Cosmetic Microdroplet Botulinum Toxin A Forehead Lift: A New Treatment Paradigm

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**ORIGINIAL INVESTIGATION**

Purpose: To investigate the safety and efficacy of a microdroplet, cosmetic, periocular botulinum toxin A method that extensively treats the eyebrow depressors but leaves the brow elevators untreated.

Methods: This is a 5-year retrospective, consecutive, nonrandomized series of botulinum toxin treatments. The study was reviewed by an institutional review board and complied with the Health Insurance Portability and Accountability Act (HIPAA). Patients were treated with 33 U onabotulinum toxin (BOTOX, Allergan, Inc., Irvine, CA, U.S.A.) injected in microdroplets of 10 to 20 μl. Sixty to 100 injections of microdroplets were needed to complete a treatment pattern concentrated at the brow, glabella, and crow’s feet area. The forehead was not treated. Patients who returned between 10 and 45 days were studied with image analysis.

Results: There were 563 consecutive microdroplet treatments on 227 unique patients (female, n = 175, mean age 46 ± 4 years; male, n = 52, mean age 44 ± 8 years). The incidence of ptosis was 0.2% and transient. Forty-nine patients returned for a follow-up visit between 10 and 45 days and were included for image analysis to compare the before and after results of treatment. The average brow height was 24.6 mm before and 25 mm after treatment (p = 0.02). Photonic scores for forehead lines, brow ptosis, and brow furrow all showed statistically significant improvements (p < 0.0001).

Conclusions: The microdroplet brow lift method safely concentrates cosmetic botulinum toxin treatment along the eyebrow, crow’s feet, and glabellar area, resulting in a brow lift effect that reduces forehead lines, elevates the eyebrow, and reduces the furrow along the brow. This new treatment paradigm results in an aesthetic improvement to the face and periocular area without the forehead paralysis associated with conventional treatment.

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Carruthers and Carruthers reported a series of patients treated with botulinum toxin A to improve glabellar rhytids. Their report marked the invention of cosmetic botulinum toxin treatment, and their study ushered in a revolution in the delivery of less invasive aesthetic procedures as an alternative to surgery. Upper eyelid ptosis is an unwanted complication of periocular cosmetic botulinum toxin treatment. Eyebrow ptosis, however, is generally not considered a treatment complication. Pan-forehead injection has become a popular treatment pattern. The clinical effect is a smooth but immobile forehead, with a fall in eyebrow position. This frozen look has been ridiculed in the press and popular media.

The senior author (K.D.S.) hypothesized that it should be possible to improve the periocular appearance by directly treating the superior orbital orbicularis oculi muscle responsible for brow depression and leaving the frontalis muscle untreated with an acceptable risk of upper eyelid ptosis. The orbicularis oculi muscle at the eyebrows inserts into the dermis along with the inferior aspect of the frontalis muscle and significant portions of the corrugator supercili muscle. Selectively weakening the orbicularis oculi muscle and the other eyebrow depressors, including the corrugator supercili, along the orbital rim releases the brow to elevate without directly treating the frontalis muscle. Even at rest, there is activity in these muscle groups accounting for static periocular rhytids. Less brow depressor tone at the orbital rim should allow the frontalis muscle to relax, thereby reducing forehead wrinkles. Reduced muscle tone along the brows also softens the pinch that tends to occur along the brows and glabella when the brow is furrowed. Brow furrowing is associated with negative emotions. Treatment is accomplished with many small volume injections of botulinum toxin A solution, which are effectively trapped between the dermis and the insertion of the muscles of facial expression at the dermis along the eyebrow and glabella. This treatment is called a microdroplet botulinum toxin forehead lift. This study describes this treatment and analyzes a 5-year clinical experience.

MATERIALS AND METHODS

Anatomic Considerations. The eyebrows primarily function to communicate emotion. For this reason, opposing muscle groups, the frontalis muscle and the orbital portion of the orbicularis oculi muscle, and medially, the corrugator supercili intersect and interdigitate at the level of the eyebrow where these muscle groups insert into the dermis (Fig. 1). Simultaneous contraction of the opposing muscle groups forces a pinched ridge along the eyebrow to make facial expressions of anger and unhappiness. Extended glide surfaces at the level of the galea have been described that account for the mobility of the eyebrow. Inframaterally, the orbital orbicularis oculi muscle continues as a flat muscle that...
on the individual, there may be 2 or 3 rows of microinjections not placed lower than the lowest eyebrow cilia. Depending on the particular treatment pattern. Note that injections are inserted into the dermis of the eyebrow.

