A POST MARKET, DOUBLE-ARM STUDY TO ASSESS THE TOLERANCE AND SAFETY OF TOPICAL FORMULATIONS IN ADJUNCT TO ABOBOTULINUMTOXINA OR HYALURONIC ACID SOFT TISSUE FILLER

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INTRODUCTION

Today, very few topical products are clinically tested for complementarity with facial injections. As an initial step, the safety of the combined use of topical formulations with injectable treatments must be confirmed. The primary goal of the study was to assess the tolerance profile of the combined use of topical formulations with neurotoxin and filler injections, as well as to determine subject sentiment about application of the test products.

METHODS

This IRB-approved study enrolled and randomized a total of 50 subjects into two distinct groups treated over a three week period.

Group 1 (n=25) consisted of subjects treated for peri-orbital rhytides with abobotulinumtoxinA injections (Galderma Laboratories L.P.) and applying a novel mineral sunscreen (SkinCeuticals Inc.) around the peri-orbital area. Group 2 (n=25) consisted subjects receiving hyaluronic acid soft tissue filler (Allergan Inc.) to enhance their vermilion border in combination with a topical cosmeceutical lip formulation (SkinCeuticals Inc.).

The topical products were applied daily beginning one week prior to injection visit and continued for the entire three week duration of the study. All injections were performed 5±3 days after topical formula application commenced.

Tolerance was assessed by the clinician immediately after initial test product application, before and after the injections, and finally 2 weeks after the injection visit. Additionally, subjects were asked to complete a daily dairy to assess the tolerance of the product, as well as answer self-assessment questionnaire at baseline, injection visit, and 2 weeks post-injection.

RESULTS

The resulting data indicated that the combined modality of topical formulations and cosmetic injections was well tolerated as indicated by clinician assessed tolerance and ecchymosis scales throughout the study.

Review of the patient completed diaries determined an absence of any severe or serious adverse reactions during the entire three week duration of the study.

Of the 9 subjects in Group 1that exhibited edema or erythema post-injection, 8 subjects showed improvement in these parameter 10 minutes after application of the mineral sunscreen. (Figure 1)

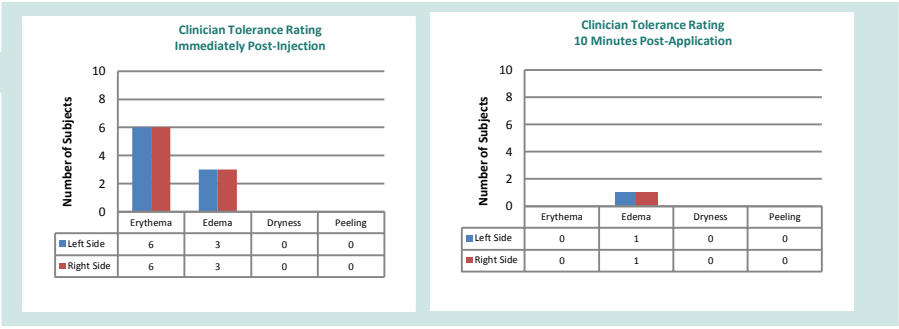

Figure 1: Clinician Rated Tolerance Immediately Post-injection and 10 Minutes Following Product Application

Of the 4 subjects in Group 1 that exhibited ecchymosis, 3 exhibited diminished ecchymosis post-application of the mineral sunscreen, with the remaining subject's ecchymosis resolving completely. (Figure 2)

Subjects in Group 2 did not encounter any increase in erythema or instances of ecchymosis.

Results from the patient questionnaire indicate a high degree of satisfaction with both test products.

Clinician Evaluated Ecchymosis Rating Immediately Post-Injection

Ecchymosis Severity	0 No color change	1 Yellowish color change	2 Light purple	3 Dark purple	4 Very dark purple
Number of Patients	21	0	**4**	0	0

Clinician Evaluated Ecchymosis Rating 10 Minutes Post-Application

Ecchymosis Severity	0 No color change	1 Yellowish color change	2 Light purple	3 Dark purple	4 Very dark purple
Number of Patients	**22**	**3**	0	0	0

Figure 2: Clinician Rated Ecchymosis Immediately Post-injection and 10 Minutes Following Product Application

CONCLUSION

- The findings suggest that the use of topical formulations in conjunction with injectable treatments result in a well-tolerated improvement in overall appearance of the treatment area.
- Usage of both cosmeceutical products as an adjunct to injections targeting peri-ocular rhytides and vermillion border was deemed safe, and was determined to be lightweight and comfortable with the added benefit of trouble-free application.
- In summation, these results offer preliminary evidence that the combination of injections and topical products is both a safe and effective way to support the clinical benefits of injections.

« The authors declare no conflict of interest »