Significantly Increased Patient Satisfaction Following Liquid Formulation AbobotulinumtoxinA Treatment in Glabellar Lines: FACE-Q Outcomes From a Phase 3 Clinical Trial

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Abstract

Background: The FACE-Q patient-reported outcome assesses patient experiences/outcomes with aesthetic facial procedure. A recent trial of abobotulinumtoxinA (ASI, liquid formulation) was the first to our knowledge to assess satisfaction with FACE-Q after glabellar line (GL) injection.

Objectives: The authors sought to evaluate patient satisfaction with ASI for GL treatment employing 3 FACE-Q scales: facial appearance, psychological well-being, and aging appearance.

Methods: This was a Phase 3, randomized, double-blind, placebo-controlled trial (NCT02353871) of ASI 50 units in adults with moderate-to-severe GL with 6-month follow-up.

Results: Significantly greater least squares mean changes from baseline were associated with ASI treatment (N = 125) vs placebo (N = 59) for satisfaction with facial appearance at all visits until day 148 (5 months; $P < 0.0001$-0.0037), psychological well-being at all visits ($P < 0.0001$-0.0279), and aging appearance at all visits except day 148 ($P < 0.0001$-0.0409). Significant differences (ASI vs placebo) were observed at all visits for individual items: "how rested your face looks" ($P < 0.0001$-0.0415), "I feel okay about myself" ($P = 0.0011$-0.0399), and "I feel attractive" ($P < 0.0001$-0.0102). Maximal least squares mean (standard error) changes in aging appearance score were −1.4 (0.3; ASI) and −0.3 (0.4; placebo). Investigators' live assessment of GL at maximum frown significantly correlated with improvements in FACE-Q facial appearance and psychological scales (all patients: r = −0.41 and r = −0.36 [both $P < 0.0001$], respectively).

Conclusions: Significant improvements in patient satisfaction with aging, facial appearance, and, importantly, psychological well-being were demonstrated with ASI employing FACE-Q scales up to 5 to 6 months post-injection. Results support a long duration of efficacy with ASI and use of FACE-Q in future trials and clinical practice.

Level of Evidence: 1

1

Therapeutic

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Botulinum neurotoxin type A (BoNT-A) injections are the most common minimally invasive cosmetic procedure worldwide, with over 5 million injections performed in 2017.[1] For elective aesthetic procedures, patient satisfaction is a defining factor for establishing the success of treatment, and therefore reporting patients' experiences and satisfaction with treatment is particularly important.[2]

To date, few patient-reported outcome (PRO) measures have been developed and employed in clinical trials assessing the efficacy of BoNT-A for aesthetic facial use. Existing measures include the Facial Line Treatment Satisfaction Questionnaire,[3,4] the Facial Lines Outcome Questionnaire,[5-7] and the Facial Line Satisfaction Questionnaire.[8] However, reviews of PRO measures in cosmetic surgical procedures and nonsurgical facial rejuvenation, including BoNT-A injections, conclude that many of these current outcome measures are not aligned to recommendations for the development and validation of PRO measures[2,9] or they do not meet US Food and Drug Association criteria.[9] In fact, only 3 PRO measures have been identified as meeting all current recommendations and US Food and Drug Association criteria for PRO measures. These are the BREAST-Q, FACE-Q Satisfaction with Facial Appearance Scale, and Skindex.[9] Of these, only the FACE-Q is appropriate for reporting outcomes from aesthetic facial procedures[10,11] and was developed specifically to address the lack of available PRO measures.

The FACE-Q consists of independently functioning scales and checklists that assess the experiences and outcomes of aesthetic facial procedures based on concepts most important to patients, including satisfaction with facial appearance, health-related quality of life, adverse effects, and the process of care.[10] The FACE-Q has undergone thorough psychometric evaluation[11-14] and has been reported to be an effective PRO measure for recording patient satisfaction following BoNT-A treatment.[15]

