A Comparison of Two Botulinum Type A Toxin Preparations for the Treatment of Glabellar Lines: Double-Blind, Randomized, Pilot Study

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BACKGROUND. **Botulinum toxins have been proven effective for reducing facial lines. There are two commercial types of botulinum toxin type A available in many countries but no published comparison studies.**

OBJECTIVE. **To compare the efficacy and tolerability of Botox Cosmetic and Dysport 50 U in the treatment of glabellar lines (using 20 U of Botox Cosmetic, which is the dose approved by the US Food and Drug Administration for the treatment of glabellar lines, and 50 U of Dysport, which has been reported to be the optimal dose for this formulation).**

STUDY DESIGN. **Parallel-group double-blind pilot study. Evaluation by observing physician, photographic, and patient evaluations.**

CONCLUSION. **Botox 20 U provided better and more prolonged efficacy than Dysport 50 U in the treatment of glabellar lines.**

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HYPERKINESIS OF the muscles in the glabellar region of the forehead contributes to the development of glabellar frown lines, and temporary paralysis of these hyperkinetic muscles can reduce the appearance of such lines. Botulinum toxin type A is effective in inducing such paralysis through its ability to block the presynaptic release of acetylcholine.

After many years of off-label use, the efficacy of botulinum toxin type A in the treatment of glabellar lines is now well documented in the literature,[1–4] and botulinum toxin has gained regulatory approval in several countries. There are two formulations available: Botox Cosmetic (Allergan, Irvine, CA, USA) and Dysport (Ipsen Limited, Slough, UK). However, these formulations behave in distinctly different ways electrophysiologically and clinically,[5] and the results obtained with one formulation cannot be extrapolated to the other.[6,7] Furthermore, there has been little research directly comparing the efficacy and tolerability of the two formulations in the treatment of glabellar lines.

Methods

Study Design

A double-blind, randomized study enrolled adult patients up to 60 years of age with glabellar lines of at least moderate severity at maximum contraction (on a scale of 0 = none, 1 = mild, 2 = moderate, or 3 = severe). Subjects were excluded from this study with factors that may interfere with the evaluation of response (eg, previous or upcoming facial cosmetic procedures, scars, asymmetry, atrophy, ptosis, or excessive dermatochalasis). Other exclusion criteria included a history of facial nerve palsy or any disease that may interfere with neuromuscular function and subjects using aminoglycoside antibiotics, curare-like agents, or agents that might interfere with neuromuscular function. Subjects who had any botulinum toxin therapy in the past year were excluded.

Treatment Regimen

Subjects were randomly assigned to receive Botox Cosmetic 20 U or Dysport 50 U (in five injections, one in the procerus muscle and two each in the corrugator muscles). The injector blinded and injected all subjects.

Outcome Measures

Glabellar line severity was assessed by a blinded investigator evaluating photographs (Modified Canfield System, Canfield Photography, Fairfield, NJ, USA) at maximum contraction. Glabellar line severity was rated as none, mild, moderate, or severe. Patients with ratings of none or mild were considered responders.

Another physician without knowledge of the patient treatment groups evaluated the photographs. Patient evaluation of global improvement used the following rating

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scale: complete improvement (100%), substantial improvement (75%), definite improvement (50%), some improvement (25%), unchanged, slight worsening (−25%), moderate worsening (−50%), and marked worsening (−75%). Patient satisfaction with appearance was measured on a scale of 0 (not at all satisfied with appearance) to 6 (extremely satisfied with appearance).

Results

Demographics

Thirty subjects were enrolled. They were predominantly white (97%) and female (80%), with a mean age of 42 years (range 27–60 years).

Subject demographics were comparable between the two groups, except that the Dysport group was significantly younger than the Botox Cosmetic Group (mean age 39 years versus 46 years; $p = .02$).

