

*THE DENTO-FACIAL TREATMENT
CENTER AND HOWARD KATZ DDS
PRESENTS*

*HYALURONIC ACID
IMPLANTATION FOR LIP
AUGMENTATION IN
DENTISTRY©*

LIP AUGMENTATION WITH HYALURONIC ACID (HA) FILLERS

The HA products utilized for the procedures covered in this dental program are similar to those used in periodontal and oral surgery procedures for bone deficiency. HA also occurs naturally joints, bone and in the cells of the skin. It is not just used for building up the lips and skin; it is also used in the treatment of

Hernias

Glaucoma

Detached retinas

Osteoarthritis (HA injections are the new breakthrough treatment for this condition)

Muscle contractures

TMJ

Prevents scarring

Peri-oral insufficiencies

Vocal cord insufficiency

Wrinkled skin

Cartilage damage

Wound healing

Ligament Healing

In the dermis and obicularis oris muscle of the lip it works by drawing in water and therefore augmenting the appearance of a deficient or collapsed lip. At this time the safest and longest lasting product of choice is Restylane®. It is a non-animal product and patch-testing is not necessary.

It is used to fill in and create fuller, symmetrical lips around the mouth harmonizing with the teeth and eliminating wrinkles. It is also used for lip enhancement creating a fuller more sensual border. The effect is not permanent and typically lasts 6-12 months.

FREQUENTLY ASKED QUESTIONS

Are the injections painful?

For all lip treatment topical anesthetic cream can be applied. Local anesthetic injections should also be used which allows the treatment to be pain free and comfortable.

How long does it take for the treatments to work?

The procedure takes about 10-20 minutes and the results are instant.

What can and can't I do after the treatment?

You may elect not to return to work the same day because the lips can swell up. Otherwise you can carry on life as normal as any redness can be covered with makeup after 24 hours. You should leave the treated area alone for 48 hours to let it settle. It is advisable to not have a facial or similar treatment that may disturb the products or expose the newly treated areas to strong sunlight for 2-3 days.

How long does the treatment last for?

For about 4-9 months.

How often will I need to top up?

Most patients have top ups when they feel the effect is starting to wear off i.e. anytime between 6 and 12 months.

Are there any side effects?

After the treatment there may be some redness and minimal swelling which normally settles in 1-2 days. Very occasionally patients can suffer some bruising at the injection site.

Swelling normally settles in 1-2 days after injection in the skin and within a week after injection to the lips.

Who is suitable for these treatments?

Almost everyone apart from those who are pregnant or breastfeeding.

What happens if I do not have a top up?

Correction of the enhanced lip effect will subside gradually until your skin looks like it did before the treatment.

Are there any long term problems?

No because it is completely natural and over time can be completely broken down by the body.

Are the injections painful?

No, as doctors do all the treatments we are able to use local anesthetic injections which allow the treatment to be pain free and comfortable.

Can it be used with botulinum toxin procedures?

Yes, sometimes to create the best effect they can be used together.

Would you have Restylane treatment yourself ?

Yes I would. I have had Restylane treatment for my naso-labial (nose to mouth) lines and have enhanced the lips of my wife and daughter. The end result was a natural improvement that I was very happy with.

PRE AND POST TREATMENT INSTRUCTIONS

At the initial visit, your doctor will likely ask you to describe in detail what you would like improved. Be specific about what you would like done. Bring photos that show what you like and don't like. If your surgeon fully understands your expectations, he'll be able to determine whether your goals are realistic.

Immediately after treatment there may be slight redness, swelling and an itching sensation in the treated area. There may be some asymmetry due to swelling. This is a normal result of the treatment and should not be corrected until the swelling subsides.

1. Avoid products that will contribute to bruising for 2 days prior to 3 days after treatment. These include Aspirin, Advil, Motrin, Retin- A Vitamin A, Vitamin E. flax oil, cod liver oil, garlic and ginkgo biloba, alcohol, caffeine, tobacco, high sodium foods and high sugar foods.
2. Avoid touching area for 6 hours after treatment. Make-up should not be applied until the following day. Only none comedogenic applications make be used to soothe the treated areas, for example Eucerin Aqauphor healing cream
3. Do not expose treated area to intense heat (e.g. tanning salons, saunas, sunbathing, yoga in a heated room) or extreme cold. Ice only the adjacent areas if necessary, not the areas treated.
4. If you have previously suffered from facial cold sores, there is a risk that needle puncture could contribute to another eruption. You should re-schedule if you develop any skin lesions in the treatment areas prior to treatment. However taking a course of Zovirax or Aciclovir tablets prior to the day of treatment can reduce the chances of this occurring. The dentist can prescribe this if needed.
5. Your diet for the first few days after the procedure should consist of soft foods that do not require much chewing for the first few days. Consider: Protein shakes, soup, applesauce, jell-O, frozen dinners, yogurt, oatmeal, cottage cheese, juice (purchase flexible straws for easier drinking)soft foods that do not require much chewing for the first few days.

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6. Lips normally need a re-treatment after 6 months.

