Protocol:

Jowl Improvement with Injectable Fillers: Jaw line Injections alone vs Jawline and Cheek Injections

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Jowl Improvement with Injectable Fillers:
Jawline Injections alone vs Jawline and Cheek Injections
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Clinical Investigation Plan

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Introduction

This is a prospective clinical study to demonstrate a reduction in jowling and laxity of the jawline that can be achieved following facial volume enhancement using JUVÉDERM VOLUMA™ XC. The secondary measure

will be if this can be achieved with jawline injection only, or if a superior result can be obtained with both cheek and jowl injection.

Present methods for treating jowling include:

1. Temporary, semi-permanent and permanent injectable filler substances
2. Tissue tightening devices and radiofrequency microneedling
3. Suture lifts
4. Surgical implants
5. Surgical face lifts

Early experimentation by the author with volume replacement using JUVÉDERM VOLUMA® XC has yielded good results with an excellent safety profile and minimal downtime or adverse events. This study was undertaken to determine if patient satisfaction and results can be measured by a reduction in jowl laxity and jawline crispness with apparent lift and whether it is enough to treat the jawline alone or it is best to treat the jawline in conjunction with the cheeks.

Study Rationale

Hyaluronic acid fillers are used primarily for the reduction of wrinkles and age-related volume deficits. A common complaint of women is the formation of jowls, and they frequently pull up their skin toward their ears to indicate an outcome they wish for. In the past, face lift was the principle method to treat this problem, but many newer less-invasive techniques attempt to improve this area. One treatment that is a few years old is the dissolvable suture lift, targeting the mid cheek and jawline to lift the face. Another newer technique is the radiofrequency needling technique. Older treatments include skin tightening treatments with radiofrequency or focused ultrasound.

Many practitioners also use fillers with high G prime along the jawline or lateral face to accomplish improving the jowls. This technique, alternatively called “jawline filler, jawline lift”, has not received FDA approval. JUVÉDERM VOLUMA® XC injectable gel is currently FDA approved for deep injection in the cheek area to correct age-related volume loss. In practice, we have seen the advent of cheek treatments with Voluma causing noticeable lifting in the jowls and also the nasolabial fold. However, recent experimentation with filler into the mandible lateral to the jowl , sometimes accompanied by injection into the preauricular area by this author has revealed that this area has been underrepresented in filler solutions for jowling.

Protocol Summary

This study is proposed to evaluate the best protocol for achieving improvement in the sagging jawline.

JUVÉDERM VOLUMA™ XC will be injected in each of 16 women with sagging of grades 1-3 using a published jawline evaluation scale (1).

Patients will be randomized 1:1 into 2 groups:

Patient Group 1: JUVÉDERM VOLUMA™ XC 1-2 syringes (each syringe is 1 cc) will be injected bilaterally into the lateral jawline and inferior cheek area (preauricular area) (the latter area will be added if necessary to achieve visual improvement in jowl attenuation). Total syringes used per person will have a range of 1-2)

Patient Group 2: JUVÉDERM VOLUMA™ XC 1-3 syringes (each syringe is 1 cc) will be injected bilaterally into the lateral cheek (zygomatic) area plus JUVÉDERM VOLUMA™ XC 1-2 syringes (each syringe is 1 cc) will be injected into the lateral jawline and inferior cheek area (preauricular area) (the latter area will be added if necessary to achieve visual improvement in jowl attenuation). Total syringes used per person will have a range of 2-5)

High resolution photographs from multiple angles will be taken in identical lighting and position with the VISIA CR and with the Fotofinder at 2 weeks, 4 weeks, 8 weeks, and 12 or 16 weeks. Additional real time video telemedicine visits will take place at 6 months and 12 months. In addition, a 72-hour safety phone call will be completed with the subject after each injection session. All visit timing will be based on the last injection session. Oneblinded dermatologist and one unblinded dermatologist will rate the patient's severity of jowling based on the Jawline Rating Scale (JRS) (1) at the 4-week, 8-week, and either 12 or 16-week visits. The patient will also rate their jowling based on the JRS as well as their satisfaction with the procedure.

Name and Intended Use of Devices and Medications

Proprietary name: JUVÉDERM VOLUMA™ XC
Common name: non-animal hyaluronic acid
Intended use: correction of cheek volume loss

Materials

The devices will be maintained according to the manufacturer's suggested maintenance. The devices will be utilized as packaged with only the needles that were included in the packaging and without manipulating the filler device or contents. No cannulae will be utilized for this study.

If needed for an adverse event, hyaluronidase will be utilized and will be stored according to manufacturers' specification (Hylenex recombinant hyaluronidase human injection,150 USP units/cc).

Benefit / Risk Analysis

The benefits of participating in this study are to potentially improve moderate to severe facial volume loss leading to an aging appearance, specifically in the jowls.

Commonly reported side effects (SEs) of JUVÉDERM® injectable fillers include, but are not limited to, injection-site erythema or redness, swelling, pain, tenderness, discomfort, firmness, lumps/bumps, bruising, discoloration, and itching. As most of these risks are common to filler injection procedures, the treating physician (TI) will use his/her medical judgment to determine any necessary intervention(s).

Additional risks to undergoing a treatment like this include infection, blindness, stroke, vascular compromise, and scarring. More detailed information regarding the possible Adverse Events (AEs), safety assessments, and investigator protocol in the event of intravascular injection will be noted below.

This study proposes to evaluate a new indication for JUVÉDERM VOLUMA™ XC, for which the benefit/risk profile has not been entirely assessed. While the risks of stroke and blindness may be small, the jawline and cheek are highly vascularized areas. Due to limited experience and research associated with dermal filler use in this area, the actual risk is unknown.

Alternatives

Alternatives to treatment include but are not limited to other injectable fillers, surgical implants, and surgery.

Study Purpose and Objectives

Purpose:

The purpose of this clinical investigation is to study the perceived reduction of jowling following a volume replacement treatment using JUVÉDERM VOLUMA™ XC in the jawline or in the jawline and the cheek

Primary Objective:

The primary objective of this study is to see that a clinically relevant jowl improvement can be achieved with hyaluronic acid filler into the jawline and/or cheek (Endpoint #1).
The secondary objective is to determine which of the 2 methods (jowl injection alone or jowl injection with cheek injection) is superior (Endpoint #2).

Study Design

Scope:

The clinical study will include 16 patients at one clinical site.

Duration:

Eligible patients will receive 1 treatment according to the study protocol, and will be followed for a period of 12 months to document safety and efficacy. Patient and/or doctor may choose to have a touchup at 1 month. All subjects will be followed for 12 months from the time of the last injection session.

Patient Selection

Each patient will be evaluated by the Investigator to assess his or her suitability for entry into the study.

Inclusion Criteria

1. Jowling grade 2-3 by the Lower Face Jawline at Rest Scale (1), by both MD evaluator and patient.

2. Female patients must not be pregnant or trying to get pregnant and must have negative urine pregnancy tests before treatment.

3. Non-pregnant females ages 35-65 in good general health.

4. A study participant must be able to give proper informed consent in writing and be willing to follow the treatment schedule and undertake to carry out all necessary precautions and instructions.

5. Able to participate in telemedicine video visits.

6. Able to understand the requirements of the study and willing and able to follow all study procedures and attend all study visits, and successfully complete the study.

7. Willing to refrain from any other cosmetic procedures on the face including surgery, thread lifting, botulinum toxin in the masseters, jawline, neck, lips or chin, chemical peels, lasers or energy-based devices meant to improve volume or laxity of the face, and additional injectable fillers from first visit through 12 months after last injection session.

Exclusion Criteria

1. Pregnancy or nursing

2. Hyaluronic acid filler injections in the past 6 months in the lower face or unwilling to refrain from such injections other than in the study for the duration of the study.

3. Radiesse or Sculptra in the past 24 months in the lower face

4. Permanent fillers or injectable fat at any time in the past.

5. Facial surgery, tissue tightening or laser treatments within the past 24 months in the lower face, or unwilling to refrain from having these treatments for the duration of the study.

6. History of keloid or scar formation

7. Unwillingness to refrain from excessive sun exposure or tanning beds during the healing process

8. Taking any medications or supplements that will increase the potential for bruising, or discontinuation of same for 10 days prior to the procedure if medically allowed. These include but are not limited to aspirin of any dosage, any prescription blood thinner, vitamin E and fish oil.

