HIGHLY ARTISTIC
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INFORMED CONSENT – NEUROLYTIC INJECTIONS

Botox®, Dysport®, Myobloc®

INSTRUCTIONS

This is an informed-consent document which has been prepared to help us inform you concerning our neurolytic agent injection, its risks, and alternative treatments. We require that you read this information carefully and completely before signing the consent for this procedure as proposed by our clinic.

GENERAL INFORMATION

Clostridia botulina bacteria produce a class of chemical compounds known as "toxins". The Botulina Type A or B 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.

Neurolytic agents have 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. Other areas of the face and body such as crows feet wrinkles and neck bands may be treated in an "off-label" fashion. Neurolytic agents have also been used to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

Neurolytic 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. Neurolytic agents cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups. neurolytic 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.

RISKS of Neurolytic 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 neurolytic injections. Additional information concerning neurolytic injection may be obtained from the package-insert sheets supplied by the corresponding companies.

Bleeding and Bruising- It is possible, though unusual, to have a bleeding episode from a neurolytic injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper neurolytic 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. Do not take these for ten days before or after neurolytic 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.

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Corneal Exposure Problems- Some patients experience difficulties closing their eyelids after neurolytic 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.

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

Migration of Neurolytic Agent- The medicine may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects. Neurolytic agent has been reported to cause swallowing problems in patients treated for spastic muscle disorders of the cervical region (cervical dystonia).

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

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

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

Other Eye Disorders- Functional and irritative disorders of eye structures may rarely occur following neurolytic injections.

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

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 neurolytic injection.

Pain- Discomfort associated with neurolytic injections is usually short duration.

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

Antibodies to BOTOX- Presence of antibodies to neurolytic agents may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to neurolytic agents is unknown.

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

Skin Disorders- Skin rash, itching, and swelling may rarely occur following neurolytic injection.

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 from neurolytic injections.

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

Unsatisfactory Result- There is the possibility of a poor or inadequate response from neurolytic injection. Additional neurolytic 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 neurolytic injections. Neurolytic 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 neurolytic agent could produce fetal harm. It is not known if neurolytic agents can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive neurolytic treatments.

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

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

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Please carefully review your health insurance subscriber information pamphlet.

ADDITIONAL TREATMENT NECESSARY

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of neurolytic injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with neurolytic 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 neurolytic injection may involve several charges. This includes the professional fee for the injections, follow-up visits to monitor the effectiveness of the treatment, and the cost of the neurolytic material itself. It is unlikely that neurolytic injections to treat cosmetic problems would be covered by your health insurance. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome Additional costs of medical treatment would be your responsibility should complications develop from neurolytic injections. **In signing the consent for this surgery/procedure, you acknowledge that your have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

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). 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 which is based on all of the facts 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.

We require that you read the above information carefully and have all of your questions answered before signing the consent. A copy of this is also available on our website http://www.highlyartistic.com