7. You can repeat the procedure as often as you like, depending on the degree of improvement required.

8. A top up treatment within 2 - 4 weeks of the initial treatment may be required to achieve optimal results. This normally requires a smaller amount of product.

9. After the initial treatment of lip augmentation most patients choose to have follow up treatment in 6 - 12 months.

Dr. Howard Katz
8654 Nottingham Place
La Jolla CA 92037.

10th July 2005

Dear Dr Workalot,

I would like to take this opportunity to introduce myself to you with the possibility of working with you as a per diem independent contractor which would greatly benefit us both.

Only dentists are specially trained in the anatomy and esthetic harmony of the teeth to the face and lips. I am an experienced cosmetic dentist who is trained in the use of Botox® administration for dento-facial conditions and HA fillers for lip and smile esthetics. As dentistry changes from a needs based profession to a desired based profession driven by the esthetics of the smile, additional services to those offered a your practice will generate increased revenue.

The rapidly expanding esthetic enhancement field appeals to all age groups that are interested in looking better and feeling better about themselves. Patients that are esthetically motivated will have another reason to choose your office. What I am proposing will not cut into your time or sharing your existing planned procedures with someone else. It will attract additional patients that we can refer to each other. .

By working in a per diem/independent contractor status I will save you from having to employ me full time which involves expenses of payroll, taxes, state unemployment, workers comp, health insurance and vacations.

Please contact me at your soonest convenience so that we can set up a meeting to discuss the win-win-win-win relationship – for you, me, your practice and your patients.

Sincerely,

Dr.Howard Katz

Types of Lip Augmentation Materials

Injectables

- **Temporary Injectable Fillers (Collagen, Restylane, Perlane, Hylaform, etc.)**
- **Permanent Injectable Implants (Artecoll, Silicone, Metacril, Aquamid, etc.)**
- **Semi-permanent Injectable Bio-catalysts (Isolagen, NewFill, Reviderm, etc.)**

Implants

- **Semi-permanent Synthetic Implants, Gore-Tex, SoftForm, UltraSoft, Advanta, etc)**
- **Human-derived Bio-implants, AlloDerm, Cymetra, Fascian, etc.)**
- **Self-derived Bio-products (Fat Grafting, Dermis Grafts, Scar Tissue, Fascian, etc.)**

As we grow older, the effects of sun damage, aging, and smoking result in loss of collagen and fat. These factors, combined with muscle movement, cause wrinkles and folds to occur on the face, particularly around the lips and nasal-labial folds (the lines from the nose to the mouth). To “plump” or “fill” out these areas, various materials are available that a doctor or dentist can inject directly into the depression, creating a more youthful appearance.

In the world of injectable hyaluronic acid fillers, there is a wide range of substances being used. Despite what you might have read or heard there isn't a “best” material to choose. For the most part, claims are not based on comparative studies or independent research. Which substance is considered “best” or “preferred” is often determined by whatever the newest procedure happens to be, what receiving attention in fashion magazines is, or, more often than not, what company is actively marketing their product.

What's disconcerting about all this is that most dermal fillers are so new they have no long-term safety data of any kind and there is little, if any, published research available. Without published research, there is no real way to assess what the risks, problems, or possible outcomes can be.

There are two primary groups of dermal fillers: synthetic and natural. Synthetic fillers tend to last much longer and are often considered semi-permanent to permanent but are considered a higher risk for lumping and migration. Natural fillers last from just 6 months to 2 years, with some risk of lumping and migration (Sources: *Journal of Oral Pathology and Medicine*, February 2004, pages 115-120; and *Dermatologic Surgery*, October 1997, pages 871-877).

As you will see from the list below, there are lots of natural dermal fillers, even those harvested from your own body, that are not automatically the preferred option. In the formidable list of injectable dermal fillers, each one has its own pros and cons (Source: *Facial and Plastic Surgery*, February 2004, pages 21-29).

Restylane injections

Restylane is a clear non animal syringable Hyaluronic acid (NASAHA) gel; the hyaluronic acid in Restylane is similar to that naturally found in the body. This is the filler of choice for this program because it is safe, long lasting, there is no sensitivity testing required and there are few side-effects.

What is Restylane?

Restylane is considered a premier filler because it is a safe, temporary, non-animal form of hyaluronic acid gel, a naturally occurring substance that binds water to cells. Restylane is injected to fill out thin lips, creases and lines. It is not to be confused with Botox® Cosmetic, which basically paralyzes muscles, and they work brilliantly together as a team. The most common areas to have done are lips, nasal labial folds, smile lines and drooping corners of the mouth.

Are there any Side Effects?

Restylane has minimal side effects. The most common is slight bruising, which is seen in about 20% of patients. The injection hurts more than collagen because collagen has anesthetic. Less common problems would include allergies, but this is very rare. Some patients experience an infection or a cold sore due to the injection of the needle. Additionally, there may be a little swelling after the needle is injected, and resolves within a day or two.

What are the Differences between Restylane and Perlane?

Restylane is thinner and better for lips and fine lines. Perlane is thicker and good for sculpting e.g. cheek bones or deep lines such as laugh lines. Both Restylane and Perlane are the exact same molecule (hyaluronic acid) and made by Q-Med.

