

Consensus Recommendations on the Use of Botulinum Toxin Type A in Facial Aesthetics: Slide Presentation

Off-Label Statement: It should be noted that the results reported in this slide presentation refer to the Allergan formulation of botulinum toxin type A (Botox[®], Botox[®] Cosmetic, Vistabel[®]) and cannot be generalized to other formulations or serotypes of botulinum toxin. Botulinum toxin type A is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients less than or equal to 65 years of age. All other uses are considered off-label. The full prescribing information should be viewed prior to using any products discussed here.

The contents of this slide presentation are based on a supplement to the *Journal*, prepared and paid for with an unrestricted grant from Allergan, Inc. This slide presentation does not constitute product or sponsor endorsement by the *Journal*.

Consensus Recommendations: The Need for Guidelines

- ▶ Lack of consistent guidelines for areas other than glabellar lines
 - Inconsistencies in: drug preparation and handling, syringe type, dosing, injection sites, patient selection, and gender differences
- ▶ Some room for improvement in patient and physician satisfaction
- ▶ Discrepancies in publications regarding techniques and methods

Consensus Conference Format

▶ Program

- 1-day conference in April 2004
- Literature review followed by discussion sessions
- Approximately 30 key opinion leaders in dermatology and plastic surgery

▶ Topics

- Multiple treatment areas (ie, glabellar lines, horizontal forehead lines, crow's feet, platysmal bands, bunny lines, perioral area, dimpled chin)
- Best practices

▶ Discussion

- Moderated by Jeffrey A. Fisher, MD, Health Learning Systems
- Polling and consensus using an electronic audience response system

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Consensus Recommendations on the Use of Botulinum Toxin Type A in Facial Aesthetics



Consensus Recommendations on the Use of Botulinum Toxin Type A in Facial Aesthetics: Supplement Content

- ▶ General principles
 - Reconstitution and handling
 - Procedural considerations (syringes, pain management)
 - Dosing and injection-site considerations
 - Aesthetic considerations
 - Patient selection, education, and counseling
- ▶ Dosing, injection techniques, male vs female patients, and special considerations for the following treatment areas
 - Glabellar complex and vertical frown lines
 - Horizontal forehead lines
 - Crow's feet
 - Bunny lines
 - Perioral treatment
 - Dimpled chin
 - Platysmal bands

Consensus Recommendations: General Principles – Reconstitution and Handling

Parameter	Recommendation
Diluent	<ul style="list-style-type: none">■ Preserved 0.9 percent saline (preferred)■ Nonpreserved 0.9 percent saline*
Concentration	<ul style="list-style-type: none">■ 4 U/0.1 mL* or any convenient concentration to deliver required units per injection site
Storage	
Before reconstitution	<ul style="list-style-type: none">■ 2°C to 8°C for up to 24 months*
After reconstitution	<ul style="list-style-type: none">■ 4 hours at 2°C to 8°C■ Up to 6 weeks at 4°C†
Handling	<ul style="list-style-type: none">■ Special precautions not required

*Please refer to the approved package insert before using BOTOX® Cosmetic. Allergan. BOTOX® Cosmetic (botulinum toxin type A) purified neurotoxin complex (package insert). Irvine, Calif: Allergan, Inc. 2004.

†From Hexsel DM et al. *Dermatol Surg.* 2003;29:523.

Consensus Recommendations: Syringe and Pain Management

- ▶ Plastic, single-use syringes are recommended
 - Insulin syringes may waste less solution
 - 32-gauge needle may reduce pain
- ▶ A topical anesthetic, including ice, may be beneficial to some patients
 - To reduce any discomfort associated with botulinum toxin type A injections

Consensus Recommendations: Variables Influencing Treatment Plan

Variable	Effect
Aesthetic goals	Development of overall treatment plan
Region(s) to be injected	Dose, injection sites, retreatment interval
Gender	Usually higher doses for men; aesthetic goals
Muscle mass	Higher doses for larger muscles
Ethnicity	Aesthetic ideals, skin thickness, functional anatomy
Skin thickness	Higher doses may be needed for thicker skin
Anatomic variation	Injection sites and dosing
Animation	Illustrates functional anatomy; injection sites

Consensus Recommendations: Aesthetic Considerations

- ▶ Understand the patient's desires and preferences
- ▶ Avoid treating any one area in isolation without regard to its effect on other areas
- ▶ Consider gender differences when treating eyebrows or lips

