STUDY PROTOCOL

PROTOCOL TITLE: Premaxillary injection for perioral rejuvenation and upper lip enhancement

COSMECEUTICAL: Restylane® Defyne

SPONSOR: Steven H. Dayan, M.D., F.A.C.S

INVESTIGATOR: Steven H. Dayan, M.D., F.A.C.S
845 North Michigan Avenue, Ste 923E
Chicago, IL 60611
Tel: (312) 335-2070

PROTOCOL NUMBER: REST-DEF-2017

PROTOCOL VERSION DATE: Version 2, July 12, 2017

NCT NUMBER: 03273543

PROTOCOL AUTHOR: Eric W. Cerrati, M.D.

INVESTIGATIVE SITE: DeNova Research
845 North Michigan Avenue, Ste 923E
Chicago, IL 60611
Tel: (312) 335-2070
Fax: (312) 335-2074

INVESTIGATOR AGREEMENT

I have read the foregoing protocol and agree that it contains all necessary details for carrying out this study. I will conduct the study as outlined herein and will complete the study within the time designated.

I will comply with Good Clinical Practice (GCP) regulations and guidelines during the conduct of this study. I certify that this study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that they are consistent with Good Clinical Practice and applicable regulatory requirements. The study must be conducted in accordance with the regulations of the United States Food and Drug Administration (FDA) as described in 21 CFR 50 and 812, applicable laws and the IRB requirements.

I will provide copies of the protocol and all pertinent information to all individuals responsible to me who assist in the conduct of this study. I will discuss this material with them to ensure they are fully informed regarding the treatment and the conduct of the study.

I will use only the informed consent form approved by the Institutional Review Board (IRB) or Ethics Committee (EC), and will fulfill all responsibilities for submitting pertinent information especially with respect to development of any serious adverse events to the Institutional Review Board or Ethics Committee responsible for this study.

_____ _____

Principal Investigator's Signature Date

___845 N Michigan Ave_____

___Suite 923 E_____

____Chicago, IL 60611_____

Address of Principal Investigator (Typed or Printed)

1 PROTOCOL SYNOPSIS

TITLE:
Premaxillary injection for perioral rejuvenation and upper lip enhancement

INDICATION:
Premaxillary injection preformed via cannula technique for perioral rejuvenation

SAMPLE SIZE:
20

NUMBER OF CENTERS:
One

PURPOSE:
To determine if subjects who receive premaxillary injection demonstrate an increase in nasal tip projection and an associated increase in upper lip projection, and vermillion height.

SUBJECTION SELECTION:
A total of 20 subjects who display signs of perioral aging or poor upper lip projection

PROCEDURE:
This is an open-label, prospective, post market study to assess the effect of premaxillary hyaluronic acid filler injection on nasal tip projection and upper lip position.

The study will enroll and treat a total of 20 subjects who are filler naïve and do not have any history of rhinoplasty, recent upper lip augmentation <12 months, lip lift or other surgical procedures involving the upper lip, chin augmentation and orthognathic surgery. Patients in study are restricted from perioral neurotoxin, peri oral ablative resurfacing, facial cosmetic surgery, all subdermal directed aesthetic treatments or filler treatment other that which is dictated in the protocol during the course of the study.

Subjects, who fulfill all eligibility criteria, will undergo pre-treatment standardized 2D portrait photography. From the profile image, baseline nasal projection measurements will be documented according to Goode's ratio. Additionally, baseline upper lip position will recorded by measuring the Z-angle, which is the intersection of the Frankfort horizontal line and the profile line as described by Merrifield. From the straight portrait image, the ratio of the upper lip vermillion height to the lower lip vermillion height will be documented. Subjects will then be injected with a maximum of 4 syringes of Restylane® Defyne to treat their premaxillary space per the discretion of the Principal Investigator (PI). If optimal correction result (OCR) has not been achieved additional touch-up injections of Restylane® Defyne may be injected 2 weeks post treatment visit to achieve OCR as per PI discretion.

Post OCR visits will be performed at 4 weeks following premaxillary injections. Subjects will be followed to assess any treatment-related adverse events (such as pain, nodules, swelling, redness, bruising, tenderness, itching, and headache) as well as pigmentation changes and/or keloid formation. Each subject will then be photographed with standardized photographs in a similar fashion as pre-treatment and the same measurements will be recorded.