What is the Cost of Treatment?

The cost of treatment depends on the amount used and the specific area of the face. Costs range significantly throughout the country and major metropolitan areas such as Los Angeles and San Diego will cost a little more. A general ballpark is between \$500-\$1,000 a shot.

Why is Restylane better than collagen?

Restylane is better than collagen because it is a smooth, clear gel and “flows” when it is injected and goes in very evenly. Most importantly, it can last six months or longer. Restylane is an excellent wrinkle filler and wrinkles can be “filled in” as needed. With collagen, you have to over correct because of the anesthetic in it -as some is absorbed, the correction decreases so it was somewhat of a guess although experience helped a great deal.

In one U.S. clinical study, Restylane outperformed a collagen-based substance by 6 to 1. Collagen can also cause allergic reactions. Because Restylane is a non-animal based gel created in the lab, there are no allergic side effects.

Collagen injections

Prepared from the collagen found in cow skin, collagen injections are used to temporarily augment the lips. Although it is purified, this collagen may cause allergic reactions in some people. For that reason, a sensitivity test should be performed before the actual lip augmentation procedure.

Collagen is injected into the lip with small needles. Because the body slowly absorbs the collagen, the results generally last between one and three months. The procedure may be repeated as needed.

Fat injections

Fat can also be injected into the lip. The fat is harvested from another area of the body (often the abdomen or thighs) and is purified before it is injected into the lips. An advantage to this procedure is that there is no possibility of an allergic reaction. As with collagen, results are temporary but usually lasts longer than collagen injections.

Fat injections can cause lumping or scarring.

Artecoll injections

Artecoll is composed mainly of tiny synthetic beads (polymethyl methacrylate) that stay in the lips, and raise them. This technique lasts longer than fat or collagen injections.

Autologen injections

Autologen is collagen extracted from the patient's own skin, often from excess skin removed in a facelift. The results are relatively long lasting, and there is no risk of an allergic reaction.

Dermalogen injections

Dermalogen is extracted from the skin of a cadaver. The donor material is screened and processed to avoid the spread of disease. The effects are temporary, and are similar to the effects of collagen injections.

Fascia injections

Fascia (white connective tissue) extracted from a cadaver can be injected or surgically implanted.

HylaForm injections

Tissue made up of a molecular component of the human body. Extracted from a cadaver.

SURGICAL PROCEDURES

AlloDerm

Alloderm is the most popular material for lip augmentation. It is a natural collagen sheet harvested from cadavers and is screened and highly processed. The standards by which it is processed are very strict. The risk of infection is approximately 2%.

Under a local anesthesia, the material is inserted through tiny incisions made in the inside corners of the mouth. Stitches are used to close the incisions. AlloDerm eventually becomes integrated with the natural tissues of the body. The material can be absorbed, so the results are only temporary, lasting from 6 months to a year.

Synthetic Implants

Gore-Tex, **SoftForm** and **soft ePTFE** are other synthetic options with permanent results. They do not shrink and are never absorbed into the body. They also remain in place because scar tissue forms on either end.

To insert the implant, a small incision is made in the inside of the lip. The material is then made into the shape of a small tube and it is inserted with a small needle.

Synthetic implants are foreign substances and may become infected or be rejected by the body. If this occurs, the implants can be removed.

Fat grafting

This procedure has permanent results in approximately half of the people who try it. Although it is possible that the body will reabsorb it, many people choose fat grafting because they are most comfortable with using the fat from their own body. The fat is harvested from another area of the body, often the abdomen. It is then prepared and inserted with a needle into the lip from more than one point.

Local flap grafts

Local flaps bring material from inside the mouth outside to enhance the lips. Results are temporary. An incision may be made inside the mouth to push the tissue inside the mouth upward, and outward, into the lip, sometimes in conjunction with grafting. Or, an incision may be

along the upper lip line. In this case, skin above the lip is removed, and the lip is then stitched along the line of the incision.

Local anesthesia is normally used for all lip augmentation procedures. It takes longer to recover from a surgical procedure than an injection.

Injections: Recovery takes about 1-2 days after an injection. Bruising and swelling may last as long as a week.

Grafts and flaps : Recovery takes about 1-2 weeks after surgical procedures. During this time, you may experience some drooling. Your lips may also feel unnaturally stiff for 2-3 months after the procedure.

Complications:

Significant complications from lip augmentation are rare. With any surgical procedure, there is always a possibility of bleeding, infection, reaction to the anesthesia, slow healing or an unexpected result. Other possible complications include asymmetrical lips, cold sores, numbing, scarring, swelling, and permanent stiffness in the lip. Implant material may move to a new location within the lips and it may also protrude unnaturally. Allergic reactions such as itching, redness, swelling may occur. Fat injections can cause lumping or scarring. Any implant that is a foreign substance (such as SoftForm) may become infected or be rejected by the body.

