

BEST PRACTICES FOR: Injecting Botox

CONTAINS: Emerging Trends Expert Discussions Recommendations Technique Comparisons

BEST PROCEDURES AND PRACTICES

Botox Best Practices

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Published by: International Association for Physicians in Aesthetic Medicine (IAPAM)

Web: www.iapam.com Tel: 1-800-219-5108 x704

Rev. 062817

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Introduction

Since first introduced to the medical community in 1989, as a treatment for eye muscle disorders, administering of Botulinum Toxin Type A: Botox® and similar neurotoxin injectables, has now become the most popular <u>non-invasive</u> aesthetic medical procedure performed worldwide.

Unfortunately, such pervasive market growth has lead to the undesired reality that physicians and non-medical professionals mistakenly think that all they need to do to capture a percentage of this market for their practice, is to simply hang out a sign and 'start injecting.'

Therefore, to assist physicians in **successfully adding aesthetic medicine offerings to their practice**, this report offers the new aesthetic medicine physician some "insights and best practices" from seasoned experts, in the use of Botulinum Toxin Type A (Botox® Cosmetic, Dysport®).

Overall, contributors agree that, "there is no substitute for expert training and extensive experience."

According to Allergan, the maker of Botox[®], "OnabotulinumtoxinA (BOTOX[®]) is a medical product containing tiny amounts of the highly-purified botulinum toxin protein refined from the bacterium. The product is administered in small injections to reduce specific muscle activity by blocking the overactive nerve impulses that trigger excessive muscle contractions or glandular activity."



It was originally approved by the FDA in 1989 and has since been approved for treatment of many cosmetic and medical conditions. It should also be noted that Botox® is a prescription medicine, and therefore can only be provided by a healthcare provider who can prescribe drugs, like a physician. Often physicians will delegate to other healthcare providers who are licensed to inject FDA controlled substances, like physician assistants and nurses.

One thing to keep in mind is that the effects are only temporary; they disappear after 4-6 months. On the plus, side, this is a quick procedure that typically only takes 15-20 minutes, there is no recovery time needed, and as you age, you can easily adjust the location and amounts to meet your patients anti-aging goals.

Botox® and similar products are specialized tools in the physician's anti-aging arsenal, so it is critical that physicians entering this field have comprehensive hands-on Botox® training to ensure the most successful patient outcomes.

How Botox[®] Cosmetic Works



Botox® Cosmetic's popularity will account for the majority of your aesthetic patient base, so if you want to add aesthetics to your practice, you must master the injection of Botox® (or other FDA approved Botulinum Toxins, like Xeomin® and Dysport ®). If you are new to offering Botox®, please make sure you complete a comprehensive hands-on CME-approved training program. If you are an experienced injector, it is important to stay up to date with the latest Botox® injection techniques.

We all use our facial muscles a lot. All of that talking and emoting and eating and everyday living gives the facial muscles a great workout all day long. This is great for the health of those muscles but can cause problems with your skin. For example, frown lines, the little lines that show up between your eyebrows, can result if you are someone who scrunches your face up when you are unhappy or very focused.

For the "Botox® Virgin," you will need to be prepared to explain how Botox® works on the face. It is important that you understand where the most requested areas are for injections, they are: forehead lines, crow's feet around the nose, and those "angry 11's" between your eyebrows.

One of the most requested procedures is to remove the wrinkles in the forehead. Many times these lines are genetic and you can see them in children as well as adults (Reminder: never inject Botox® Cosmetic in anyone under 18!). Other times, they are seen in people who are very expressive with their face. It's important to ask your patient what they want, some people don't want any wrinkles in their forehead, others are fine with wrinkles, they just don't want deep looking ones. You can provide any of these results by increasing or reducing the amount of the Botulinum toxin you inject in the muscles.

Allergan has done a wonderful job educating the public on the "angry 11's," these are the lines that appear between your eyebrows. Again, these can be genetic or caused by excessive facial movements in expressive people. Not everyone has these, but most people do not want to look angry, so if they have them, they most likely want to get rid of them! This is an easy home-run procedure, which can be done quickly, and looks great!

