Study Title: A Prospective Clinical Evaluation of the Bridging Technique Using AILEENE Vol. 2 Dermal Filler for the Treatment of Nasolabial Folds

IRAS Short Title: Bridging Technique Validation for Nasolabial Folds – JN-BRIDGE1

IRAS Project ID: 360828

REC Reference: 25/NW/0251

NHS REC Form Reference: 25/PR/1094

Sponsor Reference: JNL-BridgingNL-2025

Protocol Number: JN-BRIDGE-2025-01

Sponsor: JNL Aesthetics Limited, 10 Marsh Street, Warrington, WA1 3QA, UK

Chief Investigator: Prof. Joseph Mitchell Novoa Libermann (GMC #7200191 | MBBS | QCCP-qualified in Dermal Fillers & Neurotoxins)

NCT Number: (to be assigned upon PRS registration)

Document Title: Study Protocol

Version / Date: Version 1.0, 01 August 2025 – REC approved

Research Protocol

IRAS Project ID: 360828

Internal study reference code: JNL-BridgingNL-2025

Title: A Prospective Clinical Evaluation of the Bridging Technique Using AILEENE Vol. 2 Dermal Filler for the Treatment of Nasolabial Folds
Chief Investigator: Prof. Joseph Mitchell Novoa Libermann
Sponsor: JNL Aesthetics Limited
Site: Ascencia Aesthetics Academy, 10 Marsh Street, Warrington, UK
Version: 1.0
Date: 01 August 2025

1. Background and Rationale

Nasolabial folds (NLFs), the lines extending from the sides of the nose to the corners of the mouth, are among the most common age-related concerns in aesthetic medicine. Loss of volume in deep facial fat compartments and changes in skin elasticity contribute to their formation. While several filler techniques are available and widely used, clinical practice lacks standardisation on a technique that balances safety, minimal invasiveness, and natural outcomes.

The Bridging Technique is a novel filler method that uses a blunt-tipped cannula to place horizontal threads of HA filler across the fold within the deep dermis and subdermal (superficial fat) layer. This strategy supports the skin internally, aiming for a natural correction with low product volume and reduced risk of vascular compromise.
The term *"Bridging"* refers to the creation of **bridge-like internal support structures** beneath the nasolabial fold using small, precisely placed filler threads. These threads act as scaffolding, helping to lift and soften the fold without overfilling or distorting the natural contours of the face.
This study will evaluate the clinical and subjective outcomes of this technique using AILEENE Vol. 2, a CE-marked and MHRA-registered HA filler.

2. Objectives

Primary Objective
To assess changes in nasolabial fold appearance using the validated Nasolabial Fold Severity Scale (NLFSS) from baseline to 6 months.

Secondary Objectives

- To assess patient satisfaction using the Global Aesthetic Improvement Scale (GAIS).
- To measure treatment longevity over a 6-month period.
- To document how many participants request a top-up treatment at 4 weeks.
- To evaluate subjective feedback using a short 5-item PROM (Patient-Reported Outcome Measure).

3. Study Design

This study is designed as a prospective, interventional, single-arm clinical evaluation. It will be carried out at a single private aesthetic clinic in the UK and aims to assess the performance, safety, and patient satisfaction associated with a specific dermal filler technique used in routine aesthetic practice.

A total of 60 adult participants will receive one treatment session with AILEENE Vol. 2 dermal filler using the Bridging Technique. Participants will attend a total of four clinic visits over a six-month period, with an additional check-in conducted remotely at two weeks post-treatment. An optional top-up may be offered at the four-week visit, depending on clinical judgement and patient preference.

This is an open-label study with no control group. The intention is to evaluate the technique in a real-world clinical setting, using standardised outcome tools and anonymised photographic assessments.

Key elements of the study design are as follows:

- **Study type:** Prospective, single-arm, non-randomised, interventional
- **Setting:** Ascencia Aesthetics Academy, Warrington (private non-NHS site)
- **Sample size:** 60 participants
- **Product:** AILEENE Vol. 2 dermal filler (maximum of 1.0ml per participant)
- **Injection method:** Bridging Technique using a 25G blunt-tipped cannula
- **Injection plane:** Deep dermis / subdermal (superficial fat layer)
- **Follow-up visits:** Day 0 (treatment), Week 2 (virtual check-in), Week 4, Month 3, and Month 6
- **Outcome assessments:** NLFSS scoring, GAIS, a 5-item patient-reported outcome questionnaire (PROM), and documentation of any adverse events

This design was chosen to provide observational performance data for a CE-marked, MHRA-registered product used in a novel but routine aesthetic application. The absence of a control arm reflects the exploratory nature of the study and the focus on documenting standard clinical outcomes in a well-defined patient group.

