Participant Satisfaction With Glabellar Lines Following Treatment With TrenibotulinumtoxinE: A Pooled Phase 3 Analysis by History of Aesthetic Toxin Use

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OBJECTIVE

To evaluate satisfaction with glabellar lines (GL) after treatment with trenibotulinumtoxinE (trenibotE) across subgroups of toxin-naïve and non-naïve participants using the Facial Line Satisfaction Questionnaire

CONCLUSIONS

The majority of participants were satisfied or very satisfied with the treatment effect of trenitbotE on their GL, regardless of their history of aesthetic toxin use

A majority of participants were satisfied or very satisfied with the natural look of treatment, were likely to continue treatment, and felt that the treatment met or exceeded expectations

TrenibotE may be a treatment consideration for toxin-naïve individuals who are otherwise hesitant to commence toxin treament

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INTRODUCTION

Background

- Facial movements may result in wrinkles, such as glabellar lines (GL), that can contribute to the appearance of unintended negative facial expressions[1]
- Some individuals are hesitant to try currently marketed botulinum neurotoxin type A (BoNT/A) products to improve the appearance of wrinkles due to uncertainty around outcomes, including unnatural results
- TrenibotulinumtoxinE (trenibotE), a botulinum neurotoxin serotype E being developed as a trial toxin for the treatment of GL, has a distinct pharmacological profile from BoNT/A, demonstrates rapid clinical results and shorter duration, and addresses treatment barriers for toxin-hesitant individuals
- Given that trenibotE was developed for patients hesitant toward injectable neurotoxin treatments, there is value in evaluating satisfaction with GL following treatment in toxin-naïve and non-naïve participant subgroups

METHODS

- Pooled analysis of data from two 12-week, double-blind, placebo-controlled studies[2,3]

Participants	• Adults with moderate to severe GL at maximum frown, as assessed using the Facial Wrinkle Scale (FWS)
Treatment	• Randomized 3:1 to 700 U trenibotE or placebo at baseline
Satisfaction with treatment	• Facial Line Satisfaction Questionnaire (FLSQ)[4] Follow-Up Items: 2 (time to onset), 4 (natural look), 5 (overall satisfaction), 9 (continue teatment), 10 (recommend treatment), 11 (met expectations) • Responders for individuals items were defined as participants who were *Mostly satisfied* or *Very satisfied* (Items 2, 4, 5); *Quite a bit* or *Extremely likely* (Items 9, 10); and *Met expectations* or *Better than expected* (Item 11)

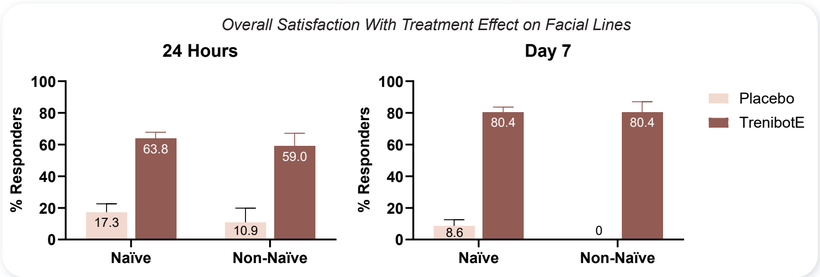
RESULTS

Participant Demographics and Baseline Characteristics

	Received TrenibotE (N = 709)	
	Toxin-Naïve (N = 562)	Toxin–Non-Naïve (N = 147)
Mean (SD) age, years	45.2 (13.2)	48.5 (12.1)
Sex, n (%)		
Female	473 (84.2)	137 (93.2)
Male	89 (15.8)	10 (6.8)
Race, n (%)		
Asian	24 (4.3)	8 (5.4)
Black or African American	32 (5.7)	3 (2.0)
White	489 (87.0)	132 (89.8)
Other[a]	17 (3.0)	4 (2.7)
Fitzpatrick skin phototype, n (%)		
I, II	228 (40.6)	57 (38.8)
III, IV	290 (51.6)	83 (56.5)
V, VI	44 (7.8)	7 (4.8)
Baseline FWS rating at maximum frown[b,c], n (%)		
Moderate	158 (28.1)	51 (34.7)
Severe	404 (71.9)	94 (63.9)