Consensus Recommendations: Patient Selection and Counseling

- ▶ Work with the patient to set realistic expectations
- ▶ Photograph the patient before and after treatment
- ▶ Obtain an accurate medical history
- ▶ Advise the patient to avoid medications that inhibit clotting for 10 to 14 days before treatment
- ▶ Use loupe magnification when injecting as aid to avoid bleeding and bruising
- ▶ Inform patient about potential adverse effects and contraindications

Consensus Recommendations: Posttreatment Instructions

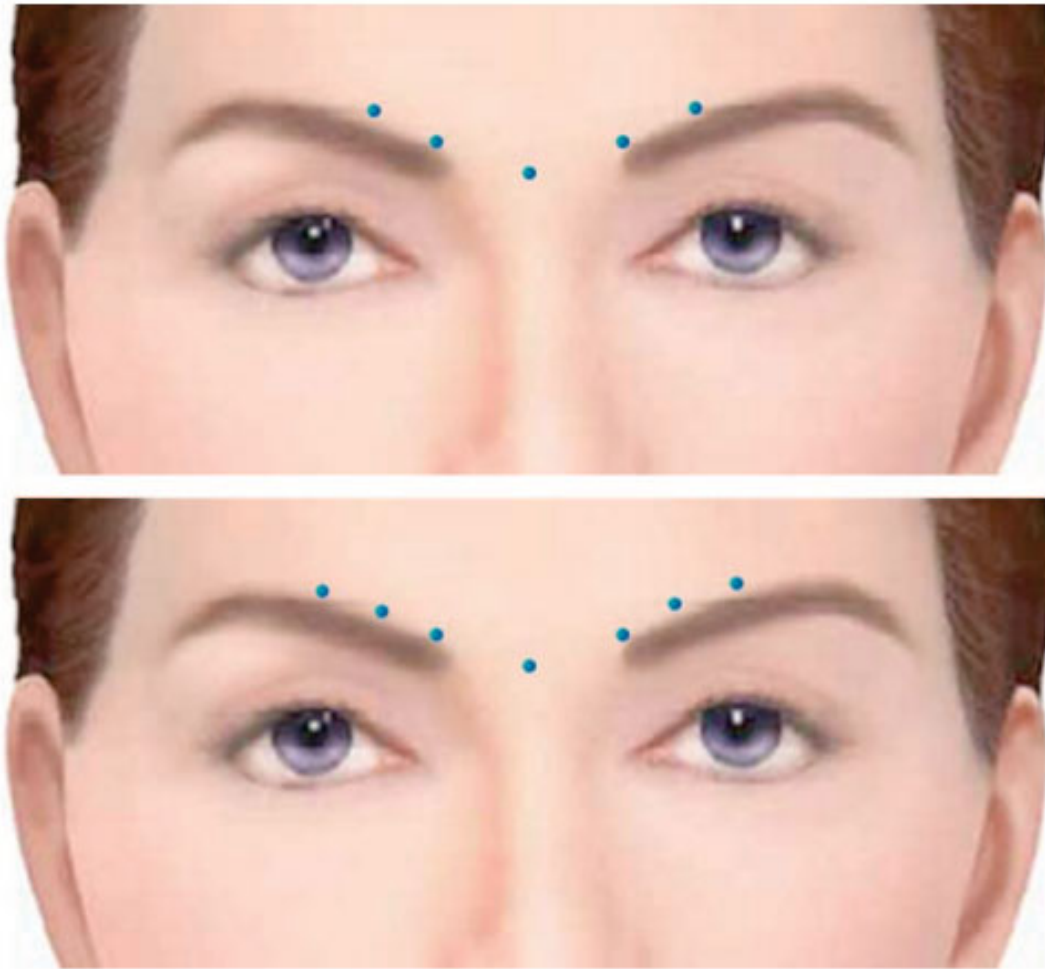
- ▶ No need to massage the treatment area
- ▶ Contract the treated muscles for 90 minutes to 2 hours
- ▶ No need to limit physical activity, or avoid bending, flying, or exposure to heat for 2 hours after treatment
 - These practices may help reduce unwanted diffusion, but no controlled studies have been conducted

Consensus Recommendations: Treating Glabellar Lines

Target Muscles	Usual Number of Injection Points (Range)	Total Starting Dose* (Usual Range)
Corrugator, procerus, depressor supercilii, orbicularis oculi, frontalis	5 to 7; men may require more sites	Women: 20 to 30 U Men: 30 to 40 U

*Higher starting doses may be used depending on individual patient variables.

