

Escalating Doses of IncobotulinumtoxinA for Extended Treatment of Glabellar Frown Lines: Results from a Randomized, Double-Blind Study

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BACKGROUND

- The effect of escalating doses of incobotulinumtoxinA (Xeomin®, Merz North America, Inc.) at >20U for glabellar frown lines (GFL) on response rates and duration of response has not been studied in a prospective, randomized, double-blind manner.
- Previously, an analysis of a pilot study done at this same site suggested a roughly linear relationship to duration of response with doses escalating in 20U increments.
- Here, the objective was to assess the effect of varying doses of Xeomin on the safety, efficacy, and duration of treatment effect for GFL.

METHODS

Study design

- 50 male and female subjects were planned to be screened, randomized, and treated
- Subjects with moderate-to-severe glabellar lines (as assessed by 5-point Merz Aesthetics Scale [MAS]) were eligible to enroll
- Randomized to 3 treatment groups: 20 U (control; n=8), 60 U (n=11) and 100 U (n=17)
- 36 subjects completed the trial and were included in the analysis
- Subjects were eligible for retreatment at return to baseline
- Efficacy was assessed using standardized photography, self-assessment and investigator evaluation (MAS)

RESULTS

Efficacy

- Treatment response was highest in the 60U and 100U dose groups.
- A progressive increase in the duration of effect (return of mean MAS score to baseline) was noted with higher doses.
 - Mean scores returned to baseline at
 - 126 days: 20U
 - 198 days: 60U
 - 271 days: 100U
- By 9 months, 23% of those in the 100U group remained responders (defined by a stringent ≥ 2 -point MAS score improvement).
- Overall subject satisfaction was high.

Safety

- 19 AEs were observed in 14 subjects; none were unexpected or considered related to distant spread of toxin
 - The most common were headache, dry eyes and blurred vision, and injection site reactions (tenderness, erythema, numbness/warmth)
 - No ptosis was observed
- Favorable safety of incobotulinumtoxinA at higher doses is observed with no unexpected findings.

Figure 1. Mean Glabellar Lines Severity Score Over Time (MAS, Investigator-Assessed)

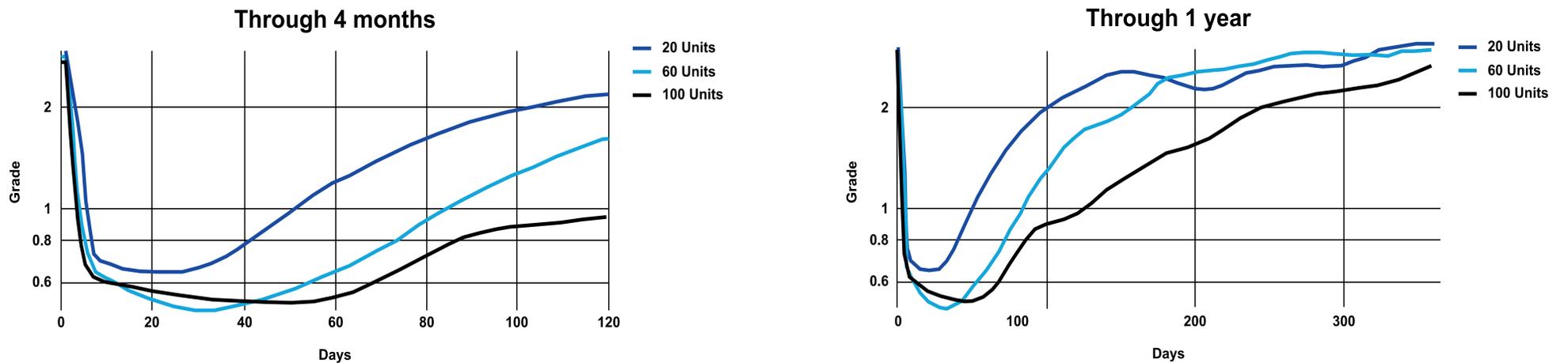


Figure 2. 60 U Dose: Results Through 9 Months



Figure 3. 100 U Dose: Results Through 10 Months



Figure 4. 100 U Dose: Results Through 1 Year



CONCLUSIONS

- A strong dose response was observed between incobotulinumtoxinA dose and duration of treatment effect
- Favorable safety of incobotulinumtoxinA at higher doses is observed with no unexpected findings
- Results show that the dosing of incobotulinumtoxinA for GFL may be safely increased from the standard 20U to help patients meet their individual treatment goals, including duration of effect
- A larger study is warranted based on these findings