participants aged 45–65 years
- Undergoing or have undergone aesthetic or surgical procedures (e.g., liposuction, breast augmentation, laser treatments, microneedling)
- Presence of skin concerns such as hyperpigmentation, scarring, or reduced elasticity
- Willing and able to comply with study procedures and follow-up
- Physician clearance for participation

Exclusion Criteria:

- Active skin infections, open wounds, or delayed wound healing
- Pregnancy or breastfeeding
- Use of conflicting topical or systemic treatments
- Known allergy to botanical ingredients in the formulation

Contacts/Locations

Central Contact Person: CEO/Master Aromatherapy Chemist Formulator
Telephone: 954-710-7599
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Central Contact Backup: Art Bradford /Clinical Field Assistant, Political Science
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Study Officials: Shanna Bynes Bradford, Master Aromatherapy
Study Principal Investigator
Grow Out Oils Clinical Aromatherapy Company

Dr. Lane Rolling MD, Virologist, Epidemiologist,
Study Director
None

Locations: **United States, Florida**
Grow Out Oils Clinical Aromatherapy Company
Weston, Florida, United States, 33326

IPDSharing

Plan to Share IPD: Yes
Detailed information for each subject, such as participant ID, treatment received, age, race, gender, disease, aesthetic surgical procedure specific outcomes at different time points during the post care treatment healing process and protocol timeline.

Supporting Information:
Study Protocol
Informed Consent Form (ICF)
Clinical Study Report (CSR)

Time Frame:
The only information that will be available with the (IPD) for supporting information will be the study protocol, clinical study report (CSR) and informed consent form (ICF)

Access Criteria:
Due to the nature of the patients privacy regulations and principles mandate by HIPAA the (IPD) details used for the clinical research will be limited based on the "need to know" and "minimum necessary".

URL: https://pmc.ncbi.nlm.nih.gov/articles/PMC4658681/

References

Citations: **[Study Results]** Citation 1 (Skin Barrier & Topicals) Proksch E, Brandner JM, Jensen JM. The skin: an indispensable barrier. Experimental Dermatology. 2008;17(12):1063-1072.

[Study Results] Citation 3 (Post-Procedure Skin Care) Draelos ZD. The role of skin care in optimizing outcomes following cosmetic procedures. Journal of Cosmetic Dermatology. 2012;11(3):169-173.

[Study Results] Citation 2 (Botanicals / Antioxidants in Skin) Pullar JM, Carr AC, Vissers MCM. The roles of vitamin C in skin health. Nutrients. 2017;9(8):866.

[Study Results] Saxena S. Mobile pediatric service. Indian Pediatr. 1972 Nov;9(11):641-2. No abstract available. PubMed 4658681

Links:	URL: https://www.growoutoils.com Description Grow Out Oils Company Website URL: https://growoutoils.com/clinical-research Description Investor-grade white paper detailing clinical rationale and study design available at:
Available IPD/Information:	Type: Other [De-identified participant-level clinical data, including skin assessment outcomes, patient-reported outcomes, photographic documentation, and post-procedural recovery metrics collected during the study period.] URL: https://pmc.ncbi.nlm.nih.gov/articles/PMC4658681/ Identifier: GOO-APPLE-PEPTIDE-001 Access to de-identified individual participant data and supporting materials (study protocol, clinical study report, and informed consent form) will be provided to qualified researchers upon reasonable request. All data sharing will comply with HIPAA privacy regulations and follow the principles of “minimum necessary” and “need to know.”

Documents

Study Protocol, Statistical Analysis Plan and Informed Consent Form
Document Date: March 1, 2026
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