Efficacy

Physician and Photographic Grading

At maximum contraction, the incidence of responders (glabellar line severity of none or mild) peaked at 53% in both groups (Figure 1). Efficacy was more prolonged with Botox Cosmetic (Figures 2 and 3). At week 12, the incidence of responders was 47% with Botox Cosmetic versus 21% with Dysport (see Figure 1). Throughout the 20-week follow-up, a greater proportion of patients remained relapse free in the Botox Cosmetic group than in the Dysport group (Figure 4).

Patient Rating

The incidence of subjects reporting ≥ 50% improvement in glabellar line severity at week 12 was 64% with Botox Cosmetic versus 33% with Dysport (Figure 5). Patients' ratings of satisfaction with their appearance improved significantly more during treatment with Botox Cosmetic than with Dysport ($p < .01$ at week 12) (Figure 6).

Tolerability

Only one treatment-related adverse event was reported: mild bruising in one patient in the Botox Cosmetic group. No subjects suffered brow or upper eyelid ptosis.

Discussion

The dose for Dysport was selected based on the conclusions of the study by Ascher and colleagues, who suggested 50 U of Dysport to be the optimum dose used.[4]

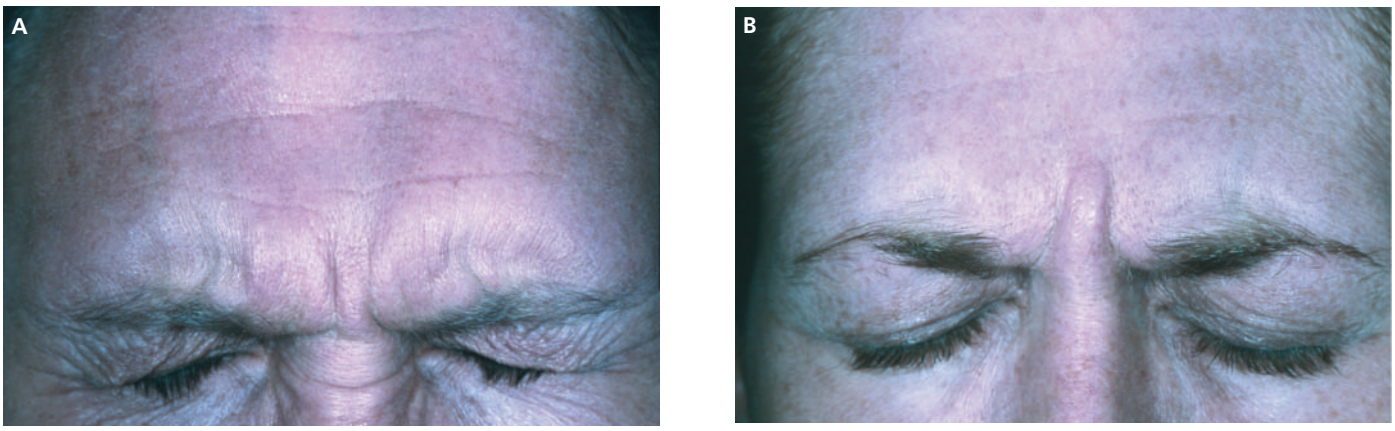

Figure 1. (A) Botox, pretreatment baseline. (B) Dysport, pretreatment baseline.

