
Introduction

Botulinum Toxin: Expanding Role in Medicine

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During the last decade, the aesthetic use of botulinum toxin type A has risen dramatically. Because of the tremendous growth in its cosmetic clinical applications, we have dedicated this first supplement of *Plastic and Reconstructive Surgery* exclusively to botulinum toxin. Botulinum toxin type A, or Botox (Allergan, Inc., Irvine, Calif.), as it is commonly called, has become a ubiquitous drug for all seasons. A myriad of applications for the treatment of facial aging are now available that can be performed safely and effectively with minimal side effects. Within this supplement, we have endeavored to provide you with all the current information on botulinum toxin from top medical professionals who are experienced in its use.

In the 1930s, botulinum toxin, produced by the bacterium *Clostridium botulinum*, was responsible for devastating the canning industry in the United States. The Army later purified the toxin for use in biological warfare research, but until the 1980s, botulinum toxin's reputation was solely that of a deadly poison. In 1980, botulinum toxin started finding medicinal use for certain conditions, such as the treatment of strabismus in children. Its use expanded over the next several years to include the treatment of facial spastic disorders as well as asymmetries caused by facial nerve paralysis (spontaneous or iatrogenic). Subsequently, it was proven to efface deep glabellar furrows in patients with benign essential blepharospasm. It garnered U.S. Food and Drug Administration approval for use in treating glabellar rhytides in 2002.

Applications for botulinum toxin continue to be developed in aesthetics and other fields with great success. Now, botulinum toxin type A is the new wonder drug, and Botox has almost become a household name. Other botulinum toxins, including botulinum toxin type B (Myobloc; Elan Pharmaceuticals, Inc., San Francisco, Calif.) and *C. botulinum* type A toxin-hemagglutinin complex (Dysport; Ipsen Pharmaceuticals, Ltd., Dublin, Ireland), have developed specific indications in this arena as well.

According to the American Society of Plastic Surgeons' statistics, 1,123,510 people were treated with botulinum toxin in 2002, making it the number 1-ranked nonsurgical procedure performed by board-certified plastic surgeons.¹ The use of botulinum toxin continues to expand, both in volume and in number of applications. Aside from its use in the effacement of dynamic or hyperkinetic facial lines, it has also found use in treating conditions such as dystonias, facial and generalized muscle spasms, incontinence, autonomic disorders, migraine headaches, jaw pain and spasm, hyperhidrosis, and involuntary movement disorders. Recently, it has also been used in the morbidly obese to decrease hunger, in those with peptic ulcer disease to decrease gastroesophageal reflux, in those with vaginismus and dyspareunia to improve quality of life, in those with anal fissures resulting from a variety of lower gastrointestinal disorders, and in infants born with clubfoot as a potential method of nonsurgical treatment. It appears that novel uses are being

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Dr. Rohrich and Dr. Fagien currently co-chair the Plastic Surgery Educational Initiative's committee, sponsored by Thomson Advanced Therapeutics Communications, ASPS/PSEF, and ASAPS/ASERF, to educate plastic surgeons on the clinical use of botulinum toxin type A. They own no stock or stock options in Allergan, Elan, or Ipsen. Dr. Rohrich has previously served as a consultant to Elan.

DOI: 10.1097/01.PRS.0000082188.55598.34

BOTULINUM TOXIN TYPE A OPERATIVE REPORT

Date: _____

Patient: _____

• History of recent NSAID: _____

• Current Medications: _____

• Significant Medical History _____

• Pregnant YES NO

1st Botox injection YES NO

Off label consent given _____

Date of last Botox injection _____

Informed consent given _____

LOCATION / MAP OF INJECTIONS:**Clinical Analysis**Upper Face

- _____ Forehead frown lines
 _____ Brow asymmetry (R / L lower)
 _____ Glabellar rhytids
 _____ Procerus lines

Eyelid

- _____ Aperture width (R / L larger)
 _____ Crow's feet

Lips/Mouth

- _____ Lateral
 _____ Central
 _____ Commissures
 _____ Rhytids

Neck

- _____ Medial bands
 _____ Lateral bands



100 units of Botox mixed in 4 cc of PFNS (2.5u / .1cc)

Amount Used: _____ Lot Number: _____ Exp. Date: _____

Complications: _____

Instructions Given: _____

Follow-Up Appointment _____ 2 weeks _____ 3 months _____ Other

Comments: _____

Physician Signature: _____

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FIG. 1. Clinical worksheet for botulinum toxin type A procedures.

developed almost every day, although at this point, most remain "off-label." Eventually, the Food and Drug Administration may approve many of these new procedures, while the potential for other new applications for botulinum toxin type A appears boundless.

As advances in the use of botulinum toxin type A have been multidisciplinary, crossing

several specialties, we have assimilated several key articles in this supplement on the use of botulinum toxin from ophthalmology, dermatology, and otolaryngology, as well as plastic surgery. We are fortunate to include the pivotal article by Drs. Jean D. Carruthers, Nicolas J. Lowe, M. Alan Menter, and John Gibson and Ms. Nina Eadie, entitled "Double-Blind, Place-

bo-Controlled Study of the Safety and Efficacy of Botulinum Toxin Type A for Patients with Glabellar Lines,"² which helped gain scientific and Food and Drug Administration approval for the use of botulinum toxin type A for glabellar frown lines. The majority of these articles have been published recently in the Journal; however, the following are new and have been peer-reviewed for publication in this supplement only:

- Botulinum Toxin Type A for Facial Aesthetic Enhancement: Role in Facial Shaping.
- Classification of Crow's Feet Patterns among Caucasian Women: The Key to Individualizing Treatment.
- The Effect of Botulinum Toxin Injections on the Nasolabial Fold.
- The Role of Botulinum Toxin Type B (Myobloc) in the Treatment of Hyperkinetic Facial Lines.
- The Cosmetic Use of Botulinum Toxin.

Follow-up articles were obtained where possible from authors who had previously published articles, and discussions are provided to bring all the information included in the supplement up to date. We have included a copy of our botulinum toxin clinical worksheet. It may be useful as a template for those who intend to perform botulinum toxin injections (Fig. 1). The American Society of Plastic Surgeons' official policy statement on the use of botulinum toxin is reprinted following this introduction.³ It outlines the profile of botulinum toxin and provides an excellent guideline for its clinical and ethical use.

It should be mentioned that many of the uses described in this supplement are considered "off-label" and are *not* approved by the U.S. Food and Drug Administration. It is, however, within the physician's prerogative to perform these procedures with proper patient informed consent.

We have asked all authors to fully disclose any affiliation they may have with any of the

manufacturers of botulinum toxin. "Journal editors are obliged to give readers all the information necessary . . . to judge the credibility of a . . . report . . . publishing conflicts of interest routinely and openly to permit the reader to evaluate the investigators' relationships surrounding their research, to assess possible bias, and to determine whether a conflict of interest diminishes the credibility of a study."⁴ We have endeavored to provide all the information needed for our readers to make this assessment for themselves.

We sincerely hope this comprehensive supplement serves as an important educational resource for our readers on the current applications of botulinum toxin. Botulinum toxin has already found a significant place within the field of plastic surgery and serves as an important and useful adjunct to facial rejuvenation. Its future usage will undoubtedly continue to grow. Familiarity with botulinum toxin and its applications will add a vital tool to the armamentarium of physicians worldwide.

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