Nonsurgical Facial Rejuvenation: Botulinum Neuromodulators

Karol A Gutowski, MD, FACS
Disclosures

RTI Surgical - Advisor
Suneva Medical - Instructor
Angiotech/Surgical Specialties - Advisory Board

Will discuss off-label uses
Will use brand names for ease of understanding
Will refer to BOTOX *Cosmetic* as BOTOX
FDA Approved

- **BOTOX Cosmetic** – *Ona*botulinumtoxinA
  - VISTABEL, VISTABEX
- **DYSPORT** – *Abob*otulinumtoxinA
  - AZZALURE
- **XEOMIN** – *Inco*botulinumtoxinA
  - XEOMEEN, BOCOUTURE, NT201
What FDA Wants You to Know

• Black Box Warning
  – Possibility of experiencing potentially life-threatening distant spread of toxin effect from injection site after local injection
  – Not reported in cosmetic uses

• Risk Evaluation and Mitigation Strategy (REMS)
  – Medication Guide to help patients understand risks & benefits

• Potency units are specific to each BoTN-A product
  – Doses or units cannot be compared or converted
BoTN-A Mechanism of Action

Block neuromuscular junction transmission by inhibiting acetylcholine release

- BoTN-A binds to cholinergic nerve terminals
- Internalized into nerve
- Light-chain translocated into nerve cytosol
- Enzymatic cleavage of SNAP-25 (essential for ACh release)
- Impulse transmission re-established by formation of new nerve endings
• Block cholinergic transmission at the neuromuscular junction by inhibiting the release of acetylcholine from peripheral cholinergic nerve endings.

• Neurotoxin binding to cholinergic nerve terminals, internalization of the neurotoxin into the nerve terminal, translocation of the light-chain part of the molecule into the cytosol of the nerve terminal, and enzymatic cleavage of SNAP25, a presynaptic target protein essential for the release of acetylcholine.

Impulse transmission is re-established by the formation of new nerve endings.

**Mechanism of Action**

*Types A and B bind to distinct acceptors*

Botulinum Type A cleaves SNAP-25

Botulinum Type B cleaves synaptobrevin (VAMP)
# Product Comparison

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HAS = Human Serum Albumin
BoTN-A Protein Comparison

BOTOX
- Ethanol Precipitation and Crystallization
  - ~900 kD

DYSPORT
- Ion Exchange
  - ~500 kD

XEOMIN
- Ion Exchange and pH Change
  - 150 kD
  - No Accessory Proteins
# Pivotal Study Doses

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*Dilution and dosage may vary as determined by clinician*

*Adjusting dose to target muscle mass may improve outcome and duration*
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Dilution and dosage may vary as determined by clinician.

Adjusting dose to target muscle mass may improve outcome and duration.
Botox Pivotal Studies

50% of patients maintain improvement at 3 months
DYSPORT Pivotal Studies

40% - 50% of patients maintain 1-Grade improvement at 3 months

GL-3 was a 6-month, single-dose, double-blind, multicenter, randomized, placebo-controlled study (N=300) to assess the safety and efficacy of 50 Units of Dysport vs placebo in subjects with moderate to severe glabellar lines at maximum frown. 60% (120/200 Dysport patients versus 0% treated with placebo) met the primary endpoint.

GL-1 was a 6-month, single-dose, double-blind, multicenter, randomized, placebo-controlled study (N=156) to assess the safety and efficacy of 50 Units of Dysport vs placebo in subjects with moderate to severe glabellar lines at maximum frown. 55% percent (86/165 Dysport patients versus 9% treated with placebo) met the primary endpoint.
Dysport Dose Response

**Efficacy and Safety of Botulinum Toxin Type A in the Treatment of Lateral Crow’s Feet: Double-Blind, Placebo-Controlled, Dose-Ranging Study**

Benjamin Ascher, MD,* Berthold J. Rzany, MD, ScM,† and Rajiv Grover, BSc, MB, BS, MD, FRCS (Plast)‡

30U & 45U better than 15U
Dysport Dose Response

Patient satisfaction similar at all doses
Dysport Dose Response

Older patients less likely to respond
15% - 25% of patients maintain 2-Grade improvement at 3 months
Xeomin Phase 3 Post Hoc Analysis

- Issue of 1 vs 2 point clinical response
- 20u divided in 5 glabella sites
- Response no worse (or better) than Botox
A Prospective Rater- and Subject-Blinded Study Comparing the Efficacy of IncobotulinumtoxinA and OnabotulinumtoxinA to Treat Crow's Feet: A Clinical Crossover Evaluation

