SUBJECTS ARE HIGHLY SATISFIED WITH TWO TREATMENTS OF ABOBOTULINUMTOXINA A YEAR: RESULTS FROM A MULTI-CENTER, YEAR-LONG, LONGITUDINAL STUDY

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INTRODUCTION

- Real-world re-treatment intervals of abobotulinumtoxinA (ABO) are frequently longer than the manufacturer-recommended minimum interval (3 months)[1-3]
- Observational studies show median re-treatment intervals with ABO range from 5 to 6.5 months[2-5]
- Larger doses (and thus more active neurotoxin delivered) have been shown to lead to longer durations[6,7]
- Greater amounts of active neurotoxin are delivered when injecting the recommended dose for glabellar lines with ABO (0.27 ng) than with onabotulinumtoxinA (0.18 ng) or incobotulinumtoxinA (0.08)[8]
  - Studies have shown high subject satisfaction with ABO treatment through 5 to 6.5 months[2-5]
  - 1-grade glabellar line severity scale (GLSS) improvement may last up to 5 months[9]
- This clinical study was conducted to evaluate subject satisfaction with a twice-yearly re-treatment with ABO

METHODS

Study Overview

- The primary objective was to evaluate subject satisfaction with treatment every six months by direct questioning of the subject at study completion (12 months).
  - Only asked to subjects treated at baseline and at 6 months
  - "Overall, how satisfied are you with the aesthetic results of treating the lines between your eyebrows every 6 months?"
- Secondary objectives were:
  - To evaluate subject satisfaction after treatment
  - To evaluate efficacy after treatment
  - To evaluate onset of treatment response
  - To evaluate safety

Inclusion/Exclusion Criteria

- Subjects 18 to 65 years of age with moderate to severe glabellar lines (score of 2 or 3 on a 4-Point Scale) at maximum frown were eligible for this study
- No toxin treatment 9 months prior to screening/baseline was allowed

Refer to Table 1 for further study details

Figure 1. Primary Endpoint: Subject Satisfaction at 12 months with Treatment 2 Times a Year

Overall, how satisfied are you with the aesthetic results of treatment of the lines between your eyebrows every six months?

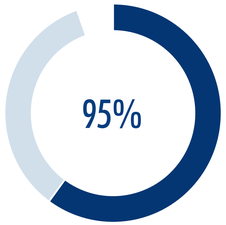

Table 1. Outline of Study Details

Study Design	• Phase IV, open-label, multi-center, interventional 12-month study (NCT03687736) • 6 centers (120 subjects) in the US
Assessments	**Efficacy** • Subject Satisfaction Questionnaire • FACE-Q - Psychological Function (psychological well-being reported by subject with their facial appearance in mind) - Appraisal of Lines Between Eyebrows • Glabellar line severity scale (GLSS) at maximum frown by: - Subject self-assessment (SSA) using the Static 4-point Categorical Scale. - Investigator live assessment (ILA) using the 4-point Photographic Scale of Glabellar Line Severity at Maximum Frown. • Time to Onset of effect (subject diary entries for the first seven days) **Safety** • Safety by adverse event reporting
Treatment	• 50 units of ABO in the glabellar lines at baseline and at month 6 • 300 U vial, 1.5 mL reconstitution • An optional re-treatment with 50 units of ABO was offered at month 12
Schedule	• Follow-up at baseline, and at 1, 3, 6, 7, 9 and 12 months • If applicable, follow-up at 1 month after optional re-treatment

