

PROTOCOL OF A STUDY IN PLASTIC AND MAXILLOFACIAL SURGERY

Title of the Protocol:

**Limited Delamination Versus Traditional Deep Plane Rhytidectomy: A
Randomized Control Trial Assessing the Enhancement of the Jowl and the
Labiomandibular fold**

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What is already known on this subject? AND
What does this study add?

The pursuit of the optimal facelift technique continues to drive innovation in plastic surgery. While the deep plane rhytidectomy is widely accepted for its superior midface correction compared to SMAS-plication techniques, the method of entering the deep plane remains a subject of debate. The **Traditional Entry Point**, defined by a line from the lateral canthus to the gonial angle, requires wide subcutaneous delamination. The newer Preservation Entry Point, or Limited Delamination technique, advocates for a lateral entry to maintain the skin-SMAS composite integrity. This study aims to compare the aesthetic improvement of the lower face between the Traditional Entry Point and Preservation Entry Point techniques.

1. INTRODUCTION/ REVIEW

The aging process of the face and neck manifests in various ways. Surgeons recognize that it is a confluence of changes in the skin, muscle, fat, and connective tissue that collectively contribute to the characteristic signs of aging in the neck region. These characteristics include diminished skin tone, alterations in skin pigmentation, ptosis and banding of the platysmal muscles, accumulation and grouping of fat compartments, and rhytids (*Thomas and Dixon, 2014*).

The "Traditional Deep Plane Rhytidectomy (TEP)," as originally described by **Hamra in 1990**, represented a paradigm shift by advocating for a composite flap of skin and the superficial musculoaponeurotic system (SMAS). This technique necessitates a specific entry point—typically a line drawn from the lateral canthus to the gonial angle—requiring wide subcutaneous delamination to visualize and release the zygomatic and masseteric ligaments. While effective, this wide undermining separates the skin from its underlying vascular and lymphatic supply before the deep plane is even entered, theoretically increasing the risk of hematoma, seroma, and skin compromise, particularly in the post-auricular and lateral facial zones.

In contrast, the "Preservation Entry Point" (PEP) or "Limited Delamination" technique, recently formalized in the literature by **Roskies et al. (2024)** and **Gordon and Sawan (2025)**, posits that the integrity of the skin-SMAS interface is paramount. By limiting subcutaneous dissection to less than 2

centimeters and utilizing a more lateral entry point (often marked by the "Sailboat" modification), proponents argue that the "composite" nature of the flap is maintained more robustly.

Minimizing skin delamination—a core principle of the 'sailboat modification' and the preservation deep plane facelift—offers significant anatomical and clinical advantages. By limiting the extent of undermining, surgeons can reduce dead space and mitigate ischemic complications in the distal flap, such as discoloration and telangiectasias. Furthermore, this approach preserves volume along the zygomatic arch and lateral flap while protecting the zygomaticus muscle complex to prevent 'smile block.' Critically, utilizing the thicker lateral SMAS provides a safer entry point and a more robust cuff for suspension, ultimately hastening visible recovery for the patient (**Roskies et al. (2024); Bray & Talei (2024)**)

The term 'Preservation' in this study refers to the maintenance of the superficial anatomical relationship between the skin and the SMAS layer, distinct from the deep retaining ligaments which are released in both groups to facilitate repositioning. (**Gentile 2025**)

While retrospective case series (Level 4 evidence) suggest that preserving the skin-SMAS connections enhances the biomechanical transmission of tension to the jowl and reduces complications such as hematoma and edema, no prospective, randomized controlled trial (Level 1 evidence) has directly compared these two distinct approaches. Consequently, there is a critical lack of quantitative data regarding whether the theoretical benefits of limited delamination translate into statistically significant superiority in the correction of the labiomandibular fold and jowl, or if they offer verifiable improvements in the longevity of the aesthetic result against gravitational descent. Furthermore, the biomechanical implications of retaining these skin-SMAS ligaments on the viscoelastic behavior (creep and stress-relaxation) of the repositioned facial flap remain unquantified in a controlled clinical setting. This study seeks to bridge this gap by providing the first randomized comparison of the aesthetic efficacy, longevity, and biomechanical properties of TEP versus PEP rhytidectomy

2. AIM/ OBJECTIVES

Primary Objective: The Aim is comparing the aesthetic enhancement of the jowl, Labiomandibular fold and prejowl sulcus between the Traditional Entry Point

and Preservation Entry Point techniques by :

1. Comparing subjective patient satisfaction using FACE-Q (**Klassen et al. 2015**).
2. Comparing objective anatomical correction using blinded physician grading of the Croma Jawline Sagging Scale.

