

INFORMED CONSENT - BOTULINA TOXINS - BOTOX INJECTIONS

INSTRUCTIONS

This is an informed-consent document to inform you about BOTOX (*Botulina* Toxin Type A, Allergan) injection, its alternative treatments, and risks.

Please read this information carefully and completely. Please initial each page, indicating that you have read and understood the contents of this page and sign the consent form for this procedure as proposed by your plastic surgeon.

GENERAL INFORMATION

Clostridia botulina bacteria is a class of chemical compounds known as “toxins”. The Botulina Type A Toxin (BOTOX) is processed and purified to produce a sterilized product that is suitable for certain therapeutic treatments. Once the diluted toxin is injected, it creates a temporary paralysis (chemodenervation) of muscle by blocking the nerve impulse channels to the muscles. The temporary muscle paralysis generally lasts for approximately three to four months.

BOTOX has been authorized to treat certain conditions involving cervical dystonia (neck spastic muscle disorder), crossed eyes (strabismus), facial nerve motor disorders (VII cranial nerve), and eyelid spasm (blepharospasm). It has been FDA-approved for the cosmetic treatment of forehead wrinkles caused by certain muscle groups since April 2002. Neck bands and crow feet wrinkles may be treated in an off-label fashion. BOTOX can also be used to treat armpit and hands excessive perspiration, migraine headaches, musculoskeletal pain disorders, and colorectal disorders.

BOTOX injections are not the same for everyone; they are catered according to the certain needs of every patient. These can be performed in the neck, eyelid region, and forehead areas. Contrary to popular belief, BOTOX cannot stop the process of aging. However, it can temporarily reduce wrinkles caused by muscle groups. BOTOX injections may either be performed as a single procedure or as a supplement to a surgical procedure.

SUBSTITUTE TREATMENTS

Substitute treatment includes not treating the skin wrinkles in any manner. Skin wrinkles can be improved by substitute surgery such as face or brow lift or blepharoplasty. Intrinsic disorders affecting the eyelid function such as eyelid ptosis (drooping eyelids due to muscle problems) or

ectropion (looseness between the eyelid and eyeball). Chemical skin peels, filling material injection, and other skin treatments can be used to remedy minor skin wrinkling. Substitute treatments are not free from possible risks and complications.

RISKS AND COMPLICATIONS OF BOTOX INJECTIONS

Every medical procedure holds a certain set of risks and complications. It's very important that you understand these and the limitations of BOTOX. A patient's choice to proceed with the procedure should be dependent upon the comparison of benefits and risks. The majority of patients do not experience these, but for your sake, you should discuss the possible risks and complications, consequences, and limitations of BOTOX injections.

Partial Block: The desired muscles may not receive the complete block. Additional injections may be needed to achieve desired results.

Asymmetry: The function and structural anatomy of the human face and eyelid area are normally uneven. There can be a disparity or difference between the two according to the BOTOX injections response.

Ptosis (Drooping Eyelids): This happens when the eyelid is raised by the muscle; this is caused when BOTOX migrates downward.

Pain and Discomfort: Pain and discomfort caused by BOTOX injections are of short duration.

BOTOX Migration: BOTOX may migrate to unintended areas and may produce temporary paralysis of muscle groups and other unintended effects. Patients treated for cervical dystonia (spastic muscle disorder of the cervical region) may difficulty swallowing.

Bleeding and Bruising: BOTOX injection can unusually cause a bleeding episode and bruising in the soft tissues. A patient with strabismus (crossed eyes) has experienced serious bleeding around the eyeball due to deeper BOTOX injections. Emergency treatment or surgery may be required if you experience post-injection bleeding. Major contributors to a bleeding problem are platelet inhibitors, vitamin E, anti-inflammatory medications, anticoagulants, ginkgo biloba, aspirin, homeopathic remedies/herbs. You are advised not to take these 10 days before or after the BOTOX injections.