A liquid formulation of ready-to-use abobotulinumtoxinA (Dysport; abobotulinumtoxinA solution for injection [ASI]; Ipsen Ltd, Slough, UK; Azzalure, Galderma Ltd, Lausanne, Switzerland) has been proven to be efficacious and well tolerated for improving the appearance of moderate-to-severe glabellar lines (GL) in phase 2b and phase 3 trials.[16,17] ASI is of great interest as a means to avoid reconstitution errors, reduce preparation time, and improve consistency of dosing. The recent phase 3 trial in GL reported high rates of treatment response with ASI compared with placebo, by both investigator and patient assessment (88.3% and 76.0% at day 29, respectively; $P < 0.0001$ compared with placebo for both), as well as a long duration of response and a safety profile comparable with that of reconstituted abobotulinumtoxinA (Ipsen Ltd; Azzalure).[17] During the previous phase 2 comparator and placebo-controlled study, similar efficacy results were observed for both ASI and reconstituted abobotulinumtoxinA.[16] This was the first phase 3 clinical trial to include scales from the FACE-Q, a validated PRO instrument, to assess patient satisfaction with BoNT-A treatment for GL. Three scales from the FACE-Q were included as tertiary endpoints: satisfaction with facial appearance, psychological well-being, and perception of aging. Here we report the results from these 3 scales to present in-depth analyses of patients' experience and satisfaction with ASI for treatment of GL.

METHODS

Objective

We sought to evaluate patients' level of satisfaction with facial appearance, psychological well-being, and aging appearance with ASI for treatment of moderate-to-severe GL. This was a tertiary objective of a recent phase 3 clinical trial.[17]

Study Design and Patients

The study protocol and achievement of primary and secondary endpoints were previously published.[17] In brief, this was a phase 3, randomized, double-blind, placebo-controlled trial with a follow-up period of 6 months that was conducted at 9 study centers across France and Germany between January 2015 and August 2015 (NCT02353871). Eligible patients were aged between 18 and 65 years (men and nonpregnant women), were botulinum toxin-naïve, and presented with moderate or severe (grade 2 or 3) vertical GL at maximum frown by investigator's live assessment (ILA; 4-point photographic scale) and patient's

self-assessment (SSA; 4-point categorical scale) at baseline. Patients were also required to have a self-assessed level of satisfaction with their GL of "dissatisfied" or "very dissatisfied" (grade 2 or 3 on a 4-point categorical scale) at baseline.

Patients were excluded if they already received treatment with dermal fillers in the upper face within the previous 3 years, skin abrasions or resurfacing within 5 years, or photo rejuvenation or skin/vascular laser intervention within 12 months. Other exclusion criteria were facial cosmetic surgery due to occur during the study period, a history of eyelid blepharoplasty or brow lift within 5 years, and the presence of any condition or use of any concomitant medication that may interfere with study assessments or increase risk to the patient.

Ethics

The study was conducted in compliance with the Declaration of Helsinki with the approval of independent ethics committees or institutional review boards (Committee for the Protection of People Île-de-France II; Ethik-Kommission Landesamt für Gesundheit und Soziales Berlin; and ethics committees of the medical associations of Bavaria, Nordrhein, Hamburg, and Hessen) and in accordance with informed consent regulations and the International Conference on Harmonisation Consolidated Guideline on Good Clinical Practice. All patients provided written informed consent before initiation of any study-related procedure or administration of study treatment.

Treatment

Eligible patients were randomized in a ratio of 2:1 to receive ASI 50 units (U) or placebo using a computer-generated randomization protocol created by a sponsor statistician independent from the study using a validated in-house system developed with SAS procedure PLAN (SAS Institute, Inc., Cary, NC). Randomization was stratified by gender and baseline GL severity at maximum frown, as assessed by the investigator.

ASI was provided in a vial containing 125 U (200 U/mL) of abobotulinumtoxinA. Placebo was similarly provided in a vial, as a liquid identical in appearance to the active treatment and containing only the excipients of ASI. For both ASI and placebo injections, the total volume (0.25 mL) was divided across 5 injection sites (0.05 mL/injection) in the glabellar region (2 injections into each corrugator muscle and 1 injection into the procerus muscle). Following injection, patients were required to remain at the study center for 30 minutes of observation.

Patients attended follow-up visits at the study center on days 8, 15, 29, 57, 85, 113, 148, and 183 (final study visit) after injection. In addition, patients were contacted by telephone 4 days after the injection to evaluate treatment-emergent adverse events and the use of concomitant medications and treatments. All patients who attended the day-183 visit were considered to have completed the study.

