

INFORMED CONSENT – BOTULINUM TOXIN & FILLER INJECTION

INSTRUCTIONS

This is an informed-consent document which has been prepared to help inform you concerning botulinum toxin injection including but not limited to BOTOX[®] (*Botulina* Toxin Type A, Allergan), XEOMIN[®] (IncobotulinumtoxinA, Merz Aesthetics), and DYSPORT[®] (*AbobotulinumtoxinA*, *Medicis Aesthetic*); and hyaluronic acid filler (animal-origin, stabilized hyaluronic acid, multiple companies) or Radiesse[®] (Calcium Hydroxylapatite, Merz Aesthetics) 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 by your physician and agreed upon by you.

GENERAL INFORMATION

Clostridia botulina bacteria produce a class of chemical compounds known as “toxins”. The Botulinum toxin is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary paralysis of muscle by preventing transmission of nerve impulses to muscle. The duration of paralysis generally lasts for approximately three to four months.

Botulinum toxin has been approved to treat certain medical conditions. As early as April 2002, it has been FDA-approved for the cosmetic treatment of forehead wrinkles caused by specific muscle groups. Other areas of the face and body may be treated in an “off-label” fashion. Botulinum toxin has also been used to treat migraine headaches, colorectal disorders, excessive perspiration disorders, and musculoskeletal pain disorders.

Botulinum toxin injections are customized for every patient, depending on need. These can be performed in areas involving the eyelid region, forehead, and neck. Botulinum toxin cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups. Botulinum toxin injections may be performed as a singular procedure or as an adjunct procedure.

Hyaluronic acid is a naturally occurring sugar found within all mammals and is our most common soft tissue filler. It is a material contained in various soft tissues. Hyaluronic acid can be synthetically produced from animal tissues, chemically stabilized, and purified for use as filler (*animal-origin, stabilized hyaluronic acid*). Hyaluronic acid has been FDA approved to treat areas of facial wrinkling and soft tissue depressions. Juvederm[®], Juvederm Voluma[®], Belotero[®], Perlan[®], and Restylane[®], are all hyaluronic acid derived products. Radiesse is another filler comprised of materials found in bone know is hydroxylapatite (CaHA). Radiesse[®], is synthetically produced and purified for injection (Radiesse, Merz Aesthetic Inc.). Radiesse is FDA approved to treat specific deep areas of soft tissue depressions. A number of other cosmetic Fillers exist and are used less frequently.

Botulinum toxin & Filler injections are customized for every patient, depending on need. Botulinum toxin & Filler like hyaluronic acid or other fillers cannot stop the process of aging. These products can however, temporarily diminish the appearance of wrinkles and soft tissue depressions. Both injections may be performed as singular procedures, in combination, or as an adjunct procedure. Filler such as hyaluronic acid injections may require regional nerve blocks or local anesthetic injections to diminish discomfort.

These products may produce temporary swelling, redness, and needle marks, which usually resolve after a few days. Continuing treatments are necessary to maintain the clinical effect over time. Botulinum toxin & Fillers will usually be slowly absorbed by the body and the length of their effect is variable.

ALTERNATIVE TREATMENTS

Alternative forms of management include not treating the skin wrinkles by any means. Improvement of skin wrinkles may be accomplished by other treatments or types of surgery such as a blepharoplasty, face or brow-lift when indicated. Other forms of eyelid surgery may be needed should you have intrinsic disorders affecting the function of the eyelid such as drooping eyelids from muscle problems (eyelid ptosis) or looseness between the eyelid and eyeball (ectropion). Minor skin wrinkling may be improved through

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chemical skin peels, lasers, dermabrasion, alternative tissue fillers, or surgery when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

RISKS of BOTULINUM TOXIN & FILLER Injections

Every procedure involves a certain amount of risk and it is important to understand these risks and the possible complications. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should make sure you understand risks, potential complications, limitations, and consequences of Botulinum toxin & Filler injections. Additional information concerning these products may be obtained from the package-insert sheets supplied or requested. Problems associated with the use of Botulinum toxin & all tissue fillers relate to normal occurrences or potential complications following injections.

NORMAL OCCURRENCES DURING BOTULINUM TOXIN & FILLER INJECTIONS

Bleeding and Bruising- It is possible, though unusual, to have a bleeding episode from injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba and other “herbs / homeopathic remedies” may contribute to a greater risk of bleeding. Do not take any of these products 5-7 days prior to injections when possible.

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 and is present for a few days.

Needle Marks- Visible needle marks from the injections occur normally and resolve in a few days.

Acne-Like Eruptions- Acne-like skin eruptions can occur and generally resolves within a few days.