Crow's feet (which are also called smile lines) are the small lines that occur around the eyes as a result of the skin wrinkling to accommodate smiling and squinting-they are the third most popular region of the face. You may find that men are fine with having these lines, but women generally want them gone! Again, this is a quick procedure that typically erases the wrinkles between 3-10 days.



It is also important to tell your patients that cosmetic injectables only treat lines that are caused by muscle movements. Explain that lines and wrinkles caused by sun damage will not respond to these treatments. As well, some patients think the deep wrinkles around their mouths (marionette lines) and nose (nasal labial fold) can be treated with Botox®, unfortunately they cannot. One will need to use a dermal filler like Allergan's Juvederm/Voluma, Merz's Boletero, or Galderma's Restylane.

Botox® vs Botox® Cosmetic: What is the Difference?

You have probably already noticed that we have been discussing Botox® and Botox® Cosmetic. There are actually two types of Botox®: Botox® and Botox® Cosmetic. They are both technically onabotulinumtoxinA, but each have their own FDA approvals. As you will see the approved uses for Botox® Cosmetic revolve around facial aesthetics, whereas the approvals for Botox® are more medically based. For example currently, Botox® Cosmetic is FDA-approved for:

- Treatment to temporarily improve the appearance of both moderate to severe frown lines between the brows and crow's feet in adults.
- Improving the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults for a short period of time (temporary).
- Improving the look of moderate to severe crow's feet lines in adults for a short period of time (temporary).

Botox® has the following FDA-approved indications:

- to treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents (urge urinary incontinence), a strong need to urinate right away (urgency), and urinating often (frequency) in adults 18 years and older when another type of medicine (anticholinergic) does not work well enough or cannot be taken
- to treat leakage of urine (incontinence) in adults 18 years and older with overactive bladder due to neurologic disease who still have leakage or cannot tolerate the side effects after trying an anticholinergic medication
- to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years or older
- to treat increased muscle stiffness in elbow, wrist, finger, and thumb muscles in people 18 years and older with upper limb spasticity
- to treat increased muscle stiffness in ankle and toe muscles in people 18 years and older with lower limb spasticity
- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in people 16 years and older
- to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older
- to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis)





Botox® Best Practices: Patients, Procedures and Practice Considerations

Consensus Recommendations

- 1. The patient consultation undertaken prior to the procedure is critical to a successful outcome for both the physician and the patient.
- 2. **Before** and **after** photographs are critical, they demonstrate to the patient the changes that have occurred 'post-procedure.'
- 3. Know your anatomy. This is the key to proper injection placement always inject based on anatomy.
- 4. One must understand the details of how Botox[®], or similar injectables, interacts with the muscles, as well as how to achieve beautiful aesthetic results by decreasing muscle contraction in a designed and organized fashion.
- 5. Always keep an 'antidote' on hand just in case a patient develops post-injection ptosis.
- 6. Watch someone else work and receive "hands-on training."
- 7. Ice is generally employed to minimize bruising, but the use of topical or other anesthetic varies from physician to physician.
- 8. Never oversell the longevity of the effect of Botox[®]. Tell patients that, on average, the Botox[®] will last about three months.
- 9. Always encourage a brief, post-procedure visit, about 10 days afterwards, especially for new patients. This visit allows the patient and doctor to assess the results, and generally cements the relationship for repeat visits.



Patient Expectations and Concerns

Before and After Consultation

Before

Share with the patient that the best use for Botox® is preventative - NOT reparative. By starting Botox® every 4 months in your late 20's or early 30's, patients effectively avoid the years of scrunching and frowning which inevitably lead to furrows. Botox® is, indeed, "a stitch in time."

Always take your time during the initial consultation to "read the patient." Realistic expectations, as well as what the patient perceives to be the "problem to be fixed," are crucial to happy outcomes.

Make it a point to study each face prior to injecting, and go through the exercise of having the patient make a series of movements that allow the physician to see exactly how the muscles interact.