Assessments and Endpoints

The primary endpoint was assessed using ILA of GL at maximum frown at day 29, the results of which were previously reported.[17] Secondary endpoints were assessed using ILA at maximum frown and at rest, and SSA of GL at maximum frown and at rest across all time points. Time to onset, duration of treatment response, and safety have also been reported. Here we report the tertiary efficacy endpoints from this study, the patient-reported assessments of treatment outcome, using the FACE-Q PRO measure.

FACE-Q is composed of more than 40 scales in 4 domains: Satisfaction with Facial Appearance, Health Related Quality of Life, Adverse Effects, and Process of Care. Each domain has one or more independently functioning scales.[10,11] Three scales from the FACE-Q were selected for use in the study based on the aims of the study and whether they were appropriate for the condition treated. These were satisfaction with facial appearance scale (Satisfaction with Facial Appearance domain), psychological well-being scale, and aging appearance appraisal visual analog scale (VAS; both scales are from Health-Related Quality of Life domain) (Table 1).

Patients were asked to complete the 3 FACE-Q scales at baseline (day 1) and at each posttreatment visit to the study center. Data were collected by investigators and entered into the electronic case report form. Efficacy endpoints for the FACE-Q scales were as follows:

1. Mean change from baseline to all posttreatment visits in the satisfaction with facial appearance scale Rasch transformed score
2. Mean change from baseline to all posttreatment visits in the psychological well-being scale Rasch transformed score
3. Mean change from baseline to all posttreatment visits in the aging appearance appraisal VAS score
4. Mean change from baseline to all posttreatment visits for each item of the satisfaction with facial appearance scale and the psychological well-being scale

The Rasch transformed scores for the satisfaction with facial appearance and psychological well-being scales were calculated by adding the 10 items of the scales (scored from 1 to 4) and converting the score to a scale from 0 to 100, where 0 is least satisfied and 100 is most satisfied.

Table 1. FACE-Q Assessment Scales Included as Tertiary Endpoints

Scale	Assessment	Outcome measure
Facial appearance scale	Patients responded to the following questions assessing satisfaction with (a) How symmetric your face looks? (b) How balanced your face looks? (c) How well-proportioned your face looks? (d) How your face looks at the end of your day? (e) How fresh your face looks? (f) How rested your face looks? (g) How your profile (side view) looks? (h) How your face looks in photos? (i) How your face looks when you first wake up? (j) How your face looks under bright lights?	Possible responses 1 = very dissatisfied 2 = somewhat dissatisfied 3 = somewhat satisfied 4 = very satisfied
Psychological well- being scale	Patients indicated their agreement with the following statements (a) I feel okay about myself (b) I'm accepting of myself (c) I am comfortable with myself (d) I feel good about myself (e) I like myself (f) I feel positive about myself (g) I feel happy (h) I feel attractive (i) I feel confident (j) I feel great about myself	Possible responses 1 = definitely disagree 2 = somewhat disagree 3 = somewhat agree 4 = definitely agree
Aging appearance appraisal	Patients responded to the following question: "How many years younger or older do you think you look compared with your actual age?"	Patients circled 1 number on a VAS ranging from −15 = I look 15 years younger 0 = I look my age +15 = I look 15 years older

VAS, visual analog scale.

Statistical Analyses

Efficacy analyses were based on the modified intent-to-treat population (randomized patients with baseline and ≥1 post-baseline values for ILA of GL at maximum frown). Sample size power calculations are detailed in the primary manuscript.[17] The FACE-Q efficacy endpoints were analyzed with a general linear model with stratification and center as a fixed effect. Results are presented as the parameter estimates, standard error (SE), and P value. For the facial appearance scale and psychological well-being scale, each item was analyzed employing a t test. All tests were 2-sided with an alpha level of 5%. Correlations between FACE-Q scores and the primary endpoint were performed posthoc using a Spearman's rank test in patients with available data on day 29.