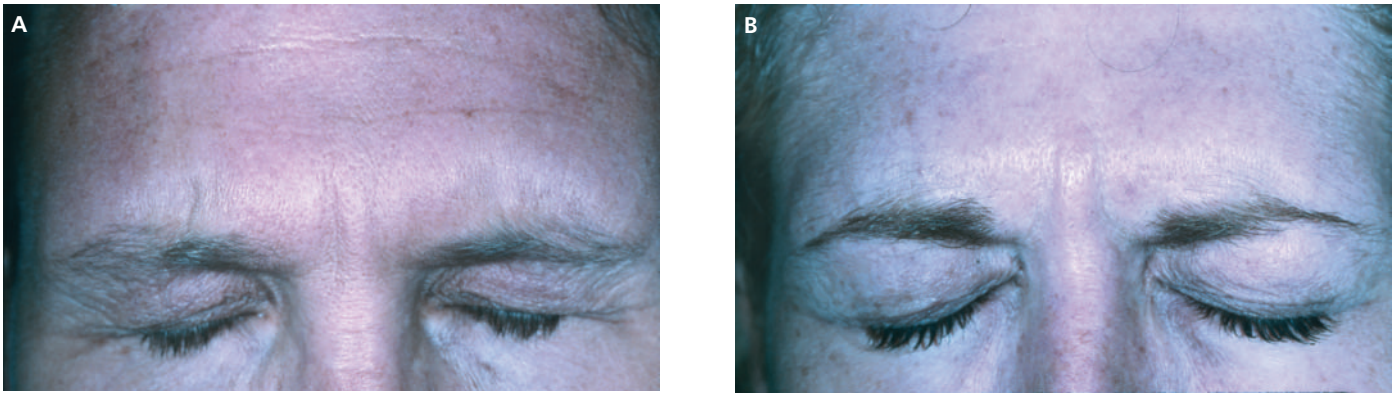

Figure 2. (A) Botox, 60 days post-treatment. (B) Dysport, 60 days post-treatment.

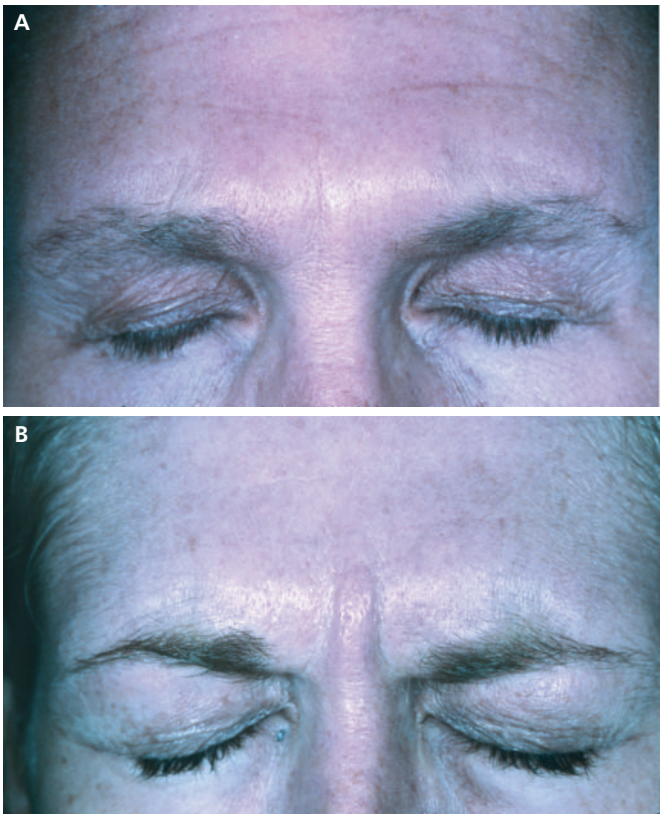

Figure 3. (A) Botox, 90 days post-treatment. (B) Dysport, 90 days post-treatment.

Using masked assessment of standardized photographs is suggested to be one objective means of evaluating glabellar line severity[4]; it was shown that Botox offers more prolonged efficacy than Dysport when the two products were compared in a 2.5:1 dose ratio (Dysport:Botox) (Figure 7). In addition, mean patient ratings of satisfaction with appearance were significantly higher with Botox than with Dysport. This is noteworthy because, although a subjective measure, patient judgment is of the utmost importance in the evaluation of cosmetic treatments.[4] Another study compared a higher dose ratio of these formulations in the treatment of glabellar and other facial rhytids.[8] A 4:1 ratio of Dysport:Botox (20 U:5 U) resulted in comparable efficacy between the two products, although only six patients were injected with Dysport.

