A Prospective Evaluation of Infraorbital Filler

Study Product JUVÉDERM® VOLBELLA® XC

Protocol Number IRB Number *852212*

Clinicaltrials.gov NCT05694286

Initial version [11.21.2022]
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Study Summary

Title	Prospective Evaluation of Infraorbital Filler
Short Title	Infraorbital Filler Study
IRB Number	*TBD*
Protocol Number	*TBD*
Methodology	Prospective Case Series / Descriptive Study
Study Duration	3 months
Study Center(s)	Single-center
Objectives	To quantify under eye volume changes over time and patient satisfaction with infraorbital dermal filler injections
Number of Subjects	Approximately 10
Main Inclusion and Exclusion Criteria	Inclusion criteria: 1) Female 2) Age 22-65 3) Interested in filler injections to reduce undereye volume loss 4) Participants must sign the informed consent form Exclusion: 1) Prior filler in tear trough/midface 2) Filler/neurotoxin injection within the past 12 months or during duration of study 3) Prior facial cosmetic surgery (ie. facelift) 4) Prior facial trauma (ie. orbital fracture) 5) Pregnant or breastfeeding

Intervention	Injection of Juvéderm Volbella XC into undereye/infraorbital region
Statistical Methodology	Descriptive statistics will be used to describe changes in volume over time and PRO's
Data and Safety Monitoring Plan	PI: Dr. Ivona Percec will oversee the study, protocol, and data monitoring and storage.

Background and Study Rationale

1 Introduction

This study will be conducted in full accordance with all applicable University of Pennsylvania Research Policies and Procedures and all applicable Federal and state laws and regulations.

The purpose of the study is to use 3D imaging to evaluate the effects of Juvéderm Volbella XC filler that is FDA approved for injection in infraorbital region. Participation is available to women ages 22 to 65 who have never received filler injections. All subjects will undergo 3D imaging using the VECTRA M3 (Canfield Scientific, Inc, Fairfield, NJ) prior to treatment with a Juvéderm filler in order to determine their baseline volumetric measurements and dimensions. Imaging will be repeated post injection to determine change over time (over a 3-month time period).

1.1 Background and Relevant Literature

Juvéderm Volbella XC is a gel implant or dermal filler that consists of crosslinked hyaluronic acid made by a Streptococcal bacteria species intended to temporarily add fullness to the facial soft tissues. It was originally approved for injection into the lips for lip augmentation and correction of perioral rhytids. It has since been FDA-approved for injection into the undereye hollows to improve the appearance of undereye hollows in adults over the age of 21 [1].

The "Zoom Effect" describes the recent upsurge in demand for cosmetic procedures during the COVID-19 pandemic. The reason for this appears to be that people are now constantly seeing their own and other faces on the screen, making them particularly conscious of potential facial irregularities, aging changes, and asymmetries. According to statistics from the Aesthetic Society, facial procedures have increased 55% in 2021 [2]. Soft tissue filler injections are the 2nd most common non-surgical cosmetic procedure performed in the US and have increased 42% in 2021 [2,3].

Undereye or infraorbital hollowing is a result of a loss of volume causing shadowing and darkness of the infraorbital region often interpreted as a tired, stressed, and aged appearance. The Allergan Infraorbital Hollows Scale is a validated scale for objective and reproducible comparisons of infraorbital hollows

before and after dermal filler injection [4]. The Tear Trough Rating Scale (TTRS) is another validated method of evaluating tear trough deformities that measures depth of trough, degree of hyperpigmentation, prolapse of nasal fat pads/pockets, and lower eyelid skin rhytidosis [6]. 3D photogrammetry technology allows for high level feature enhancement and microscopic anatomical evaluation that was not previously possible and can be used to make volumetric measurements at injection sites to evaluating minimally invasive injection efficacy. [7-9]. In this study, we aim to use these volumetric measurements to describe undereye volume after infraorbital dermal filler injection and further understand the behavior of the product in soft tissues over time.