Consensus Recommendations: Treating Glabellar Lines

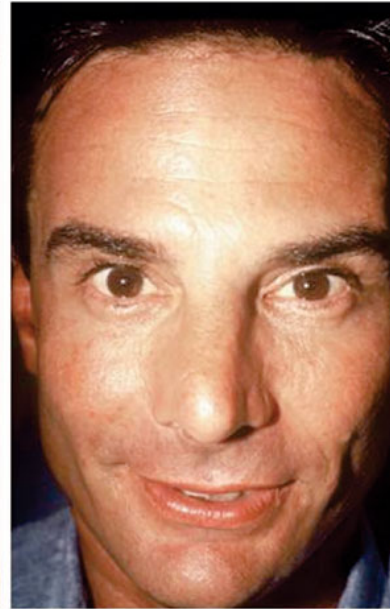
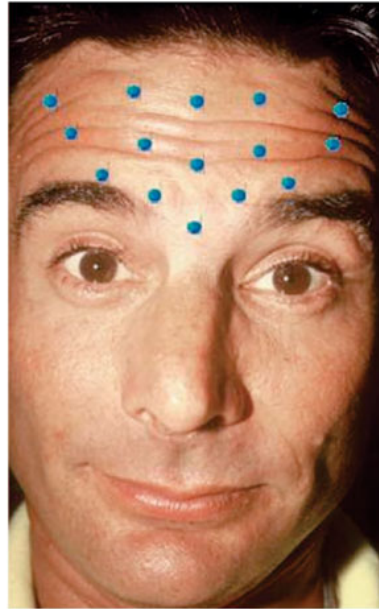


Injection sites for the glabellar complex in women (above) and men (below). Please note: avoid injecting too low over the orbit; in general, to be ultimately safe, injecting should be directed “outside” the orbital rim. Courtesy of Steven Fagien, MD.

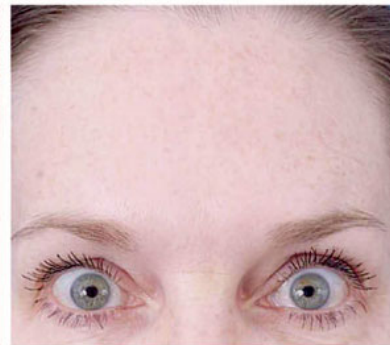
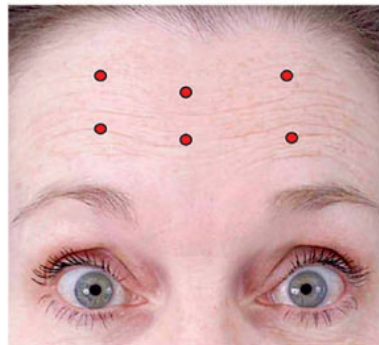
Consensus Recommendations: Treating Horizontal Forehead Lines

Target Muscles	Usual Number of Injection Points (Range)	Total Starting Dose (Usual Range)
Frontalis, but consider interactions with procerus, corrugators, and orbicularis oculi in overall facial shape	4 to 8; but more or fewer may be required based on anatomic and aesthetic evaluations	Women: 15 U 10 to 20 U Men: 20 to 30 U

Consensus Recommendations: Treating Horizontal Forehead Lines



Photographs of male patient reprinted from Fagien S. Botulinum toxin type A for facial aesthetic enhancement: role in facial shaping. *Plast Reconstr Surg.* 2003;112(suppl):6S.



Photographs of female patient courtesy of Rod Rohrich, MD.