Gabriele Muti, MD,* and Laura Harrington, PhD†
BOTOX vs DYSPORT Duration

Duration From a Double-Blind, Randomized, Parallel-Group Study

Incidence of at least 1-grade improvement from baseline in glabellar line severity at maximum contraction

- **8 Weeks**
  - **BOTOX® Cosmetic (20 Units) (n = 31)**: 94% (29/31)
  - **Dysport® (50 Units) (n = 31)**: 97% (29/30)

- **12 Weeks**
  - **BOTOX® Cosmetic (20 Units) (n = 31)**: 77% (24/31)
  - **Dysport® (50 Units) (n = 31)**: 59% (17/29)

- **16 Weeks**
  - **BOTOX® Cosmetic (20 Units) (n = 31)**: 53% (16/30)
  - **Dysport® (50 Units) (n = 31)**: 28% (8/29)

**P = .04**
Meta-analysis established 1:1 dose effectiveness but not duration.
Fields of Effect

Fields of Muscular and Anhidrotic Effects of 2 Botulinum Toxin-A Commercial Preparations: A Prospective, Double-Blind, Randomized, Multicenter Study

Doris Hexsel, MD, *† Mariana Soirefmann, MD, MS, *† Manoela D. Porto, MD, * Carolina Siega, BSc, * Juliana Schilling-Souza, BPharm, * and Ticiane C. Rodrigues, MD, PhD *†

- Dysport greater anhidrotic effect than Xeomin
- Similar muscular effects by EMG
Personal Experience

- Fastest time to onset: DYSPORT (1-3 days)
Personal Experience

- Fastest time to onset: DYSPORT (1-3 days)
- Duration: Equal
Personal Experience

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- Cost*: BOTOX > DYSPORT > XEOMIN

* Depends on dose & rebates
Personal Experience

- Fastest time to onset: DYSPORT (1-3 days)
- Duration: Equal
- Cost*: BOTOX > DYSPORT > XEOMIN
- Pain: Same (technique?)
- Spread: Same (dilution & technique?)

* Depends on dose & rebates
## Personal Experience

- **Fastest time to onset**: DYSPORT (1-3 days)
- **Duration**: Equal
- **Cost***: BOTOX > DYSPORT > XEOMIN
- **Pain**: Same (technique?)
- **Spread**: Same (dilution & technique?)
- **Dose**: 1 BOTOX = 1 XEOMIN = 3 DYSPORT

* Depends on dose & rebates
Personal Experience

- Accessory proteins  Do they matter?
- Interchangeable   Maybe (more similar than different)
- Split face        Not much difference
- Patient cross-over Not much difference
- BOTOX non-responders It’s the same molecule but worth a try?
Applications
Observe Patient During Conversation

• Watch for expressions & muscle movements during a normal conversation
• More appropriate initially than treating exaggerated or extreme movements
Patient Education

• Explain what it can & what it can’t improve
• Introduce the “4 R’s”
  – Relax, Resurface, Refill, then Relift
Product Dilutions

Assume vial with 100 units of BOTOX

- 1.0 cc = 10u/0.1 cc
- 2.0 cc = 5u/0.1 cc
- 2.5 cc = 4u/0.1 cc
- 4.0 cc = 2.5u/0.1cc

Low injection volume limits diffusion (Glabella)
More product waste

High injection volume increases diffusion (Forehead)
Less product waste
Injection

Assume vial with 100 units of BOTOX

- 1.0 cc = 10u/0.1 cc
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0.3 cc insulin syringe with fixed 31G needle
Needle dulls after a few injections

1.0 cc syringe with removable 32G needle
(Less discomfort than 30G needle)
Document the Treatment

Injectable Product Worksheet

Patient: Jenny Smith  
Date: 10/2/14

Allergy & Medical Update: None

Results after last injection: Loved it!