2 Study Objectives

2.1 Primary Objective

The primary objective of the study is to quantify and describe under eye volume changes over time after infraorbital hyaluronic acid filler injections.

3 Investigational Plan

3.1 General Design

This study is a prospective case series/descriptive study – 10 patients will be enrolled to receive hyaluronic acid filler injections (Juvéderm Volbella XC). Each patient will receive FDA approved dosages of filler to the infraorbital region to treat undereye, as per FDA approved indications. All injections will be performed by an Allergan-trained physician (Ivona Percec, MD, PhD) according to a preset injection plan per FDA approved administration guidelines. Prior to injection patients will be imaged with 3-dimensional photogrammetry. Subjects will return post-injection in 2 weeks, 1 month, and 3 months for re-imaging. The study drug will be stored in a locked room that is only accessible to the research team.

3.2 Allocation to Interventional Group

All subjects will receive filler injections to the infraorbital region at standardized injection sites

3.3 Study Measures

3D photogrammetry imaging of each subject at the pre-determined time points will be obtained using the VECTRA M3 (Canfield Scientific, Inc., Fairfield, NJ) which allows for volumetric measurements. Three-dimensional coordinates will be calculated to generate each subject's topographic configuration, displacement, and volume of each detected point on the surface of the face relative to its original reference image.

3.4 Study Endpoints

3.4.1 Primary Study Endpoint

The primary endpoint is volume changes of the infraorbital area over time after injection of filler quantified using 3D facial imaging measurements.

3.4.2 Secondary Study Endpoints

1) Correlation of patient satisfaction with undereye volume changes as determined by PRO's (via FACE-Q)
2) Allergan Infraorbital Hollow Scale

TABLE 1. Allergan Infraorbital Hollows Scale Descriptors

Grade	Term	Descriptor
0	None	No visible hollowing or volume loss medially or laterally
1	Minimal	Presence of hollowing with some volume loss medial to the mid-pupillary line; smooth lateral lid–cheek transition
2	Moderate	Defined hollowing extending laterally beyond the mid-pupillary line with moderate volume loss; smooth lateral lid–cheek transition with mild volume loss
3	Severe	Defined hollowing extending laterally beyond the mid-pupillary line with moderate volume loss creating a defined groove along the lid–cheek junction
4	Extreme	Defined hollowing extends from medial to lateral canthus; severe volume loss creates a marked step along the lid–cheek junction

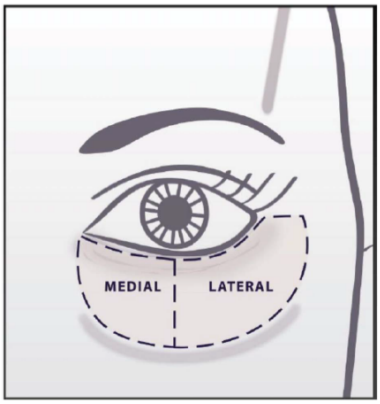
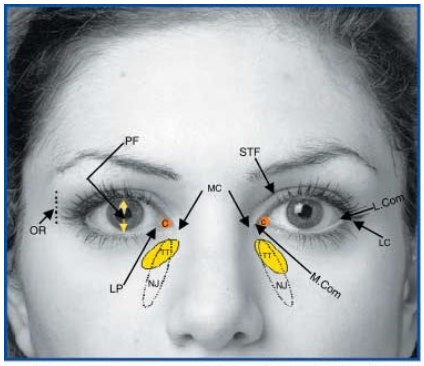


Figure 2. Assessment guide for the Allergan Infraorbital Hollows Scale.