CLINICAL COMPARISON OF FILLERS

Injectable	Source	Adverse effects	Length of Effect
Zyderm/ Zyplast	Bovine collagen	Allergic reaction (3-4%), redness, swelling	3-6 months
Cymetra	Cadaver	Bruising	2 months
Cosmoderm/ Cosmoplast	Human tissue in petri dish	Bruising	6 months
Autologen/ Isologen	Own skin	Bruising, time consuming, expensive	4-9 months
Fat	Own Fat	Harvesting, lumpiness	3-6 months
Restylane	Non-animal derived hyaluronic acid	Redness, swelling, rare allergic reaction	3-6 months
Radiance/ Radiesse	Calcium hydroxylapatite	Redness, bruising, lumping and granulomas	2-5 years
Silicone	polydimethylsiloxane oil	Hardens, migrates, inflammation, necrosis	permanent

PHYSICIAN-PATIENT ARBITRATION AGREEMENT

Article 1: Agreement to Arbitrate: Both parties to this contract, by entering into it, are giving up their constitutional rights to have any such dispute decided on a court of law before a jury, and instead are accepting the use of arbitration.

All medical malpractice disputes that were rendered under this contract that were unnecessary or unauthorized or were improperly, negligently, or incompetently rendered, will be determined by submission to arbitration as provided by (State)_____ law, and not by a lawsuit

Article 2: All Claims Must be Arbitrated: It is the intention of the parties that this agreement bind all parties whose claims may arise out of or related to treatment or service provided by the physician including any spouse or heirs of the patient and any children, whether born or unborn, at the time of the occurrence giving rise to any claim. In the case of any pregnant mother, the term "patient" herein shall mean the mother and the mother's expected child or children.

All claims for monetary damages exceeding the jurisdictional limit of the small claims court against the physician, and the physician's partners, associates, association, corporation or partnership, and the employees, agents and estates of any if them, must be arbitrated including, without limitation, claims for loss of consortium, wrongful death, emotional distress or punitive damages. Filing of any court by the physician to collect any fee from the patient shall not waive the right to compel arbitration of any malpractice claim.

Article 3: Procedures and Applicable Law: A demand for arbitration must communicate in writing to all parties. Each party shall select an arbitrator (party arbitrator) within thirty days and a third arbitrator (neutral arbitrator) shall be selected by the arbitrators appointed by the parties within thirty days of a demand for a neutral arbitrator by either party. Each party to the arbitration shall pay such party's pro rata share of the expenses and fees of the neutral arbitrator, together with other expenses of the arbitration incurred or approved by the neutral arbitrator, not including counsel fees or witness fees, or other expenses incurred by a party for such party's own benefit. The parties agree that the arbitrators have the immunity of a judicial officer from civil liability when acting in the capacity of arbitrator under this contract. This immunity shall supplement, not supplant, any other applicable statutory or common law.

Either party shall have the absolute right to arbitrate separately the issues of liability and damages upon written request to the neutral arbitrator.

The parties consent to the intervention and joinder in this arbitration of any person or entity which would otherwise be a proper additional party in a court action, and upon such intervention and joinder any existing court action against such additional person or entity shall be stayed pending arbitration.

The parties agree that provisions of California law applicable to health care providers shall apply to disputes within this arbitration agreement, including, but not limited to, Code of Civil Procedure Section 340.5 and 667.7 and Civil Code Sections 3333.1 and 3333.2. Any party may bring before the arbitrations a motion for summary judgment or summary adjudication in accordance with the Code of Civil Procedure. Discovery shall be conducted pursuant to Code of Civil Procedure section 1283.05, however, depositions may be taken without prior approval of the neutral arbitrator.

Article 4: General Provisions: All claims based upon the same incident, transaction or related circumstances shall be arbitrated in one proceeding. A claim shall be waived and forever barred if

(1) on the date notice thereof is received, the claim, if asserted in a civil action, would be barred by the applicable California statute of limitations, or

(2) the claimant fails to pursue the arbitration claim in accordance with the procedures prescribed herein with reasonable diligence. With respect to any matter not herein expressly provided for, the arbitrators shall be governed by the California Code of Civil Procedure provisions relating to arbitration.

Article 5: Revocation: This agreement may be revoked by written notice delivered to the physician within 30 days, or signature. It is the intent of this agreement to apply to all medical services rendered any time for any condition.

Article 6: Retroactive Effect: If patient intends this agreement to cover services rendered before the date it is Effective as of the date of first medical services.

Patient's or Patient Representative's Initials _____

If any provision if this arbitration agreement is held invalid of unenforceable, the remaining provisions shall remain in full force and shall not be affected by the invalidity of any other provision.

I understand that I have the right to receive a copy of this arbitration agreement. By my signature below, I acknowledge that I have received a copy.

NOTICE: BY SIGNING THIS CONTRACT YOU ARE AGREEING TO HAVE ANY ISSUE OF MEDICAL MALPRACTICE DECIDED

BY NEUTRAL ARBITRATION AND YOU ARE GIVING UP YOUR RIGHT TO A JURY OR COURT TRIAL. SEE ARTICLE 1 OF

THIS CONTRACT.

By: _____

Patient's or Patient Representative's Signature (Date)

By: _____

Physician's or Authorized Representative's (Date) By:

Signature Print Patient's Name

Print or Stamp Name of Physician, (If Representative, Print Name and Relationship to Patient)

Medical Group or Association Name

A signed copy of this document is to be given to Patient. Original is to be files in Patient's medical records.