Secondary Objectives

1. Quantifying the viscoelastic properties of the intervening tissue between the 2 entry points using biomechanical test.
2. Comparing the incidence of complications (hematoma, seroma, nerve injury, skin necrosis).

3. METHODOLOGY

Type of Study:

1. A prospective, randomized, single-blind controlled clinical trial.

Evaluation of objective outcomes (Croma Jawline Scale, Marionette Lines Grading Scale) will be performed by two independent, consultant plastic surgeons who are blinded to the treatment allocation. Standardized pre-operative and post-operative photographs (Frontal, 45°, Lateral) will be randomized and presented to the graders without timestamps or group labels to ensure objectivity.

2. The **ex-vivo** biomechanical arm (Correlation Study).

Study period

- **Enrollment Period:** 1 years
- **Follow-up Period:** 1 year
- **Data Analysis and Reporting:** 3 months

Study Setting:

This study will be conducted at Ain Shams University Hospitals department of Plastic, Burn and Maxillofacial surgery.

Participants/population

- **Inclusion Criteria:**

1. Candidates for Primary Rhytidectomy (Facelift).
2. Age: 50–70 years.
3. Gender: Male and Female.
4. Presence of visible jowling (Presence of visible jowling defined as **Grade 2 or higher** on the Croma Jawline Sagging Assessment Scale) and **Labiomandibular fold (Marionette line)**
5. Medical fitness for general anesthesia.
- **Exclusion Criteria:**
 1. History of previous facelift (secondary cases).
 2. Active smokers.
 3. Connective tissue disorders (e.g., Ehlers-Danlos).
 4. Uncontrolled diabetes ($HbA1c > 7$).
 5. Body Mass Index (BMI) > 30 .
 6. Unrealistic expectations or body dysmorphic disorder.

Sample Size

Based on a review of FACE-Q validation studies (**Pusic et al., 2013**), the Minimal Clinically Important Difference (MCID) for Satisfaction with Lower Face and Jawline is estimated between 6-8 points. To detect a conservative difference of 8 points with a standard deviation of 12 (derived from similar facelift cohorts), a Power of 80%, and an Alpha of 0.05, a sample size of 36 patients per arm (N=72 total) is recommended to account for a 10% attrition rate at the 1-year follow-up

Randomization

Patients will be randomized using a computer-generated list (R Software 4.4.2) into two groups:

- **Group A:** Traditional Entry Point (TEP).
- **Group B:** Preservation Entry Point (PEP).

Surgical Techniques

Common Steps:

- Intraoperative Anesthesia Protocol
- Airway Management:

Type: Reinforced Endotracheal Tube (ETT).

Positioning: Supine; Pressure points padded; Eyes taped.

- Medication & Maintenance

Induction Drugs:

1. Midazolam: 0.05 mg/kg.
2. Fentanyl: 1:2 mcg/kg.
3. Propofol: 2 mg/kg.
4. Tracrium: 0.5 mg/kg.

Maintenance:

Sevoflurane at 2:3%.

Tracrium: 0.1 mg/kg/20 min.

Ancillary Medications:

1. Dexamethasone (Dexa): 8 mg.
2. Ondansetron (Danset): 8 mg.
3. Pantoprazole (Controloc): 40 mg.
4. Paracetamol (Perfalgan): 1 g.
5. Antibiotic (cefazolin): 1-2 gm 30 minutes before procedure.

- Fluid Management

1. Crystalloids: Ringer's Acetate (administered in 500 mL increments).
2. Monitoring: Continuous monitoring of Heart Rate (H.R.), Blood Pressure (B.P.), and SpO₂

- **Tumescent Solution:**

Infiltration with a solution containing 500cc saline, 1% lidocaine, 1:1000 epinephrine.