The inherent differences between the formulations in diffusion and electrophysiologic characteristics mean that it is not possible to propose a single dose conversion ratio.[6,9] At a 2.5:1 dose ratio, the results of the study presented here suggest that Botox offers more prolonged efficacy relative to Dysport.

Conclusions

Botox 20 U offers more prolonged efficacy in reducing glabellar line severity than Dysport 50 U, with both products being well tolerated.

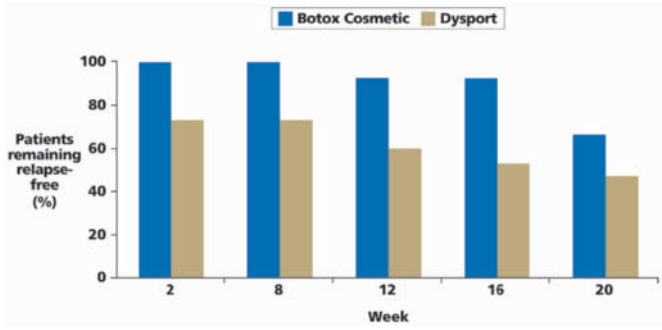

Figure 4. Percentage of patients remaining relapse free at 2 to 20 weeks.

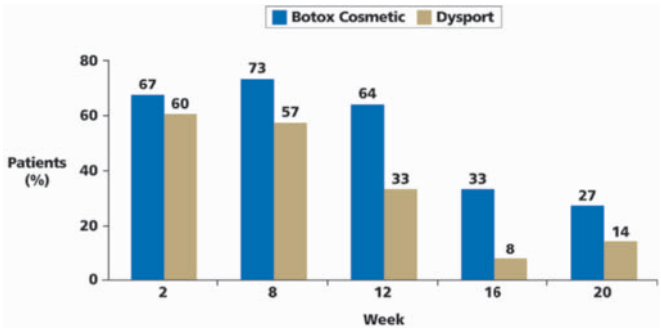

Figure 5. Patient self-satisfaction rating of glabellar rhytids.

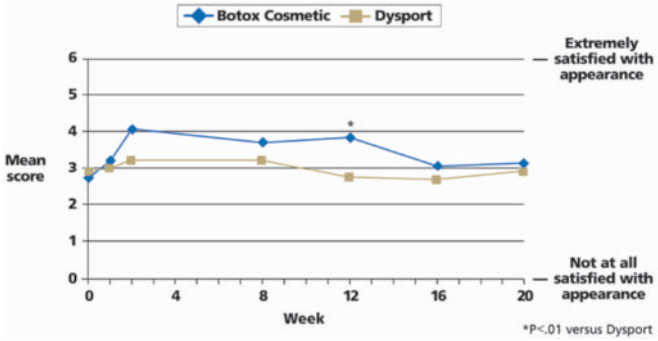

Figure 6. Patient satisfaction scores on a 0 to 6 score (score: 0 = not at all satisfied, 6 = extremely satisfied) between 0 and 20 weeks.

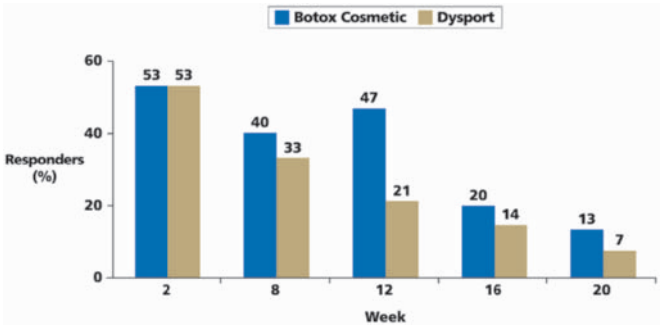

Figure 7. Percentage of respondents graded by photographic examination at maximum frown.

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