Show patients in the mirror what specifically they can expect to have improved. Have a patient smile big - note the wrinkles around the eyes, both at rest and during a smile, then show them what will be different after the Botox® injection, i.e. "when one smiles, no wrinkles will bunch up here at said discrete location."

Always use *Before* and *After* photos - they can be a patient's and a physician's best friend, since many people forget what they looked like prior to their treatment.

Ask patients to avoid any medicine that may increase their potential for bruising for at least two weeks prior to injections (i.e. aspirin, ibuprofen, etc.).

After

If a patient is unsure whether or not the desired effect has been achieved, give them a hand mirror and ask them to move only the muscles involved (i.e. raising the eyebrows, frown lines, etc.). Most patients will try to squint as hard as possible and therein note some muscle activity outside the range of treatment, which is very normal. Remind them that the treated muscles are not contracting and thus he/she is using additional muscles to 'try' to move the others.

Botox® is not active 'instantly'. It can take up to 4 days for the full effect to be realized. Patients need to know this so they do not start to worry the next day or two when the results have not fully begun.

Always contact the "first time" patient at the 2-week mark. Contact can be in person or by phone, but the doctor or his/her staff need to make sure that the patient is satisfied, because if they are not they are likely to migrate to an alternate physician.

Equally, by asking every patient to return in 10 days to 2 weeks - post injection, the physician can assess their result. This helps the doctor to constantly fine tune his/her technique. [Dr. Foxx noted that he finds that only about 1/3 of the patients return to the office, post procedure, and he makes the assumption the other two-thirds are happy with their results].



Procedures

Product Preparation

Do not try to extend the economic value of the product be diluting it further than recommended. It is an occasional mistake of physicians, and generally leads to "unhappy" patients.

Reconstitute with PRESERVED saline and use a 1:1 reconstitution (1.1 cc per vial of Botox®). It makes the math easier, is less painful for the patient and does not affect the efficacy of the product.

Store reconstituted Botox® in the fridge for up to 6 weeks. Again, the efficacy has been proven to hold. However, do NOT allow the product to freeze/thaw/freeze/thaw. This cycle will break the disulphide bond in the product's molecule and decrease its efficacy.

Clinical Implications

Avoid superficial veins (particularly around the eyes, e.g. the sentinel vein), as this will lead to excessive bruising.

Apply direct pressure to the injection sites to minimize post-injection bruising.

For those with limited experience, when injecting in the forehead, place the needle through the periosteum (the covering of the bone). The doctor will feel a 'crunch,' after which, retract the needle back a few millimetres. This will ensure that one does not inject subperiosteally, which can significantly increase the risk for ptosis (eyelid droop).

To achieve the nice brow arch in the lateral thirds of the eyebrows, maintain the injections from mid-pupillary line to midpupillary line. It is acceptable to inject slightly beyond these areas and still achieve the same effect.

Know your anatomy. This is the key to proper injection placement. Also, while landmarks are FINE, the anatomy tells the story and is the physician's best guide. Therefore, one will need to repeatedly ask the patient to: "frown, relax, frown, relax," as one is injecting, to locate the muscles EXACTLY before commencing.

Incorrect land-marking in the upper face will usually only cause a cosmetic deficit (except for lid pstosis, which is rare), but lower face errors will cause functional deficits that can last for 6 weeks. Proper muscle isolation and identification is critical in the lower face. If one does get a functional deficit, "hold the patient's hand," but do NOT chase it "to even things up" this always makes it worse.

Treat the frontalis muscle conservatively - it is the only muscle in the upper face that lifts, so over-treatment can easily lead to brow ptosis. It is much better to have to add a few units at the 2-week mark than to over treat in the beginning.

One does not want to hit periosteum, but remember that the frontalis lies over corrugators, so if one injects the lateral corrugators and the superior medial corrugators too superficially, one will cause a brow ptosis.

Be cautious in dosing for the lateral corrugators and superior medial corrugators, i.e. if debating between 3 or 4 units, opt for 3 because overdosing in these areas can lead to higher diffusion into the frontalis and a medial brow ptosis.



Other Techniques and Emerging Trends

Use Botox® when performing scar revisions or excisions, in areas such as the glabella to facilitate healing with minimal tension on the wound (with no muscle contraction, there is minimal tension on the healing incision).