- **Incisions:**

- *Female:* Post-tragal incision, curving around the earlobe, preserving the temporal hair tuft via a beveled incision.
- *Male:* Pre-tragal incision to avoid hair transfer to the tragus.

- **Deep Plane Release:**

Both groups undergo release of zygomatic and masseteric.

- **Hemostatic Netting:**

Application of the Auersvald hemostatic net (4-0 Prolene) to the neck and undermined flaps for 48 hours to obliterate dead space. (**Auersvald & Auersvald; 2014; Janssen et al., 2023**)

Group A: Traditional Entry Point (TEP): (Hamra (1990);

- Subcutaneous dissection is performed to the lateral canthus-gonial angle line.
- SMAS incision is made at this line.
- Independent rotation and suspension of the SMAS flap.
- Skin redraping and excision.

Group B: Preservation Entry Point (PEP): (Roskies et al. 2024; Talei et al., 2024)

- Subcutaneous dissection is restricted to <2 cm from the incision.
- **Entry Point:** Followed the same general steps published by **Roskies et al. (2024)** and the ideas of **Gordon & Sawan (2025)**.
- **Composite Flap:** The skin and SMAS are elevated as a single unit, preserving the intervening fibrous septa.
- **The "Sailboat" Modification:** Utilization of the specific marking described by Roskies/Bray to define the entry point.

To isolate the variable of the deep plane entry point, adjunctive procedures will be strictly standardized. All patients will undergo midline platysma plication if banding is present and conservative open submental liposuction. No perioral fat grafting will be performed to avoid confounding the labiomandibular fold assessment.

Post-Anesthesia Recovery Protocol

- **Modified Aldrete Score (Aldrete & Kroulik 1970).**
- **Pain Assessment: using VAS Score. (Zealley & Aitken 1969).**

Biomechanical Analysis Methodology (Saulis et al, 2002)

In the traditional excision group, samples will be harvested from patients requiring preauricular reduction. Tissue will be obtained from the redundant superior/anterior extension of the excision, ensuring the samples are of sufficient dimensions for biomechanical analysis.

To maximize reproducibility and minimize confounding variables, an internal control design will be utilized, comparing samples harvested from both sides of the same patient. These findings will be interpreted within the context of the total sample volume to ensure statistical significance.

Specimen Preparation: Fresh (non-fixed) SMAS tissue discard will be collected immediately following surgical excision. Specimens will be immersed in chilled (4°C) physiological saline (0.9% NaCl) to prevent dehydration and autolysis and tested within 6 hours of harvest. Chemical fixation (formalin) will strictly not be used to preserve viscoelastic integrity.

Using template cutters, tissues will be standardized into dumbbell shapes (10 x 3 mm) for tensile testing and rectangular strips (10 x 5 mm) for suture tearing. Thickness will be measured with a digital gauge (0.001-inch accuracy) to calculate cross-sectional stress.

2. Quasi-Static Testing Using a Universal Testing Machine at a constant extension rate of 2.54 cm/min:

- **Breaking Strength:** Dumbbell samples will be pulled until rupture; peak force per cross-sectional area will be recorded in Megapascals (MPa).
- **Suture Tearing:** A 3-0 suture will be pulled through the specimen until failure to measure maximum force in Newtons (N).

3. Viscoelastic Analysis * Stress-Relaxation: Samples will be tensed to 80% of their breaking strength. Elongation will be held constant for five 1-minute cycles to record the percentage decrease in tension.

- **Tissue Creep:** A constant load (80% of suture tearing force) will be applied, with deformation measured in millimeters at 2 and 3 minutes.

- **Data Collection and Analysis**

Data will be collected on standardized case report forms (CRFs). Statistical analysis

will be performed using IBM SPSS Statistics 27.0. Continuous variables (FACE-Q, surface area of SMAS Samples) will be compared using independent t-tests. Categorical variables (complications) will be compared using Chi-square tests. A p-value of <0.05 will be considered statistically significant.

Preoperative:

The patient's details include their ID, age, gender, and BMI. Information about their smoking status and alcohol use, as well as their medical history, previous surgeries, and current medications, to be recorded.