Informed Consent for Labial Filler Injections

Patient Name: _____

Account #: _____

Date: _____

INSTRUCTIONS

This is an informed consent document, which has been prepared to help inform you concerning tissue filler injection therapy, its risks, and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for this procedure as proposed.

INTRODUCTION

Hyaluronic acid is a naturally occurring substance that is found within all mammals. It is a material that is contained in various soft tissues. Hyaluronic acid can be synthetically produced from bovine, avian or bacterial sources, chemically stabilized, and purified for use as an injectable soft tissue

SOFT TISSUE FILLER has been approved to treat areas of facial wrinkling and soft tissue depressions.

SOFT TISSUE FILLER injections are customized for every patient, depending on their particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips. SOFT TISSUE FILLER cannot stop the process of aging. It can however, temporarily diminish the appearance of wrinkles and soft tissue depressions. Soft tissue filler injections may be performed as a singular procedure, in combination with other treatments, or as an adjunct to a surgical procedure. SOFT TISSUE FILLER injections require regional nerve blocks or local anesthetic injections to diminish discomfort. Soft tissue fillers, including SOFT TISSUE FILLER produce temporary swelling, redness, and needle marks, which resolve after a few days time.

Continuing treatments are necessary in order to maintain the effect of SOFT TISSUE FILLER over time. SOFT TISSUE FILLER once injected will be slowly absorbed by the body. The length of effect for SOFT TISSUE FILLER injections is variable.

ALTERNATIVE TREATMENTS

Alternative forms of management include not treating the features of the smile, skin wrinkles or soft tissue depressions by any means. Improvement of the appearance of the smile, and features of the lips, teeth and mouth be accomplished by other treatments including intra-oral prostheses, veneers, crowns, orthodontics, oral surgery and periodontal surgery. Other beneficial skin treatments include: laser treatments, chemical skin-peels, or dermabrasion, alternative types of tissue fillers, or surgery when indicated. Risks and potential

complications are associated with alternative forms of dental and medical surgical treatments.

RISKS of SOFT TISSUE FILLER Injections (non-animal, stabilized hyaluronic acid, Q-Med)

Every procedure to inject soft tissue filler materials involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of SOFT TISSUE FILLER injections. Additional information concerning SOFT TISSUE FILLER may be obtained from the package insert sheets supplied by the product's manufacturer (Q-Med).

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections, including SOFT TISSUE FILLER. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve SOFT TISSUE FILLER.

NORMAL OCCURRENCES DURING TISSUE FILLER INJECTIONS, INCLUDING SOFT TISSUE FILLER

Patients undergoing injections of SOFT TISSUE FILLER may normally experience the following events.

- **Bleeding and Bruising** – It is possible, though unusual, to have a bleeding episode from a SOFT TISSUE FILLER injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, Ginko biloba and other “herbs/homeopathic remedies” may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before SOFT TISSUE FILLER injections. Also avoid alcoholic beverages 12 hours before and after treatment.
- **Swelling** – Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.
- **Erythema (skin redness)** – Erythema in the skin occurs after injections. It can be present for a few days after the procedure.
- **Needle marks** – Visible needle marks from the injections occur normally and resolve in a few days.
- **Acne-like skin eruptions** – Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.
- **Skin Lumpiness** – Lumpiness can occur following the injection of SOFT TISSUE FILLER. This tends to smooth out over time. In some situations, it may be possible to feel the injected tissue filler material for long periods of time.

- **Visible Tissue Filler Material** – It may be possible to see any type of tissue filler material that was injected in areas where the skin is thin.
- **Asymmetry** – The human face and eyelid region is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filler injections. There can be a variation from one side to the other in terms of the response to SOFT TISSUE FILLER injections.
- **Pain** – Discomfort associated with SOFT TISSUE FILLER injections is normal and usually of a short duration.

COMPLICATIONS

Complications attributable to the injection of soft tissue fillers, including SOFT TISSUE FILLER.

- **Infection** – Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth can occur following a tissue filler treatment. This applies to both individuals with a past of history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.
- **Damage to deeper structures** – Deeper structures such as nerves, blood vessels, and the soft tissues may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.
- **Skin Necrosis** – It is very unusual to experience death of skin and deeper soft tissues after SOFT TISSUE FILLER injections. Skin necrosis can produce unacceptable scarring. Should this rare complication occur, additional treatments, or surgery may be necessary.
- **Granulomas** – Painful masses in the skin and deeper tissues after a SOFT TISSUE FILLER injection are extremely rare. Should these occur, additional treatments including surgery may be necessary.
- **Combination of Procedures** – In some situations, BOTOX injections or other types of tissue filler materials may be used in addition to SOFT TISSUE FILLER in order to specifically treat areas of the face or to enhance the outcome from tissue fillers therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with SOFT TISSUE FILLER is unknown.
- **Pregnancy and Nursing Mothers** – Animal reproduction studies have not been performed to determine if SOFT TISSUE FILLER could produce fetal harm. It is not known if SOFT TISSUE FILLER or its breakdown products can be excreted in human milk. It is not recommended that pregnant woman or nursing mother receive SOFT TISSUE FILLER treatments.
- **Drug Interactions** – It is not known if SOFT TISSUE FILLER reacts with other drugs within the body.