A typical treatment pattern. Note that injections are spaced as shown in FIG. 1. The orbital orbicularis oculi muscle, frontalis muscle, and the transverse head of the corrugator supercilii muscle insert into the dermis of the eyebrow.

Technique. After removal of the vacuum, 3 ml sterile saline was slowly instilled into a sterile vial containing 100 U of onabotulinum toxin (cosmetic BOTOX). The agent was stored between 2°C and 8°C and used within 24 hours of reconstitution. All patients were treated with 1 ml of the solution (33 U). A cream containing prilocaine and lidocaine was applied to the skin for 15 minutes. The cream was removed and the skin was prepared with a benzalkonium chloride solution specifically avoiding the cornea and conjunctiva. The botulinum toxin solution was drawn into a 1-ml syringe with 0.01 ml graduations. A 32-gauge needle was used for injection. Figure 2 shows a typical microdroplet pattern. The needle is inserted just below the dermis approximately 1 mm below the skin surface. This traps the injected solution between the dermis and the insertion of the muscle to be treated. Individual microdroplets were approximately 10 to 20 μl (0.01–0.02 ml). A treatment pattern consisted of 60 to 100 microdroplet injections to place the entire 1 ml botulinum toxin solution. No injections were placed below the lowest brow cilia to reduce the risk of ptosis. Laterally, injections stopped at the lateral border of the brow ptosis (Fig. 3).13,14 These were made available by Merz in color and printed on 10 by 16 inch photo paper. A new brow furrow photometric scale was developed to quantify the effect of muscular compression of the glabellar and brow musculature along the brow line (Fig. 4). This scale was reproduced in color on 13 by 19 inch paper. The scales were provided to the investigators to use to perform grading of these before and after image pairs. Three authors were presented images as before and after pairs for grading. Graders were not masked for this purpose. The senior author (K.D.S.) did not participate in grading.

The Student t test was used for paired parametric data and the Wilcoxon signed rank test for Likert scale data. Weighted κ was calculated to assess inter-rater agreement of the facial photometric Likert scales. A p value of 0.05 or less was considered statistically significant. A waiver of Institutional Review Board review for this retrospective study was obtained from Fox Institutional Review Board. The principles of Helsinki and HIPAA were adhered to in the conduct of this study.

RESULTS

There were 563 consecutive microdroplet treatments on 227 unique patients (female, n = 175, mean age 46 ± 14 years; male, n = 52, mean age 44 ± 8 years). A single injector (K.D.S.) performed all the treatments. Among patients having repeat treatment, the average time between retreatment was 6.4 ± 5.7 months (range 2–48 months; women 6.7 ± 6.0 months [range 2–48 months]; men 5.0 ± 3.8 months [range 2–18 months]). An office follow-up visit was performed in 256 cases (256/563, 45%). Phone follow-up was performed in 60 cases (60/563, 11%) and there was no follow-up information in 247 cases (247/563, 44%). There were 8 treatments corresponding to 8 patients who specifically complained that they were able to move their forehead after treatment, including 2 who were concerned with residual forehead lines. Two of these individuals requested additional direct frontalis botulinum toxin A treatment to simulate the effects of results they had experienced in the past. One patient complained of bilateral upper eyelid ptosis, which resolved within 2 weeks without treatment (incidence of ptosis = 0.2% [1/563]). Two patients reported flu-like symptoms following treatment. There were no skin infections and no significant bruises. There were no cases of diplopia or brow ptosis. Patient satisfaction was not measured in this study.

Forty-nine (49) treatments on 45 unique patients had a follow-up visit between 10 and 45 days (female, n = 32, mean age 42 ± 9 years; male, n = 13, mean age 48 ± 12 years). This allowed direct assessment of paired changes in the eyelid and brow positions before and after

FIG. 1. The orbital orbicularis oculi muscle, frontalis muscle, and the transverse head of the corrugator supercilii muscle insert into the dermis of the eyebrow.

FIG. 2. A typical treatment pattern. Note that injections are not placed lower than the lowest eyebrow cilia. Depending on the individual, there may be 2 or 3 rows of microinjections across the eyebrows.

Study Design. A 5-year period, July 2006 through June 2011, was selected for study. This corresponded to a time when a single cosmetic botulinum toxin A product (onabotulinum toxin A) was in use in the senior author’s practice. Patients were asked to return for a follow-up visit within 3 weeks of treatment. Those who did not return were contacted by phone to determine if there was a need for follow up. Patients who received filler services to the brow or upper eyelid or who had eyelid or brow surgery within 1 year of treatment were excluded from the study. All charts were reviewed for complaints related to treatment, including the incidence of upper eyelid ptosis. Patients seen 10 to 45 days after treatment were included for quantitative image analysis using ImageJ software (National Institutes of Health, Bethesda, MD, U.S.A.).15 Photographs were taken at each visit prior to any service with standardized illumination with the patient seated, face relaxed, and with a chin down position.