Other Practice Management Considerations

Never oversell the longevity of the effect of Botox[®]. Tell patients that, on average, the Botox[®] will last about three months. Many patients can get up to 4-6 months, and are exceedingly pleased. Those that eke out three months are not disappointed and gladly return. The longevity is indeterminate and very individualized.

If a patient asks for multiple areas to be treated but can not afford all, make sure that at least one area is "done well." When a patient sees the results, they will likely be back with additional finances.

Be sure you know what you are doing before starting to try higher risk injections or switching to Dysport[®], because news of bad results can travel faster than your reputation can recover, even if you are considered an expert in the field of Botox[®] injections.

Physician Training

Training should provide an in-depth discussion of facial anatomy, and how to evaluate muscle movements to decide on product placement. Learn from the experts, like a board certified dermatologists.



One must understand the details of how Botox® interacts with the muscles; the natural variations of the musculature of the face, as well as how to achieve beautiful aesthetic results by decreasing muscle contraction in a designed and organized fashion.

Effective training programs should also offer preparation on how to effectively handle any adverse events, both from a medical standpoint, as well as helping the patient to understand the situation.

Marketing assistance is also very valuable, and good training should discuss how to market one's services.

Before picking up a needle, satisfy yourself that your understanding and knowledge of facial musculature is thorough. To do that, delve deeply into anatomy texts and watch surgeries.

Adopt the experts' technique for handling the product, diluting it, etc.

Moreover, any effective training program should provide tips on how to give an effective consultation with each patient. This should include a thorough evaluation of the individual characteristics of the face, a comprehensive discussion with the patient regarding risks and benefits, and most importantly, how to appropriately set and manage realistic patient expectations.

Stay Informed: For example, read special sections in professional literature, such as the Plastic and Reconstructive Surgery Journal, when newly published.

Watch someone else work and receive "hands-on training." Every injector interested in honing his/her technique should take every opportunity to watch someone else work.





Effective Pain Management for Botox® Patients

Consensus Recommendations

- 1. Universally, experts agree that the critical factor in minimizing discomfort and bruising is *technique*.
- 2. However, topical anesthetic can be used to minimize, but not extinguish, the pain associated with subcutaneous injections.
- 3. Ice is generally considered the best tool to minimize bruising.
- 4. Other tools in the physicians' arsenal to minimize pain are size of needle (32 gauge is recommended) and ensuring the minimal volume is injected (e.g. dilute the Botox® at 2.5 cc per bottle =4u/.1 cc).
- 5. Finally, for a select group of physicians and patients, ice and topical anesthetic completely take a back seat to a "gentle" hand.



General Techniques: Anesthesia, Needles/Syringes and Ice

Proponents of Anesthesia and Ice

Use ice around areas that are very vascular for a minute prior to injection (i.e. around the eyes) especially for patients with thinner skin, to minimize bruising.

Adopt the technique of using a topical anesthetic (and giving it enough time to work), and afterward, begin the preinjection consultation. Whether a repeat patient or a new patient, apply a topical anesthetic and leave it on for about 15 minutes, then begin injecting. Ask the patient to move their muscles and then make an appropriate mark with a white pencil. Prior to injecting, apply a small packet of ice for 15 seconds or so to each area.

Use iced gel packs, which hold the low temperature well, and don't melt. Further, they may be able to be chilled slightly colder than regular ice.

If one leaves the cold pack on long enough the tissue chills very well, however, the patient may find the cold intolerable. Interestingly, that is the ideal time to quickly inject the Botox®, which should only take a few seconds to inject in small volumes. The ice chills the dermis and subcutaneous tissues, which topical anesthetics do not.

Use topical BLT anesthetic (benocaine, lidocaine, tetracaine), with cold packs only with those very few patients who are extremely intolerant of any discomfort, as it minimizes the discomfort of the 32 gauge needle at the skin level only.