- **Long-Term Effects** – SOFT TISSUE FILLER injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the SOFT TISSUE FILLER material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing SOFT TISSUE FILLER treatment (injections) are necessary in order to maintain the effect of SOFT TISSUE FILLER. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to SOFT TISSUE FILLER injections. Future surgery or other treatments may be necessary. SOFT TISSUE FILLER injection does not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for SOFT TISSUE FILLER injections used to treat medical and dental conditions. Please carefully review your health insurance subscriber information.

ADDITIONAL TREATMENT NECESSARY

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of SOFT TISSUE FILLER injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with SOFT TISSUE FILLER injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained with the use of SOFT TISSUE FILLER injections. The practice of medicine and surgery is not an exact science.

FINANCIAL RESPONSIBILITIES

The cost of SOFT TISSUE FILLER injection may involve several charges. This includes the professional fee for the injections, follow up visits to monitor the effectiveness of the treatment, and the cost of the SOFT TISSUE FILLER material itself. It is unlikely that SOFT TISSUE FILLER injections to treat cosmetic problems would be covered by your health insurance.

Additional costs of medical treatment would be your responsibility should complications develop from SOFT TISSUE FILLER injections. You would also be responsible for additional forms of treatments or surgery recommended to improve the appearance of facial wrinkles and soft tissue depressions. If additional interim injections of SOFT TISSUE FILLER are recommended in order to maintain or improve results, you will be responsible for the costs of this additional treatment.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your physician may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing this consent.

I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.

I consent to the administration if necessary of local anesthesia (regional nerve blocks or direct infiltration) to diminish discomfort of injection of SOFT TISSUE FILLER.

IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:

- a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
- b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
- c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE OR SOFT TISSUE FILLER INJECTIONS. I AM SATISFIED WITH THE EXPLANATION THAT I HAVE RECEIVED BEFORE DECIDING TO UNDERGO THIS TREATMENT OR PROCEDURE. I ACCEPT RESPONSIBILITY FOR THE RISKS, CONSEQUENCES AND BENEFITS OF THIS DECISION.

PATIENT SIGNATURE

DATE

WITNESS SIGNATURE

DATE

Patient Analysis and Operative Report

Patient Information

Patient Name _____ Date _____

Current Treatment

Treated Feature	Product and Amount	Clinical Analyses / Comments
Frontalis / Horizontal Rhytids		
Brow Asymmetry		Right Lower? Left lower?
Glabellar Complex / Frown Lines		
Aperture Width		Right Lower? Left lower?
Crows Feet		
Nasalis (Bunny)		
Malar		
Nasolabial Folds		
Marionette Lines		
Vertical Lip Lines / Orbicularis Oris		
Vermillion Border		
Lip		
Oral Commissures / Mouth Corners		
Chin		
Platysma Bands		
Necklace Lines		

Product Information

Product Name	Product Lot Number/Label	Product Expiration Date
1		
2		
3		

Post Treatment Information

Complications	
Instructions given	
Follow-up Appointment	
Comments	

Physician Signature

For our own safety this form must be completed before treatment.

DERMAL FILLER MEDICAL HISTORY

Name _____ Date _____

Address _____

City _____ State _____ Zip _____

Day Phone: _____ Night/Cell Phone: _____

Payment preference: Cash__ Check__ Visa/Mastercard__ Payment Plan: _____

Primary physician's name: Phone #:

Date of last visit to Dr:

DOB: _____ Height: _____ Weight: _____ BP: _____

1. Are you under currently under the care of a physician ? Yes No

For:

2. Medications you are currently taking:

3. List drug/medicine allergies:

4. Have you taken other drugs not listed above in the past 6 months (such as steroids, cocaine, any over the counter medications or herbal remedies or vitamin supplements?

Yes No List:

5. Have you had any serious illnesses or operations in the last five years? Yes No

If yes, please describe:

6. Have you ever had a blood transfusion? Yes No If yes, list dates:

7. Have you ever had a bad reaction to local anesthetic? Yes No

If yes, please describe:

8. WOMEN ONLY: Are you pregnant? Yes No Maybe Nursing?
 Yes No

Are you taking birth control pills? Yes No Hormone medication
 Yes No

9. Do you need antibiotic premedication before treatment? Yes No

List the condition:

10. Your current physical health is: Good Fair Poor

Please click in the check box if you had or are now having any of the following:

AIDS Auto-immune disease Anemia
 Arthritis, Rheumatism Artificial heart valves Artificial
joints Asthma Allergies to beef or chicken Rash
 Itching Rhinitis Wheezing)

Blood disease Date of last collagen testing:
 Chemotherapy Circulatory problems Cold
 Cortisone

Congenital heart lesions Cough, persistent Cough up blood

Diabetes Drastic weight loss Drug dependant

Excessive bleeding Fainting Food allergies

Heart murmur

Heart problems, describe:

Hemophilia Herpes Hepatitis, Type:

High blood pressure HIV positive Jaundice

Lupus Latex allergy

Mitral valve prolapse

Previous dermal filler procedures Describe:

Did it cause a skin rash Special diet:
Describe

Previous plastic surgeries to face and neck & year of procedures
 Satisfactory result

Swelling, feet/ankles Thyroid disease

Tobacco use: Cigarette Chew Pipe

Are you allergic to any of the following drugs?