9. Any of the following significant medical problems: diabetes, obesity, autoimmune disease, cancer, inflammation at the site of injection, current infection any place on the body, dental work in the prior 2 weeks or scheduled for the post treatment 2-week period, dementia, facial nerve abnormalities, history of blood clot, Bell's Palsy or any neurological condition affecting the facial muscles or nerves.

10. Prior tattoos, piercings, facial hair or scars below and including the subnasal area that could interfere with visual assessment of the chin, jowls, jawline and could promote bias in evaluation of improvement or safety.

11. Known allergy or sensitivity to any components of the injection material, lidocaine or hyaluronidase.

12. Current enrollment in any other investigational drug or device trial.

13. Any condition that the investigator believes might interfere with study results or put subject at significant risk with participation.

14. Patients planning to undergo any dental procedure (other than prophylaxis and dental) fillings).

15. Patients who have undergone mesotherapy or cosmetic treatment (laser, photomodulation, intense pulsed light, radio frequency, dermabrasion, moderate or greater depth chemical peel, liposuction, lipolysis, or other ablative procedures) anywhere in the face or neck, or botulinum toxin treatment below the subnasal region (including injections to the masseter muscles) within 6 months before enrollment or was planning to undergo any of these procedures during the study.

16. Patients who experienced trauma to the chin and jaw area within 6 months before enrollment or had residual deficiencies, deformities, or scarring.

17. Patients with a history of anaphylaxis or allergy to lidocaine (or any amide-based anesthetics), hyaluronic acid products, or Streptococcal protein, or was planning to undergo desensitization therapy during the term of the study are typically excluded for safety reasons.

18. Patients who have porphyria, untreated epilepsy or active autoimmune disease.

19. Patients who have current cutaneous or mucosal inflammatory or infectious processes (e.g., acne, herpes, gum disease), abscess, an unhealed wound, or a cancerous or precancerous lesion, below the subnasal (study device injection may have been delayed for participants with a history of recurrent oral herpes lesions who take prophylactic doses of antiviral/herpes medication for at least 2 days before study treatment administration).

20. Patients on a concurrent regimen of lidocaine or structurally-related local anesthetics (e.g., bupivacaine) or a concurrent regimen of drugs that reduce or inhibit hepatic metabolism (e.g., cimetidine, beta-blockers).

21. Patients on a regimen of anti-coagulation therapy (e.g., warfarin, clopidogrel) or other prescription anti-coagulation therapy.

22. Patients on a regimen of medications (e.g., aspirin or ibuprofen) or other substances known to increase coagulation time (e.g., herbal supplements with garlic or gingko biloba) within 10 days of undergoing study device injection (study device injection may have been delayed as necessary to accommodate this 10-day washout period).

23. Patients who received any investigational product within 30 days prior to study enrollment or was planning to participate in another investigation during the course of this study.

24. Patients who have begun using any new over-the-counter or prescription oral or topical, anti-wrinkle products below the subnasal area within 30 days before enrollment or was planning to begin using such products during the study (participants who had been on a regimen of such products for at least 30 days were eligible for the study if they intended to continue their regimen throughout the study).

25. Patients who have a pigmentation disorder.

26. Patients currently on immunosuppressive therapy for the duration of the study.

27. Patients unwilling to use contraceptive methods to prevent pregnancy for the duration of the study.

Information on Gender and Racial Inclusion/participation in study:

Men have been excluded from this study for two reasons:(1) the technique pioneered in this study may not give a desirable aesthetic effect for men even if they reach the endpoint of improved jowling, due to the fact that they have a different shape of jawline than women and (2) men often need a higher amount of filler than women to achieve endpoint and product is limited to grant from Allergan.

The original Voluma study (see Package Insert), showed that there was no difference in response nor safety signals depended on Fitzpatrick skin types. Although this study is looking at a different area of study than that already approved (cheeks), there is no reason to presume this would change this initial observation. We may not have access to all skin types to recruit for this single center Investigator Initiated Clinical Trial, although we will attempt to recruit skin types 4-6.

Clinical Procedures

Pre-Procedure Evaluation

1. At the first visit, the Investigator will obtain a detailed patient history, examine the patient and determine if she fits the study criteria.

2. The Investigator will discuss treatment options with the patient including injectable fillers and other treatment modalities.

3. During the first visit, the physician should obtain an informed consent from the subject, clearly indicating his / her understanding of the requirements and risks involved with study participation, including but not limited to:

    a. One to two treatments will be performed using JUVÉDERM VOLUMA™ XC

    b. A photographic record at baseline and all follow-up visits (2 weeks, 4 weeks, 8 weeks, 12 weeks, and 16 weeks).

c. There may be discomfort / pain / bruising and complete discussion of side effects potentially resulting from the treatment, including possible stroke, blindness and scarring

d. Transient edema may occur immediately following the treatment.

e. Erythema and bruising may occur following treatment and last up two weeks or longer.

f. A full disclosure and written consent will be provided and signed.

g. If necessary as deemed by patient and/or physician, a touch up may be performed at the 1-month visit.

h. Evaluations by phone and/or telemedicine will be performed at 72 hours after treatment, 6 and 12 months.

I. Patients will complete a safety diary daily via email for 30 days following treatments.

If the patient passes all of the inclusion and exclusion criteria for entry into the study the investigator will obtain signed Informed consent, enroll the patient into the study, and record required data on the appropriate study data form. Pre-treatment photographs will be taken.

Treatment

1. Photographs will be taken prior to treatment with the VISIA CR system and Fotofinder and with an iPad. Frontal, 45- and 90-degree angle shots at standard illuminations will be taken.

2. Patients will be randomized to 2 groups:

Patient Group 1: JUVÉDERM VOLUMA™ XC 1-2 syringes (each syringe is 1 cc) in will be injected bilaterally into the lateral Jawline/lateral medial or and inferior cheek area (preauricular area) (the latter area will be added if necessary to achieve visual improvement in jowl attenuation). Total syringes used per person will have a range of 1-2.

Patient Group 2: JUVÉDERM VOLUMA™ XC 1-3 syringes (each syringe is 1 cc) will be injected bilaterally into the lateral cheek (zygomatic) area plus JUVÉDERM VOLUMA™ XC 1-2 syringes (each syringe is 1 cc) will be injected into the lateral jawline and inferior cheek area (preauricular area) (the latter area will be added if necessary to achieve visual improvement in jowl attenuation). Total syringes used per person will have a range of 2-5.

Note: Based on preclinical studies and a toxicological risk assessment, subjects will be limited to 20 mL of JUVEDERM VOLUMA™XC per 60 kg (130 lbs) body mass per year. This includes any “Touch-up Volume”

3. During treatment cold air will be directed toward the injection sites to reduce discomfort.

4. Any complications will be noted at each visit and the patient will complete a diary via email or text every day.

5. Side Effects and possible adverse reactions will be monitored and documented before and after each treatment. Safety measures will be outlined below.

6. Safety exams will be performed prior to and 30 minutes after treatment. These tests include the Snellen Eye Exam, Ocular Motility Exam, and Confrontational Visual Fields Exam. Cranial Nerve evaluations will also be performed prior to and 30 minutes after treatment.

7. The patient will be given postoperative instructions.

8. Inclusion in the study will require participation in all the follow-up visits.

Return Visits

The subject will have a phone call with the study coordinator at 72 hours.

The subject will return at 2 weeks,4 weeks, 8 weeks, and either 12 or 16 weeks following the treatment.

The subject will have a live video telemedicine visit at 6 and 12 months after the last injection session.

At all follow up in person visits, photographs will be taken.

Any side effects or adverse events will be noted at each study visit. Any changes in condition, medical history, or medications will be noted.

Safety eye exams will be performed. These tests include the Snellen Eye Exam, Ocular Motility Exam, and Confrontational Visual Fields Exam. Cranial Nerve evaluations will also be performed to further assess vision, oculomotor function, and lower face function.

Patient questionnaire will be completed noting discomfort from the treatment, downtime following treatment, their perception of the results, would they have the treatment performed again in the future if they had the choice, and if they feel they need a touch-up (see below).