4. Eligibility Criteria

Inclusion Criteria

- Adults aged 30 to 65 years
- Bilateral nasolabial folds graded ≥2 on the NLFSS
- General good health
- Willingness to abstain from additional facial aesthetic procedures for the study duration
- Capacity to provide written informed consent
- Individuals of childbearing potential will be required to undergo a urine pregnancy test on the day of treatment. The test will be provided at the clinic. Only those with a negative result will be eligible to proceed with treatment on that day.

Exclusion Criteria

- Known allergy to hyaluronic acid, lidocaine, or any filler components
- Active local skin infection or inflammation
- History of permanent implants or semi-permanent fillers in the treatment area
- Anticoagulant therapy or bleeding disorder
- Pregnancy or breastfeeding:
    - There is currently insufficient research to establish the safety of dermal fillers, including AILEENE Vol. 2, during pregnancy or breastfeeding. Although no specific risks to the mother or fetus have been conclusively identified, the absence of evidence does not confirm the absence of risk. As a precaution, individuals who are pregnant, planning to become pregnant, or breastfeeding are not eligible to participate in this study and should not undergo this treatment.
- Keloid or hypertrophic scarring history
- Uncontrolled diabetes or severe systemic illness
- Recent cosmetic procedures in the lower face (within 6–12 months depending on treatment type)

5. Study Schedule

Each participant will be involved in the study for a period of six months and will attend four in-person visits, along with one virtual check-in. The schedule is as follows:

- **Visit 1 (Day 0):** Following informed consent and screening, participants will undergo baseline assessments, including clinical photographs, and will receive the initial treatment using the Bridging Technique.
- **Check-in (2 weeks post-treatment):** A virtual follow-up will be conducted by phone or video to assess short-term safety and patient experience.
- **Visit 2 (Week 4):** Participants will return for an in-clinic review. Standardised photographs will be taken, PROMs collected, and an optional top-up treatment offered if clinically indicated.
- **Visit 3 (Month 3):** A follow-up appointment will assess progress, capture updated photography, and gather further feedback using GAIS and PROMs.
- **Visit 4 (Month 6):** The final study visit will include repeat clinical photography, final PROM completion, and closure of participation.

6. Outcome Measures

Primary Endpoint
Change in NLFSS score from baseline to 6 months, assessed by blinded independent reviewers using anonymised photographs.
Statistical Method: Paired T-Test

Secondary Endpoints

- GAIS scores at each follow-up
- Subjective PROM results on satisfaction, comfort, and naturalness
- Proportion receiving top-up filler at Week 4
- Documentation of adverse events

7. Data Management

Each participant will be assigned a unique study ID.
Clinical photographs will be obtained using the Bitmoji A5-AI device, stripped of metadata and securely stored.

All data will be recorded electronically in **Clever Clinic**, with access restricted to the investigator and authorised staff. Data will be managed in accordance with the **UK GDPR** and **Data Protection Act 2018**.

8. Safety and Risk Considerations

Risks are consistent with routine aesthetic filler procedures and include bruising, swelling, tenderness, nodules, asymmetry, or in rare cases, vascular occlusion or allergic reaction.

Emergency protocols, including the use of hyaluronidase, will be in place. The Chief Investigator has extensive training in complication management. No data monitoring committee is required due to the low-risk profile and non-NHS setting.

9. Insurance and Indemnity

The study is sponsored by **JNL Aesthetics Limited**, which holds indemnity cover. The Chief Investigator holds additional professional indemnity insurance. This is not a CTIMP and does not involve the use of an investigational device.

10. Dissemination

Study findings will be submitted for publication in academic journals and presented at national or international conferences. A plain-language summary will be made available to participants who opt in to receive it. The study will be listed on **ClinicalTrials.gov** prior to the first enrolment.

End of Document

Protocol Version: 1.0 Date: 01 August 2025