

## Introduction to the Supplement: A Review of AbobotulinumtoxinA (Dysport)

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It would be hard to imagine practicing dermatology, plastic surgery, or any other cutaneous aesthetic field without BotulinumtoxinA (BoNT-A). Yet it was only in 2002 that this toxin was first approved by the United States Food and Drug Administration (FDA) for use in the treatment of glabellar lines.<sup>1</sup> Of the myriad of advances in aesthetic medicine from the last several decades, no other clinical development comes close to the impact that BoNT-A has had in this field. If it was not for the pioneering work of Dr Alan Scott in the 1960s and 1970s, and the enlightened clinical efforts of numerous other researchers, we would not have the engine that drives many aesthetic practices today.<sup>2,3</sup>

BoNT-A had the first medical uses in the 1980s when the FDA approved BoNT-A for strabismus and blepharospasm in 1989.<sup>4</sup> Subsequently, AbobotulinumtoxinA [ABO; Azzalure (Ipsen Limited, Slough UK/Galderma, Lausanne CH)/Dysport (Ipsen Biopharm Limited, Wrexham UK/Galderma LP, Fort Worth, TX)] gained marketing authorization in the United Kingdom in December 1990 for the treatment of blepharospasm and hemifacial spasm. Since then, new indications have included the treatment of cervical dystonia, upper limb spasticity, spastic equinus in cerebral palsy and hyperhidrosis, among others.<sup>5</sup>

Since the 1989 landmark paper reporting BoNT-A's first application in aesthetics by Clark and Berris,<sup>6</sup> the number of patients treated with BoNT-A has risen year-on-year. Marketing authorization for the aesthetic treatment of glabellar lines and upper facial kinetic lines followed

throughout Europe, Asia, and the United States in 2009. BoNT-A has been used in millions of individuals and patient satisfaction rates are high. For example, the number of BoNT-A injections performed in the United States in 2015 was estimated to be 4.2 million with continual projected increases in the coming years.<sup>7</sup> A significant majority of those treated with BoNT-A are so pleased with the results that they become regular return visitors to their physician's office.

The number of BoNT products remained relatively constant until recently, when several new products entered the market in various countries. These products are continuing to expand their footprint. In addition to BoNT products from the 3 industry leaders in facial injectables (Allergan, Parsippany, NJ; Ipsen and Merz, Frankfurt, Germany), several smaller companies have started producing biosimilar versions. The quality, efficacy, and safety of the biosimilars need to be confirmed through long-term follow-up of large numbers of patients. In contrast, ABO has been a global product for 25 years, and has a very well-established

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efficacy and tolerability profile, documented through the many clinical trials with the product.

To mark the 25th anniversary of the launch of ABO, this supplement details the developments in ABO, as the product now enters a third decade. The papers beautifully summarize the story of ABO, from the early history and the best treatment parameters to the practical, safe and potential new uses.

Drs Monheit and Pickett detail the discovery and development of ABO from a historical perspective, telling the tale of the identification and later classification, elucidating the astonishing story of ABO for both medical and aesthetic use.<sup>8</sup> The paper begins with the reports of outbreaks of botulism from back in the late 1700s and continues to the first publications describing botulism in the 1800s, then focusing on the 25-years since Dysport was launched in the United Kingdom. Examining the 25-year history of ABO provides us with a clearer picture of where the product came from and opens up novel lines of inquiry for future use.<sup>8</sup>

The many practical applications of BoNT in aesthetics are assessed by Drs Kane and Monheit, encompassing the solid foundation within minimally invasive aesthetic treatments.<sup>9</sup> The properties and characteristics of ABO are highlighted, calling attention to the subject of toxin diffusion. The importance of patient suitability is discussed where medical and psychological factors are taken into account. Optimal injection techniques and individual anatomical factors are also explored.<sup>9</sup>

Drs Nestor, Ablon, and Pickett review patient satisfaction with ABO in aesthetic treatments detailing the key parameters.<sup>10</sup> The effects of muscle mass, injection technique and BoNT formulation are discussed in relation to their impact on onset of effect and duration of action. Key assessment scales used to determine efficacy are also described. Caution is recommended when using equivalent doses for different forms of BoNT and expecting equivalent potency and outcomes. This contribution demonstrates how knowledge of such factors will allow the physician to provide a greater individualized approach, enabling an even higher level of patient satisfaction.<sup>10</sup>

A systematic review by Drs Cohen and Scuderi assesses the published literature over 16 years, detailing the safety of ABO and patient satisfaction for aesthetic uses.<sup>11</sup> The remarkable use of a neurotoxin in medicinal and aesthetic treatments has naturally sparked intrigue and concern, which has formed an integral part of the ABO story. Issues of neutralizing antibodies and systemic toxicity are brought to light. This systematic review now enables physicians to make their own evidence-based assessment of the information currently available.<sup>11</sup>

In conclusion, Drs Schlessinger, Gilbert, Cohen, and Kaufman consider the new and future uses of ABO, with the rising tide of procedures and wider clinical audiences inquiring after such treatments. The potential use of BoNT to ameliorate or even prevent hypertrophic scars, with the implications in wound healing, plus a wide range of developments, including ABO in combination with other treatments are also detailed.<sup>12</sup> The huge range of new medicinal uses are highlighted, including treatment for skin conditions such as acne, rosacea, psoriasis, and rarer skin diseases, in addition to pain relief and treatment of inflammatory diseases.<sup>12</sup>

This supplement offers a comprehensive overview of the efficacy, safety, and current aesthetic uses of ABO based on new studies and the wide experience in the growing markets over the years. Despite a growing literature supporting BoNT-A, certain misconceptions remain. These papers address the misconceptions, place ABO in a clinical context based on the latest research and offer glimpses of potential new uses. For a product now entering a third decade of use, the durability and consistency of results obtained with ABO are remarkable.

What a great way for those of us in the field to update our knowledge and to learn in more depth just how effective this agent is, and how it will impact our practices for many years to come.

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