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## Repeated Botox use improves patient satisfaction with no additional safety risk

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According to the third study in a phase 3 program, repeated Botox treatments of 24 U and 44 U significantly improved glabellar lines and crow's feet lines as assessed through Facial Wrinkle Scale and patient-reported outcomes.

The multicenter, double-blind, randomized, parallel-group, placebo-controlled study was an extension study of subjects who completed a 7-month phase 3 study, which allowed for up to two additional treatment cycles and up to 1 year of treatment exposure.

Subjects who had received Botox (onabotulinum toxin A, Allergan) in the first studies continued to receive the same dose in this study: 44 U for crow's feet lines (CFL) and glabellar lines (GL), or 24 U for CFL alone.

Those who received placebo previously were re-randomized to either 44U for CFL and GL or to placebo in a 1:1 ratio.

Primary end point was the proportion of subjects with a grade of none or mild at maximum smile on Day 30 based on investigator's Facial Wrinkle Scale ratings, according to researchers.

Patient-reported outcomes included the Subject's Global Assessment of Change in Crow's Feet Lines (SGA-CFL), the Facial Line Outcomes Questionnaire (FLO-11), Self Perception of Age and the Subject Satisfaction of Appearance.

A total of 667 subjects received the third treatment and most subjects (80.2%) received the third dose at the first study visit.

The responder ratings at Day 30 in achieving none or mild on Facial Wrinkle Scale for Botox were significantly greater than for placebo treatment, 63.6% for 44 U group, 56.5% for 24 U group and 1.1% for placebo.

At all other time points assessed the BTX-A responder rates were significantly greater.

Botox also showed greater improvement from baseline of at least one grade on the Facial Wrinkle Scale.

Patient-reported outcomes also favored Botox.

The proportion of responders for FLO-11 Items 2, 5 and 8 was significantly greater in the Botox treatment groups than in placebo on Day 30 and up to at least Day 60 in each treatment cycle. For Items 2, 5 and 8 Botox scored 76.3%, 66.0% and 61.4%, respectively, compared with 32.6%, 26.7% and 27.3%, for the corresponding placebo rates.

More Botox patients reported looking younger than their current age, 47.5% in the 44 U group, 38.7% in the 24 U group, vs. 5.1% in the placebo group.

Researchers also found that adverse events did not increase with repeated treatments and no new safety concerns arose. *-by Abigail Sutton*

**Disclosure:** Carruthers is a consultant and investigator for Allergan Inc. Please see the full study for a full list of all other authors' relevant financial disclosures.