The patient or treating physician may request one touchup at one month, with the identical amounts and procedures as the first injection. If this takes place, the patient will have another safety phone visit at 72 hours, another 1-month follow-up visit similar to the first and shall not be eligible for a touch up at the second 1-month visit. The patient shall then have a 3 month visit after the second injection as well as a 6- and 12-month videoconference visit from the second injection. Additional treatment is optional for the patient.

Additional treatment is optional for the patient, but must be agreed upon by both patient and physician that additional improvement may be obtained of the jowl by the treatment.

Safety Assessments

Safety measures include:

Ophthalmologic exams that include Snellen Eye Exam, Ocular Motility Exam, and Confrontational Visual Fields Exam. These exams will be performed prior to any treatment, 30 minutes after treatment, and at all follow up in person visits. Refer to the case report forms (CRFs) for examination procedures.

To further assess vision and oculomotor function, cranial Nerves II, III, IV, and VII will be assessed (left and right sides separately). To assess lower face function, cranial nerves V, VII, IX, X, and XII will be assessed. These exams will be performed prior to any treatment, 30 minutes after treatment, and at all follow up visits. Subjects will also be asked about cranial nerve functionality in their safety diaries. Refer to the case report forms (CRFs) for examination procedures and criteria.

Patient will also have a jaw function assessment at all in person visits. Please refer to the CRF for examination procedures and criteria.

Patients will fill out a daily safety diary to monitor for any adverse events. Patients will be instructed to seek immediate medical attention if any signs of vascular compromise occur (pain in treatment site, excessive redness, purple coloration or blanching (white patches), blisters, and crusts.

Adverse Reactions

AEs will be monitored at every patient visit and through patient safety diaries completed daily for 1 month following treatment. Patients will be followed for a period of 12 months after final treatment.

Adverse Events of Special Interest, including vision changes, will be reported to Allergan and the FDA within 10 days. SAEs will be reported within 24 hours. All other AEs will be reported annually.

More detailed information including the AE report form will be included below.

The following is a list of common anticipated adverse reactions that have been reported with facial injection procedures in the area or at the injection site:

- Bleeding
- Bruising
- Redness
- Swelling
- Lumps/bumps mass or nodule
- Itching
- Discoloration

In rare circumstances, facial fillers have been associated with the following severe adverse events (SAEs):

- Allergic reaction
- Herpes Simplex Virus 1 outbreak
- Giant cell reaction or granuloma formation
- Vision changes (blurred vision, double vision, loss of peripheral vision, partial loss of the visual field)
- Blindness (complete or partial)
- Stroke
- Vascular compromise
- Scarring
- Skin necrosis, ulceration and/ or nerve damage
- Inability to chew or speak normally

While rare, unintentional injection into a blood vessel has been reported for facial injections which can be serious and may be permanent. Any incidence of visual disturbances (including, but not limited to, any loss of vision, blurry vision, double vision, pain in or around the eye, blind spot or shadow in the visual field, trouble

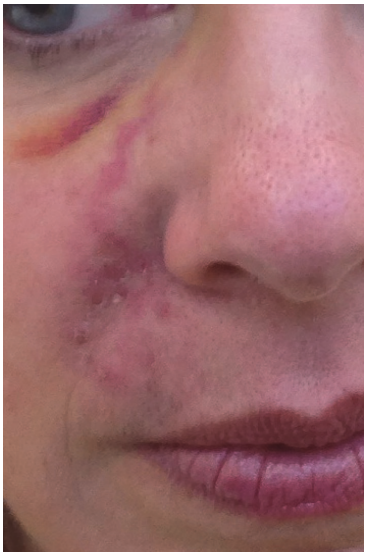
moving eyes, dizziness, confusion, weakness or numbness of the arms or legs, changes to consciousness or alertness, difficulty speaking or speech impairment, facial drooping etc.) will be immediately reported to the treating physician and the sponsor. In the event of blindness or any ophthalmic signs or symptoms, the subjects must undergo immediate evaluation by a retinal specialist. More details pertaining to the reporting protocol and treating vascular compromise will be outlined below.

The incidence of serious adverse events associated with intravascular injection is very low. If a complication occurs, the subject will be advised to contact the study staff and treating physician immediately and the treating physician will use his/her medical judgement to determine the necessary interventions to treat the subject.

There are also unforeseeable risks or results associated with this procedure. If the subject experiences any unanticipated adverse event an additional visit and/ or report form may be required.

Vascular Compromise Procedure and Protocol

Recognition and Treatment of Vascular Occlusion:



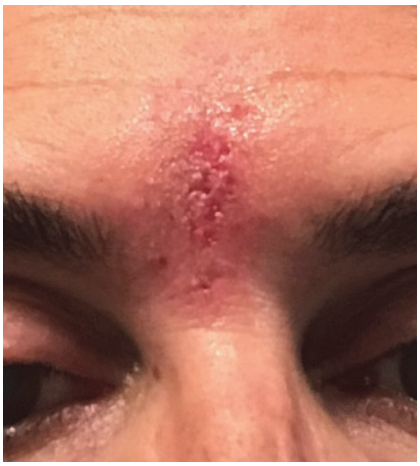
Recognition:

Recognize vascular occlusion by a livedoid or violaceous appearance to the treatment area and/or blanching of the treatment area and/or patient pain.

Early signs:

- Blanching followed by violaceous patches in distribution of artery
- Pain

* especially if they have had a filler treatment before and it is unusual and/or more severe in days following injection



Delayed signs:

- Violaceous or dusky reticulated patches in distribution of arteries
- Pain
- Necrosis

Arterial Compromise vs. Bruising:

- Does not typically develop yellow coloration like bruising
- Not typically round or in dependent areas like bruising

Treatment:

When vascular occlusion is suspected, it is crucial that the injection is stopped immediately and treatment is rapidly instigated. The objective is to facilitate blood flow to the affected area. The steps for treatment of a vascular occlusion are:

1. Immediately flood the entire treatment area with injected 200-300 U of Hyaluronidase (1.25-2.0 cc of Hylenex, 150 u/cc).
2. Apply a warm compress
3. Massage the area.
4. If no reduction in violaceous or blanching appearance and/or pain after 10 minutes, apply 2% nitroglycerin paste to promote vasodilatation.
5. 60 min later if no improvement, reinject 200-300U of hyaluronidase.
6. Repeat Hourly and daily
7. If none of these measures work and depending on severity, institute daily hyperbaric oxygen chamber treatments.

Hyaluronidase should be injected immediately, regardless of the filler used, and administered hourly and/or daily in liberal doses where signs and symptoms are present.

When injecting hyaluronidase to treat acute ischemia, consensus recommendations are that the entire ischemic area be treated, not just the site where HA was originally injected. Doses up to 1500 U may be required to achieve reversal of vascular compromise.

References:

1. Urdiales-Gálvez F, Delgado NE, Figueiredo V, Lajo-Plaza JV, Mira M, Moreno A, Ortíz-Martí F, Del Rio-Reyes R, Romero-Álvarez N, Del Cueto SR, Segurado MA, Rebenaque CV. Treatment of Soft Tissue Filler Complications: Expert Consensus Recommendations. Aesthetic Plast Surg. 2018 Apr;42(2):498-510. doi: 10.1007/s00266-017-1063-0. Epub 2018 Jan 5. Review.

2. Henderson R, Reilly DA, Cooper JS. Hyperbaric Oxygen for Ischemia due to Injection of Cosmetic Fillers: Case Report and Issues. Plast Reconstr Surg Glob Open. 2018 Jan 11;6(1):e1618.

Recognition and Treatment of Retinal Occlusion

If patient complains of loss of vision, periorbital pain, blurred vision, ptosis, or impairment of extraocular muscle functionality immediately perform Snellen Chart Visual Acuity Calculation.

Fortunately, recent review of the literature asserted that the most common locations of injection leading to this complication were the forehead, nose and temple, and specifically the jawline was NOT involved in any single case

Nevertheless, preparations will be made in event of this catastrophic complication. There is no definitive and completely accepted protocol for treating this complication.