Figure 2. Subject Satisfaction with Twice-Yearly ABO Treatment Over Time

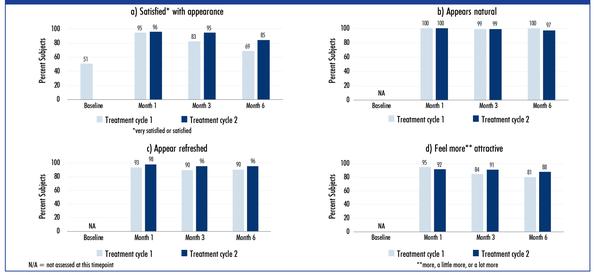

Table 2. Demographics

	Overall (N = 120)
Subjects treated, n (%)	
Baseline	120 (100)
Month 6	113 (94.2)
Month 12 (optional)	101 (84.2)
Subjects, n (%)	
Female	108 (90.0)
Male	12 (10.0)
Age, years	
Mean (SD)	43.8 (11.13)
Min – max	21 - 64
Race, n (%)	
Asian	5 (4.2)
Black or African American	4 (3.3)
White	107 (89.2)
Other	4 (3.3)
Toxin Naïve Status, n (%)	
Toxin Naïve	39 (32.5)
Non-toxin Naïve	81 (67.5
Baseline Subject Self-Assessment at Maximum Frown, n (%)	
Moderate	42 (35.0)
Severe	78 (65.0)
Baseline Investigator Self-Assessment at Maximum Frown, n (%)	
Moderate	38 (31.7)
Severe	82 (68.3)

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RESULTS

- A total of 120 subjects were enrolled in the study (Table 2).
- The primary objective was met. At study end, 95% of subjects were highly satisfied or satisfied with two treatments a year of 50 U of ABO in their glabellar lines (Figure 1). Throughout the study, subjects were more satisfied with their appearance and felt more attractive after treatment (Figure 2). At every time point assessed, subjects felt they looked natural (97-100%) and appeared refreshed (90-98%) (Figure 2).
- At 6 and 12 months after treatment, subjects were very satisfied with the results and would recommend the treatment to others (Figure 2, 3). When compared to any prior toxin treatment, 84% were at least as satisfied with two treatments of ABO a year (Figure 3).
- FACE-Q results (Rasch transformed mean total score) showed that overall, subjects felt better about themselves. Subjects were less bothered by their glabellar lines' appearance at 6 months post-treatment than at baseline (13.0-20.4 improvement). Subjects also reported improved psychological well-being at 6 months post-treatment when compared to baseline (4.0-5.3 improvement).
- Subjects reported a median onset of effect of 2 days for both treatments (Figure 4 a). At 6 months post-treatment, 37% of subjects (6 months) and 50% of subjects (12 months) had at least a 1-grade improvement from baseline in investigator-assessed GLSS (Figure 4 b). Figure 5 shows selected photos of subjects who were satisfied or highly satisfied with their treatment at study end.
- Treatment-emergent adverse events were reported for 22.5% of subjects. One treatment-emergent adverse event was considered related to treatment (mild injection site bruising), with no cases of ptosis reported. Treatment-emergent AEs experienced by >1 subject were arthralgia, urinary traction infection, herpes simplex, fall, upper respiratory tract infection, and fungal skin infection (all experienced by 2 subjects each).

SUMMARY

- The primary objective was met: at study end (12 months) 95% of subjects were highly satisfied or satisfied with 2 treatments a year of 50 U of ABO injected in the glabellar lines
- Quality of life and psychological wellness for subjects, as shown by increased satisfaction, improved with treatment and was maintained through 6 months post-treatment
- At 6 months post-treatment, 37% of subjects (6 months) and 50% of subjects (12 months) had at least a 1-grade improvement from baseline in investigator-assessed GLSS

Figure 3. Subjects With at Least a 1-grade Improvement in GLSS

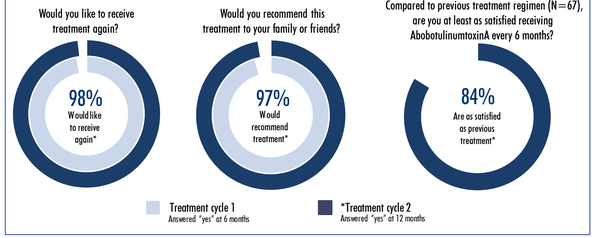

Figure 4. Onset of ABO and Efficacy of ABO Measured with a Greater Than or Equal to 1-grade Improvement in Glabellar Line Severity Scale (GLSS)

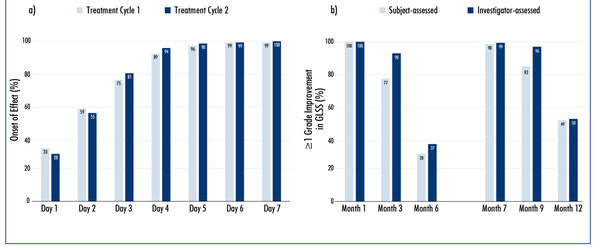

Figure 5. Selected Subject Photos. Investigator-assessed GLSS at Maximum Frown Shown

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