3) Tear Trough Rating Scale



- TT – [Tear Trough]
- NJ – [Nasojugal Groove]
- C – [Caruncle]
- MC – [Medial Canthus]
- LC – [Lateral Canthus]
- L.Com – [Lateral Commissure]
- M.Com – [Medial Commissure]
- Supra Tarsal Fold [STF]
- Palpebral Fissure [PF]
- Lacrimal Puncta [LP]
- Orbital Rim [OR]

TTRS

The tear trough was assessed based on multiple characteristics defined by a novel TTRS. The multicontoured area of the tear trough is the additive product of multiple factors. Each separate component was evaluated individually, and the score was totalled. The factors accounted for the evaluation scale are described below:

- Depth of the trough – distance from the anterior lacrimal crest to the depth of the trough; each millimeter of depth is given 1 point (i.e., a prominent trough with a 3-mm depth is given 3 points)
- Hyperpigmentation – dyspigmentation, while not directly contributing to the depth of the trough, creates an illusion of depth; no hyperpigmentation is given 1 point; mild is given +2 points; moderate pigmentation is given +3 points; and intense or deep hyperpigmentation is given 4 points; subdermal dark casting caused by venous pooling can be graded as hyperpigmentation.
- Prolapse of nasal fat pads/pockets – prominent prolapse of the nasal fat pad accentuates the depth of the trough and was rated as mild (1 point), moderate (2 points), or severe (3 points).
- Lower eyelid skin rhytidosis accentuates the fatty prolapse and the depth of the trough – skin rhytidosis is rated 1+ to 4+ (mild, moderate, advanced, severe – according to Glogau's scale); 1+ is given 1 point, and 4+ is given 4 points

Because tear troughs are often asymmetric, both sides should be evaluated individually.

4 Study Population and Duration of Participation

4.1 Duration of Study Participation

The duration of study participation is 90 days. Subjects will receive injections on day 1, and follow up imaging will occur on day 14, 30, and 90 post intervention. Each individual subject's participation time in the study will consist of the duration of the initial imaging session (approximately 20 minutes), procedure (15 minutes), follow up imaging (20 min).

4.2 Total Number of Subjects and Sites

We anticipate about 10 patients from at a single location, the Hospital of the University of Pennsylvania. Subjects will include females, ages 22-65, who are interested in infraorbital filler injection (FDA approved use).

4.3 Inclusion Criteria

Adult female subjects, ages 22-65, who are interested in infraorbital filler injection FDA approved use. Each participant will participate for 90 days.

- Female
- 22-65 years of age
- Interested in filler injections to reduce undereye volume loss
- Participants must sign the informed consent form

4.4 Exclusion Criteria

- Female under 22 or above 65 years of age
- Male
- Prior filler in tear trough/midface
- Filler/neurotoxin injections within 12 months or during duration of study
- Prior facial cosmetic surgery
- Prior facial trauma (ie. orbital fracture)
- Pregnant or breastfeeding

4.5 Subject Recruitment

Patients will be recruited through the plastic surgery clinic, which is a high-volume practice for those who may be interested in cosmetic injections. Additionally, we plan to use of a flyer posted throughout the health system and campus. Filler injections to the infraorbital region to reduce undereye volume loss are a popular procedure and we do not anticipate significant difficulty in recruiting about 10 willing participants.

4.6 Vulnerable Populations:

Children, pregnant women, fetuses, neonates, or prisoners are not included in this research study.

5 Study Procedures

5.1 Screening

The screening visit involves patient evaluation of inclusion and exclusion criteria. This information is readily available on the intake visit and does not deviate from standard of care for a clinic visit, including

age and past medical history. Once patients are deemed eligible, the process of informed consent will begin. Informed consent will take place.

5.2 Study Intervention or Observational Phase

5.2.1 Visit 1 (sometimes referred to as the baseline visit)

Visit 1 involves screening, consent, baseline imaging, randomization, intervention. The subject will be photographed using 3D imaging to measure baseline undereye volume. After these images, subjects will complete a FACE-Q questionnaire and then be injected with Juvéderm Volbella XC filler in the infraorbital region according to a preset injection plan per FDA approved administration guidelines. Medication will be prepared as described on the FDA approved medication guide. A second set of 3D images will be taken after filler injection to measure starting infraorbital volume.

5.2.2 Visit 2

Visit 2 which will occur 14-days post-injection, will consist of a repeat of the above measurements using 3D imaging. Subjects will also complete the FACE-Q via electronic REDCap survey and communicate any questions or concerns.