RESULTS

Patients

In total, 185 patients were enrolled and randomized 2:1 to receive ASI 50 U (N = 125) or placebo (N = 60). Baseline data were previously reported in the primary publication.[17] The overall mean ± standard deviation (SD; range) age of patients was 47.8 ± 9.52 (24.0-65.0) years, and 47.7 ± 9.8 (24.0-65.0) and 48.0 ± 9.1 (27.0-63.0) years in the ASI 50 U

Table 2. Scores for the FACE-Q Scales at Baseline

FACE-Q scale	Placebo (N = 59)	ASI 50 U (N = 125)
Satisfaction with facial appearance[a]	39.4 ± 13.5 (16-100)	40.5 ± 14.1 (0-100)
Psychological well-being[a]	53.5 ± 16.4 (17-100)	55.2 ± 17.8 (5-100)
Aging appearance appraisal[b]	−1.3 ± 4.0 (−10 to 10)	−0.5 ± 3.8 (−10 to 10)

Data are presented as the mean ± standard deviation (range). ASI, abobotulinumtoxinA solution for injection; VAS, visual analog scale. [a]Rasch transformed score (0-100). [b]Measured using a VAS (−15 to +15 years compared with actual age).

and placebo groups, respectively. Overall, 160 women and 25 men were enrolled, with women comprising 86.4% and 86.7% of patients in the ASI 50 U and placebo groups, respectively; 99.2% and 98.3% of patients were Caucasian, respectively. The mean ± SD (range) duration of follow-up was 179.0 ± 17.8 (15.0-189.0) days in the ASI 50-U group and 171.1 ± 31.4 (57.0-191.0) days in the placebo group.

At baseline, GL severity was comparable between the ASI 50 U and placebo groups as shown by the proportion of patients with severe GL at maximum frown assessed by both ILA (ASI 50 U: 58.4%; placebo: 57.6%) and SSA (ASI 50 U: 45.6%; placebo: 50.8%) as well as the proportion of patients very dissatisfied with the appearance of
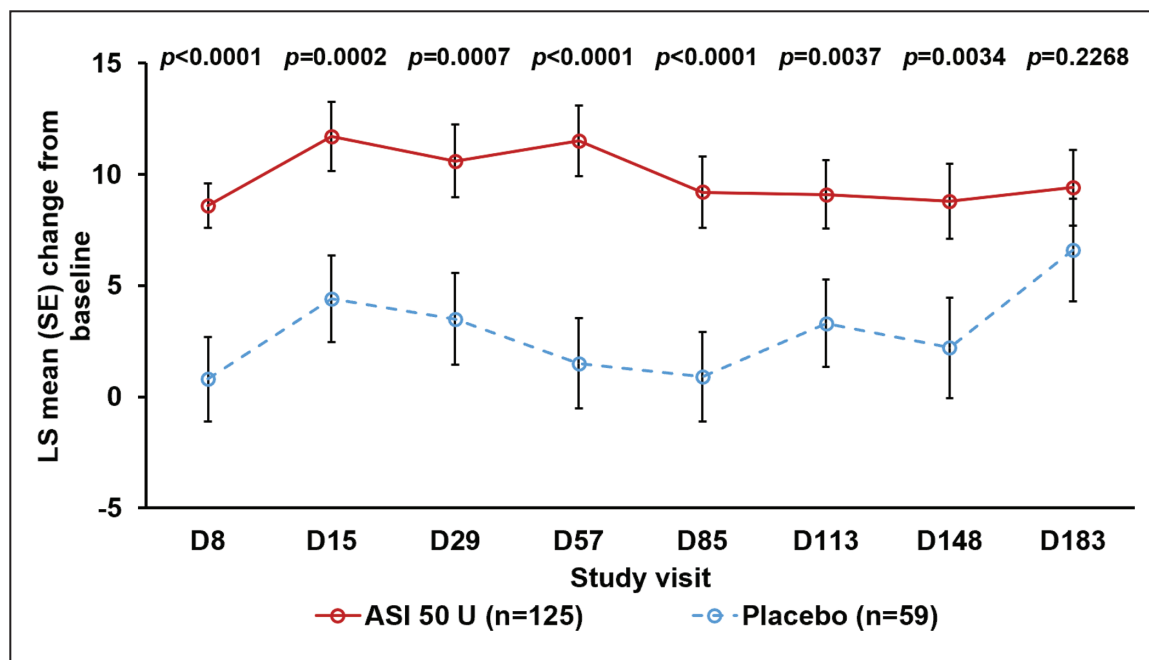
Figure 1. Least square (LS) mean changes (± standard error [SE]) from baseline to each posttreatment visit in the FACEQ satisfaction with facial appearance overall (Rasch transformed score). Rasch transformed score on a scale from 0 to 100. ASI, abobotulinumtoxinA solution for injection; D, day.