However, most experts recommend:

1. Assess visual acuity with Snellen Chart examination
2. Make sure pupils are round and equal and respond to light.
3. Immediately arrange for transfer to a retinal surgeon office and transfer at first opportunity (surgeon or associate to drive).
4. Apply 1 drop of Timolol to affected eye.
5. Begin massage of the eye
    a. Digital massage should start immediately
    b. The patient should be placed in a supine position.
    c. Ensure the patient’s eyes are closed.
    d. Apply firm pressure (enough to ensure that the eyeball is indented about 2–3 mm) on the eyeball through the closed eyelids.
    e. Apply firm pressure for 5–15 s and quickly release.
    f. Repeat this cycle for at least 5 min.
6. Flood the area of the supraorbital and supratrochlear notch on the side with deficit with hyaluronidase.

7. Have the patient rebreathe into a plastic or paper bag
8. Put either 325 mg ASA OR sublingual nitroglycerin 0.6 mg under the patient's tongue.
9. Only as a last resort and after blindness has been established by Snellen Chart, Retinal surgeon not available, then undertake a retrobulbar injection with hyaluronidase up to 1500 U, as in rare cases, it has been effective, although is not recommended due to poor literature and proof.

Retinal Surgeon:
Michael Blair, MD - Ophthalmologist (Retina Consultants, Ltd)
C: 847- 217-5436
O: (847) 299-0700
michaelblairmd@gmail.com

Aneta - Practice Manager
(847) 299-0700 / 0701 (direct #) Fax: 847.390.0616

Mondays: Libertyville 1-4:30 pm
Tuesdays: Des Plaines 9-12:45 pm; Libertyville 2-4:30 pm
Wednesdays: Libertyville 12-4:30
Thursdays: Des Plaines 2 pm- 4:30 pm
Fridays: Libertyville 1-4:30 pm
Saturday: 4th Saturday of the month (select)

Main Locations:

2454 E Dempster St Ste 400
Des Plaines, IL 60016
13.3 miles from Lincolnshire
14.2 miles from Glencoe

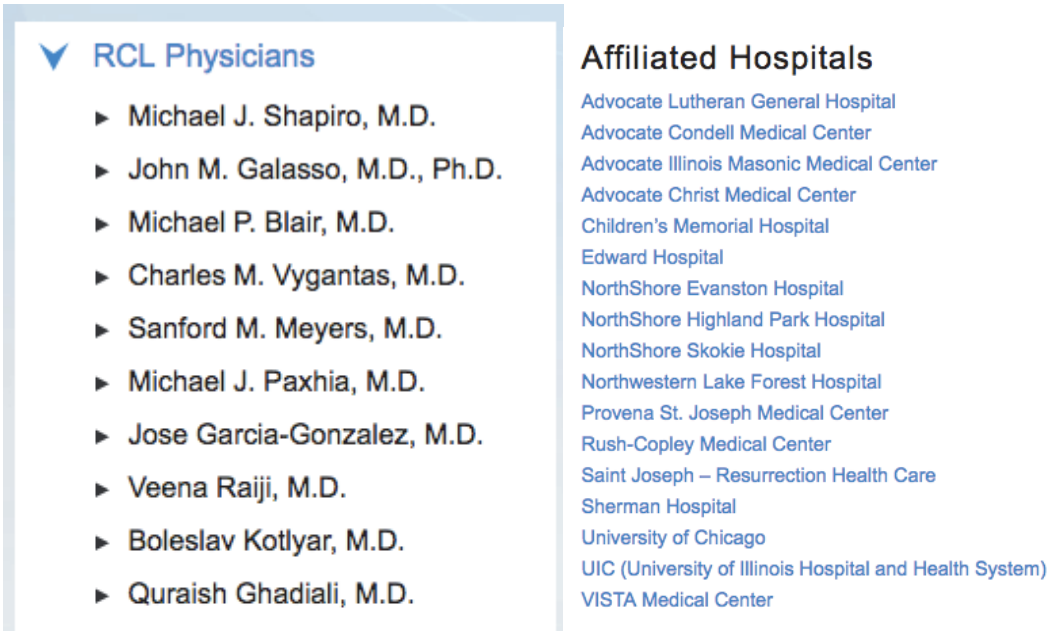
755 South Milwaukee Ave.
Suite 101
Libertyville, IL 60048
7.2 miles from Lincolnshire
18.8 miles from Glencoe

Other locations:

3100 Ogden Ave.
Lisle, IL 60532

2250 Point Blvd.
Suite 120
Elgin, IL 60123

Hickory Square Plaza
7667 West 95th St.
Suite 103
Hickory Hills, IL 60457



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1. Thanasarnaksorn W, Cotofana S, Rudolph C, Kraisak P, Chanasumon N, Suwanchinda A. Severe vision loss caused by cosmetic filler augmentation: Case series with review of cause and therapy. J Cosmet Dermatol. 2018 Oct;17(5):712-718.
2. J Cosmet Dermatol. 2018 Oct;17(5):712-718. doi: 10.1111/jocd.12705. Epub 2018 Jul 13.
3. Paap MK, Milman T, Ugradar S, Goldberg R, Silkiss RZ. Examining the Role ofRetrobulbar Hyaluronidase in Reversing Filler-Induced Blindness: A Systematic Review. Ophthalmic Plast Reconstr Surg. 2019 Dec 24.
4. Kapoor KM, Kapoor P, Heydenrych I, Bertossi D. Vision Loss Associated with Hyaluronic Acid Fillers: A Systematic Review of Literature. Aesthetic Plast Surg.2019 Dec 10.

Discontinuation Criteria

Reasons for early discontinuation from the study for individual subjects include:

- ***Serious Adverse Event (including vascular embolic event, leading to skin necrosis, vision loss or stroke)***
- ***Pregnancy***
- ***Protocol deviation***
- ***Physician decision***
- ***Subject withdrawal***
- ***Lost to follow-up***
- ***Death***

Should any vascular embolic event, vision loss, or stroke occur, the study will be discontinued. The enrollment and treatment will be suspended and a root cause investigation will be conducted to determine the cause of the event and whether the outcome was anticipated (the investigator did not properly follow the treatment SOP) or unanticipated (the investigator DID properly follow the treatment SOP). If the event was unanticipated, the study will be immediately suspended and enrollment will be halted until the event can be properly characterized and an appropriate treatment strategy to avoid this unanticipated event can be devised.

Patients enrolled in the study will be informed of any new events or risks to the study treatment and may choose to continue participation or be withdrawn at any time.

Withdrawal

Patients enrolled in the study will be free to discontinue their participation in the study at any time. A decision to discontinue participation will not prejudice their medical care. In those instances, the investigator will attempt to obtain clinical results and side effect evaluation concerning the patient prior to his / her withdrawal. Details of the subject's withdrawal from the study will be noted and reported to sponsor.

Data Analysis

Data will be collected via digital photographs and questionnaires by the subjects.

Photographs will remain unretouched. One blinded dermatologist and one unblinded dermatologist will rate the patient's severity of jowling based on the Jawline Rating Scale (JRS) (1) at baseline, the 4-week, 8-week, and 12 or 16-week visits. The patient will also rate their jowling based on the JRS as well as their satisfaction with the procedure.

Analysis of Scientific Soundness of the Protocol

The proposed study has been designed to provide a valid method to analyze the safety and efficacy of facial volume replacement. Measure taken to assure that the study provides valid data are as follows:

1. Photographs will be taken under standardized conditions. Photographs will be taken with a VISIA CR, a device made by Canfield Scientific specifically to be utilized for clinical research to provide uniformity in patient photographs.

2. Adverse or unanticipated effects that occur during the course of this clinical study will be recorded and carefully analyzed as to their relationship to the treatment.

3. Evaluators will review individual photos without knowledge of if they are before or after photos.

Primary Outcome Measure:

1. The primary outcome is a reduction of 1 or more points of the Jawline Rating Scale (JRS) Assessment (on scale of 0 to 4) at baseline versus that at 4 weeks from the last injection (whether initial or touch-up) based on any or all of one blinded dermatologist rating, one unblinded dermatologist rating, and patient rating. (A lower number will mean a better outcome) Time Frame: Baseline to 4 weeks after last injection.