Skin Lumpiness- Lumpiness can occur following injection of Botulinum toxin & Fillers. This tends to smooth out over time. In some situations, it may be possible to feel the tissue filler for long periods of time.

Visible Fluid or Tissue Material- It may be possible to see Botulinum toxin or 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 injections. There can be variations from one side to the other in response to injections. This may require additional injections or treatment.

Pain- Discomfort associated with Botulinum toxin & filler injections is normal and usually of a short duration.

Skin Sensitivity- Skin rash, itching, tenderness and swelling may occur following Botulinum toxin or Filler injections. After treatment, you should minimize excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. If you are considering laser treatment, chemical skin peeling, or any other skin procedure, or you have recently had such treatments and the skin has not healed completely, there is a possible increases risk of an inflammatory reaction.

RISKS OF BOTULINUM TOXIN INJECTIONS

Damage to Deeper Structures- Deeper structures such as nerves, blood vessels, and the eyeball may be damaged during injection. Injury to deeper structures may be temporary or permanent.

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Corneal Exposure Problems- Some patients experience difficulties closing their eyelids after Botulinum toxin and dryness of the cornea. Should this rare complication occur, additional treatments, protective eye drops, contact lenses, or surgery may be necessary.

Dry Eye Problems- Individuals who have dry eyes should be cautious with injections around the eyelid.

Migration of Botulinum toxin- Botulinum toxin may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects. BOTOX has been reported to cause swallowing problems in patients treated in the cervical region (cervical dystonia). You agree that you were given access to the “black box” warning or package insert as it relates to diffusion or migration.

Drooping Eyelid (Ptosis) - Muscles that raise the eyelid may be affected if Botulinum toxin migrate downward.

Double-Vision- Double-vision may result if Botulinum toxin migrates to eyeball muscles that control movement.

Eyelid Ectropion- Abnormal looseness of the lower eyelid can occur following Botulinum toxin injection.

Other Eye Disorders- Functional & inflammatory disorders of the eye may occur following Botulinum toxin.

Blindness- Blindness or other eye problems are extremely rare after Botulinum toxin. However, blindness can be caused by bleeding around the eyeball or needle stick. In a period of 10 years of Botulinum toxin administration, complications of blurred vision, retinal vein occlusion, and glaucoma were reported in three patients.

Allergic Reactions- As with all biologic products, allergic reactions can occur and may require treatment.

Antibodies to Botulinum Toxin- Presence of antibodies to Botulinum toxin may reduce effectiveness in subsequent injections. The health significance of antibodies to Botulinum toxin is unknown.

Infection- Infection is rare after Botulinum toxin and antibiotics or treatment may be necessary.

Neuromuscular Disorders- Patients with peripheral motor neuropathic disorders (amyotrophic lateral sclerosis, myasthenia gravis, motor neuropathies) may be at greater risk of clinically significant side effects.

Migraine Headache Disorders- Botulinum toxin is used to treat muscles involved with migraine headaches. Patients are advised that results for migraine headaches may be variable and improvement may not occur following injection. Botulinum toxin injection has been rarely reported to induce migraines in some patients.

RISKS OF ALL SOFT TISSUE FILLER INJECTIONS

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 treatment. This applies to individuals with a past history of infections and those with no history of infections in the mouth area. Specific medications must be taken both prior to and following treatment in order to suppress the virus. Should skin infection occur, additional treatment including antibiotics may be necessary.

Skin Necrosis- It is very unusual to experience death of skin and soft tissues after injection with any filler. Skin necrosis can produce unacceptable scarring resulting in additional treatments or surgery.

Granulomas- Painful masses in the skin and deeper tissues after a filler injection are extremely rare. Should these occur, additional treatments including surgery may be necessary.

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Allergic Reactions and Hypersensitivity- As with all biologic products, allergic reactions may occur. Hyaluronic acid is extracted from chicken tissues. **Hyaluronic acid should not be used in individuals with a history of allergic reactions to chicken (avian protein) materials as local and systemic reactions can occur.** Patients with allergies to Hydroxylapatite should avoid Radiesse® injections. Allergic reactions to any soft tissue Filler may require additional treatment.

Scarring- Fillers should not be used in patients with known susceptibility to keloid formation, hypertrophic scarring, or pigmentation disorders.

Accidental Intra-Arterial Injection- It is extremely rare that during injection, any filler including hyaluronic acid or hydroxylapatite could be accidentally injected into arterial structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection is not predictable.