For first time injections
- Limitations discussed
- Duration of results explained
- Risk & complications discussed
- Pictures taken
- Aftercare instructions given
- Artefill skin test negative

Neuromodulator
- Xeomin [X]
- Dysport [X]
- Botox [X]

Filler or Stimulator
- Arcula [A]
- Restylane [Rs]
- Perlane [P]
- Juvederm Ultra [U]
- Radiesse [Rs]
- Sculptra [S]

Injection
- 32G Needle
- 27G Microcannula

Anesthetic
- None

F = 2u x 6 = 12u

Malar = 0.5cc per side

May need more in 2 weeks

Additional Notes

Treatment outcomes: None

Complications: None

Place Product Stickers Here

C 32 1578
Voluma 13-578
**BoTN-A Non-responders**

- True non-responders are rare
- May have antibodies to BoTN-A
  - Presence of antibody ≠ no response
  - Absence of antibody ≠ response
- Antibodies may disappear over time
- May respond to BoTN-B (Myobloc)
  - Acts on synaptobrevin (not SNAP-25)
Zinc Supplementation to Increase Duration

Double-blinded, placebo-controlled cross-over study
Inclusion: “Hard to Treat” patients
BOTOX, DYSPORT, XEOMIN

BoTN-A is zinc dependent
Phytates block zinc absorption
Zinc Supplementation to Increase Duration

- 92% of patients reported 30% increase in duration
- Older patients
  - Greater improvement
  - No increase in duration

- Zytase $40 per treatment
Can I Really Store BoTN-A for 4 Weeks?

Consensus Statement Regarding Storage and Reuse of Previously Reconstituted Neuromodulators

Murad Alam, MD,*†‡ Diana Bolotin, MD, PhD,§ Jean Carruthers, MD,‖ Doris Hessel, MD,¶# Naomi Lawrence, MD, ** Kira Minkis, MD, PhD, *†‡ and Edward Victor Ross, MD‡‡

- Literature review & 2 round Delphi process
- Can be refrigerated or refrozen for 4 weeks
- Can use on multiple patients (proper handling)
Does Injection Depth Matter?

Injecting Botulinum Toxin at Different Depths Is Not Effective for the Correction of Eyebrow Asymmetry

Jason Sneath, MD,* Shannon Humphrey, MD,* Alastair Carruthers, MD, FRCPA, FAAD,* and Jean Carruthers, MD, FRCS†

Selective eyebrow depressors cannot be targeted due to BoTN diffusion radius
Clinical Examples
Aesthetic Uses of Neuromodulators: Current Uses and Future Directions

Michael S. Gart, MD
Karol A. Gutowski, MD

*Chicago, Ill.*

**Background:** The introduction of neuromodulators for aesthetic facial improvements greatly expanded the limits of nonsurgical facial rejuvenation. Although many current uses are considered “off-label,” the widespread acceptance and favorable safety profile of properly used botulinum toxins have made them one of the most common aesthetic treatments available.
Individual Patient Assessment for Natural Result

Although clinical trials have emphasized the efficacy of the drug with full doses, the frozen and nonmovement of the glabella and upper face including brows is undesirable for most of our patients today. Thus, the full dosage of 20–30 units of onabotulinum/incobotulinum toxin or 50–60 units of abobotulinum toxin can be reduced to allow movement and expression. This makes it the physician’s responsibility to evaluate the patient at rest and with full movement of the upper facial units. This is accomplished with

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**NEUROTOXINS**

Neurotoxins: Current Concepts in Cosmetic Use on the Face and Neck—Upper Face (Glabella, Forehead, and Crow’s Feet)

Gary Mounthetis, MD
Birmingham, Ala.

Summary: There are 5 Food and Drug Administration-approved botulinum toxin formulations now being successfully used for treatment in the upper face. The most common areas for botulinum toxin treatment are the upper face, including the glabella, forehead, brows, and lateral canthal lines or crow’s feet. The frozen look is no more desired in patients. Thus, physicians are more commonly individualizing the dosage based on the patient’s condition in anatomy, muscle mass, symmetry, and, most importantly, desired outcome. (Plast. Reconstr. Surg. 135: 728, 2015.)
BoTN-A & the Four R’s

• **Relax** the muscle: BoTN-A
• **Refill** the face (volume): Fillers
• **Resurface** the skin: Lasers
  – Fractional CO₂
• **Relift** the tissue: Energy-based
  – Ultherapy
  – Neck laser-assisted liposuction
Eyelid Ptosis Reversal

- Alpha-adrenergic agonist ophthalmic eye drops
  - Apraclonidine 0.5% (Iopidine)
  - Naphazoline (Naphcon)
  - Phenylephrine 2.5% (Myfrin)
- Stimulate Mueller’s muscle to elevate ptotic eyelid
  - Typical 2 mm of lid elevation
Nonsurgical Facial Rejuvenation: Botulinum Neuromodulators