The cold usually works well enough for 90% of patients. A minority of patients don't like the feeling of ice packs and just take the Botox® 'straight'." Moreover, "ice compresses" put the tiny vessels in spasm and make them harder to injure especially in the glabellar area. Unfortunately, this does not apply so much to the veins at the lateral orbicularis.

Technique rather than Anesthetic

Some physicians have been disappointed with topical anesthetic creams and ice application.

Be gentle with your technique and the patients will have a remarkably comfortable experience.

"Talkesthesia" works well, and keep the patient comfortable and relaxed. Tell them before doing anything, and apply pressure near the needle as a distraction.

Occasionally use ice to vasoconstrict. If one applies the ice to another area with the assistance of a nurse, it can also work well as a distraction.

Most patients do well with cues for relaxed breathing, squeezy balls, coupled with tiny gauged needles and 2 cc dilution of Botox®.



In Both Camps

Give patients a variety of options.

Use both a topical anaesthesia and ice for admittedly "wimpy" patients.

For the average patient, use ice, but in a special way. Place a single half moon shaped piece of ice into the finger of a glove and hold it in place until the patient says 'cold'. This gives targeted anaesthesia and vessel spasm with minimal discomfort (and perhaps less bruising as well).

Some patients have a higher tolerance to the needle coupled with a cold sensitivity to the ice, which they don't like. Also, many busy people do not want to wait 20-40 minutes for the anaesthetic cream to work.

Use the ice because it is immediate and doctors find that the topical cream EMLA (Eutectic Mixture of Lidocaine and Prilocaine) takes longer. Moreover, the ice causes vasoconstriction of small arteries and veins which diminishes the chance of capillary disruption and subsequent bruising.

Also, the key is small needles. Use 32 gauge, which are tiny, and minimize discomfort significantly.

Topicals for Botox® do not really work and it is simply because when one is giving the injection, the needle goes deeper than the cream can penetrate. Having said that, go patient by patient, and always offer the cream, but let them know that it does not really make much difference for an injectable. If one is getting a laser treatment, which is much more superficial, topicals are great. But for an injectable, not as much.



Botox® vs. Dysport®: An Expert Discussion

Introduction



Given the FDA approval of the new botulinum toxin A product, Dysport®, in 2009, a competitor to the well established Botox® Cosmetic, the IAPAM recently queried its members and physicians with comprehensive experience in the use of botulinum toxin injectables, to develop a report comparing these two products. This discussion is considered a critical element in the IAPAM's comprehensive botox training programs.

Dysport® has been studied in Europe since 1988, has been available for use outside the US since 1991, and was recently approved for cosmetic use in the US in May 2009. Botox® has been manufactured and studied in the

US since 1985, and was officially approved by the FDA for cosmetic use in April 2002.

Botox® and Dysport® are not interchangeable because the products are dosed and injected differently. To assist physicians in selecting the best product for each patient's need, a number of physicians have offered their expertise in a comparison of Botox® Cosmetic and Dysport®.

Consensus Recommendations

- The manufacturing process is slightly different, which leads to some potential, subtle differences in clinical practice.
- Some people feel that Dysport® may provide a slightly faster onset of action (24 hours versus 72 hours for Botox®).
- It is important to know that the unit size of Dysport® is smaller than the unit size of Botox®. According to the FDA, it takes a minimum of two times more units of Dysport® to get the same effect as Botox®. So, if the patient has opted for Botox® and received 20 units, the same patient will need 40 units of Dysport® for an equivalent treatment. (Cost for Botox® @ \$9.99 per unit vs. Dysport® @ \$3.99 per unit). However, among physicians, it has been debated, yet somewhat accepted, that 1 unit of Botox® is "similar" to 2.5 or 3 units of Dysport®.
- Initially, doctors were anecdotally saying that "one Botox® unit should equal 2.5 Dysport® units." However, most seasoned physicians now believe that "a 3:1 ratio is a more accurate dosage in the quest for equipotent treatment between the two drugs."
- Dysport® has been shown to "drift" or diffuse more than Botox®, increasing the chances of an accidental droopy eyelid or unintentional relaxation of a neighboring muscle due to diffusion of the product.



Discussion

Jennifer Linder, M.D.