5.2.3 Visit 3

Visit 3 which will occur 30-days post-injection, will consist of a repeat of the above measurements using 3D imaging. Subjects will also complete the FACE-Q via electronic REDCap survey and communicate any questions or concerns.

5.2.4 Visit 4

Visit 4 which will occur 90-days post-injection, will consist of a repeat of the above measurements using 3D imaging. Subjects will also complete the FACE-Q via electronic REDCap survey and communicate any questions or concerns.

TABLE 1 SCHEDULE OF STUDY PROCEDURES

	Baseline Visit 1	Intervention	Follow-up Visit 2 Day 14	Follow-up Visit 3 Day 30	Follow-up Visit 4 Day 90
Visit Window	**Day 1**	**Day 1**	**Day 14 ± 5**	**Day 30 ± 5**	**Day 90 ± 7**
Eligibility	**X**				
Informed Consent	**X**				
Demographic	**X**				
Medical History	**X**				
Consultation	**X**				
Vectra Photography		**X (pre and post injection)**	**X**	**X**	**X**

FACE-Q		**X**	**X**	**X**	**X**
Adverse Events		**X**	**X**	**X**	**X**

5.3 Unscheduled Visits

Unscheduled visits will be handled on a case by case basis dependent upon the reasoning for the patients' visit. If subjects are displaying signs of immediate danger or instability, they will be referred to emergency department or directly admitted. However, unscheduled visits are rare for this type of procedure.

5.4 Subject Withdrawal

Subjects may withdraw from the study at any time without impact to their care. They may also be discontinued from the study at the discretion of the Investigator. Subjects may also be withdrawn following an adverse event that does not allow them to continue with the study. It will be documented whether or not each subject completes the study. Subjects who withdraw early will have one final communication to collect final evaluations and assess for adverse events.

5.4.1 Data Collection and Follow-up for Withdrawn Subjects

Patients must document in a letter asking not to use the data collected and formalize the withdrawal. Otherwise, data up until withdrawal will be available for analysis.

5.5 Early Termination Visits

This may be due to the subjects' own choice or the investigator's decision. If the investigator makes the decision, subjects will be contacted and reasons for study termination will be thoroughly explained.

6 Statistical Plan

6.1 Sample Size and Power Determination

The sample size of this case series will be 10 female patients between the ages 22 and 65.

6.2 Statistical Methods

Descriptive statistics will be used to describe volume changes of undereye hollows over time. The results of this study will not have true statistical significance.

6.3 Control of Bias and Confounding

All patients will be injected with the same filler product in the same locations.

6.3.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive statistics (including mean and standard deviation for continuous variables such as age and standard percentages for categorical variables such as race).

6.3.2 Analysis of Primary Outcome of Interest

The primary analysis of volumetric measurements will be done using the Allergan Infraorbital Hollow Scale and the Tear Trough Rating Scale.

7 Safety and Adverse Events

7.1 Definitions

7.1.1 Adverse Event

An **adverse event** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

For FDA regulated studies the FDA defines an adverse event as the following: any untoward medical occurrence associated with the use of a drug in humans whether or not considered drug related.

7.1.2 Serious Adverse Event

Adverse events are classified as serious or non-serious. A **serious adverse event** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as **non-serious adverse events**.

7.2 Recording of Adverse Events

At each contact with the subject, the investigator will seek information on adverse events by specific questioning and, as appropriate, by examination. Information on all adverse events will be recorded immediately in the source document, and also in the appropriate adverse event module of the case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic procedures results should be recorded in the source document, though should be grouped under one diagnosis.

All adverse events occurring during the study period will be recorded. The clinical course of each event will be followed until resolution, stabilization, or until it has been determined that the study intervention or participation is not the cause. Serious adverse events that are still ongoing at the end of the study period will be followed up to determine the final outcome. Any serious adverse event that occurs after the study period and is considered to be possibly related to the study intervention or study participation will be recorded and reported immediately.