Secondary Outcome Measures

1. Reduction of 1 or more points of the Jawline Rating Scale (JRS) Assessment (on scale of 0 to 4) at baseline versus that at 4 weeks from the last injection based on the patients rating while looking in the mirror and at before and after photographs. A lower number will mean a better outcome. Time Frame: 4 weeks from last injection
2. Whether group 1 and group 2 has a higher reduction in the Jawline Rating Scale (JRS) (on scale of 0 to 4) at 4 weeks from the lastinjection compared to baseline based on ratings from one blinded dermatologist and one unblinded dermatologist. . A lower number will mean a better outcome. Time Frame: 4 weeks from last injection
3. Whether group 1 or group 2 has a higher reduction in the Jawline Rating Scale (JRS) (on scale of 0 to 4) at 4 weeks from the last injection compared to baseline based on the patients rating while looking in the mirror and at before and after photographs. . A lower number will mean a better outcome. Time Frame: 4 weeks from last injection
4. Jawline Rating Scale (JRS) Assessment on scale of 0 to 4 at 4 weeks: One blinded dermatologist and one unblinded dermatologist will rate the patient's severity of jowling based on the Jawline Rating Scale (JRS). The patient will also rate their jowling based on the Jawline Rating Scale (JRS). The scale is on a rating of 0 to 4. A lower number will mean a better outcome. [Time Frame: 4 weeks]
5. Jawline Rating Scale (JRS) Assessment on scale of 0 to 4 at 8 weeks: One blinded dermatologist and one unblinded dermatologist will rate the patient's severity of jowling based on the Jawline Rating Scale (JRS). The patient will also rate their jowling based on the Jawline Rating Scale (JRS). The scale is on a rating of 0 to 4. A lower number will mean a better outcome. [Time Frame: 8 weeks]
6. Jawline Rating Scale (JRS) Assessment on scale of 0 to 4 at 12 or 16 weeks: One blinded dermatologist and one unblinded dermatologist will rate the patient's severity of jowling based on the Jawline Rating Scale (JRS). The patient will also rate their jowling based on the Jawline Rating Scale (JRS). The scale is on a rating of 0 to 4. A lower number will mean a better outcome. [Time Frame: 3 months from last treatment]
7. Incidence of abnormal eye exam (Confrontational Visual Fields Exam) findings (Safety): Ophthalmologic exams that include Confrontational Visual Fields Exam will be performed prior to any treatment, 30 minutes after treatment, and at all follow up in-person visits. [Time Frame: up to 18 months]
8. Incidence of abnormal eye exam (Snellen Eye Exam) findings (Safety): Ophthalmologic exams that include Snellen Eye Exam will be performed prior to any treatment, 30 minutes after treatment, and at all follow up in-person visits. [Time Frame: up to 18 months]
9. Incidence of abnormal eye exam (Ocular Motility Exam) findings (Safety): Ophthalmologic exams that include Ocular Motility Exam will be performed prior to any treatment, 30 minutes after treatment, and at all follow up in-person visits. [Time Frame: up to 18 months]
10. Incidence of abnormal cranial nerves II, III, IV and VII assessments findings (Safety): To further assess vision and oculomotor function, cranial nerves II, III, IV, and VII will be assessed (left and right sides separately). To assess lower face function, cranial nerves V, VII, IX, X, and XII will be assessed. These exams will be performed prior to any treatment, 30 minutes after treatment, and at all follow up visits. [Time Frame: up to 18 months]
11. Adverse events:

Adverse events will be recorded until 12 months after last treatment. [Time Frame: up to 12 months after last treatment]

Adherence to Protocol

The investigator will review the contents of this protocol. Any alterations to the protocol will be made in writing to the sponsor.

Records and Reports

Data from the pre-treatment evaluation, the treatment procedure, complications, if any, the post-treatment evaluation and all follow up evaluations will be recorded on the clinical data forms prepared for the study.

All records and reports concerning the clinical study will be forwarded to the Sponsor within a reasonable amount of time. The Investigator shall retain copies of all documentation for a period of two years following the date on which the entire clinical investigation is terminated or discontinued.

Confidentiality

This study is confidential. Information made public regarding subjects enrolled in this study will not disclose the name of any individual.

Information made public regarding subjects enrolled in this study will not disclose the name of any individual. All our research records are stored securely in locked cabinets and password protected computers. Only a few people who are closely concerned with the research will be able to view information from participants. Data is coded.

The results of this study will be provided to Allergan, including photographs, but no identifying subject information will be disclosed.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Subject identities will not be disclosed in any of these meetings or publications.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by

U.S. Law. This Web site will not include information that can identify subjects. At most, the Web site will include a summary of the results.

Documentation of Consent Process

Consent will be obtained prior to any study procedures being performed. Informed consent will be discussed with subject. A copy of the consent form will be provided for subject (in a language understandable to the patient) and/or authorized subject representative review. Subject and/or authorized subject representative will be given adequate time to read the consent form and discuss the study with study investigators and/or family members. All questions will be answered. Subject and/or authorized subject representative will be given time to discuss. HIPAA form will be reviewed with subject. Informed Consent process will be conducted in a manner and location that ensure patient privacy.

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Voluma Jowl/Jawline Study 10001 Appendix 1: Study Schematics Retreatment

Visit #	1	2	3	4	5	6	7	8	9	10
	Screening	Treatment	Safety Follow Up Call	In Office Follow Up	In Office Follow Up	Safety Follow Up Call	In office Follow Up	In Office Follow Up	Tele medicine Video Call	Tele medicine Video Call
			72 hours after treatment	2 weeks +/- 3 days	4 weeks +/- 3 days	72 hours after RTx	8 weeks +/- 3 days	16 weeks +/- 3 days	6 months after RTx +/- 3 days	12 months after RTx +/- 3 days
Informed Consent	X									
Inclusion/Exclusion	X									
Medical History	X								0	
Urine Pregnancy Test	X	X			X					
Photography		X		X	X		X	X		
Blinded Evaluation	X				X		X	X		
Adverse Events		X	X	X	X	X	X	X	X	X
Physical Exam		X		X	X		X	X		
Safety Eye Assessments		X**		X	X		X	X		
Cranial Nerve Assessments		X		X	X		X	X		
Patient Questionnaire/ Evaluation	X			X	X		X	X	X	X
Patient Pain Evaluation		X	X	X	X	X	X	X	X	X
Patient Safety Diary***		X	X		X	X				
Retreatment					X*					

*If requested by physician or patient and agreeable to both

**Safety Eye Assessments will be performed prior to treatment and 30 minutes after treatment

***Patient diary to be completed daily by email for 30 days following treatment

Voluma Jowl/Jawline Study 10001 Appendix 1: Study Schematics No Retreatment

Visit #	1	2	3	4	5	6	7	8	9
	Screening	Treatment	Safety Follow Up Call	In Office Follow Up	In Office Follow Up	In office Follow Up	In Office Follow Up	Tele medicine Video Call	Tele medicine Video Call
			72 hours +/- 4 hours	2 weeks +/- 3 days	4 weeks +/- 3 days	8 weeks +/- 3 days	12 weeks +/- 3 days	6 months after Tx +/- 3 days	12 months after Tx +/- 3 days
Informed Consent	X								
Inclusion/Exclusion	X								
Medical History	X								
Urine Pregnancy Test	X	X							
Photography		X		X	X	X	X		
Blinded Evaluation	X				X	X	X		
Adverse Events		X	X	X	X	X	X	X	X
Physical Exam		X		X	X	X	X		
Safety Eye Assessments		X*		X	X	X	X		
Cranial Nerve Assessments		X		X	X	X	X		
Patient Questionnaire/ Evaluation	X			X	X	X	X	X	X
Patient Pain Evaluation		X	X	X	X	X	X	X	X
Patient Safety Diary**		X	X						
Retreatment***									

* Safety Eye Assessments will be performed prior to treatment and 30 minutes after treatment