"I have tried Dysport® on myself and on one staff member, on whom I did as split face. Definitely no faster onset. I personally think mine, which was done full face, is wearing off faster and it definitely had a wider diffusion. I do think that due to the dilution ratio and the different technique for injection, using Dysport® is like learning a whole new language as there is no direct conversion.

Because of the variability in the size of the molecules in Dysport® there is variability in the diffusion ratio. I was one of 30 doctors nationwide that Allergan brought in for the medical advisory board for comparison of Botox® and Dysport®. In general, they are <u>very different</u> and Botox® is more consistent and precise. My biggest concern, as an experienced practitioner, is if an inexperienced office has both products it might be really easy to mix up the ratios and put too much Botox® in someone or too little Dysport®. I suspect complication ratios may increase.

For now, I am not planning on using [Dysport] on patients, as it currently is not worth the cost savings to spend the time trying to convert patients over to a new product."

Dr. Steven Jepson

"Botox® Cosmetic is a purified protein designed to relax the muscle movements in the face that can cause wrinkles. It is the #1 cosmetic procedure in the world, has an excellent safety history, and continues to grow in popularity year after year. It is the most popular procedure at my office. The most commonly injected area is the "mad look" between the eyebrows. Relaxing this "scowl" can help you look more relaxed, refreshed, and younger. Other common wrinkly areas that can be relaxed include the forehead lines and the crows feet wrinkles around the eyes. Tiny needles are used, so the procedure is associated with very little discomfort. The effects of Botox® last anywhere from 3-5 months and once it wears off, you can choose to continue injecting for ongoing effect, or allow your wrinkles to return to their baseline.

Dysport® is actually not new. It's simply new to the United States. It has been available in Europe for over 10 years. It is very similar to Botox®... but it has a tendency to spread further from the injection site than Botox® does. What this means is that muscles you don't want relaxed may relax due to the "spread" of the Dysport®. Therefore, with Dysport® injections, there is a higher risk for problems with over-relaxed droopiness and a higher incidence of the "plastic" too-relaxed look. This is the main reason I am holding off using it for now. In fact, even though Dysport® has been available alongside Botox® Cosmetic in Europe for over 10 years, Europeans still favor Botox® 5 to 1 (85% of injections are done with Botox®)."



Conclusions

The preceding report offers **a wealth of clinical and practice information** from physicians who have <u>decades of experience</u> in the delivery of cosmetic injectables. It offers both the physician new to cosmetic injectables, and the seasoned professional, "industry best practices" to enhance their clinic's current offerings.

However, it seems clear that the key to successfully adding aesthetic medicine procedures into one's practice is to "**be informed**" and to begin by engaging in "**hands-on training**."

Faculty member of the IAPAM, dermatologist Dr. Jennifer Linder concludes,

"when looking for a Botox® training program, one should look for a comprehensive curriculum that covers the entire procedure: from initial consultation through to satisfied patient. First and foremost, ensure that the person who trains the physician is very experienced so that they can answer all of the doctor's questions. I personally believe that a tiered approach is important to becoming as proficient as possible with the injection of Botox®. The first tier should be an introduction to the basics of the treatment. One should be comfortable performing within this tier prior to advancing to some of the more advanced techniques, such as treatment to the lower half of the face. All training should include didactic as well as hands-on teaching methods."



About the International Association for Physicians in Aesthetic Medicine (IAPAM)

The International Association for Physicians in Aesthetic Medicine is a voluntary association of physicians and supporters, which sets standards for the aesthetic medical profession. The goal of the association is to offer education, ethical standards, credentialing, and member benefits. IAPAM membership is open to all licensed medical doctors (MDs) and doctors of osteopathic medicine (DOs). Information about the association can be accessed through IAPAM's website at <u>www.IAPAM.com</u>.

Additional information about the Aesthetic Medicine Symposium, the medically-supervised Clean Start Weight Loss Training, and other educational programs can be accessed through <u>www.AestheticMedicineSymposium.com</u> or by contacting:

International Association for Physicians in Aesthetic Medicine (IAPAM) 1-800-219-5108

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