7.3 Relationship of AE to Study

The relationship of each adverse event to the study procedures should be characterized. The PI or medical monitor will determine how the relationship of the AE will be classified as:

- likely related – a well-known effect of the device or clearly not related to the subject or environmental factors
- probably related – is known or suspected effect of device or cannot be readily explained by subject or study procedures
- possibly related – is a possible effect of the device or can be explained by the subject or study procedures
- unlikely related – is not a suspected effect of the device or can readily be explained by the subject or environmental factors
- unrelated – is not a known effect of the device and can readily be readily and easily explained by the subject or environmental factors

7.4 Reporting of Adverse Events, Adverse Device Effects and Unanticipated Problems

Investigators and the protocol sponsor (which may or may not be a Penn Investigator) must conform to the adverse event reporting timelines, formats and requirements of the various entities to which they are responsible,

If the report is supplied as a narrative, the minimum necessary information to be provided at the time of the initial report includes:

- Study identifier
- Study Center
- Subject number
- A description of the event
- Date of onset
- Current status
- Whether study intervention was discontinued
- The reason why the event is classified as serious
- Investigator assessment of the association between the event and study intervention

Additionally, all other events (unanticipated problems, adverse reactions, unanticipated adverse device effects) and subject complaints will be recorded and reported with respect to institutional and federal policies.

7.4.1 Follow-up report

If an SAE has not resolved at the time of the initial report and new information arises that changes the investigator's assessment of the event, a follow-up report including all relevant new or reassessed information (e.g., concomitant medication, medical history) should be submitted to the IRB. The investigator is responsible for ensuring that all SAE are followed until either resolved or stable.

7.4.2 Investigator reporting: notifying the study sponsor

Investigators from all participating sites should report all unexpected and related adverse events, regardless of whether they are serious or not, and all unanticipated problems to the sponsor.

Any study-related unanticipated problem posing risk to subjects or others, and any type of serious adverse event, will be reported to the study sponsor by telephone within 24 hours of the event. To report such events, a Serious Adverse Event (SAE) form will be completed by the investigator and emailed to the study sponsor within 24 hours. The investigator will keep a copy of this SAE form on file at the study site. Report serious adverse events by sending via email to: [Evolus., Company Call Center: 1-877-EVOLUS1 (1-877-386-5871), Company Email: EvolusMI@druginfo.com]

Within the following 48 hours, the investigator will provide further information on the serious adverse event or the unanticipated problem in the form of a written narrative. This should include a copy of the completed Serious Adverse Event form, and any other diagnostic information that will assist the understanding of the event. Significant new information on ongoing serious adverse events should be provided promptly to the study sponsor.

7.4.3 Investigator reporting: notifying the Penn IRB

For single and multi-site studies each site PI will need to follow their local IRB reporting requirements in addition to the protocol outlined reporting.

7.4.4 Sponsor reporting: Notifying Participating Investigators

For clinical trials, in addition to reporting certain unanticipated problems and adverse events noted above to the FDA, it is the responsibility of the study sponsor to report those same adverse events or findings to participating investigators.

7.5 Medical Monitoring

It is the responsibility of the site Principal Investigator to oversee the safety of the study at his/her site. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above. The lead PI will monitor all AEs reported.

7.6 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

7.7 Data Collection and Management

REDCap will be used to store and maintain the primary study records. The data entered into REDCap will be obtained from the study-relevant patient EMRs. Study personnel will be granted access to this project created in REDCap with each user obtaining individual access authenticated by a login system. Minimal patient identifiers will be collected and stored in the REDCap database. Patient name and date of birth will be collected in REDCap.

Source data will mainly be from the patient's EMR. When the study requires data not normally collected in the patient's EMR, the case report forms will also be the source document. Data from source documents (Appendix15.4, case report forms (case report forms definition- Appendix 15.5), will be entered into an electronic data capturing system. All source documents should be secure in private spaces with restricted access. After Visit 1 the FACE-Q will be sent electronically to the subject for each follow-up visit via a REDCap survey.

During procurement of data charts will be reviewed in private spaces to ensure the confidentiality of acquired data. Data will be stored for up to 7 years after completion of the last follow-up visit of the last patient randomized. Data may be collected for up to two years following the treatment.