Damage to Deeper Structures: The eyeball, nerves, and blood vessels may be damaged during the process. Injury to the deeper structures may be temporary or permanent.

Corneal Exposure Problems: Cornea problems may occur due to dryness, and some patients may have difficulties in closing their eyelids caused by BOTOX injections. Although these are rare, patients are advised to use or seek contact lenses, additional treatments, additional treatments, or surgery.

Unknown Risks: UNKNOWN long-term effects of BOTOX are unknown. The consequences and risks associated with accidental intravascular injection of BOTOX are unknown and unpredictable. Additional risk factors may possibly occur.

Dry Eye Problems: Patients who have normally dry eye problems are advised to take special cautionary measures in considering BOTOX around the eyelid area.

Double-Vision: You may experience double-vision if the BOTOX material migrates into the muscle region that controls the movements of the eyeball.

Eyelid Ectropion: BOTOX injections may cause abnormal looseness of the lower eyelid.

Other Eye Injections: Functional and irritative eye disorders of eye structures may rarely occur after BOTOX injections.

Blindness: Although extremely rare after BOTOX injections, it can be caused by a needle stick injury or internal bleeding around the eyeball. Three patients have reported retinal vein occlusion, glaucoma, and complications of blurred vision after 10 years of BOTOX administration.

Allergic Reactions: Allergic and systemic anaphylactic reactions may occur. You may be required to seek additional treatment should these occur.

BOTOX antibodies: The effectiveness of the BOTOX material may be reduced due to the presence of antibodies to BOTOX. The health significance of antibodies to BOTOX is undetermined.

Infection: Although extremely rare after BOTOX injections, infections may occur. Should these occur, an additional treatment accompanied by antibiotics may be necessary.

Skin Disorders: After a BOTOX injection, swelling, skin rash, and itching may rarely occur.

Neuromuscular Disorders: BOTOX has clinically significant side effects that may be a greater risk for patients with motor neuropathies, amyotrophic lateral sclerosis, myasthenia gravis (peripheral motor neuropathic disorders).

Migraine Headache Disorders: BOTOX has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results may vary, and may not occur after the procedure.

Unsatisfactory Result: Unsatisfactory results are possible after the procedure. Additional BOTOX injections may be necessary. Skin wrinkles and those caused by muscle activity may require treatments or surgical procedures.

Long-Term Effects: Eyelid appearance and subsequent changes in the face may occur as a result of sun exposure, weight loss, a result of aging, weight gain, pregnancy, menopause or other circumstances not caused nor related to BOTOX injections. BOTOX injections do not halt the aging process nor produce a permanent eyelid area tightening. Further treatments or surgeries may be necessary.

Nursing and Pregnant Mothers: Nursing and pregnant mothers are not advised to take BOTOX injections.

Drug Interactions: Aminoglycoside antibiotics or other drugs known to interfere with neuromuscular circulation can enhance the effect of BOTOX.

GENERAL RISKS

Bleeding: A bleeding episode during or after the procedure is normal but unusual. Should bleeding occur after the procedure, you may require a blood transfusion or emergency treatment to drain the accumulated blood. Strenuous activities are discouraged after the procedure because they can increase the chance of bleeding and additional surgery. Observe postoperative instructions to prevent these. You will be exposing yourself to HIV or hepatitis should you need a blood transfusion. Decreased blood platelets and bleeding can be produced by heparin medications that are used to prevent blood clots in veins.

Infection: Infection is unlikely after the procedure. Inform your surgeon of any infections because it may lead to an infection in the operated area.

ADDITIONAL ADVISORIES

Female Patient Information: Inform your surgeon prior to the procedure regarding pregnancy suspicion, pills, contraception, estrogen replacement. Antibiotics can counteract the effects of these preventive medicines.

Elective Surgery and Mental Health Disorders: Please communicate openly with your surgeon regarding mental disorders or emotional depression prior to the procedure. The surgeon will discuss with you regarding the psychological effects of elective surgery.