GL (ASI 50 U: 44.8%; placebo: 44.1%). Baseline scores for FACE-Q satisfaction with facial appearance and psychological well-being scales were similar between treatment groups (Table 2).

Effect of Treatment on Patients' Satisfaction With Facial Appearance

Least squares (LS) mean change from baseline in the score for satisfaction with facial appearance was significantly higher with ASI 50 U than with placebo at all posttreatment visits, except for day 183 (Figure 1).

The most pronounced effect of ASI 50 U compared with placebo on an individual item of the FACE-Q satisfaction of facial appearance scale was for the item "how rested your face looks," with a significant treatment difference at every study visit (mean change: +0.5 to +0.7 vs −0.1 to 0.2, respectively, $P < 0.0001$ to $P = 0.0415$; Supplementary Table 1).

Significant treatment differences were observed with ASI 50 U compared with placebo at 6 of the 8 study visits for questionnaire items "how balanced your face looks" ($P = 0.0018$ to 0.0481), "how fresh your face looks" ($P = 0.002$ to 0.6490), and "how your face looks at the end of the day" ($P = 0.0042$ to 0.0266). The remaining items were significant compared with placebo at 1 or more of the 8 study visits; "how symmetric your face looks" ($P = 0.0462$; study visit on day 57), "how well-proportioned your face looks" ($P = 0.0481$; day 57), "how your profile (side view) looks" ($P = 0.0197$; day 57), "how your face looks in photos" ($P = 0.0031$ to 0.0292; days 8, 57, and 85), "how your face looks when you wake up" ($P = 0.0055$ to 0.0456; days 8, 29, 57, and 85), and "how your face looks under bright lights" ($P = 0.0028$ to 0.0240; days 8, 29, 57, and 85). Item-level details of the mean change in patients' satisfaction with facial appearance are shown in Supplementary Table 1.

Improvements in satisfaction with facial appearance (ie, increases from baseline FACE-Q score) were correlated with improvements in the primary endpoint (ie, decreases in ILA severity grades at day 29): Spearman's rho (r) = −0.41 ($P < 0.0001$), all subgroups; similar correlations were found in the ASI 50 U (r = −0.34 [$P < 0.0001$]) and placebo groups (r = −0.28 [$P = 0.0307$]), respectively. For instance, at day 29, mean ± SD (range) overall score for FACE-Q satisfaction with facial appearance in the ASI 50-U group was higher at lower ILA at maximum frown severity grades, ranging from a minimum of 42.5 ± 9.4 (35.0-56.0) at an ILA grade of 3 (ie, severe) to a maximum of 59.1 ± 18.5 (19.0-100.0) at an ILA grade of 0 (ie, none) (Supplementary Table 2). Furthermore, improvements in satisfaction with facial appearance were correlated with improvements in SSA at day 29 (all subgroups, r = −0.46 [$P < 0.0001$]; ASI 50 U, r = −0.46 [$P < 0.0001$]; placebo, r = −0.22 [$P = 0.1031$]). Overall scores by SSA severity grade are shown in Supplementary Table 2.
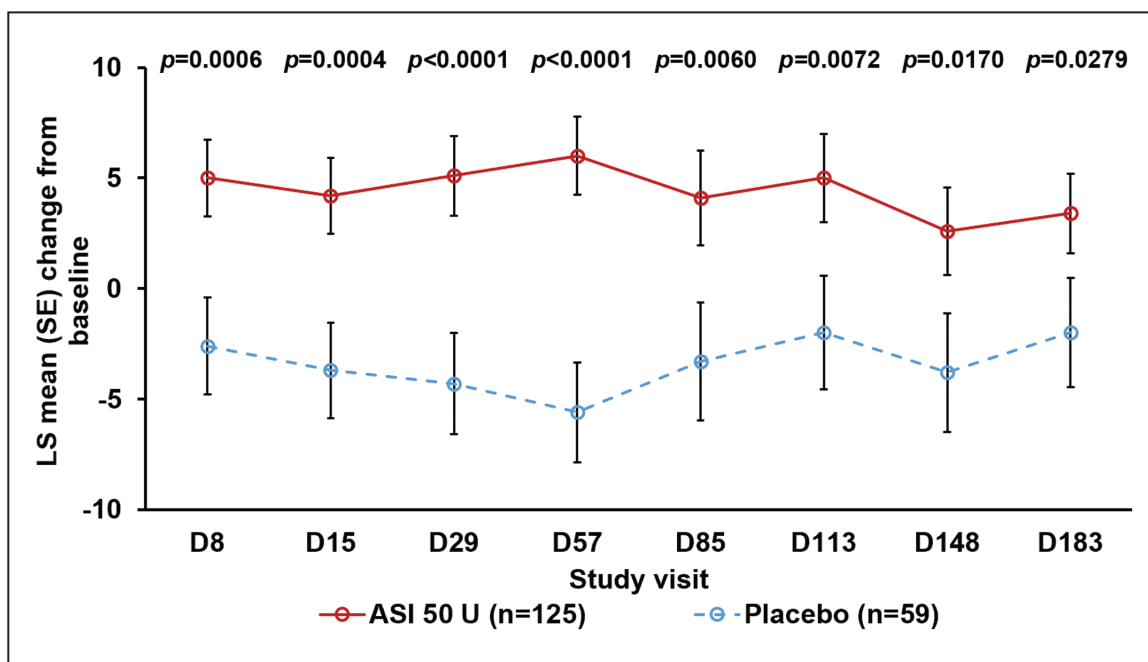
Figure 2. Least square (LS) mean changes (± standard error [SE]) from baseline to all posttreatment visits in the FACE-Q psychological well-being (Rasch transformed score). Rasch transformed score on a scale from 0 to 100. ASI, abobotulinumtoxinA solution for injection; D, day.