Upon study culmination, pre-treatment and 1-month post OCR photographs will be assessed. Each patient will be evaluated to determine if nasal tip projection was increased causing an increase in upper lip projection. Additionally, the vermillion ratios will be compared to evaluate for change in upper lip vermillion height.

STUDY DURATION:
Each subject will undergo screening assessment of eligibility criteria, pre-treatment photography, and if eligible for treatment, injections of the premaxillary area. All enrolled subjects will be followed up to 1-month post OCR visit to evaluate the injections effect on nasal tip projection and upper lip projection.

OBJECTIVES:

The Primary Objective of this study is to determine the increase in nasal tip projection (measured by Goode's ratio) and the increase in upper lip projection (measured by the Z-angle) following perioral rejuvenation with premaxillary hyaluronic acid filler injections.

The Secondary Objective of this study is to assess the change in upper lip height by comparing the pre and post-treatment injection ratio of upper lip vermillion height to lower lip vermillion height.

CLINICAL HYPOTHESES:
Subjects who are treated with premaxillary injection will demonstrate an increase in nasal tip projection and have an associated increase in upper lip projection. Additionally, the upper lip will demonstrate an increase in upper lip vermillion height. As a result, the single injection site will address multiple factors that contribute to perioral aging.

2 BACKGROUND

Earlier this year, Cerrati and Dayan demonstrated the causal relationship between nasal tip projection and upper lip projection. This new correlation, which was discovered in examining post-surgical rhinoplasty patients, was published last month in *JAMA Facial Plastic Surgery*. As the nasal tip was projected, a statistically significant increase in the upper lip projection was

measured. For tip projection, Goode's ratio was used. This value is defined as the nasal height over the nasal length. Upper lip projection was measured by the Z-angle, which is created by the Frankfort horizontal plane and the profile line. A change in the angle to a more acute value on postoperative photographs would indicate an increase in upper lip projection. Additionally, the study demonstrated a trend toward an increase in upper lip vermillion height. By applying this new correlation, Dayan was able to recreate the findings in a small subset of aging patients using hyaluronic acid filler.

While the perioral aging process has been well described in the literature, the treatment options have remained limited. The most common attempt at rejuvenation is injection of hyaluronic acid filler into the lips and philtral columns. However, studies have shown that changes occur at deeper levels. Within the orbicularis oris muscle, the curvature relaxes resulting in an overall increase in lip length. More importantly, selective bony resorption occurs in specific areas of the facial skeleton including the maxilla. The retrusion of the maxilla along with widening of the piriform aperture contribute to the overlying soft tissue changes in the nose.

The premaxillary injection adds a new tactic for addressing perioral aging. The single injection will allow treatment of the fundamental cause of aging by re-building the foundation of the face. Treatment will provide patients with nature appearing facial rejuvenation. Since the aging process affects both the nose and the upper lip, these patients receive a significant benefit, both aesthetically and cost-effectively.

3 STUDY OBJECTIVES

The Primary Objective of this study is to determine the increase in nasal tip projection (measured by Goode's ratio) and the increase in upper lip projection (measured by the Z-angle) following perioral rejuvenation with premaxillary hyaluronic acid filler injections.

The Secondary Objective of this study is to assess the change in upper lip height by comparing the pre and post-treatment injection ratio of upper lip vermillion height to lower lip vermillion height.

4 INVESTIGATOR

Steven H. Dayan, MD, FACS
845 N. Michigan Ave, Ste 923E
Chicago, IL 60611
Tel: 312.335.2070
Fax: 312.335.2074

5 STUDY DESIGN

This is an open-label, prospective, postmarket study to assess the effect of premaxillary hyaluronic acid filler injection on nasal tip projection and upper lip position.

The study will enroll and treat a total of 20 subjects who are filler naïve and do not have any history of rhinoplasty, recent , 6 months upper lip augmentation, lip lift or other surgical procedures involving the upper lip, chin augmentation and orthognathic surgery. Patients in study are restricted from perioral neurotoxin or ablative resurfacing, facial cosmetic surgery, all subdermal directed aesthetic treatments or filler treatment other that which is dictated in the protocol during the course of the study.