Measurements were made of the brow position using a modification of methods described by Huang et al.12 Each eyebrow was measured from the center of the cornea to the top of the eyebrow cilia temporally, centrally, and nasally. The brow measurements were averaged and analyzed statistically to compare before and after treatment. Additional measures included the right and left margin to corneal light reflex distance 1 and total platform show. These measurements were performed using ImageJ software on digitally captured images. To further assess the effect of treatment, before and after image pairs were rated using a previously developed and validated grading scale for forehead lines and brow ptosis (Fig. 3).13,14 These were made available by Merz in color and printed on 10 by 16 inch photo paper. A new brow furrow photometric scale was developed to quantify the effect of muscular compression of the glabellar and brow musculature along the brow line (Fig. 4). This scale was reproduced in color on 13 by 19 inch paper. The scales were provided to the investigators to use to perform rating of these before and after image pairs. Three authors were presented images as before and after pairs for grading. Graders were not masked for this purpose. The senior author (K.D.S.) did not participate in grading.

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treatment. Among the 49 treatments, 5 patients were treated twice with follow up in this time frame. The time interval between treatments in this subgroup was 8.4 ± 3.5 months (range 5–14 months). This suggests that “stacking” of treatment is not a factor in the analysis of the treatments with follow-up visits between 10 and 45 days in this study. No patient in the follow-up group was treated more than twice. Figures 5 to 8 show representative before and after images. The average brow height prior to treatment was 24.6 mm. Following microdroplet treatment the average brow height was 25 mm (p = 0.02). The margin to corneal reflex distance 1 was 3.6 mm bilaterally before treatment and RE 3.6 mm and LE 3.5 mm after treatment (p = 0.7). The tarsal platform show was also unchanged. There were no cases of eyebrow or eyelid ptosis in the 10 to 45 day follow-up group.

Photonumeric rating scales were used to rate the before and after pairs. The brow lift rating scale (Fig. 3A) ranges from 0—“high arched eyebrow” to 4—“flat, eyebrow with barely any arch; marked visibility of folds; very tired appearance.” Graders found before treatment an average brow lift rating of 2.00 and after treatment an average brow lift rating of 1.6 (p < 0.0001). The static forehead line scale (Fig. 3B) ranges from 0—“no lines” to 4—“very severe lines.” Using this scale, graders found an average pretreatment forehead line scale rating of 1.2 and a post-treatment rating of 0.8 (p < 0.0001). The brow frown rating scale (Fig. 4) ranges from 0—“youthful, relaxed brow” to 4—“tensed brow with furrows and muscle volume.” The average brow frown rating before treatment was 1.7 and after treatment was 1.0 (p < 0.0001). To assess inter-rater reliability, a weighted κ statistic was calculated to evaluate agreement among raters. The weighted κ statistic for these observations varied from 0.42 to 0.75, which is considered moderate to substantial agreement.

FIG. 3. A, The Merz Brow Positioning Scale. B, The Merz Forehead Line Scale. These scales are reprinted with the permission of Dr Carruthers and Merz Pharmaceuticals, GmbH (scales@merz.de). Copyright Merz Pharmaceuticals, GmbH.

FIG. 4. The Brow Frown Scale. This scale is reprinted with permission. 2014 copyright Kenneth Steinsapir, M.D.

FIG. 5. A, Before microdroplet botulinum toxin A treatment. B, After treatment. Note that this 43-year-old also received under eye and nasolabial fold fillers.
The risk of inducing upper eyelid ptosis has influenced the way in which periocular and forehead cosmetic botulinum toxin treatment is performed. The literature strongly advises the injector to stay at least 1 cm away from the orbital rim. This has profoundly limited the ability of injectors to directly treat the bulk of the brow depressor musculature. By trapping very small volumes of botulinum toxin solution high in the interface between the brow dermis and the insertion of the orbicularis oculi, frontalis muscle where it inserts into the brow, corrugator, procerus, and depressor supercili muscles, unwanted diffusion is limited compared with injecting botulinum toxin in larger volumes in or deep to these muscles.