**Patient diary to be completed daily by email for 30 days following treatment

***No Retreatment done per patient and/or physician

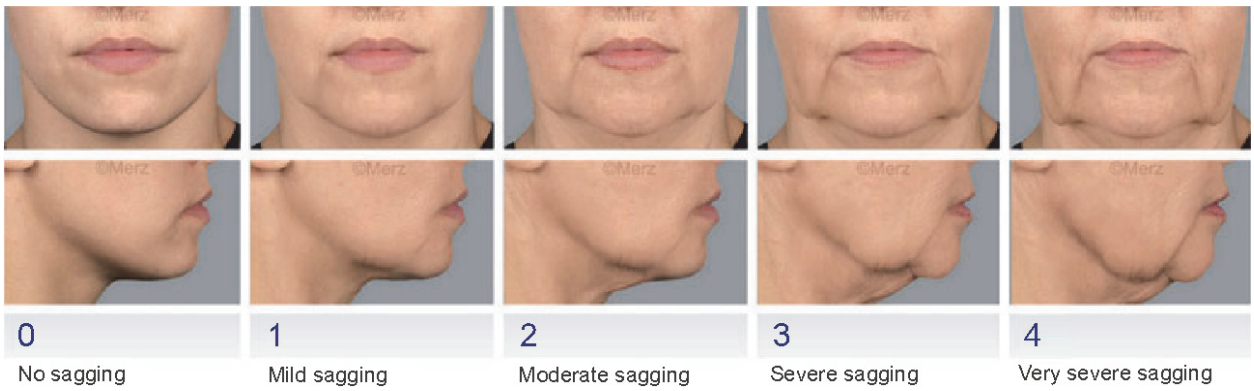
advanced DERMATOLOGY

Jowl Improvement with Injectable Fillers: Jawline Injections alone vs Jawline and Cheek Injections

Blinded Physician Assessment

Patient Number_____ Date: _____

Baseline or Date post 1st Injection: Baseline____ 4w_____ 8w_____ 12 week____ 16 week__
Baseline or Date Post 2nd Injection: Baseline____4w_____ 8w_____12 week___ 16 week ___



MERZ AESTHETICS scales

Grading of Jowls Instructions: Without referring to previous photographs and using the Grading scale pictured above, put an X by the value you feel represents the appearance of this patient today.

1_____ 2_____ 3_____ 4_____ 5_____

Grading of Jowls by photographic assessment of before and after photos: Reviewing the photographs of the patient prior to injection and the photograph of the patient today, please evaluate the subjects (dis)improvement by putting an X by the value you feel represents the change in these photographs.

Much improved___
Improved____
No change____
Worse____
Much Worse _____

Comments:_____
_____
_____

Blinded Physician: Name_____Signature_____
Date:_____

advanced DERMATOLOGY

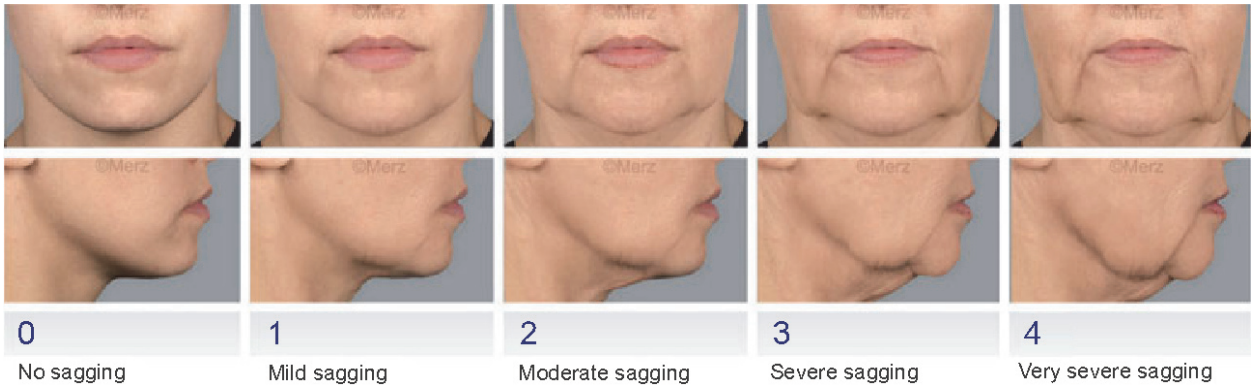
Jowl Improvement with Injectable Fillers: Jawline Injections alone vs Jawline and Cheek Injections 10001

Subject Self-Assessment of Results

Patient Number_____

Date: _____

Baseline or Date post 1st Injection: Baseline_____ 4 w____ 8w_____ 12 w_____16 week___
Or:
Date Post 2nd Injection: Baseline 4 w_____ 8w_____ 12 w_____16 week___



MERZ AESTHETICS scales

Grading of Jowls Instructions: Without referring to previous photographs and using the Grading scale pictured above, put an X by the value you feel represents the appearance of your jowls/jawline today.

1_____ 2_____ 3_____ 4_____ 5_____

Grading of Jowls by photographic assessment of before and after photos: Reviewing the photographs of yourself prior to injection and the photograph of yourself today, please evaluate your (dis)improvement by putting an X by the value you feel represents the change in these photographs.

Much improved___
Improved____
No change____
Worse____
Much Worse _____

Comments:_____
_____

Signature of Coordinator_____Date: _____

Voluma Jowl/Jawline Study 10001-Patient Diary

Patient Number_____ Date_____

Days since treatment_____

Please Complete all of the following questions daily. Record your patient number, the date, and how many days it has been since treatment above. For the questions which require to answer mild, moderate, or severe, please follow these guidelines:

- Mild: mild symptoms; clinical or diagnostic observations only; no intervention needed
- Moderate: minimal, and/or local or noninvasive intervention needed
- Severe: significant but not immediately life threatening; hospitalization or prolongation of hospitalization needed

Have you experienced any of the following symptoms?

- Moderate to Severe Dizziness **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Confusion **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Weakness or numbness in your arms or legs **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Changes to consciousness or alertness **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Difficulty speaking/ speech impairment **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Facial droop **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

***If you have answered yes to any of the above questions, please dial 911 and seek immediate medical attention.

- Changes in vision (i.e. loss of vision, blurriness, double vision, pain in or around your eye, blindness, blind spots, problems moving your eyes) **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Skin changing color on any portion of the face? **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Crusty or scabby skin around the eyelids or any other area of the face **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Moderate to Severe Pain in any area? **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Moderate to Severe Headache **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Fever **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Difficulty Chewing or Swallowing **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

- Moderate to Severe Pain in Jaw at Rest **YES_____ NO_____**
  If yes was it Mild_____ Moderate_____ Severe_____

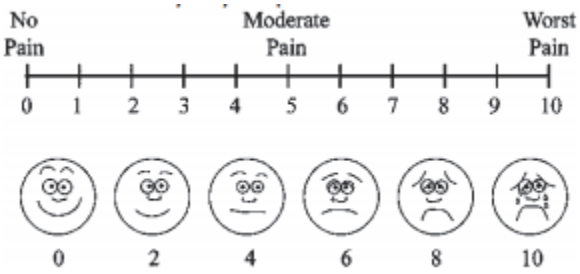
**If you have answered yes to any of the above questions, please call the office immediately at 847-459-6400 during business hours, or Dr Taub at 847-772-8180 if after hours

These questions will track any adverse events that may occur. Please let us know if you have had any of the following:

1. Have you noticed any other symptoms not listed above? Yes_____ No_____
   If yes, list symptoms_____
   _____
   If yes was it Mild_____ Moderate_____ Severe_____
2. Have you had any continuing symptoms since your last diary? Yes_____ No_____
   If yes, please list_____
   _____
3. Have any symptoms/side effects subsided since last diary? Yes_____ No_____
   If yes, please list_____
   _____
4. Any change in medications, including over the counter medications since your last visit or diary?
   Yes_____ No_____
   If yes, list medications_____
   _____
5. Have you been diagnosed with any new medical conditions since your last visit or diary?
   Yes_____ No_____ If yes, please list_____
   _____
6. Have you had any illnesses since your last visit or diary? Yes_____ No_____
   If yes, list illness_____
   _____
7. Have you undergone any surgeries since your last visit or diary? Yes____ No_____
   If yes, list surgeries_____

_____

8. Please rate your pain on the pain scale:



9. Are you experiencing any of the following today:
   - Bruising Yes_____ No_____
     If yes was it Mild_____ Moderate_____ Severe_____
   - Redness
     If yes was it Mild_____ Moderate_____ Severe_____
   - Firmness
     If yes was it Mild_____ Moderate_____ Severe_____
   - Lumps/Bumps
     If yes was it Mild_____ Moderate_____ Severe_____
   - Itching
     If yes was it Mild_____ Moderate_____ Severe_____

