CANADIAN PLASTIC SURGERY CENTRE

Informed Consent

Botulina Toxins—Botox®, Dysport®, Xeomin® Neurotoxins

AMERICAN SOCIETY OF PLASTIC SURGEONS®

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you about Botulina toxin A (BTA)—BOTOX®, Dysport®, and Xeomin® injections, their risks, and alternative treatment(s).

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 surgery as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

Clostridium botulina produces a class of chemical compounds known as "toxins." The Botulina toxin A is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary weakness (chemodenervation) of muscle by preventing transmission of nerve impulses to muscle. The duration of muscle weakness lasts approximately three to four months.

BOTOX® 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. As of April 2002, it has been approved by the FDA for the cosmetic treatment of wrinkles between the brows caused by specific muscle groups. Conditions in other areas of the face and body such as crow's feet wrinkles and neck bands may be treated in an "off-label" fashion. BOTOX® has also been used to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

BTA 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. BTA cannot stop the process of aging. It can, however, temporarily diminish the appearance of wrinkles caused by muscle groups. BTA 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 or 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 fillers or fat, or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

INHERENT RISKS OF BTA 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 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 discuss each of them with your plastic surgeon to make sure you understand risks, potential complications, limitations, and consequences of BTA injections. Additional information concerning BTA may be obtained from the package insert sheets supplied by Allergan.

SPECIFIC RISKS OF BOTOX® (BOTULINA TYPE A TOXIN) INJECTIONS

Incomplete Result:

It is possible to not obtain a complete result in targeted muscles. Additional injections to reach the desired level of result can be performed until the goal is achieved.

Asymmetry:

The human face and eyelid region are 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 BTA injection.

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Drooping Eyelid (Ptosis):
Muscles that raise the eyelid may be affected by BTA, should this material migrate downward from other injection areas. If this problem occurs, it is temporary and additional treatments such as eye drops may be necessary.

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

Migration of BTA:
BTA may migrate from its original injection site to other areas and produce temporary weakness of other muscle groups or other unintended effects. BTA has been reported to cause swallowing problems in patients treated for spastic muscle disorders of the neck region (cervical dystonia).

Bleeding and Bruising:
It is possible, though unusual, to have a bleeding episode due to a BTA injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper BTA injections for crossed eyes (strabismus) has occurred. Should you develop post-injection bleeding, you 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. Do not take these for ten days before BTA injections. If you are taking these medications, please inform your surgeon prior to proceeding.

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 difficulty closing their eyelids after BTA 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 BTA on tissue is unknown. The risk and consequences of accidental intravascular injection of BTA are unknown and not predictable. There is a 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 BOTOX® injections around the eyelid region.

Double Vision:
Double vision may occur if the BTA material migrates into the region of muscles that control movements of the eyeball.

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

Other Eye Disorders:
Functional and irritive disorders of eye structures may rarely occur following BTA injections.

Blindness:
Blindness is extremely rare after BTA injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. In a period of 10 years of BOTOX® 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.

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Allergic Reactions:
As with all biologic products, allergic and systemic anaphylactic reactions may occur. Serious systemic reactions including shock (anaphylaxis) may occur in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment. It is important to notify your physician of any previous allergic reactions. Allergic reactions may require additional treatment.

Antibodies to BTA:
Presence of antibodies to BOTOX® may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to BTA is unknown.

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

Skin Disorders:
Skin rash, itching, and swelling may rarely occur following BTA 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 BTA.

Migraine Headache Disorders:
BOTOX® has been used to treat forehead muscle groups that are involved in migraine headache. Patients are informed that results of BTA treatment for migraine headaches may be variable and improvement in this disorder may not occur following BTA treatments.

Unsatisfactory Result:
There is a possibility of a poor or inadequate response to BTA injection. Additional BTA injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity. Unsatisfactory results may NOT improve with each additional treatment.

Long-term Effects:
Subsequent alterations in face and eyelid appearance may occur as a result of aging, weight loss, weight gain, sun exposure, pregnancy, menopause, or other circumstances not related to BTA injections. BTA injection does not stop the aging process or produce permanent tightening of skin. Future surgery or other treatments may be necessary.

Pregnancy and Nursing Mothers:
Animal reproduction studies have not been performed to determine whether BTA causes fetal harm. It is not known whether BTA can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive BTA treatments. Please inform your surgeon prior to proceeding if you are pregnant or think you could be or if you are nursing.