Brow raised before injection

Brow raised after injection

Consensus Recommendations: Treating Crow's Feet

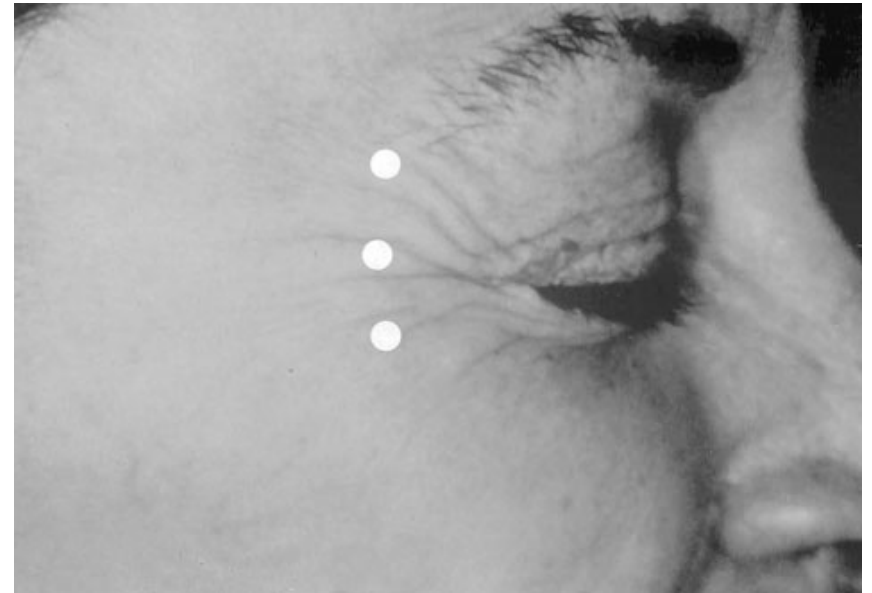
Target Muscles	Usual Number of Injection Points (per side)	Total Starting Dose* (Usual Range)
Lateral portions of the lateral orbicularis	2 to 5 (higher in selected cases)	12 to 30 U

*Gender differences in muscle mass are balanced by gender differences in aesthetic goals. Women generally prefer fewer lateral canthal rhytids than men.

Consensus Recommendations: Treating Crow's Feet



Courtesy of Steven Fagien, MD



Reprinted from Matarasso SL, Matarasso A. Treatment guidelines for botulinum toxin type A for the periocular region and a report on partial upper lip ptosis following injections to the lateral canthal rhytids. *Plast Reconstr Surg.* 2001;108:208.

Consensus Recommendations: Treating Bunny Lines

Target Muscle	Usual Number of Injection Points	Total Starting Dose (Usual Range)
Nasalis	1 per side	2 to 5 U, divided evenly
Procerus (for transverse nasal)	1 in midline	1 U, if needed

Consensus Recommendations: Treating Bunny Lines



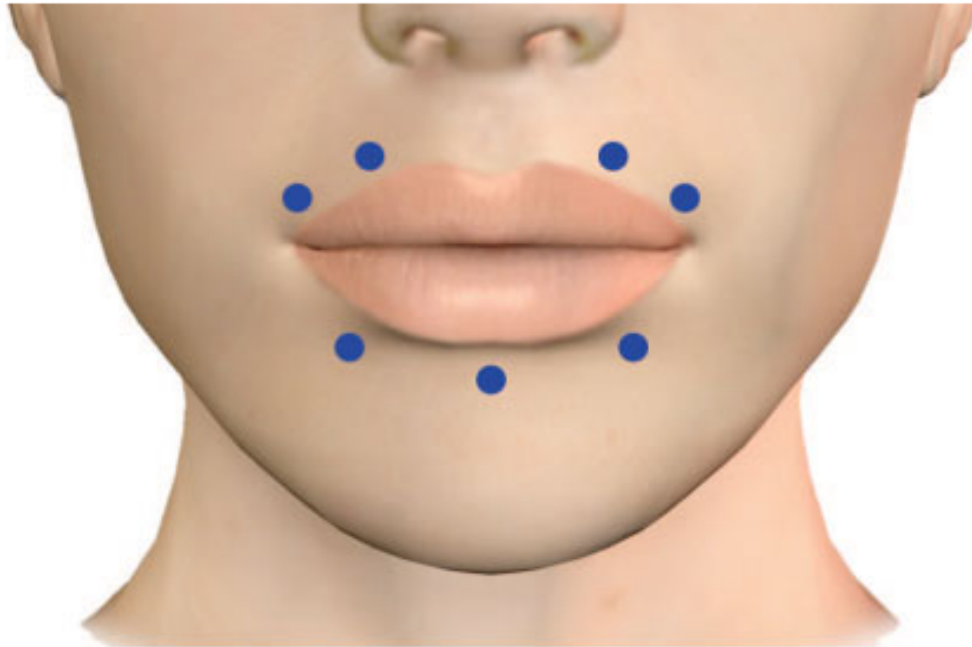
Courtesy of Steven Fagien, MD

Consensus Recommendations: Treating the Perioral Area

Target Muscle	Usual Number of Injection Points*	Total Starting Dose (Range)
Orbicularis oris	2 to 6 To start: 4 sites, 1 site/lip quadrant	4 to 10 U, evenly divided among the sites

*All injections in this area should be symmetrical.