Do you feel comfortable going out in public today? Yes_____ No_____

If not, why not?_____

Any other observations or comment you have?_____

_____

advanced
DERMATOLOGY

Jowl Improvement with Injectable Fillers: Jawline Injections alone vs Jawline and Cheek Injections-Operative Note

Subject # _____ Date_____
Start Time of Injection_____ Stop Time of Injection_____
Lot # Voluma _____ Expiration Date Voluma _____

This form is to be completed at the time of injection. Areas injected will be represented by hand drawing on the diagram by the injector indicating the below labels (A1-D2). The amount (cc) placed in each area represented by the labels below injected will be written into the boxes below by the injector and the depth of injection as abbreviated herein will be circled.
Depth of Injection: P=Periosteal, SC=Subcutaneous

A1: ____ ___cc
P SC (circle one both)

A2: ____ ___cc
P SC (circle one both)

B1: ____ ___cc
P SC (circle one both)

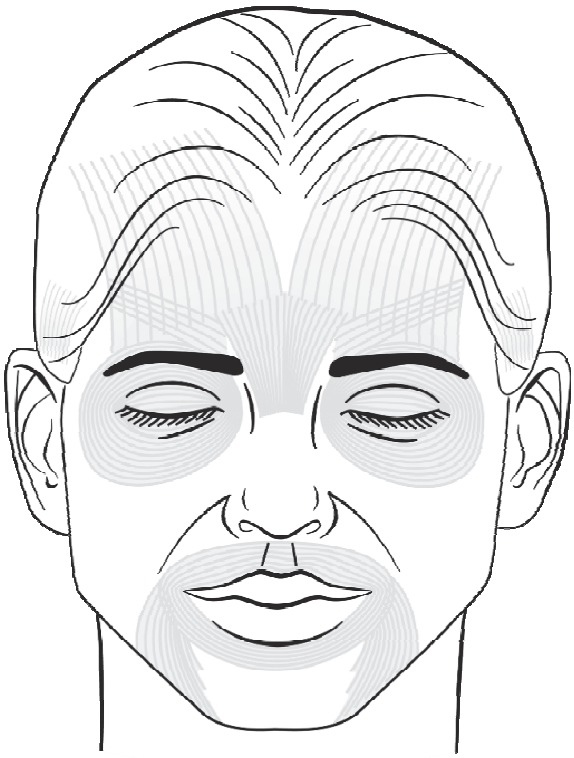
B2: ____ ___cc
P SC (circle one both)

C1: ____ ___cc
P SC (circle one both)

C2: ____ ___cc
P SC (circle one both)

D1: ____ ___cc
P SC (circle one both)

D2: ____ ___cc
P SC (circle one both)



Signature_____ Date _____
Amy Forman Taub, MD

Cranial Nerve Evaluations CRF

Subject Number: _____ Date: _____ Visit Type:_____

Cranial Nerves II-VII; IX, X, XII Evaluation Criteria			
Cranial Nerve	**Nerve Name**	**Function**	**Test**

ASSESSMENT OF CRANIAL NERVES II-VII; IX, X, XII

II III	Optic Nerve Oculomotor Nerve	Pupillary reaction to light and accommodation	Tell the subject to look into the distance. Shine a bright light obliquely into each pupil. Look for: • Direct light reflex – Pupillary constriction in the same eye. • Consensual reaction – Pupillary constriction in the opposite eye. • Accommodation – move the penlight toward the nose and observe pupillary constriction.
III IV VI	Oculomotor Nerve Trochlear Nerve Abducens Nerve	Extraocular movements	Stand two feet directly in front of subject. Use your finger to make a horizontal sweep from the subject's left to the right at the level of the subject's eyes. Repeat this horizontal sweep at the level of the forehead and the chin. Look for normal conjugate movement of the eyes in each direction or any deviation from normal. A few beats of nystagmus on far lateral gaze is normal.
V	Trigeminal Nerve	Motor	Ask the subject to clench their teeth. Palpate the temporal and masseter muscles and note strength of muscle contraction.
		Gross sensation	Tell subject to close their eyes. Using a cotton swab stick or similar object, touch the subject's forehead, cheeks and jaw with the dull cotton end and the sharper wooden end in random fashion. Ask the subject to say if they feel the object is dull or sharp. Compare sensation on both sides of the face.
VII	Facial Nerve	Motor	The Regional House-Brackmann Facial Nerve Grading System will be used to evaluate the facial nerve branches at rest and during conversation with the subject. Ask the subject to: • Raise both eyebrows • Frown • Close both eyes tightly while Investigator tries to open eye lids • Show both upper and lower teeth • Smile • Puff out both cheeks
IX X	Glossopharyngeal Nerve Vagus Nerve	Gagging, swallowing (gross sensation and motor); Speech	Ask subject to swallow while palpating front of the neck. Subject should have no issues or discomfort when swallowing. (Assess gag reflex if patient reports changes from baseline and if there is reason to suspect related pathology). Ask subject to say "Ahhh". The uvula should elevate symmetrically as a normal response. Subject should have no difficulty or impairments when speaking. Note if hoarseness is present.
XII	Hypoglossal	Tongue Movement (Motor)	Ask patient to stick their tongue out and have them move side to side, from cheek to cheek. Tongue movements should be symmetrical.

Rating/Description

1 = Normal
2 = Abnormal, not clinically significant
3 = Abnormal, clinically significant
4 = Not assessed

Cranial Nerve #	Nerve	Function	Result Score each side for each nerve function	
			Right Side of Face	**Left Side of Face**
II	**OPTIC**	Pupillary Reaction to Light and Accommodation		
III	**OCULOMOTOR**			
III	**OCULOMOTOR**	Extraocular Movements		
IV	**TROCHLEAR**			
VI	**ABDUCENS**			
V	**TRIGEMINAL**	Motor		
V	**TRIGEMINAL**	Gross Sensation		
VII	**FACIAL**	Motor	*Complete Regional House-Brackmann Facial Nerve Grading System*	
IX	**GLOSSOPHARYNGEAL**	Gross Sensation and Motor		
X	**VAGUS**	Gross Sensation and Motor		
XII	**HYPOGLOSSAL**	Motor		

Subject Number: _____ Date: _____ Visit Type:_____

Subject Number: _____ Date: _____ Visit Type:_____

REGIONAL HOUSE-BRACKMANN FACIAL NERVE GRADING SYSTEM

VII - Facial Nerve Assessment (Motor function)

Region and Score Description	Score each side of face for each region	
	Right Side of Face	**Left Side of Face**
Forehead 1 = Normal forehead movement 2 = Slight weakness in forehead movement 3 = Obvious but not disfiguring asymmetry with motion, symmetric at rest 4 = Obvious weakness of disfiguring asymmetry with motion, symmetric at rest 5 = Barely perceptible motion in forehead, asymmetric at rest 6 = No movement		
Eye 1 = Normal eye closure 2 = Mild weakness in eye closure 3 = Obvious weakness but able to close eyes 4 = Unable to close eye with maximal effort 5 = Barely perceptible eyelid movement 6 = No movement		
Midface 1 = Normal midface movement 2 = Slight weakness in midface movement 3 = Obvious but not disfiguring weakness, symmetric at rest 4 = Obvious weakness and disfiguring asymmetry with motion, symmetric at rest 5 = Barely perceptible motion in midface, asymmetric at rest 6 = No movement		
Mouth 1 = Normal corner of mouth movement 2 = Slight weakness of corner of mouth movement 3 = Obvious but not disfiguring weakness, symmetric at rest 4 = Obvious weakness and disfiguring asymmetry with motion, symmetric at rest 5 = Barely perceptible corner of mouth movement, asymmetric at rest 6 = No movement		
Synkinesis (voluntary muscle movement causing the simultaneous involuntary contraction of other muscles) 1 = None 2 = Mild - obvious but not disfiguring 3 = Severe - disfiguring or interferes with function		