Ramey and Woodward\textsuperscript{13} studied the mechanism of upper eyelid ptosis after botulinum toxin chemodenervation and concluded it could be avoided “through careful superficial positioning of the injection needle, using appropriately low volumes.” This study supports that assertion. Direct before and after measurements were possible in the 49 treatments where patients returned for a follow-up visit 10 to 45 days after treatment. These measures showed no evidence of eyelid or eyebrow ptosis associated with this treatment. Among all treatments in the study, there was a single case of upper eyelid ptosis, which was short lived (1/563, 0.2%). The incidence of upper eyelid ptosis with previously described periocular cosmetic botulinum treatments varies and is reported as high as 11% depending on the series.\textsuperscript{1,16} Not all patients in this study were seen in follow up. There may have been cases of ptosis among the patients who chose not to return for follow up. It is the authors’ experience that patients having a complication are generally motivated to return for follow-up care.

Cosmetic botulinum toxin studies often feature before and after photographs of a patient demonstrating maximal contraction of the glabellar area before treatment and a complete inability to corrugate the glabellar area in the after photograph.\textsuperscript{17} This dramatic demonstration of the paralytic effect of cosmetic botulinum toxin A has little to do with patient concerns, which are not necessarily the same as provider concerns.\textsuperscript{18} The patients do not need to resemble “wax figures” to have aesthetic benefit from cosmetic botulinum toxin.\textsuperscript{19,20} The microdroplet botulinum toxin forehead lift described here creates a lifted, less pinched brow complex without the need to paralyze the forehead.

Brow elevating treatment strategies have been described by Ahn et al.,\textsuperscript{20} Frankel and Kamer,\textsuperscript{21} Huilgol et al.,\textsuperscript{22} and Huang et al.\textsuperscript{23} These investigators avoid upper eyelid ptosis by using treatments that significantly limit the amount of the orbital orbicularis oculi muscle treated. Typically these treatments are placed superolateral to the eyebrow and 1 cm or more away from the orbital rim. This has led to hybrid treatments where glabellar treatment is combined with crow’s feet and extensive forehead treatment.\textsuperscript{2} While these treatments do substantially decrease forehead rhytids, the overall aesthetic result can be adynamic and inauthentic, and can cause significant brow ptosis.\textsuperscript{13,15} In some cases, undesirable, unopposed lift at the lateral edges of the forehead is seen as muscle recruitment lines and ripples.\textsuperscript{21}

Botulinum toxin is known to diffuse and spread from the site of initial injection. The spread of botulinum toxin is a mechanical effect related to physical aspects of the injection methods, including injection volume, infusion rate, type of needle, and possibly other physical factors. Diffusion relates to the thermodynamic behavior of concentrated microscopic particles to disperse over a larger region. Increasing dilution is associated with increased spread of botulinum toxin A.\textsuperscript{24} Diffusion is often assessed by measuring the anhidrotic halo around an injection site. The anhidrotic halo does not correlate with the paralytic effect of the treatment.\textsuperscript{25} Borodic et al.\textsuperscript{26} investigated the spread of botulinum toxin in a longissimus dorsi rabbit model. They found that relatively dilute botulinum toxin injections (1.25 U/0.1 ml) at a dose of 2 to 3 U/kg could be found to spread up to 30 mm from the site of injection.\textsuperscript{26} Hsu et al.\textsuperscript{24} also

\textbf{DISCUSSION}

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examined the effect of injection volume on postinjection botulinum toxin diffusion using a 5-U dose of botulinum toxin A in a single injection point in each frontalis muscle belly of volunteers. On one side the dose was in 0.25 ml preserved saline and on the other side the dose was in 0.05 ml preserved saline. The more dilute injection affected a greater area in their subjects.24

In this study, the authors limited injections to 10 to 20 μl (0.01–0.02 ml) injections that contained 0.33 to 0.66 U of onabotulinum toxin. They did not specifically test for diffusion. It was their impression that small doses of onabotulinum in small volumes diffused very little. No formal dose ranging studies were performed to establish the 33-U dose of onabotulinum toxin. The senior author (K.D.S.) has treated patients using this method in dosages ranging from 8 to 100 U and in dilutions ranging from 100 to 250 U/ml, but historically has used 33 U/ml. All the commercially available botulinum toxin A formulas have been successfully used to perform the microdroplet botulinum toxin forehead lift. Anecdotally the dose of 33 U has worked well for approximately 95% of patients with treatment effects lasting 3 to 4 months, which is consistent with the duration of effect noted with conventional treatment methods.2

While patients in this study received their treatment in microinjections of 10 to 20 μl containing between 0.33 and 0.66 U onabotulinum toxin A (Botox), or incobotulinum toxin A (Xeomin), Merz Pharma GmbH & Co. KGaA, Frankfurt, Germany. It is the authors’ hypothesis that these macroinjections of botulinum toxin solution, which typically are not controlled for depth of injection, are the source of many of the side effects that are caused by unwanted diffusion of the products, including excess or focal forehead paralysis, muscle recruitment effects, and eyelid ptosis. It should be noted that the eyebrow ptosis associated with conventional pan-forehead treatment is likely the primary result of the treatment design itself, with diffusion also contributing to the effect.