Consensus Recommendations: Treating the Perioral Area

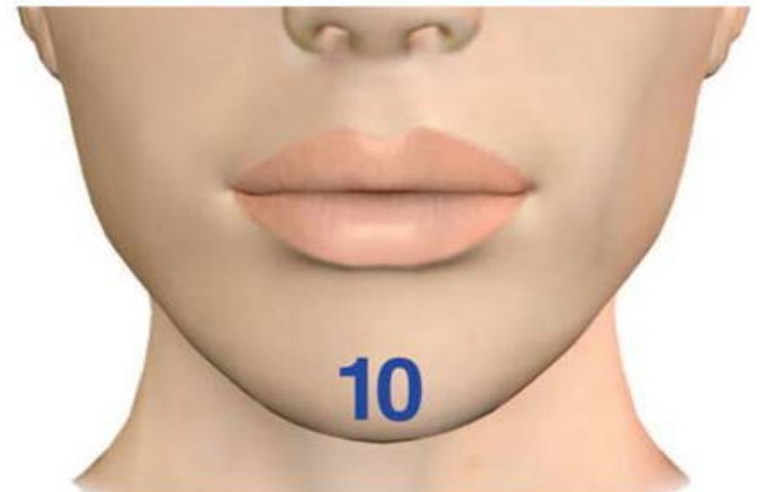
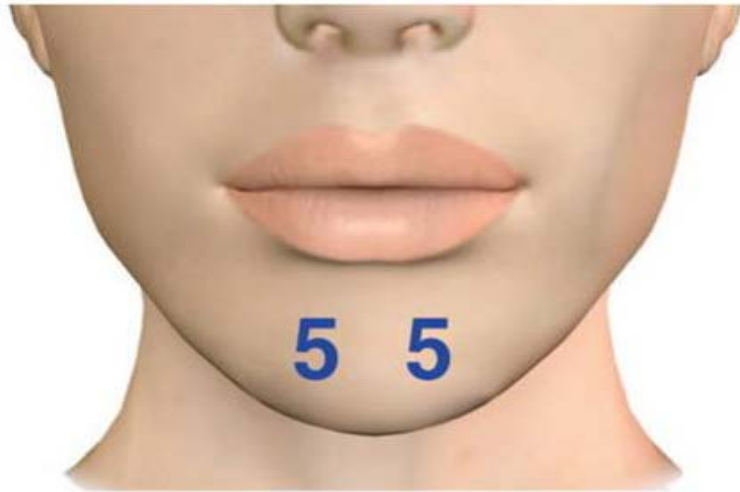


Injection sites for the perioral area.

Consensus Recommendations: Treating Dimpled Chin

Target Muscle	Usual Number of Injection Points	Total Starting Dose (Usual Range)
Mentalis	1 to 2 (start with 1 midline or 2 symmetrical, lateral injections)	Women: 2 to 6 U Men: 2 to 8 U

Consensus Recommendations: Treating Dimpled Chin



Injection sites and dosage of botulinum toxin type A for dimpled chin.

Consensus Recommendations: Treating Platysmal Bands

Target Muscle	Usual Number of Injection Points	Total Starting Dose* (Usual Range)
Platysma	Women: 2 to 12/band Men: 3 to 12/band	Women: 10 to 30 U Men: 10 to 40 U

*Some experts use total doses of up to 100 U.

Consensus Recommendations: Treating Platysmal Bands



Photograph courtesy of Rod Rohrich, MD

Consensus Recommendations on the Use of Botulinum Toxin Type A in Facial Aesthetics

Summary

- ▶ Guidelines for using botulinum toxin type A in
7 areas of the upper, mid, and lower face
 - General principles
 - Injection and dosing
- ▶ Individualized aesthetic planning is the key to success
- ▶ Patient involvement in the treatment plan is critical