Any allergies and family history will be noted.

The reason for the rhytidectomy is provided, and it's confirmed that informed consent has been given. The surgery specific date to be recorded, and the patient is assigned via computer-generated randomization to a particular group:

Group A (Traditional Entry Point) or Group B (Preservation Entry Point).

Physical Examination includes:

- Baseline standardized photographs (Frontal, 45° Oblique, and Lateral).
- Videos of the face and neck in animation.
- Grading of jowl severity using the **Croma Jawline Sagging Assessment Scale (Pooth et al., 2022).**
- Grading of labiomental (marionette) folds using the **Marionette Lines Grading Scale (Carruthers et al., 2008).**

Intraoperative:

- Duration of surgery and recording of any intraoperative complications.
- Application of the **Auersvald Hemostatic Net (4-0 Prolene/Monocryl)** to be removed at 48 hours to minimize dead space.

Postoperative: Follow-up at 1 week, 1 month, 3 months, 6 months, and 1 year (to assess longevity). **Assessments will include:**

- **Complication recording:** Monitoring for hematoma (sub-SMAS vs. subcutaneous), seroma, skin necrosis, and facial nerve injury (House-Brackmann scale) (**House & Brackmann; 1985**) at every follow-up.
- **Patient satisfaction:** Using validated **FACE-Q scales** (*Satisfaction with Lower*

Face and Jawline, Appraisal of Scars, and Satisfaction with Facial Appearance) at 3 months, 6 months, and 1 year.

Condition or domain being studied:

Facial Aesthetic Surgery.

Type of Intervention:

Surgical

Statistical Analysis

Continuous variables will be compared using t-tests, and categorical variables will be compared using chi-square tests. A p-value of <0.05 will be considered statistically significant.

Ethical Considerations:

This study will be conducted in accordance with the ethical principles that have their origin in the **Declaration of Helsinki**, and that are consistent with Good Clinical Practice (GCP) after approval of local ethical committee of faculty of medicine, Ain Shams University respecting the following ethical considerations:

- **Voluntary Participation**

All participants will be informed that their involvement in the study is entirely voluntary. They will have the right to withdraw from the study at any point without any consequences or loss of benefits to which they are otherwise entitled.

- **Informed Consent**

Prior to participation, each participant will receive a detailed explanation of the study's purpose, procedures, potential risks, and benefits. Informed consent will be obtained in writing, ensuring that participants fully understand the information provided and agree to participate willingly.

- **Anonymity and Confidentiality**

The identities of participants will be protected using unique codes instead of personal identifiers. All data collected will be stored securely, and access will be restricted to authorized personnel only. Confidentiality agreements will be signed by all researchers involved.

- **Potential for Harm**

The study will be designed to minimize any potential risks to participants. A thorough risk assessment will be conducted, and measures will be implemented to mitigate identified risks. Participants will be monitored throughout the study to ensure their safety and well-being.

- **Scientific Validity**

The research will be conducted using robust and scientifically sound methodologies to ensure the validity and reliability of the results. This includes appropriate study design, data collection methods, and statistical analyses.

- **Fair Subject Selection**

Participants will be selected based on the scientific objectives of the study, ensuring a fair and equitable distribution of the research's benefits and burdens. Vulnerable populations will not be targeted unless the study specifically addresses issues relevant to them.

- **Independent Review**

Approval will be obtained from the Scientific Researchers Committee at the Faculty of Medicine at Ain Shams University before starting the study.

- **Respect for Participants**

Throughout the study, the rights, dignity, and autonomy of participants will be respected. Participants will be treated with respect and courtesy, and their decisions regarding participation will be honored without any pressure or coercion.

- **Results Communication**

The findings of the study will be reported honestly and transparently. Any instances of data fabrication, falsification, or misrepresentation will be strictly prohibited. Results will be shared with the scientific community and participants in a manner that respects confidentiality and privacy.

- **Statistical Consideration:**

Statistical analysis will be performed using computer software IBM SPSS Statistics 27.0.1.0.

- **Funding sources/sponsors**

Will be declared if available.

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