Subjects, who fulfill all eligibility criteria, will undergo pre-treatment standardized 2D portrait photography. From the profile image, baseline nasal projection measurements will be documented according to Goode's ratio. Additionally, baseline upper lip position will recorded by measuring the Z-angle, which is the intersection of the Frankfort horizontal line and the profile line as described by Merrifield. From the straight portrait image, the ratio of the upper lip vermillion height to the lower lip vermillion height will be documented. Subjects will then be injected with a maximum of 4 syringes of Restylane® Defyne to treat their premaxillary space per the discretion of the Principal Investigator (PI). If optimal correction result (OCR) has not been achieved additional touch-up injections of Restylane® Defyne may be injected 2 weeks post treatment visit to achieve OCR as per PI discretion.

Post OCR visits will be performed at 4 weeks following premaxillary injections. Subjects will be followed to assess any treatment-related adverse events (such as pain, nodules, swelling, redness, bruising, tenderness, itching, and headache) as well as pigmentation changes and/or keloid formation. Each subject will then be photographed with standardized photographs in a similar fashion as pre-treatment and the same measurements will be recorded.

Upon study culmination, pre-treatment and 1-month post OCR photographs will be assessed. Each patient will be evaluated to determine if nasal tip projection was increased causing an increase in upper lip projection. Additionally, the vermillion ratios will be compared to evaluate for change in upper lip vermillion height.

6 SUBJECT SELECTION

A total of 20 subjects.

All Subjects must comply with the following inclusion and exclusion criteria:

6.1 Inclusion Criteria

1. Subjects Age 21 to 70.
2. Subjects who demonstrate signs of perioral aging or poor upper lip projection.

6.2 Exclusionary Criteria

1. Subjects who plan to undergo peri oral neurotoxin treatments or ablative skin treatments, or have had either of these treatments in the previous 6 months, other injectable filler treatments during the course of the study.
2. Subjects who are pregnant or nursing.
3. Subjects with a known allergy or sensitivity to any component of the study ingredients.
4. Any history of nasal filler injections.
5. Recent history of upper lip augmentation (surgical and non-surgical) within the last 12 months.
6. Any history of lip lift or other surgical procedures involving the upper lip.
7. Any history of chin augmentation (surgical and non-surgical).
8. Any history of orthognathic surgery.
9. Any history of bleeding disorders (iatrogenic or otherwise).
10. Current history of chronic drug or alcohol abuse.
11. Concurrent therapy that, in the investigator's opinion, would interfere with the evaluation of the safety or efficacy of the study product (i.e. immunosuppressive therapy).
12. Subjects who, in the Investigator's opinion, have a history of poor cooperation, noncompliance with medical treatment or unreliability.

7 TREATMENT AND STUDY MATERIAL SUPPLIES

7.1 Description of Study Supplies and Handling

7.1.1 Packaging and Labeling

7.1.1.1 Restylane® Defyne

Injectable Gel with 0.3% Lidocaine

2.1.2 Method of Application

Pre-treatment Guidelines

Prior to treatment, the patient should avoid taking aspirin, nonsteroidal anti-inflammatory medications, St. John's Wort, or high doses of Vitamin E supplements. These agents may increase bruising and bleeding at the injection site.

Treatment Procedure

1. It is necessary to counsel the patient and discuss the appropriate indication, risks, benefits and expected responses to the *Restylane® Defyne* treatment. Advise the patient of the necessary precautions before commencing the procedure.

2. Assess the patient's need for appropriate anesthetic treatment for managing comfort, i.e., topical anesthetic, local or nerve block.

3. The patient's face should be washed with soap and water and dried with a clean towel. Cleanse the area to be treated with alcohol or another suitable antiseptic solution.

4. Sterile gloves are recommended while injecting *Restylane® Defyne*.

5. Attach the syringe to a 22-gauge cannula, which provides additional safety when injecting in this area. Before injecting, press rod carefully until a small droplet is visible at the tip of the cannula.

6. Using a 20-gauze needle, a small access point is created for the cannula. The access points are located within the superior portion of the nasolabial folds bilaterally

7. Inject *Restylane® Defyne* applying even pressure on the plunger rod. It is important that the injection is stopped just before the cannula is pulled out of the skin to prevent material from leaking out or ending up too superficially in the skin.

8. Only correct to 100% of the desired volume effect. Do not overcorrect. The degree and duration of the correction depend on the character of the defect treated, the tissue stress at the implant site, the depth of the implant in the tissue and the injection technique.

9. Typical usage for each treatment session is specific to the amount of correction desired.

Injection Techniques

1. *Restylane® Defyne* can be injected by a number of different techniques that depend on the treating physician's experience and preference, and patient characteristics.

