INFORMED CONSENT for BOTULINUM TOXIN INJECTION
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This is an informed-consent document that has been prepared to help inform you about Botulina Toxin Type A injections, its risks, as well as alternative treatment(s). It is important that you read this information carefully and completely. Please initial each page, and sign the consent as proposed by your provider and agreed upon by you.

GENERAL INFORMATION

Clostridia botulina bacteria produce a class of chemical compounds known as "toxins". The Botulina Type A 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 (chemodenervation) of muscle by preventing transmission of nerve impulses to muscle. The duration of muscle paralysis generally lasts for approximately three to four months.

Botulinum toxin has been approved to treat certain conditions involving crossed eyes (strabismus), eyelid spasm (blepharospasm), cervical dystonia (spastic muscle disorder with the neck) and motor disorders of the facial nerve (VII cranial nerve). As of April 2002, it has been FDA-approved for the cosmetic treatment of forehead wrinkles caused by specific muscle groups and more recently approved for treatment of crow's feet wrinkles as of September 2013. Other areas of the face and body such as smoker's lines around the lips and neck bands may be treated in an "off-label" fashion. Botulinum toxin has also been used to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

Botulinum toxin injections are customized for every patient, depending on his or her particular needs. 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 to a surgical procedure.

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 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 chemical skin peels, lasers, injection of filling material, or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

INHERENT RISKS OF BOTULINUM TOXIN INJECTIONS

Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. 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 discuss each of them with your physician 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 by the manufacturer.

SPECIFIC RISKS OF BOTULINUM TOXIN INJECTIONS

Incomplete Block: It is possible to not experience a complete block of desired muscles. Additional injections to reach the desired level of block can be performed until the goal is achieved.

Asymmetry: The human face and eyelid region is normally asymmetrical with respect to structural anatomy and function. There can be a variation from one side to the other in terms of the response to botulinum toxin injection.

Drooping Eyelid (Ptosis): Muscles that raise the eyelid may be affected by botulinum toxin, should this material migrate downward from other injection areas.

Pain: Discomfort associated with botulinum toxin injections is usually of short duration.

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. Botulinum toxin has been reported to cause swallowing problems in patients treated for spastic muscle disorders of the cervical region (cervical dystonia).

Bleeding and Bruising: It is possible, though unusual, to have a bleeding episode 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 a bleeding problem. You should disclose any prescriptions to your physician and discontinue any of the abovementioned over-the-counter medications for supplements for ten days before or after botulinum toxin injections.

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

Corneal Exposure Problems: Some patients experience difficulties closing their eyelids after botulinum toxin injections and problems may occur in the cornea due to dryness. Should this rare complication occur, additional treatments, protective eye drops, contact lenses, or surgery may be necessary.

Unknown Risks: The long-term effect of botulinum toxin on tissue is unknown. The risk and consequences of accidental intravascular injection of botulinum toxin is unknown and not predictable. There is the possibility that additional risk factors may be discovered.

Dry Eye Problems: Individuals who normally have dry eyes may be advised to use special caution in considering botulinum toxin injections around the eyelid region.

Double-Vision: Double-vision may be produced if the botulinum toxin material migrates into the region of muscles that control movements of the eyeball.

Eyelid Ectropion: Abnormal looseness of the lower eyelid can occur following botulinum toxin injection.

Other Eye Disorders: Functional and irritative disorders of eye structures may rarely occur following botulinum toxin injections.

Blindness: Blindness is extremely rare after botulinum toxin injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. In a period of 10 years of botulinum toxin administration, complications of blurred vision, retinal vein occlusion, and glaucoma have been reported in three patients. The occurrence of eye problems appears to be very rare.

Allergic Reactions: As with all biologic products, allergic and systemic anaphylactic reactions may occur. Allergic reactions may require additional treatment.

Antibodies to Botulinum Toxin: Presence of antibodies to botulinum toxin may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to botulinum toxin is unknown.

Infection: Infection is extremely rare after botulinum toxin injection. Should an infection occur, additional treatment including antibiotics may be necessary.

Skin Disorders: Skin rash, itching, and swelling may rarely occur following botulinum toxin injection.

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

Migraine Headache Disorders: Botulinum toxin has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results of botulinum toxin treatment for migraine headaches may be variable and improvement in this disorder may not occur following botulinum toxin treatments.

Unsatisfactory Result: There is the possibility of a poor or inadequate response from botulinum toxin injection. Additional botulinum toxin injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity.

Long-Term Effects: Subsequent alterations in face and eyelid 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 of the eyelid region. Future surgery or other treatments may be necessary.

Pregnancy and Nursing Mothers: Animal reproduction studies have not been performed to determine if botulinum toxin could produce fetal harm. It is not known if botulinum toxin can be excreted in human milk. It is not recommended that pregnant women or nursing mothers 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.

Off-Label FDA Issues: There are many devices, medications and injectable fillers and botulinum toxins that are approved for specific use by the FDA, but this proposed use is “Off-Label”, that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your provider believes it to be safe and effective.

CONSENT FOR PROCEDURE or TREATMENT

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

   BOTULINUM TOXIN INJECTION OF THE FOLLOWING AREAS:

   _____

   _____

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   I have received the following information sheet: INFORMED CONSENT for BOTULINUM TOXIN INJECTION

2. I acknowledge that I have been informed about the Off-Label FDA status of botulinum toxin and I understand it is not experimental and accept its use.

3. I am not pregnant and I am not breastfeeding. (Female patients only)

4. Before and after treatment instructions have been discussed with me. The procedure, potential benefits and risks, and alternative treatment options have been explained to my satisfaction.

5. I understand that the procedure is purely elective, that the results may vary with each individual, and multiple treatments may be necessary.

6. 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.

7. 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.

8. I understand what my physician can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

9. I consent to be photographed or televised before, during, and after the 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.

10. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.

11. If a secondary procedure is necessary, further expenditure will be required.

12. I realize that not having the procedure is an option.

13. 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 (1-13). I AM SATISFIED WITH THE EXPLANATION.

Signature of Patient or Patient's Legal Representative (if under 18 or incapacitated)/Date

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Signature of Witness/Date

Signature of Physician/Date