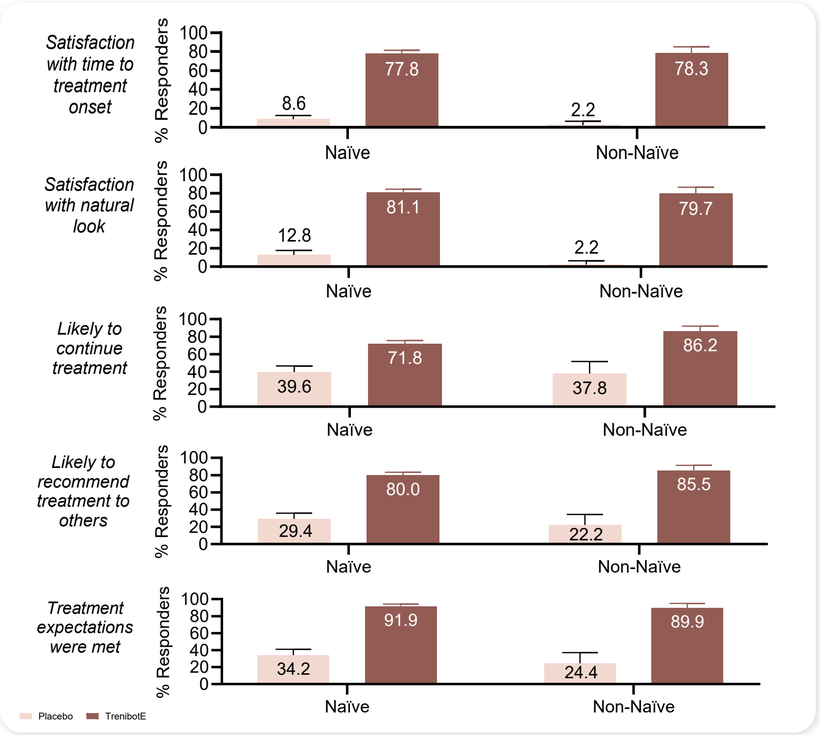
[a] "Other" included the options *American Indian or Alaska Native*, *Native Hawaiian or Other Pacific Islander*, or *Multiple*.
[b] Based on investigator rating.
[c] Two participants in the Toxin–Non-naïve group had a baseline FWS rating at maximum frown of "mild".

Majority of Toxin-Naïve and Non-Naïve Participants Were Satisfied or Very Satisfied at 24 Hours and at 7 Days After Receiving TrenibotE



Toxin-naïve: Placebo, N = 192; TrenibotE, N = 562. Toxin–Non-naïve: Placebo, N = 46; TrenibotE, N = 147.
Responders were participants who were *Mostly satisfied* or *Very satisfied* with FLSQ Follow-Up Item 5. Data are presented with 95% confidence intervals.
Intent-to-treat population (all randomized participants).

Majority of Toxin-Naïve and Non-Naïve Participants Responded Positively With Other Items of the FLSQ at Day 7 After Receiving TrenibotE



Toxin-naïve: Placebo, N = 192; TrenibotE, N = 562. Toxin–Non-naïve: Placebo, N = 46; TrenibotE, N = 147.
Responders were participants who were *Mostly satisfied* or *Very satisfied* for FLSQ Follow-Up Items 2 and 4; *Quite a bit* or *Extremely likely* for Items 9 and 10; and *Met expectations* or *Better than expected* for Item 11. Data are presented with 95% confidence intervals.
Intent-to-treat population (all randomized participants).

Safety

- The incidence of treatment-related treatment-emergent adverse events (TEAEs) was comparable in the toxin-naïve (7.4%) and non-naïve (8.7%) groups; most were mild and none were serious
- There were few discontinuations due to TEAEs in the toxin-naïve (1.2%) and non-naïve (0.7%) groups