2. Given the close proximity to large vessels within the premaxillary space, the cannula technique is advocated. The use of large cannulas (22-gauge) helps minimize the risk of vascular injury. The cannulas are introduced through the skin by a small puncture site created by a slightly larger hypodermic needle.

3. Once the cannula is inserted, linear threading (includes retrograde and antegrade) is accomplished along with fanning to produce an even layer of material. The material should be deposited in the premaxillary space, which is located between the maxilla and the orbicularis oris muscle spanning between the alar bases.

8 STUDY PROCEDURES

8.1 Screening Visit

The PI and/or designee is responsible for keeping a record of all subjects screened for entry into the study and those subjects that were excluded, including exclusionary reason.

The following procedures will be performed:

1. The PI and/or designee is responsible to evaluate and confirm that a subject meets inclusionary/exclusionary criteria.
2. Subjects must provide signed informed consent with confirming signature from investigator/site designee.
3. Subject undergo standard 2D digital portrait photography.

8.2. Visit 1: Baseline/Treatment Procedures

The following procedures will be performed:

1. The injection area will be wiped with a Benzalkonium Chloride towlette.
2. A topical anesthetic containing lidocaine (30%) will be applied to anesthetize injection areas Or subject may choose to receive a nerve block to numb the treatment area.

3. The subject will be injected with *Restylane® Defyne* in a volume sufficient to deliver satisfactory cosmetic results (not to exceed 4mL/4syringes total).
4. The volume injected into each area will be recorded.

8.3. Visit 2: Two Week Touch-up Visit

The following procedures will be performed:

1. At PI's discretion, subjects may receive touch-up treatment to reach Optimal Cosmetic Result (OCR) (not to exceed a total use of 4mL/4 syringes of Restylane® Defyne).
2. Subject will report any AE or Concomitant medications

8.4. Visit 3: One Month Follow-up Visit

The following procedures will be performed:

1. Subject will undergo standardized 2D digital portrait photography.

9 RESPONSE CRITERIA

9.1 Primary Variable Assessments

The primary assessment of this study is to determine the effect of premaxillary injection on nasal tip projection and upper lip projection for perioral rejuvenation. Efficacy of the injection on the subjects' 1-month post OCR with Restylane® Defyne will be done through comparative measurements taken on pre and post-treatment photographs.

Nasal tip projection will be assessed by Goode's ratio. The value is defined as nasal height over the nasal length. The nasal height is measured from the alar-facial groove to the tip-defining point and the nasal length is measured from the root of the nose, or nasion, to the tip-defining point. Upper lip projection will be measured by a method outlined by Merrifield in 1966. As described, a profile line is drawn tangent to the soft tissue chin and to the most anterior point of the upper lip. This line is then extended upward to the Frankfort horizontal plane. The angle at which these two lines intersect is called the Z angle. A change in the angle to a more acute value on postoperative photographs would indicate an increase in upper lip projection. This method was chosen because it is calculated independent of any postoperative nasal changes.

9.2 Secondary Variable Assessments

The secondary assessment is to evaluate the change in upper lip height by comparing the pre and post-injection ratio of upper lip vermillion height to lower lip vermillion height. This method was chosen because ratios eliminate any bias created by camera distance, angle, lighting, etc.

10 DATA MANAGEMENT

10.1 Case Report Forms (CRFs)

For each subject enrolled who has given informed consent, completed the screening process, and began the study process, a CRF will be created and signed by PI or designee to certify completeness and correctness.

If a subject is withdrawn from the study due to a treatment-limiting adverse event, due diligence must be used to document the outcome. Source documentation verification will be performed by the study monitors. All CRFs will remain at the study site.

10.2 Data Handling

Data management based on GCP refers to the activities defined to achieve safe routines to enter clinical data information into a database, efficiently and avoiding errors. The data management routines include procedures for handling CRFs, database set-up and management, data entry and verification, data validation, and documentation of the performed activities including information of discrepancies in the process.

The database, the data entry screens, and program will be designed in accordance with the study protocol and the CRF. Single data entry and proofreading will be used for data entry and verification. Data validation will be performed after data entry and verification by manual review. When the clinical study coordinator has made all efforts to ensure that the data recorded in the CRFs and entered in the database is as correct and complete as possible, "clean file" is declared, and the database is closed. The clinical study coordinator should document the database closure in a signed written document. Final statistical analysis should be generated using data from the closed database. Any additional subsequent changes or corrections to the closed database should be documented in an audit trail.

