

INFORMED CONSENT – BOTULINUM TOXIN INJECTION

INSTRUCTIONS

This is an informed-consent document which has been prepared to help your physician inform you concerning botulinum toxin injection including but not limited to products: BOTOX[®] (*Botulina Toxin Type A*, Allergan), XEOMIN[®] (*IncobotulinumtoxinA*, Merz), and DYSPORT[®] (*AbobotulinumtoxinA*, Medicis[®] *Aesthetic Inc.*), 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 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 paralysis generally lasts for approximately three to four months. Botulinum toxin has been approved to treat certain conditions. Since 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 clinical need. 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 to other procedures.

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 alternative types of surgery when indicated. Minor skin wrinkling may be improved through chemical skin peels, lasers, injection of filling material, or other skin treatments. Risks and potential complications are associated with alternative forms of treatment.

RISKS of Botulinum Toxin Injections

Every procedure involves a certain amount of risk and it is important that you understand these risks and possible complications. In addition, every procedure has limitations. An individual's choice to undergo a procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should review them to make sure you understand risks, potential complications, limitations, and consequences of Botulinum toxin injections. Additional information concerning Botulinum toxin may be obtained from the package-insert sheets supplied or requested.

NORMAL OCCURRENCES DURING BOTULINUM TOXIN INJECTIONS

Bleeding and Bruising- It is possible, though unusual, to have bleeding from a Botulinum toxin injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper Botulinum toxin injections for crossed eyes (strabismus) has occurred. Should you develop post-injection 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. Avoid these products when possible for 5-7 days before Botulinum toxin injections

Swelling- Swelling (edema) is a normal occurrence following the injections. Lumpiness and bruising may take 5-7 days to fully resolve. If swelling is slow to resolve, medical treatment may be necessary. This settles over time, but avoid Botulinum toxin application at least 7 days prior to a social event when possible.

Erythema (Skin Redness)- Erythema in the skin occurs after injections and may last for a few days.

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

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

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Asymmetry- The human face and eyelid region is normally asymmetrical in its appearance and anatomy. It is not possible to achieve or maintain exact symmetry with Botulinum toxin injections. There can be variations from one side to the other in response to injections. This may require additional injections.

Pain- Discomfort with injection is normal and of a short duration. Applying numbing cream before can help.

Skin Sensitivity- Skin rash, itching, tenderness and swelling may occur following Botox. After treatment, minimize Sun or UV exposure and extreme cold weather until swelling or redness has gone. If you are considering laser, chemical peeling, or other skin procedure the risk of inflammation is increased.

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.

Migration of Botulinum Toxin- Botulinum toxin may migrate from its injection site to other areas and produce temporary paralysis of muscle groups or unintended effects. Botulinum toxin has caused swallowing problems in patients treated for spastic disorders of the neck (cervical dystonia). I have been given access to manufactures “black box” warning on Botulinum toxin as it relates to diffusion or migration.

Corneal Exposure Problems- Some patients experience difficulties closing eyelids or cornea dryness after BOTOX. Should this rare complication occur, additional treatments, drops, or surgery may be necessary.

Dry Eye Problems- Patients with dry eyes should use caution with injection around the eyelid region.

Drooping Eyelid (Ptosis) - Muscles that raise the eyelid may be affected by migration of Botulinum toxin.

Double-Vision- Double-vision may occur if the Botulinum toxin migrates to muscles that control the eyeball.

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

Other Eye Disorders- Functional and irritation disorders of eye structures may rarely occur following Botulinum toxin injections. The forehead may temporarily sag decreasing function or vision.

Blindness- Blindness is extremely rare after Botulinum toxin injections. It can be caused bleeding around the eyeball or needle injury. In a 10 year period of administration, complications of blurred vision, retinal vein occlusion, and glaucoma were reported in three patients. Eye problems appear to be very rare.

Allergic Reactions- As with all biologic products, allergic and systemic anaphylactic reactions may occur.

Antibodies- Presence of antibodies may reduce effectiveness, the health significance is unknown.

Infection- Infection is extremely rare after Botulinum toxin and treatment may include antibiotics.

Neuromuscular Disorders- Patients with peripheral motor neuropathic disorders (amyotrophic lateral sclerosis, myasthenia gravis, motor neuropathies) may be at greater risk from Botulinum toxin injection.

Migraine Headache Disorders- Botulinum toxin has been used to treat muscle groups involved with migraine headaches. Patients are advised that Botulinum toxin treatment for migraines may be variable and improvement may not occur. Some patients report that injection actually induced migraine headaches.

Unsatisfactory Result- There is the possibility of a poor or inadequate response from Botulinum toxin injection. Additional injections may be necessary. Other treatments may be needed to improve wrinkles.

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Long-Term Effects- Subsequent alterations in appearance may occur as the result of aging, weight loss, weight gain, sun exposure, pregnancy, menopause, or other circumstances not related to Botulinum toxin injections. Botulinum toxin injection does not arrest the aging process or produce permanent tightening.

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

Drug Interactions- The effect of Botulinum toxin may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

Prosthetic or Medical Device Injury or Adverse Interaction- Some patient have medical devices or stimulators placed in proximity to injection sites. Injection in these areas could injure, potentiate infection, deactivate, or result in removal or failure of such devices. We try not to inject in proximity to medical devices. All patients with such devices need a written release or letter of medical clearance prior to any injection application. It is the patient's duty to report such devices to our practice and Dr. Lowe to avoid complications or incident. Botulinum toxin may not be indicated.

Unknown Risks- The long-term effect of Botulinum toxin is not fully known. The risk and consequences of accidental intravascular injection is not predictable. Additional risk factors 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 Botulinum toxin for cosmetic purposes. **We do not treat any medical conditions with Botulinum toxin though 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. 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 other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

FINANCIAL RESPONSIBILITIES

The cost of Botulinum toxin injection may involve several charges. This includes professional fee, follow-up visits, supplies, and the cost of the material itself. Additional costs of treatment would be your responsibility should complications occur. **In signing the consent you acknowledge you have been fully informed and accept responsibility along with the financial costs of all current & future treatments.**

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed treatment along with disclosure of risks and alternative treatment(s). The informed-consent process attempts to define principles of risk disclosure that generally meet the needs of most patients in most circumstances. However, this document should not be considered all-inclusive in defining methods of care and risks. Your physician may provide you with additional information which is based on the current clinical facts and 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 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.

INFORMED CONSENT – BOTULINUM TOXIN INJECTION

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 INJECTION FACE or BODY

(the patient may list specific areas to 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 and 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 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