Safety Eye Exams

1. **Snellen Visual Exam:**

RIGHT EYE: 20/10____ 20/15____ 20/20____
20/25____ 20/30____ 20/40____ TIME:_____

LEFT EYE: 20/10____ 20/15____ 20/20____
20/25____ 20/30____ 20/40____ TIME:_____

2. **Ocular Motility Exam:**

RIGHT EYE: TIME:_____
Elevation Central: Normal____ Abnormal___
Elevation Upper Lateral Quadrant: Normal____ Abnormal____
Elevation Upper Medial Quadrant: Normal____ Abnormal
Depression Central: Normal ____Abnormal_____
Depression Inferior Lateral: Normal____ Abnormal_____
Depression Inferior Medial: Normal ____ Abnormal____
Change from Previous Exam: Yes_____ No_____

LEFT EYE: TIME:_____
Elevation Central: Normal____ Abnormal___
Elevation Upper Lateral Quadrant: Normal____ Abnormal____
Elevation Upper Medial Quadrant: Normal____ Abnormal
Depression Central: Normal ____Abnormal_____
Depression Inferior Lateral: Normal____ Abnormal_____
Depression Inferior Medial: Normal ____ Abnormal____
Change from Previous Exam: Yes_____ No_____

3. **Confrontational Visual Fields Exam:**

RIGHT EYE: **TIME:_____**
Right upper outer quadrant: Normal_____ Abnormal_____
Right lower outer quadrant: Normal_____ Abnormal_____
Right inner outer quadrant: Normal_____ Abnormal_____
Right inner outer quadrant: Normal_____ Abnormal_____
Change from Previous Exam: Yes_____ No_____

LEFT EYE: **TIME:_____**
Right upper outer quadrant: Normal_____ Abnormal_____
Right lower outer quadrant: Normal_____ Abnormal_____
Right inner outer quadrant: Normal_____ Abnormal_____
Right inner outer quadrant: Normal_____ Abnormal_____
Change from Previous Exam: Yes_____ No_____

Physical and Visual Exam

Visual Evaluation:

Is Any Drooping of the Face Observed **Yes_____ No_____**
Is There Any Change in Skin Color Around the Eyelids **Yes_____ No_____**
Is there any Crusty or Scabby Skin Around the Eyelids **Yes_____ No_____**
Any Other Observations or Notes **Yes_____ No_____**

_____
_____
_____
_____
_____

Was Evaluation of Neurological Function Completed **Yes_____ No_____**
Notes:_____
_____
_____
_____

TMJ Exam

TMJ examination begins with palpation of the muscles in the face and neck regions.

Palpation of the Right masseter muscle:

- **Pain: Yes_____ No_____ Explain**_____
- **Masses: Yes_____ No_____**

Palpation of the Left masseter muscle:

- **Pain: Yes_____ No_____ Explain**_____
- **Masses: Yes_____ No_____**

1. **Patient open and close mouth:** **Yes_____ No_____**
2. **Normal range of motion:** **Yes_____ No_____**
3. **Pain with opening or closing mouth:** **Yes_____ No_____**
   Explain_____
   _____
4. **Any reported problems with chewing or swallowing:** **Yes_____ No_____**
5. **Any pain with chewing?** **Yes_____ No_____**
   Explain_____
   _____

Any other observation? **Yes_____ No_____**

_____
_____
_____
_____

PAIN ASSESSMENT FORM CRF

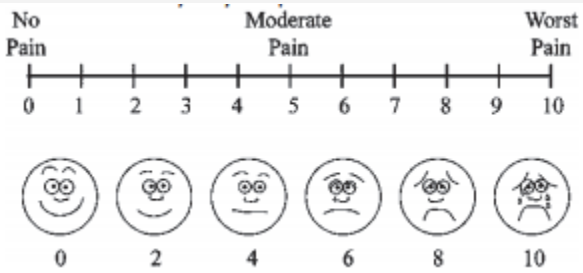
Subject	**Date:**

1. Are you experiencing any pain today? Yes____ No_____ * If yes please answer the following questions.
2. Where is your paint located?

3. When did your pain begin?

4. Does the pain radiate or travel to other areas?

5. Is your pain: (please check answer) o Intermittent o Continuous o Both?
6. Does your pain vary in intensity? o Yes o No
7. **Rate the intensity of your pain:**



8. How does your pain affect your lifestyle? (↑, ↓ , no change)

Choose	☐ Sleep?				
	☐ Appetite?				
	☐ Activity?				
	☐ Energy?				
Are you experiencing any other symptoms?	Nausea			☐ Yes	☐ No
	Sleepiness			☐ Yes	☐ No
	Weakness				
	Vomiting	Confusion	Itching		

Additional Notes:

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Hyaluronic Acid

POST-TREATMENT INSTRUCTIONS

- Immediately after the treatment, there may be redness, swelling, tenderness, bruising and an itching sensation in the treated area. This is a normal result of the injections. The inconvenience is temporary and generally disappears within a few days. If the inconvenience continues or, if other reactions occur, please contact the office.

- Some patients experience swelling for about a week and can look somewhat uneven during this time. This means that the result directly after the treatment should not been seen as the final result. Cool compresses or ice packs for 48 hours may help to reduce swelling. Bruising in all treated areas may last up to 2 weeks.

- Avoid excessive sun and UV lamp exposure until any initial swelling and redness have resolved.

- The treated areas may be washed with soap and water. If required, light makeup may be applied with clean fingers following treatment.

- Until the initial swelling and redness have resolved, do not expose the treated area to intense heat (e.g. sauna and sunbathing) or extreme cold.

- If you have previously suffered from facial cold sores, there is a risk that the needle punctures could contribute to another eruption of cold sores. Please tell your provider if you have a history of cold sores.

- If you are using aspirin or any similar medication, be aware that these may increase the bruising and bleeding at the injection site. If pain medication is necessary, please use Tylenol (acetaminophen).

- In a study to evaluate Voluma for injection of the cheeks, the average duration for the majority of patients was up to 2 years, but not every patient achieved this duration. This study of of Voluma in the jawline and cheeks is not intended to study duration of effect. After the effect of the injection wears off (estimate from 6 months to 2 years), you would have to be reinjected outside of the study to reestablish effect. To properly evaluation the safety in this study, you would not be eligible for reinjection until 12 months after your last study injection.
- Complete Patient diary daily for 30 days following treatment.

- If you experience any side effects or unusual symptoms, or have any other questions or concerns, please contact the office immediately at: 847-459-6400.

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Photography Release Consent Form

I, _____, hereby authorize Advanced Dermatology to release the photograph(s) obtained during my participation in the Jowl/Jawline Voluma Study

This authorizes Advanced Dermatology to use the photographs listed below in promotional or educational materials. These materials might include printed or electronic publications, websites or other electronic communications/presentations. These images may be used indefinitely without compensation to the owner. I understand that my name will not be released.

For internal use: (dates of photos)

Baseline: _____ /_____ /_____

2-week Follow-up: _____ /_____ /_____

4-week Follow-up: _____ /_____ /_____

8-week follow-up: _____ /_____ /_____

I consent to the release of photos.
Patient:

_____ _____
Print Name Signature

_____ _____
Today's Date Date of Birth

Witness:

_____ _____
Print Name Signature

_____
Today's Date

Medical Director:

_____ _____
Amy Forman Taub, MD Today's Date

DOCUMENTATION OF CONSENT PROCESS

Subject Name: _____ Time Obtained:_____

Person obtaining consent to initial each completed step in the process:

____ Informed consent was discussed with subject for the above referenced study. Copy of the consent form was provided for subject (in a language understandable to the patient) and/or authorized subject representative review.

____ Subject and/or authorized subject representative was given adequate time to read the consent form and discuss the study with study investigators and/or family members.

____ All questions were answered. Subject and/or authorized subject representative was given time to discuss.

____ Subject and/or authorized subject representative signed and dated the informed consent. A copy of the consent form was provided to the subject and/or authorized subject representative upon conclusion of the consent process.

____ HIPAA form was reviewed with subject. Informed Consent process was conducted in a manner and location that ensured patient privacy.

____ During informed consent process, the following questions were asked by the subject and/or authorized representative and were answered by study personnel:

_____
_____
_____

_____ Consent has been signed prior to any study procedures being performed.

Consent process documented by: _____
Print Name

_____ _____
Signature Date

Consent process verified by: _____
Print Name

_____ _____
Signature Date