Aspirin Codeine Local Anesthetics Erythromycin Latex

Penicillin Tetracycline

Do you have any other conditions, diseases, or problems not listed above? Yes

No If yes, please describe:

I accept full responsibility for the correct and honest completion of this form .

Patient Signature: _____ Date: _____

LIPS AND THE PERFECT SMILE

Upper lip shape, width and length

- Teeth relative to lips
- Separation between relaxed lips
- Amount of front teeth visible smiling
- Alveolar bone, gingival and dental support

- Cupid's bow and philtral columns

- Angle between nose and lip

- Distance of the nose to upper lip

- Distance of chin to lower lip

- Lower lip volume

- Balance of upper/lower lip

- Lower lip support

- Texture

CORRECT ORDER OF TREATMENTS

PERMANENT BEFORE REVERSIBLE

DENTAL TREATMENT BEFORE COSMETIC SURGERY

COSMETIC SURGERY BEFORE TATTOO'S

TATTOO'S BEFORE AUGMENTING/FILLING SOFT TISSUES

DENTAL CONSIDERATIONS

Vermillion borders should be visible

Filled lips should not have to strain to cover teeth

Long lips – ideal candidate for thickening/pouting because teeth will show

Long upper lips display more mandibular anterior teeth

Short lips with teeth visible- caution not to increase pouting, reveal too much teeth or gums

Don't pout lips when patient has a gummy smile – more teeth become visible

Lengthening teeth creates horsey appearance – rather shorten lip by creating pout, or, extend lip with injections close to wet-dry junction

Define lip shape to reveal visible teeth below lipline for older patients with denture > 2mm

Smiling line - Lower lip should parallel incisal edge of the upper anterior teeth

People with short upper lips display the maximum maxillary anterior teeth surface

Sculpture lip so that younger patients have more cuspid visible

Entire facial surface of anteriors should be visible with minimal gum showing

Always complete cosmetic dentistry BEFORE building up the lips – altered lip size shape and volume affects appearance of teeth

Incisal edges, occlusal plane and the location of the midline in harmony with lip line & smile line

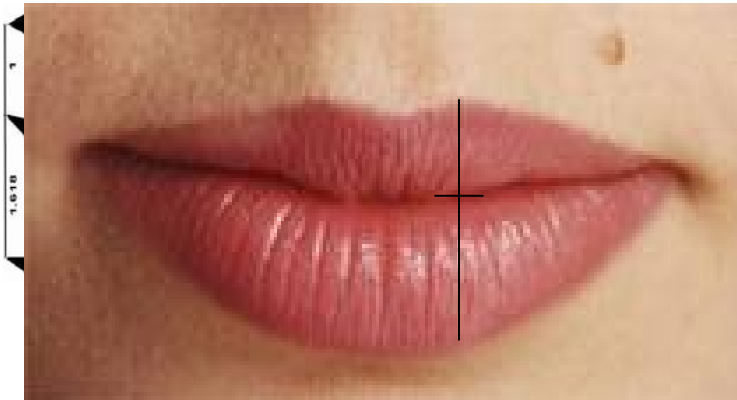
Evaluate the amount and location of tooth display while the patient rests, speaks, and smiles.