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

GENERAL RISKS OF SURGERY

Infection:
Infection, although uncommon, can occur after procedures. Should an infection occur, additional treatment including antibiotics, hospitalization, or surgery may be necessary. It is important to tell your surgeon of any other infections, such as a history of methicillin-resistant Staphylococcus aureus (MRSA) infections, an open wound, recent upper respiratory infection/pneumonia, ingrown toenail, insect bite, tooth abscess, or

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urinary tract infection. Infections in other parts of the body may lead to an infection in the areas with ski breakage. Infections can result in more extensive scarring and predispose to revision surgery.

Scarring:
All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, this surgery will result in long, prominent scars that are permanent. Abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color from the surrounding skin. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). These scars may become raised, red, or discolored in the first few weeks/months, but usually settle down over time. However, some patients are prone to "hypertrophic" or "keloid" scars, which are prominent, raised, red scars that do not settle. Further treatments with medications and/or surgery may be required.

Firmness:
Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may be necessary.

Skin Sensitivity:
Itching, tenderness, or exaggerated responses to high or low temperatures may occur after surgery. Usually, this resolves during healing, but in rare situations, it may be chronic.

Damage to Deeper Structures:
There is the potential for injury to deeper structures including nerves, blood vessels, lymphatics and muscles around the area that the injection is occurring. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

Pain:
You may experience pain after your procedure. Pain of varying intensity and duration may occur and persist after the procedure. If you are a chronic pain patient followed by a pain therapy practitioner, you may be asked to see this practitioner preoperatively to assist you in the management of your pain disorder in the postoperative period. Chronic pain may occur very infrequently because of nerves becoming trapped in scar tissue or because of tissue stretching.

There are nerve endings that may become involved with healing scars from any procedure. While there may not be a major nerve injury, the small nerve endings may become too active during the healing period, producing a painful or oversensitive area due to the small sensory nerves involved with scar tissue. Often, massage and early nonsurgical intervention resolve this. It is important to discuss pain management with your surgeon.

Drug Reactions:
Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important for you to inform your physician of any problems you have had with any medication or allergies to medication, prescribed or over the counter, as well as medications you now regularly take. Provide your surgeon with a list of medications and supplements you are currently taking.

Persistent Swelling (Lymphedema):
Persistent swelling can occur following surgery.

ADDITIONAL ADVISORIES

Medications and Herbal Dietary Supplements:
There are potential adverse reactions that occur as a result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with the forming of blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting such as Plavix®, Coumadin®, Xarelto®, Effient®, or Pradaxa®, discuss

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management of these medications around the time of procedure with your plastic surgeon. Your plastic surgeon may sometimes coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a medical condition, do not stop them without discussing it first with your plastic surgeon. Stopping these medications abruptly may result in a heart attack, stroke, or death. Be sure to check with your physician about any drug interactions that may exist with medications that you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room.

Sun Exposure – Direct or Tanning Salon:
The effects of the sun are damaging to the skin. Exposing of skin to the sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use of sun block or clothing coverage.

Travel Plans:
Any surgery holds the risk of complications that may delay healing and your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired timeframe. Allow at least 7-10 days to travel via airplane.

Long-term Results:
Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your surgery.

Future Pregnancy and Breastfeeding:
This surgery is not known to interfere with pregnancy. If you are planning a pregnancy, your breast skin may stretch and offset the results of surgery. You may have more difficulty breastfeeding after this operation.

Mental Health Disorders and Elective Surgery:
It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery, and are often stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

ADDITIONAL SURGERY NECESSARY (Re-Operations):
There are many variable conditions that may influence the long-term result of injections. It is unknown how your tissue may respond. Additional injections necessary to achieve the desired cosmetic result desired. Should complications occur other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are associated with this procedure. Other complications and risks can occur but are less common. 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. In some situations, it may not be possible to achieve optimal results with a single procedure. You and your surgeon will discuss the options available should additional treatments be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology, and lab testing.

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PATIENT COMPLIANCE:

Follow all physician instructions carefully; this is essential for a successful outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activities need to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation, and the need to return to surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

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), including no surgery. 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 plastic surgeon may provide you with additional or different information that is based on all the facts in 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

CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. Quinton Chivers and such assistants as may be selected to perform **Botulina Toxins Injection.**

   I have received the following information sheet: **Botulina Toxins Injection.**

2. 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.

3. I understand what my surgeon can and cannot do and understand that 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.

4. 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.

5. For purposes of advancing medical education, I consent to the admittance of observers to the procedure room.

6. I authorize the release of my Ontario Health Insurance Plan number to appropriate agencies for legal reporting and medical-device registration, if applicable.

7. I realize that not having the procedure is an option. I opt out of having this procedure _____.

8. 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 (1-8).
I AM SATISFIED WITH THE EXPLANATION.

_____

Patient or Person Authorized to Sign for Patient

Date/Time _____ Witness _____

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