7.8 Records Retention

The Principal Investigator at each site is responsible for storing regulatory documents, subject files and financial records for the period specified by law. The time period for maintaining research records is defined first by HIPAA regulations that require any HIPAA-regulated information, authorizations, waivers, etc. must be maintained for at least 6 years subsequent to the Institutional Review Board (IRB) acknowledgement of the termination of the research project and secondly by DHHS regulations (45 CFR 46.115) and FDA regulations (21 CFR 56.115) state that IRB records relating to research shall be retained for at least 3 years after completion of the research.

8 Study Monitoring, Auditing, and Inspecting

8.1 Study Monitoring Plan

This study will be closely monitored by the PI and the project manager. The PI will be participating and the data will be collected by the PI and one other study steam member from the patient's EMR. The study team member will enter the data into the REDCap and the project manager will monitor the entry to verify the compliance with respect to the protocol, data collection, and source documents.

8.2 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the EC/IRB, the sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

9 Ethical Considerations

This study is to be conducted in accordance with applicable US government regulations and international standards of Good Clinical Practice, and applicable institutional research policies and procedures.

This protocol and any amendments will be submitted to a properly constituted independent Ethics Committee (EC) or Institutional Review Board (IRB), in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the EC/IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor before commencement of this study.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the EC/IRB for the study. The formal consent of a subject, using the EC/IRB-approved consent form, must be obtained before that subject undergoes any study procedure. The consent form must be signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent.

9.1 Risks

All treatments used in this protocol will be used according to the FDA approved intended use. No unexpected risks should occur. Risks/side effects of injections include skin infection, redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, itching, and dryness. Specific risks from dermal filler injections include unintentional injection into a blood vessel. This is a serious complication and may be permanent, although rare. Sequela of this complication can include vision abnormalities, blindness, stroke, skin necrosis or scarring.

There is minimal risk from the 3D imaging involved in this study to make volumetric measurements. The images will be identifying as they are of the face. All identifying images will be stored on a database or computer behind the firewall and a password.

Subjects should not be injected if they are allergic to lidocaine or Gram-positive bacterial proteins used in Juvéderm products or if they have had a previous allergic reaction to hyaluronic acid fillers.

The product has not been studied in pregnancy or breastfeeding patients, so these patients will be excluded.

9.2 Benefits

Subjects participating in this trial may benefit from improvement of undereye hollows from participating in this study. Although the benefits may not be readily apparent on an individual basis, the advancement of knowledge gained will serve the medical society and community.

There is financial compensation for participation in this study. Subjects will be compensated $15 for each follow-up visit and questionnaire completed. The payment will be administered after completion of the final follow-up visit for a maximum total of $45. The subjects will receive the dermal filler injections for no charge.

9.3 Risk Benefit Assessment

Subjects participating in this trial will unlikely experience an increase in risk as this is an observational study of FDA approved dermal filler injections. No change in patient care will happen if the subject is consented. All subjects will be asked to return for four follow-up visits for observation and surveys.

9.4 Informed Consent Process / HIPAA Authorization

All subjects for this study will be provided a consent form describing this study providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the IRB for the study. The formal consent of a subject, using the IRB-approved consent form, must be obtained before that subject undergoes any study procedure. The subject, or legally acceptable surrogate, must sign the consent form, and the investigator-designated research professional obtaining the consent. Subjects will be consented by the study Principal Investigator, or appropriate designee, in a room we have selected in which to perform consent, which is located outside of the clinic. Potential subjects will review the consent form in detail with the person designated to consent (either PI or CRC) and have the ability to take the consent home for further review.

10 Study Finances

10.1 Funding Source

Funding Sources pending

10.2 Conflict of Interest

None

10.3 Subject Stipends or Payments

There are no subject payments or stipends.

11 Publication Plan

Following data analysis and summary, data may be presented to relevant conferences and submitted for publication. Once published, data will be destroyed.

12 References

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13 Attachments