Patient Satisfaction With OnabotulinumtoxinA Treatment of Glabellar and Lateral Canthal Lines Evaluated Using the FLSQ®: A New Patient-Reported Outcome Measure

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ABSTRACT

Objective: Determine subject satisfaction with onabotulinumtoxinA treatment of glabellar lines (GL) and lateral canthal lines (LCL) using the Facial Line Satisfaction Questionnaire (FLSQ®), a recently developed and validated patient-reported outcome measure.

Materials and Methods: This randomized, double-blind, placebo-controlled, multicenter study enrolled subjects with moderate or severe GL and with LCL. Subjects received a total of 44 U of onabotulinumtoxinA (20 U for GL; 24 U for LCL) or placebo. Assessments were performed at 30, 60, 90, and 120 days after treatment. The FLSQ Follow-up Version is a 13-item instrument with 5 domains: treatment satisfaction, treatment impact, treatment expectations, recommending treatment, and continuing treatment. A validated stand-alone question from FLSQ® (#5) was used to assess overall satisfaction with GL and LCL. Additional assessments included severity of GL and LCL using the Facial Wrinkle Scale with photonumeric guide (FWS), and investigator- and subject-evaluated improvement in facial lines on the Global Aesthetic Improvement Scale (GAIS).

Results: Of 125 subjects enrolled in the study, 117 (mean age, 46.5 years; females, 83.8%) met the criteria for the per-protocol analysis. Most subjects (81.7.0%) receiving onabotulinumtoxinA were “satisfied”/“very satisfied” with treatment effect on GL and LCL at the primary time point of day 60 versus placebo (0%; *P*<.001). Similar results were seen at all time points. Treatment exceeded or met expectations in at least 86% of subjects at all time points (Figure 1). On the FWS, 83.3% and 86.7% of subjects achieved none or mild for GL and at least a 1-grade improvement for LCL at day 30 versus placebo (1.8% and 8.8%, respectively; Figure 2). Most subjects were “improved”/“much improved” on the GAIS at day 60 as assessed by the investigator and subject (86.7% and 83.3%, respectively). Adverse events were infrequent and typical of those seen in similar clinical trials, with 6 subjects experiencing 7 onabotulinumtoxinA-related adverse events (one moderate [headache], the rest mild in severity). No subjects experienced ptosis.

Figure 1. Proportion of subjects in the per-protocol population who reported that treatment results met their expectations (FLSQ®) at day 60 for the treatment of glabellar lines and crow’s feet lines combined.

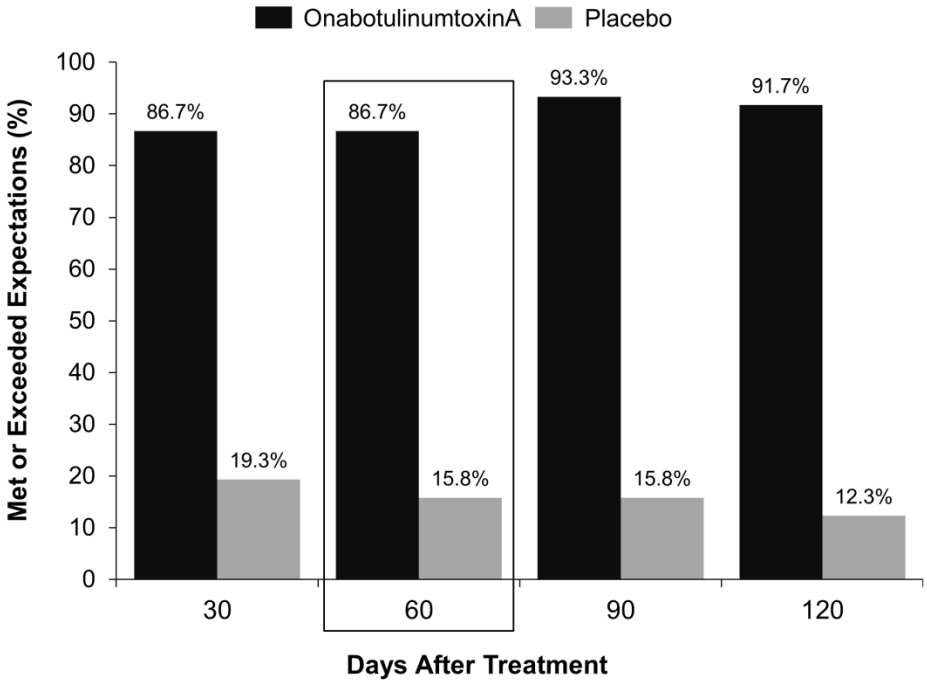
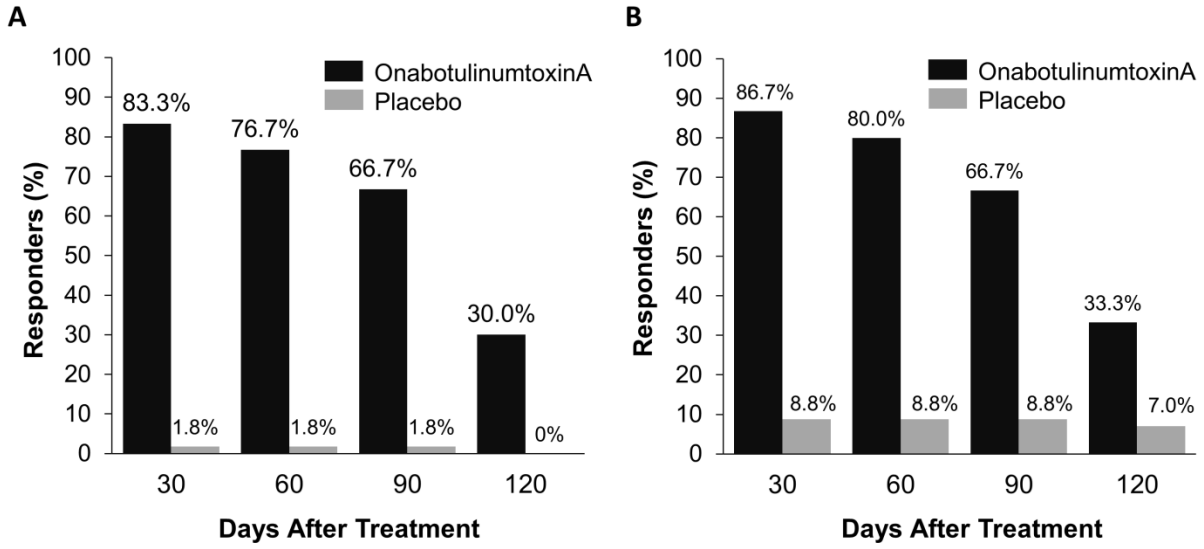


Figure 2. Responses on the investigator-assessed Facial Wrinkle Scale for (A) glabellar lines, based on ratings of “none” or “mild,” and for (B) crow’s feet lines, based on at least a 1-grade improvement from baseline.



Conclusions: High and sustained satisfaction in subjects treated with onabotulinumtoxinA for GL and LCL was achieved. At least 86% of subjects reported that treatment met or exceeded expectations at all time points.