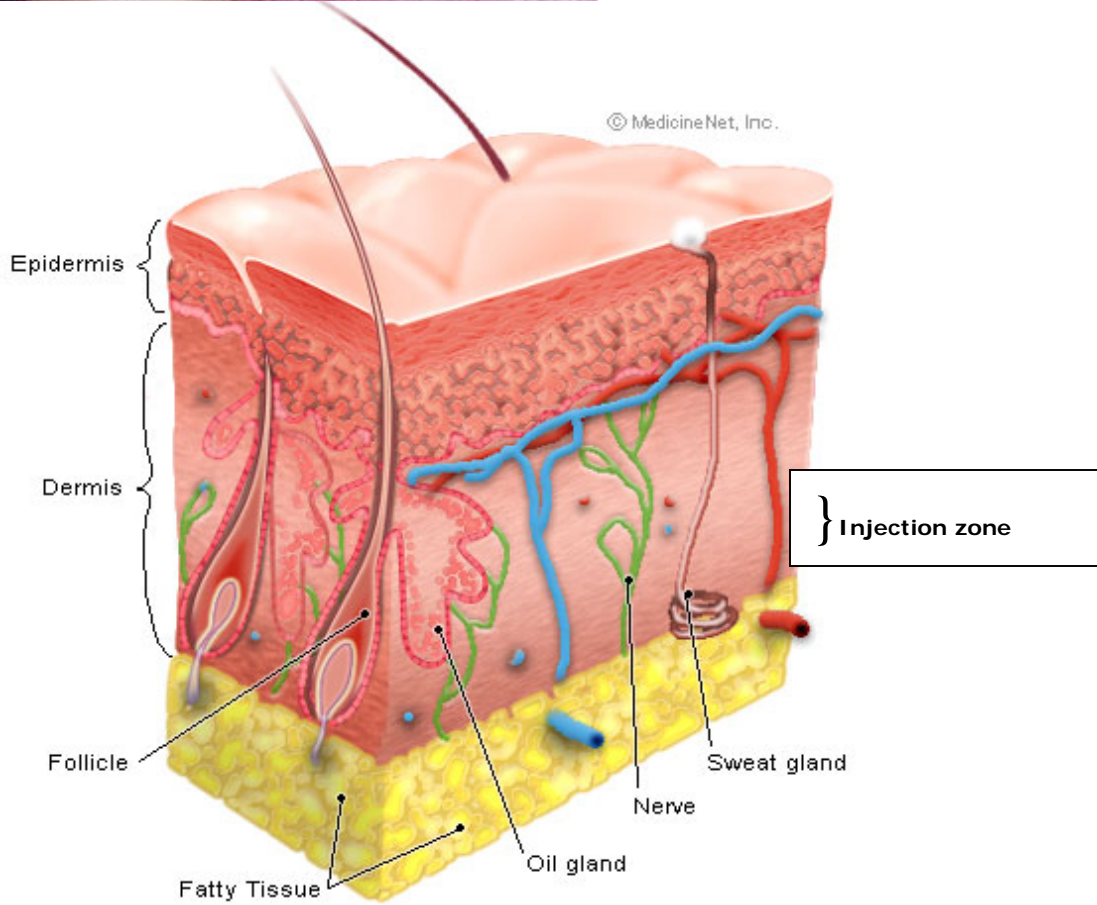
Amount of anterior teeth visible should be individualized to the patient's age, race and sex

Inadequate tooth and alveolar bone lip support hides the vermillion border of the upper lip

Upper lip support in the maxilla created by building up teeth in line with gingival margin, the cervical half of the teeth and the alveolar process

RULES OF GOLDEN PROPORTION





NORMAL SKIN – ¼ INCH THICK

IDEAL PATIENTS

- Young patients with nice lips better than older
- Nasio-labial folds, lip rhytides, thin or assymetric lips that require less than 1.5cc at each site,
- Insufficient/ excessive teeth visible and inadequate lip support
- Knowledgeable about the procedure – reversible/ temporary, out of pocket expenses, side-effects
- Aware of alternative treatments – not wanting dental
- In good physical and psychological health
- Wanting to improve their appearance without surgery
- Realistic in their expectations
- Not using marijuana or anabolic steroids
- Not a heavy user of alcohol

Contraindications

- Advanced periodontal disease or dental abscesses
- oral herpes

Patient who is prone to lesions:

Valtrex 500mg TID on day of procedure and 3-5 days after procedure

Acyclovir therapy : 200mg 5 times daily from day of treatment for 10 days.

- Accutane for six months prior or following. Accutane may increase your chances of keloid-like scarring.
- collagen/scarring/connective tissue disorders
- lupus
- diabetes
- problems with clotting
- Sunburn
- Active inflammation – cysts, hives, infection, rash, pimples
- Pregnancy or lactation
- Immunosuppressant therapy
- Hyper allergenic Tx: Prednisone 40 – 60mg daily

BEFORE INITIAL CONSULT

- Obtain medical history – (anti-coagulants, blood dyscrasias, recent collagen testing, hypersensitivity to avian products (Hylaform))
- Ask about previous treatments – when last?
- Obtain an extensive consent form – reversible; bruising
- Inform patient that treatment not covered by insurance and patient is responsible for payment (on consent form)
- Inform patient that touch up may be necessary after two weeks at an additional fee (on consent form)
- Take photos - left, front, right
- Set realistic expectations – fillers inadequate for advanced wrinkling and skin folds. Refer to C. Surgeon
- Inform patient that local anesthetics are necessary

PATIENT EVALUATION AT TREATMENT

- Have patient remove all make up
- Seat patient in chair – do not lie down
- Cleanse the treatment area
- Aim light on patients face
- Have patient assess face with hand mirror
- Demonstrate asymmetries to patient before treating
- Have patient demonstrate concerns to you in mirror
- Pre treatment photo's – front and side

POST TREATMENT INSTRUCTIONS

- Inform patient of bruises, swelling for 2-3 days
- Tylenol only
- Ice compress ADJACENT areas
- No topical skin acids/make-up that day
- Don't touch for 6 hours
- Then wash with soap and water
- No exercise, alcohol, cigarettes, sun
- Sleep on back with head elevated
- Touch up no sooner than 1 week after swelling subsides

HANDLING PROBLEMS

May be part of desired result

Not a problem if not cosmetically visible

- Massage with thumb and index finger– up to 3 months
- Over-massaging may eliminate intended effect, cause bruising and swelling
- Drain – No 11 blade and surgical suction
- Aspirate -20 gauge needle

Injection site usually swells up soon after treatment

- Do not correct asymmetries for 1 week
- Inform patient to expect this