

CONSENT TO BOTULINUM TOXIN TREATMENT

Rationale

I am aware that when a small amount of purified botulinum toxin (BOTOX) is injected into a muscle it causes weakness or paralysis of that muscle. This appears in 2-6 days and usually lasts 3-4 months but can be shorter or longer. Repeated injections are necessary to maintain its effects.

Frown lines between the eyebrows are due to contraction of small muscles around them between the eyebrows. Injecting BOTOX into this area will result in the relaxation of these muscles causing temporary improvement or disappearance of the lines and wrinkles that the targeted muscle action produced.

Similarly, crow's feet and horizontal forehead lines can also be improved by the injection of BOTOX into the area that will weaken the muscles and cause improvement in wrinkles in this area. Lines and wrinkles at rest may not improve with BOTOX alone since BOTOX is designed to treat lines caused by facial muscle action.

I understand that Botulinum A Toxin (Botox) injection has been FDA approved for use in the cosmetic treatment for glabellar (frown) lines only – the wrinkles between the eyebrows.

I request treatment by the doctor for the following areas: _____

Results and Postoperative Care

- ❖ I understand that I will not be able to move the targeted muscles as vigorously while the injection into this area is effective, but that it will reverse itself after a period of months, at which time retreatment is appropriate.
- ❖ I understand that I must stay in the erect posture and that I must not manipulate the area of injection for 3-4 hours post-injection. I will not wear any tight-fitting headgear for 4-6 hours after receiving BOTOX injections
- ❖ I understand that it would be advantageous for me to forcibly and repeatedly use the treated muscles in 3-4 hours post-injection to get a better result.

Risk and Complication

This list is not meant to be inclusive of all possible risks associated with Botox as there are both known and unknown side effects associated with any medication or procedure.

The possible side effects of Botox include but are not limited to:

- I understand there is a risk of swelling, rash, headache, local numbness, pain at the injection site, bruising, respiratory problems, and allergic reaction.
- Infections can occur which in most cases are easily treatable but in rare cases a permanent scarring in the area can occur.
- Most people have lightly swollen pinkish bumps where the injections went in, for a couple of hours or even several days.

- Although many people with chronic headaches or migraines often get relief from Botox, a small percent of patients get headaches following treatment with Botox, for the first day. In a very small percentage of patients these headaches can persist for several days or weeks.
- Local numbness, rash, pain at the injection site, flu like symptoms with mild fever, back pain.
- Respiratory problems such as bronchitis or sinusitis, nausea, dizziness, and tightness or irritation of the skin.
- Bruising is possible anytime you inject a needle into the skin. This bruising can last for several hours, days, weeks, months and in rare cases the effect of bruising could be permanent.
- While local weakness of the injected muscles is representative of the expected pharmacological action of Botox, weakness of adjacent muscles may occur as a result of the spread of the toxin.
- I understand more than one injection may be needed to achieve a satisfactory result.
- Another risk when injecting Botox around the eyes included corneal exposure because people may not be able to blink the eyelids as often as they should to protect the eye. This inability to protect the eye has been associated with damage to the eye as impaired vision, or double vision, which is usually temporary. This reduced blinking has been associated with corneal ulcerations.
- BOTOX treatment of frown lines can cause minor temporary droop of one eyelid or eyebrows in less than 3% of injections. This usually lasts 2-4 weeks. There are medications that can help lift the eyelid, however, if the drooping is too great the eye drops are not that effective.
- I will follow all aftercare instructions as it is crucial I do so for healing. As Botox is not an exact science, there might be an uneven appearance of the face with some muscles more affected by the Botox than others. In most cases this uneven appearance can be corrected by injecting Botox in the same or nearby muscles. However in some cases this uneven appearance can persist for several weeks or months.

Occasionally, numbness of a small area on the forehead lasting 2-3 weeks, bruising, asymmetry, twitching, and transient headache have also occurred. Other reported side effects have included nausea, flu-like symptoms, double vision, and elevation of the outer part of the eyebrow, swelling of the lower eyelid, drooping of an eyebrow, and muscle weakness.

- The FDA has placed a black box warning on BOTOX regarding the potential for distant spread of the toxin to sites beyond the injection site and to weaken or paralyze muscles used for breathing or swallowing. In adults, most reports of distant spread of botulinum toxin occurred in patients who received BOTOX for unapproved uses in muscle spasticity or for approved use in cervical dystonia. The agency noted that it has identified “no definitive serious adverse-event reports of distant spread of toxin effect associated with dermatologic use of BOTOX” for cosmetic purposes at approved doses

Additionally

- The number of units injected is an estimate of the amount of Botox required to paralyze the muscles.
- I understand there is no guarantee of results of any treatment. I understand the regular charge applies to all subsequent treatments.
- I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost
- Although results are frequently dramatic, as high as 10% of patients may not respond for unknown reasons or the treatment may not last as long as usual. Repeated sessions may be necessary to obtain desired results.

Photographs

I authorize the taking of clinical photographs and their use for scientific purposes both in publications and presentations. I understand my identity will be protected.

Pregnancy, Nursing, Neurologic Disease, and Medications

I am not aware that I am pregnant nor that I have any significant neurologic disease. If taking amino glycoside antibiotics, Penicillin, or Quinine, these medications may potentate the effect of BOTOX Cosmetic.

Payment

I understand that this procedure is cosmetic and that payment is my responsibility.

I have read the above consent form and understand all of it. The doctor has answered all my questions to my satisfaction. I understand the risk and complications and give my informed consent for this procedure.

Patient Signature

Date

Print Name

Date