The authors believe that individual injectors can work with the botulinum toxin solution concentration they are accustomed to with this method, provided they limit the microdroplet volume to 10 to 20 μl per injection at a tissue depth of approximately 1 mm with treatment placed no lower than the lowest brow cilia.25 For example, an injector working with a dilution of 50 U/ml (100 U onabotulinum toxin in 2 ml injectable saline or 0.5 U in 10 μl) would draw up 0.66 ml of this solution, which would contain a total dose of 33 U. One 10 μl (0.01 ml) microdroplet would contain 0.5 U onabotulinum. A total treatment pattern would consist of 66 microdroplet injections for a total dose of 33 U. Commercially available tuberculin syringes are marked in 0.01 ml graduations, which can assist in controlling the microdroplet volume.

In this entire series, there were no patients who were missing all of their eyebrow cilia. It might be argued that performing this treatment would be difficult in a patient who had no brow cilia. This was not an issue in this series. Among the 49 patients who returned for a follow-up visit between 10 and 45 days, no one changed how their eyebrows were groomed, so this possible confounding factor did not materialize for this study. Due to opposing muscle groups that meet at the brow, an edge is formed when the brow is maximally contracted.26 The oblique ridge that is formed corresponds to the path of the brow cilia which would allow one to identify the course of the brow even if no brow cilia are present.

Investigators have written about facial shaping with cosmetic botulinum toxin without really defining what is meant by “shaping” and precisely how it is achieved.29,30 Affect theorists and neuropsychologists have demonstrated that the face is the primary instrument for both experiencing and communicating basic emotional states.8 The muscles arrayed about the eyebrow can be used to communicate anger, sadness, and fear.6,7,21,32 Experiments based on facial feedback theory demonstrate the power of glabellar botulinum toxin treatment to influence the emotional state of the individual.6,32 If there is a semiotics of facial shaping, beneficial changes should convey emotional valences associated with happier, less stressed, and more youthful-appearing faces without evidence of paralysis. The microdroplet botulinum toxin forehead lift seems to meet these requirements. The photonic numeric rating scales demonstrate that this treatment is associated with less frowning at the eyebrow, fewer forehead lines, and an elevation in brow position.

The brow furrow scale introduced here is a photonic numeric scale that grades increasing activity of the muscles of facial expression that act at the eyebrow and glabellar area. This study did not look to validate this new scale, which the authors hope to do in a future study. The authors did not quantitate or measure the retained toxin to move naturally after service. Only the most inferior aspect of the frontalis muscle, where it inserts into the brow, was treated. For this reason, patients retain a normal ability to move the forehead together with brow elevation, fewer forehead lines, and less brow frowning with this service. It is their impression that preserving natural forehead movement after treatment contributes to patient acceptance of this service, and this also deserves further investigation.

The microdroplet botulinum toxin forehead lift is an important shift in how cosmetic periocular botulinum toxin can be performed. The result softens the harsh pinch along the brow that signals disapproval and anger.29,33 With the brow depressors weakened, the frontalis muscle is able to lift the brow with less effort, accounting for a reduction in forehead lines without direct forehead treatment. Patients accustomed to an immobile forehead after cosmetic botulinum toxin may require re-education regarding why it is better to preserve forehead movement. Patients who are concerned about the persistence of forehead lines may request direct frontalis treatment with botulinum toxin in follow up. Anecdotally, patients have regretted this choice because it reduces the brow elevation effect.

It is a valid criticism that patients in this study were not given an opportunity to assess how they felt about the treatment. This was a retrospective study and patient self-assessment was not formally recorded. This study weakness will be addressed in future prospective studies. The natural movement that is preserved in the forehead results in a treatment that does not telegraph the use of cosmetic botulinum toxin. The authors believe that this service may appeal to consumers who have been reluctant to have treatment due to concerns about forehead paralysis that has come to typify treatment with previously described cosmetic botulinum toxin methods.

The authors firmly believe that experienced injectors who understand the rationale behind this treatment will easily adapt to the microdroplet botulinum toxin paradigm. It is important not to confound this treatment paradigm using superficial microdroplets of botulinum toxin solution with older treatments using larger volume injections of botulinum toxin solution in the brow. Placing larger volume injections of botulinum toxin low in the brow will foreseeably lead to upper eyelid ptosis. It is important to respect the principle of small volume injections that are kept superficial to avoid unwanted upper eyelid ptosis.
REFERENCES