11 STATISTICAL METHODS

11.1 Study Populations

The study population will include all subjects who are enrolled, and the entire study population will be included in statistical analyses.

11.2 Study Endpoints

The endpoint is a comparative analysis of pre and post-treatment photographs. Measurements and calculation will be performed based off of the portrait and profile images.

11.3 Analysis Method

The PI's study coordinator will perform all statistical analyses. This is in an effort to avoid any potential bias that could be created by the treating physician participating in the analysis. Given that there is inherent variability even in standardized portrait photography, the decision was made to perform measurements based on facial landmarks and distance ratios. Statistical analysis will be conducted using a paired *t* test.

12 ADVERSE EVENT

12.1 Definition

An adverse event is defined as any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical or medical device product that does not necessarily have a causal relationship with this treatment. Adverse events include the following: all suspected adverse device or procedure reactions, occurrence of apparently unrelated illnesses (i.e., symptoms or diseases that were not present at study entry), worsening of a pre-existing illness (i.e., concurrent symptoms or diseases), injuries or accidents, or abnormalities in physiological or laboratory testing or physical examination findings that require clinical intervention or further investigation (beyond ordering a repeat confirmatory test). Throughout the study, subjects will be monitored for signs and symptoms of adverse events.

All adverse events reported during the study period will be recorded in detail in the subject's medical file and CRF.

12.2 Recording of Adverse Event

Subjects will be instructed by the PI to immediately report the occurrence of any adverse event. Each subject should be questioned at all visits whether any side effects or adverse events have occurred. All spontaneously volunteered, inquired, and observed adverse experiences will be recorded in detail.

12.3 Serious Adverse Events (SAE) and Unanticipated Adverse Device Effects

12.3.1 Definitions

Serious Adverse Events (SAEs) are defined as undesirable events experienced by a subject that suggest a significant hazard, contraindication, side effect, or precaution, whether or not considered to be device-related by the Investigator. An AE is defined as being serious if:

1. It is fatal or life threatening (life threatening means that in the opinion of the Investigator, the subject was at immediate risk of death from the adverse reaction).
2. It is permanently or temporarily disabling.
3. It requires inpatient or prolonged hospitalization.

4. Is a congenital anomaly/birth defect.

An unanticipated adverse device effect is defined as any serious adverse effect on health or safety, any life threatening problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relate to the rights, safety, or welfare of subjects.

12.3.2 Serious Adverse Event (SAE) Recording and Reporting

Any serious and/or unexpected adverse event that occurred while on study or one month after completion of study must be reported to DeNova Research via telephone and the Serious Adverse Event Report Form must be completed and faxed to DeNova Research and IRB within 24 hours of notification.

In addition, the local IRB (Institutional Review Board) or ERC (Ethics Review Committee) must be notified of all adverse events that are serious and/or unexpected.

All adverse events, including serious and unexpected events, must be recorded by the Investigator on the standard Adverse Event Report. This form will be included in the CRF. All Adverse Event Reports describing adverse events other than serious or unexpected adverse events will be inserted into the CRF. In addition, any serious and treatment-related unexpected adverse events must be reported to the local IRB (Institutional Review Board) within 5 business days of the event.

Subjects who have had a serious adverse event must be followed clinically until all parameters, including laboratory values, have either returned to normal, or are otherwise explained. If death was the outcome of the event on the initial Adverse Event Report, a Follow-up/Final Report, including autopsy report, when performed, must be completed.

13 QUALITY ASSURANCE

13.1 Institutional Review Board Approval

An IRB shall review and have authority to approve, require modifications in, or disapprove the investigation. Accordingly, this protocol, the informed consent document, and any relevant supporting information must be submitted to the IRB for review and receive approval prior to study initiation. Except in an emergency, any amendments to the protocol require approval by both Sponsor and the IRB prior to their implementation.

Additionally, the PI is responsible for providing the IRB with progress reports of the investigation at regular intervals (at least once per year), as well as with any other accurate, complete, and current information that the IRB may request concerning the investigation.

13.2 Informed Consent

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy of the final, IRB-approved document must be provided for record-keeping purposes. Originals of the IRB-approved consent form and sign individual consent documents must be retained in the site's study files. Each subject must be provided with a copy of his/her signed consent form.