Under / Over Correction- The injection fillers including hyaluronic acid to correct wrinkles and soft tissue contour deficiencies may not achieve the desired outcome. The correction may be inadequate or excessive. It may not be possible to fully control the process of injection due to factors attributable to each patient's situation. If under correction occurs, you may want to consider additional injections of tissue filler.

Migration of Filler – Fillers may migrate and produce fullness in adjacent tissue or unintended effects.

Drug and Local Anesthetic Reactions- A systemic reaction could occur from either the local anesthetic or epinephrine sometimes used for anesthesia with filler injections. This would include the possibility of light-headedness, rapid heartbeat, and fainting. Medical treatment of these conditions may be necessary.

ADDITIONAL ADVISORIES

Unsatisfactory Result- Botulinum toxin & Fillers injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response from injection(s). Additional injections may be necessary. Surgical procedures or other treatments may be recommended in addition to Botulinum toxin & Fillers like hyaluronic acid treatments.

Combination of Procedures- In some situations, Botulinum Toxin or Filler may be used in combination to enhance the outcome. The full effect of other skin treatments (i.e. laser, light therapies, microdermabrasion, dermabrasion, or chemical peels) on the treated areas has not been fully determined.

Pregnancy and Nursing Mothers- Animal reproduction studies have not been performed to conclusively determine if Botulinum toxin & Fillers produce fetal harm. It is not known if Botulinum toxin or Fillers or breakdown products can be excreted in human milk. Pregnant women or nursing mothers should not receive Botulinum toxin or any filler.

Long-Term Effects- Botulinum Toxin & Fillers should not be considered a permanent treatment. Over time, both products are absorbed by the body and wrinkles or soft tissue depressions reappear. Continuing treatments are necessary to maintain the effect. 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 injections. Future surgery or other treatments may be necessary. These products do not fully arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

Drug Interactions- Botulinum toxin may be potentiated by aminoglycoside antibiotics or drugs known to interfere with neuromuscular transmission. There is no evidence that fillers reacts with any drugs.

Prosthetic or Medical Device Injury or Adverse Interaction- Some patient have had medical devices or stimulators placed in proximity to Botulinum Toxin or Filler injection sites. Injection of Botulinum toxin or

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Filler in these areas could injure, potentiate infection, deactivate, or result in removal or failure of such devices. In general, our practice will not inject in proximity to medical devices. All patients with such devices will require a written release or letter of medical clearance prior to Botulinum toxin or Filler application. It is the patient's duty to report such devices to our practice and Dr. Lowe to avoid complications or incident. Cosmetic treatment may not be indicated in certain situations.

Unknown Risks- The long-term effect of Botulinum toxin and Filler on tissue is not fully known. The risk and consequences of accidental intravascular injection is not fully known and not predictable. Additional risks and complications attributable to Botulinum toxin and filler material such as hyaluronic acid may be discovered.

Off Label Use - You agree that soft tissue fillers may be applied in areas at your request that are "off-label." This means the product is routinely applied in areas that the FDA has not officially approved. You agree that you were given access to the package insert as it relates to the general risk and indications for fillers.

HEALTH INSURANCE

Health insurance excludes coverage for cosmetic procedures and treatments or any complications that might occur. Please review your health insurance information pamphlet for concerns. This practice only utilizes cosmetic Botulinum Toxin and Filler for cosmetic purposes. **We do not treat any medical conditions with these products through medical insurance, regardless of any clinical improvements the patient may experience.**

ADDITIONAL TREATMENT NECESSARY

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

FINANCIAL RESPONSIBILITIES

This treatment provides a defined amount of Botulinum toxin & Filler like hyaluronic acid for the treatment of wrinkles and other conditions. If additional interim injections are needed to maintain or improve results, you will be responsible for these costs in addition to the cost of this treatment session. Additional costs of medical treatment would be your responsibility should complications develop from injections. You would also be responsible for additional forms of treatments or surgery recommended to improve your appearance. **In signing the consent for this procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions along with the financial costs of all current and future treatments.**

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed 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 care giver may provide you with additional information pertaining to your particular case and the current 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 of 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 the consent on the next page.

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CONSENT FOR SURGERY/ PROCEDURE or TREATMENT

1. I hereby authorize Dr. Lowe and such assistants as may be selected to perform the following procedure or treatment:

BOTULINUM TOXIN AND/OR FILLER INJECTION_ FACE or BODY
(patient may list where they will be injected i.e. forehead, crows-feet, face and/or lips)

I have received the following information sheet:

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2. I recognize that during the course of the procedure and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician, assistants, or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
7. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
8. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
9. I realize that not having the operation or procedure is an option.
10. 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 AND THE ABOVE LISTED ITEMS (1-10). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____