A Multicenter, Open-Label, Prospective Study of Cannula Injection of Small Particle Hyaluronic Acid Plus Lidocaine for Lip Augmentation

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INTRODUCTION: The use of blunt-tipped microcannulas is on the rise in augmenting facial soft tissue with dermal fillers.

PURPOSE: This study was conducted to assess the safety and effectiveness of Restylane® Silk (Q-Med AB, Uppsala, Sweden), a small particle, hyaluronic acid gel plus lidocaine (SPHAL), in conjunction with a small blunt-tipped cannula (range 25G-30G) for lip augmentation and optional correction of perioral rhytids.

METHODS: An open-label, non-comparative 12 week prospective study conducted in 4 U.S. centers evaluated the safety and effectiveness of SPHAL in conjunction with a blunt-tipped cannula. Adverse events (AEs) were collected throughout the study. Subjects reported predefined, expected post-treatment injection site reactions during the first 2 weeks post-treatment via diary. Effectiveness assessments at 4 and 12 weeks post-treatment included treating investigator- and subject-reported Global Aesthetic Improvement Scale (GAIS) scores and treating investigator-reported evaluations using the Medicis Lip Fullness Scale (MLFS).

RESULTS: Sixty subjects aged >=23 years (93% women; 88% Caucasian; mean age, 46.5 years), were enrolled. Mean (SD) total volume injected (ie, both lips and optional perioral rhytids) was 2.2 (0.6) mL. Of the 27 treatment emergent adverse events (TEAEs) reported, 21 were assessed as related to the product and/or injection procedure - injection site swelling (13.3%), injection site bruising (6.7%), and injection site pain (1.7%). Related events were typically mild and transient in nature (median duration - 5 days). No serious AEs (SAEs) were reported. Following treatment, clinically significant improvement using the GAIS and MLFS was demonstrated in a vast majority of subjects through study end (GAIS improvement at week 12: investigator-reported, 98%; subject-reported, 84%; MLFS improvement at week 12: investigator-reported, 96%).

CONCLUSION: SPHAL was well tolerated and effective following injection with a blunt-tipped microcannula. No new safety concerns were identified in the study population.

Subjective and Objective Facial Dynamics Using Dermal Fillers Formulated for Facial Movement Adaptation

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INTRODUCTION: The fear of looking unnatural is a well-known concern for patients contemplating dermal aesthetic procedures. Facial dynamics
is an increasing area of clinical focus extending beyond 3-D volume restoration, as naturalness of clinical outcomes at rest and with animation may vary. We evaluated the dynamic face using subjective and objective methods following treatment with dermal fillers formulated with physicochemical properties for facial movement adaptation.

METHODS: Thirty Caucasian females (40–65 years) with moderate to severe, bilateral wrinkles in the lower face were treated with HA fillers (20mg/mL with XpreshAn Technology™) and followed 4 weeks post-optimal correction. Subjective, dynamic assessments evaluated pre- versus post-expressions in motion (2D videos), using a series of standardized expressions. Facial dynamics were objectively evaluated and quantified using 3-D stereophotogrammetry (Canfield Scientific, Inc), including a younger, untreated Caucasian female cohort (N=20; 25–35 years). Satisfaction of treated subjects was assessed using a 5-point Likert scale.

RESULTS: Subjective facial dynamics revealed naturalness of the lower face in motion to be at least maintained in 100% of subjects (naturalness maintained or enhanced). Collectively, 83.3% of subjects were rated with enhanced attractiveness and looked younger, without compromise in naturalness. Rater agreement was high for individual assessments of attractiveness, youthfulness, and naturalness (70.0% – 83.3%). Subject satisfaction ratings were consistent with treating investigator assessment, with post-treatment improvement across all items assessed based on proportions of subject agreement (strongly agree or agree). Highest levels of subject satisfaction (>80%) observed post-treatment pertained to overall facial appearance is pleasing (90.0%); overall facial appearance looking natural (100%); face looking natural when relaxed (96.7%) and when smiling (93.3%), and looking younger than actual age (83.3%). For specific anatomic areas (marionette lines), global dynamic assessment using 3-D stereophotogrammetry showed significantly higher levels of stretch in older (20.1%, pre-treatment) versus younger subjects (17.7%; p<.05), with stretch levels significantly reduced post-treatment (17.9%; p<.05) such that older subjects post-treatment resembled younger subjects.

CONCLUSION: Dermal fillers formulated with XpreshAn Technology™ resulted in subjective dynamic assessments characterized by improvements in attractiveness and youthfulness, without compromising naturalness. Objective facial dynamics provided quantitative evidence of stretch levels resembling a younger phenotype, in areas specifically prone to dynamic volumetric effects of facial aging. This work underscores the importance of objective dynamic assessment as the fourth dimension of facial aesthetics.

Juvederm Volbella for Use in Periorbital Volumization

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INTRODUCTION: Periorbital volume loss contributes significantly to facial aging and can result in tear trough deformities and infero-lateral skeletonization of the orbit. Tear trough augmentation with injectable hyaluronic acid based filler is an established technique for augmenting periorbital volume loss, but it has thus far been limited by swelling, contour abnormalities, and the Tindell effect. Juvederm Volbella (Allergan Inc., Irvine, CA, USA) is a new 15mg/mL hyaluronic acid dermal filler formulated using a majority of low molecular weight hyaluronic acid and a minority of high molecular weight hyaluronic acid for tighter cross-linking (“VYCROSS”). As a hydrophilic, malleable, homogenous matrix, the rheology of Volbella allows it to distribute evenly in treated tissue beds.

PURPOSE: To date, tear trough augmentation has most commonly been performed with Restylane, Belotero, and Juvederm. In this paper, we studied Volbella, which has been FDA approved for lip augmentation and perioral rhytids, for off-label use in tear trough augmentation.

METHODS: A retrospective chart review was conducted on a cohort of all periorbital aging patients in a single-surgeon practice who underwent tear trough augmentation using Volbella. Patients who underwent tear trough augmentation with other dermal fillers or with autologous fat grafting were excluded. Mean follow up time was 2 weeks.

RESULTS: 81 patients met inclusion criteria and were included in this technique analysis. Of those, 2 had had previous lower eyelid blepharoplasties. Patients were treated with between 0.55cc and