Effect of Treatment on Patients' Psychological Well-Being

Treatment with ASI 50 U resulted in statistically significantly higher LS mean change from baseline for psychological well-being scores compared with placebo at all posttreatment visits ($P < 0.0001$ to $P = 0.0279$; Figure 2).

The most pronounced effect of ASI 50 U compared with placebo on individual items of the FACE-Q psychological well-being scale were for the items "I feel okay about myself" and "I feel attractive," with a significant treatment difference at each study visit (mean change: +0.2 to 0.3 vs −0.2 to 0.0, respectively, $P = 0.0011$ to 0.0399; and +0.2 to 0.3 vs −0.3 to −0.1, respectively, $P < 0.0001$ to $P = 0.0102$; Supplementary Table 3).

There were significant treatment differences at 7 of the 8 study visits for the item "I feel great about myself" ($P = 0.0001$ to 0.0220), and at 6 study visits for the item "I like myself" ($P = 0.0001$ to 0.0296). The remaining items were significant treatment differences observed with ASI 50 U compared with placebo at 2 to 4 study visits for the following items: "I am accepting of myself" ($P = 0.0010$-0.0302; days 8, 29, and 57), "I am comfortable with myself" ($P = 0.0073$ to 0.0481; days 29, 57, and 113), "I feel good about myself" ($P = 0.0019$ to 0.0176; days 8, 29, and 57), "I feel positive about myself" ($P = 0.0008$ to 0.0295; days 28 and 57), "I feel happy" ($P = 0.0027$ to 0.0496; days 15, 29, 57, and 148), and "I feel confident" ($P = 0.0065$ to 0.0292; days 14, 29, 57, and 85). Item-level details of the mean change in psychological well-being are shown in Supplementary Table 3.

Improvements in psychological well-being were correlated with improvements in the primary endpoint in all patients, regardless of treatment group (r = −0.36 [$P < 0.0001$]), and in the ASI 50 U group (r = −.23 [$P = 0.0110$]). No relationship between these endpoints was apparent in the placebo group (r = −0.10 [$P = 0.4464$]). For instance, at day 29, the mean ± SD (range) overall score for FACE-Q psychological well-being in the ASI 50 U group was higher at lower ILA at maximum frown severity grades, ranging from a minimum of 48.2 ± 10.0 (36.0-58.0) at an ILA grade of 3 (ie, severe) to a maximum of 66.4 ± 22.0 (5.0-100.0) at an ILA grade of 0 (i.e., none; Supplementary Table 4). Furthermore, improvements in psychological well-being were correlated with improvements in SSA at day 29 (all subgroups, r = −0.38 [$P < 0.0001$]; ASI 50 U, r = −0.30 [$P = 0.0007$]; placebo, r = −0.14 [$P = 0.2879$]). Overall scores by SSA severity grade are shown in Supplementary Table 4.