Sun Exposure: Direct tanning or salon tanning may cause color changes, poor healing, and scarring to the treated areas. Discuss this with your surgeon to either delay the treatment or avoid tanning until it is safe to do so. Sunblock and clothing coverage are ineffective when it comes to blocking the damaging effects of the sun.

Medications and Herbal Dietary Supplements: Always consult your physician regarding the allowed and prohibited medications or supplements before or after the procedure. They can either neutralize the effects of the procedure or may have adverse effects on you.

Travel Plans: Please notify your surgeon of any planned or important travels, so the surgeon can schedule the procedure.

Off-Label FDA Issues: This proposed use is “off-label” and is not specifically approved by the FDA. It is important that you understand that this procedure is not experimental, and your physician believes it to be safe and effective.

_____ I acknowledge that I have been informed regarding the Off-Label FDA status of Botox, and I understand that the procedure is not experimental and accept its use.

HEALTH INSURANCE

Please review your healthcare insurance policy before proceeding with this procedure. **Most insurance companies do not provide coverage of cosmetic surgical operations or any complications that may arise after.**

NECESSARY ADDITIONAL TREATMENT

Possible risks and complications may occur, and you may need a separate treatment or additional surgery. Although good results are expected, there is no warranty or guarantee, expressed or implied, that the results may be obtained afterward.

FINANCIAL RESPONSIBILITIES

The cost of a Botox injection includes the professional fees of the injections and the follow-up treatments thereafter. Such costs may not be covered by your health insurance, and that corrective procedures shall also be shouldered by you. **In signing the consent for this procedure, you have understood the risks and complications of this procedure, and that you accept all responsibility for all the clinical decisions that were made along with the financial costs of all future treatments.**

_____ I understand and unconditionally, and irrevocably accept this.

DISCLAIMER

Informed consent offers the general knowledge of the surgery or procedure along with its risks and complications. However, your plastic surgeon may provide additional information that is not stated here, and are based on your current situation and the current state of medical knowledge.

Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change technology advance and scientific knowledge and as practice patterns evolve.

It is important that you have read and understood all of the information presented here and have your questions answered before you sign the consent form on the next page.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ and selected assistants to perform the following surgery or procedure: **BOTOX INJECTION**.

(list of anatomic areas where Botox will be injected)

I have received the following information sheet:

INFORMED CONSENT - BOTOX INJECTION

2. I understand that during the procedure or medical treatment or anesthesia, unforeseen circumstances may require different procedures than those stipulated above. I, therefore, authorize the abovenamed physician and assistants or designees to perform other procedures that are in the practice of their professional judgment necessary and sensible. The authority granted 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 responsible use of anesthetics considered necessary or advisable. I understand that the use of anesthesia may involve risks, complications, injury, and sometimes death.

4. I understand the limitations of what my surgeon can and cannot do, and I understand that there are no warranties or guarantees, specific or implied involving my outcome. I have discussed with the surgeon regarding my goals and understood which are attainable and which are not. All of my questions are answered and understand the specific risks, complications, benefits, as well as the alternatives. Understanding all of this, I choose to proceed.

5. For medical, educational, or scientific procedures, I consent to be televised or photographed before, during, or after the treatment or procedure to be performed, including exact portions of my body, as long as my identity is concealed by the pictures.

6. I consent to the presence of observers in the treatment for the sole purpose of furthering medical education.

7. I authorize my Social Security number to be released to appropriate agencies for medical device registration and legal reporting, if applicable.

8. I understand that the hospital charges and anesthesia are separate from the surgeon's fees, and the fees are acceptable by me. Additional disbursement will be required if a secondary procedure is necessary.

9. I acknowledge that not having the operation is an option.

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

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

I CONSENT TO THE PROCEDURE OR TREATMENT AND THE ABOVE LISTED ITEMS (1-10), AND I AM SATISFIED WITH THE EXPLANATION.

Patient or authorized representative to sign for the patient

Date

Witness