13.3 Study Monitoring

The PI will allow designees from the study sponsor to periodically audit all CRFs and corresponding source documents for each subjects, as well as, any data related to the study file. The monitoring visits provide for an opportunity to evaluate the progress of the study, to verify the accuracy and completeness of CRFs, to resolve any inconsistencies in the study records, and to assure that all protocol requirements, applicable regulations, and Investigator's obligations are being met. The PI must maintain source documents such as lab reports, photographs, history, and physical examination reports, etc., for possible review.

13.4 Modification of Protocol

If modification of the protocol is necessary, the modification must be confirmed with the IRB. No change to the protocol that significantly affects the safety, scope, or quality of the study may be implemented prior to written approval of the IRB. However, changes to the protocol may be made when necessary for the health of the subject. All modifications must be documented at the site. Moreover, if the study protocol is revised at any point during the study, IRB will be notified according to CRF 21 Part 812.

13.5 Departure from the Protocol

Minor deviations to the study protocol may be permitted if they will not increase the subject's risk or affect the validity of the study. All deviations must be documented at the study site.

When an emergency occurs that requires a departure from the protocol for an individual, a departure will be only for that subject. The PI in such an emergency will, if circumstances and time permit, contact the IRB prior to departing from the protocol. If this is not possible, such contact must be made as soon as possible, to allow an evaluation of the significance of such departure to the affected subject and to other subjects, and to permit a decision as to whether or not the subject (for whom the departure from the protocol was affected) is to continue in the study. The CRFs will completely describe the departure from the protocol and state the reasons for such departure. In addition, IRB will be notified in writing of such departure from protocol.

13.6 Confidentiality of Subject Records

The information obtained during the conduct of this study is confidential, and will be disclosed only to the Investigator and regulatory authorities as deemed necessary and/or as required by law. The PI must provide full disclosure of all study data and make study files available for inspection upon request by the IRB and/or relevant authorities including the study sponsor. Upon notice, the local authorizes may inspect and copy records that identify subjects through number and initial combinations. However, such copies have to be blinded (i.e., all personally indentifying data have to be blacked out) in order to prevent identification. The sponsor will be notified of any impending inspections relating to the study

13.7 Record Retention

The PI shall maintain accurate, complete, and current records relating to the participation in this study, including the following:

1. All correspondence including required reports.
2. Records of device shipment and disposition.
3. Signed Investigator Agreements.
4. The protocol and any protocol amendments.
5. Records concerning adverse events whether anticipated or not.
6. Documentation of each subject's case history and exposure to the device, including any CRFs, signed and dated consent forms, and any relevant medical records.
7. Any other records that the applicable authorities require to be maintained by regulation or by specific requirement for a particular device or category of devices.

The PI shall maintain all detailed essential documents for the duration of the investigation and for a period of at least 2 years since the formal discontinuation of clinical development of the investigational product, or 2 years after the last approval of any marketing application, or as required by the applicable regulatory requirements, whichever of them is a longer period.

13.8 Additional Principal Investigator Responsibilities

The PI is responsible for protecting the rights, safety, and welfare of subjects under his/her care. The PI is responsible for ensuring that the study is conducted according to the signed agreement with the investigational protocol, applicable regulations, and any condition of approval imposed by the IRB.

14 Appendices

Appendix A: Photography Standardization

Appendix B: Diagram of planned measurements

Appendix A: Photo SOP

Photography and Poses

- Use the grid feature on any of these viewers to ensure the Frankfort Plane (imaginary line from tragus to infraorbital rim) is parallel to the floor
- Stand approximately 1.5m from patient with the camera in a portrait position. The location will be marked on the floor of the photography studio.
- Ensure the patient has a relaxed expression and that their lips are closed and eyes are open for each photo.
- Give instructions like, "Slowly move you're your chin down" or "Slowly turn your nose to the left" to achieve the desired poses listed below

Standard Poses (all @ 1.5 m)

1. Frontal
    a. Make sure the patient doesn't have their chin high or low by checking the Frankfort Plane. For this view, the line on the viewfinder should extend from the right tragus, across both infraorbital rims and across the left tragus. This should be parallel to the floor
2. Left Profile
    a. For this view, ensure the patient is not rotated to the left or right (hint: look at the eyebrows to see how much of the glabella you see).
2. Right Profile
    a. For this view, ensure the patient is not rotated to the left or right (hint: look at the eyebrows to see how much of the glabella you see).

Appendix B: Measurements