Effect of Treatment on Aging Appearance

Statistically significantly larger improvements from baseline were observed in VAS scores for ASI 50 U compared with placebo for the aging appearance appraisal at all posttreatment visits, except day 148 (Figure 3).

In the ASI group, LS mean (SE) changes from baseline for aging appearance peaked at −1.4 (0.3) on day 57 and day 85 and ended the study at −0.8 (0.3). Patients in the placebo group had a maximal LS mean change from baseline (SE) of −0.3 (0.4) at day 57 and ended the study at 0.0
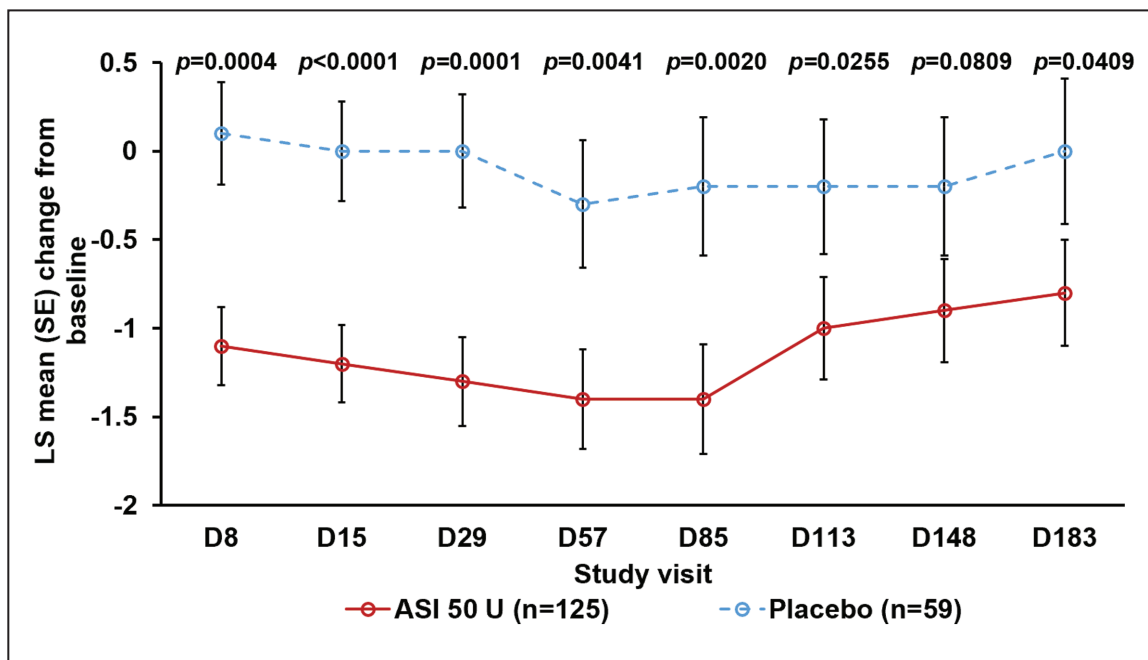
Figure 3. Least square (LS) mean changes (± standard error [SE]) from baseline to all posttreatment visits in the FACE-Q aging appearance appraisal (visual analog scale [VAS]). VAS from −15 ("I look 15 years younger than my actual age") to +15 ("I look 15 years older than my actual age"). ASI, abobotulinumtoxinA solution for injection; D, day.

(0.4). Mean change in satisfaction with aging appearance appraisal by visit is shown in Supplementary Table 5.

DISCUSSION

The present analyses demonstrate that treatment of moderate-to-severe GL with liquid formulation ASI significantly improves PROs for all FACE-Q scales assessed. Significantly greater improvements in patient satisfaction ratings were associated with ASI treatment compared with placebo at all timepoints until day 148 (5 months) for facial appearance, at all visits (ie, up to 6 months) for psychological well-being, and (with the exception of day 148) at all visits for aging appearance.

The most pronounced treatment effects on perceived improvements in facial appearance related to items assessing how rested, fresh, and balanced the patient's face looked as well as how it looked at the end of the day. These improvements in facial appearance with ASI may reflect the most important outcomes for patients seeking treatment,[3,10] whereas for physicians it is reported that the primary goal is patient happiness.[3] A review discussing the psychological outcomes for patients following cosmetic surgery found that, although high levels of patient satisfaction are often reported, not all patients experience improvements in psychological or psychosocial well-being.[18] It is therefore important that we demonstrate significant improvements in psychological well-being associated

with ASI were consistently reported at all study visits, with the most pronounced effects in patients feeling "okay" or "great" about themselves and feeling more attractive.

Furthermore, there were statistically significant correlations between improvements in 2 FACE-Q scales (satisfaction with facial appearance and psychological well-being) with the primary endpoint (ILA of GL at maximum frown at day 29), thus demonstrating the clinical relevance of these FACE-Q scales. The correlations between the FACE-Q satisfaction with facial appearance overall score and the primary endpoint, and between the FACE-Q psychological well-being score and the primary endpoint were present and statistically significant in all patients, irrespective of treatment group, indicating the robustness of these correlations. When placebo group data were analyzed, there was no correlation between improvements in the FACE-Q psychological well-being score and the primary endpoint, likely as a result of a lack of treatment effect on psychological well-being with placebo. Similarly, significant correlations were observed between these 2 FACE-Q scales (satisfaction with facial appearance overall score and psychological well-being score) and SSA of GL at maximum frown at day 29 following injection, supporting the clinical relevance of these scales from the patients' perspective.

The marked improvements from baseline in FACE-Q scores associated with ASI treatment across all FACE-Q scales were in accordance with previously reported improvements in efficacy parameters with ASI, that is,

significantly higher responder rates (percentage of patients with ≥1 grade improvement on a validated 4-point GL severity scale) for ASI 50 U compared with placebo for GL at maximum frown (as assessed by both the investigator and patients) at all study visits.[16,17] In addition, the long duration of improved patient satisfaction indicated by FACE-Q scores paralleled the long duration of the treatment response reported in the primary publication (median 4.5 months [137 days; 95% CI: 106.0, 141.0]), where 5% of patients maintained a treatment response until the end of the study (6 months).[17]

As reported in the primary results manuscript,[17] the safety profile of ASI 50 U was consistent with the well-established safety profile of abobotulinumtoxinA for treatment of GL, and no new or unexpected safety issues were identified.

The recognized limitations of the present study included the lack of diversity of the study population, because the majority of participants were women and Caucasian. Further limitations are discussed in the primary results manuscript.[17]

The present study is the first to our knowledge to employ FACE-Q scales in a large phase 3 clinical trial. The positive results for the FACE-Q scales demonstrated here paralleled the primary and secondary efficacy endpoints of the study.[17] The correlation between changes in FACE-Q scores with changes in ILA and SSA at maximum frown demonstrate the clinical relevance of the FACE-Q PROs and advocate the use of FACE-Q as an endpoint in future clinical trials of facial aesthetic treatment with botulinum toxins. The added value of the FACE-Q over other PROs (eg, the self-assessment of GL or patient satisfaction scales also used in the primary publication) is the ability to identify overall and item-level changes in the patient-response for specific outcomes, both pre- and posttreatment visits, allowing assessment of changes over time in items of particular importance to patients. These results are relevant to both patients and physicians and support the implementation of the FACE-Q in future trials and clinical practice.

CONCLUSIONS

For the first time to our knowledge in a large phase 3 trial involving patients with GL, improvements in patient satisfaction with facial appearance, psychological well-being, and aging appearance were demonstrated using the FACE-Q, a validated PRO. The results support the use of FACE-Q, as both an endpoint in future clinical trials and as a patient-centric measure in clinical practice. Importantly, patients who received abobotulinumtoxinA (ASI, liquid formulation) consistently reported significantly greater improvements in each PRO scale compared with patients who received placebo. These highly relevant results demonstrate the long duration of efficacy of ASI as reported by patients receiving treatment for GL.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

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