Bimatoprost Proves to Be Well Tolerated

BY MARY ELLEN SCHNEIDER

Just as patients are beginning to come into the office seeking eyelashes as long and thick as those belonging to Brooke Shields, Dr. Christopher B. Zachary gave his run-down on the safety and efficacy of bimatoprost 0.03%.

The bottom line appears to be that the product has a clinically meaningful benefit and is well tolerated in healthy adults, Dr. Zachary said at a cosmetic dermatology seminar sponsored by Skin Disease Education Foundation (SDEF).

"Appropriate studies have been performed to demonstrate the efficacy and safety of this product," he said in an interview. "But as with any new cosmetic procedure, patients need to be aware of the potential for side effects."

Eyelash growth using bimatoprost was first characterized in two controlled phase III trials in glaucoma. The discovery of a secondary application for bimatoprost is not a surprise, said Dr. Zachary, chair of the department of dermatology at the University of California, Irvine. "Many products when developed and utilized extensively for one indication will inevitably be associated with effects in other systems," said Dr. Zachary, who serves on various academic advisory boards for Allergan Inc.

Since the benefit was first observed in glaucoma patients, researchers performed an open-label trial showing the efficacy of bimatoprost when directly applied to the eyelid margin.

The open label, proof-of-concept study included 28 women who applied the product daily over the course of 12 weeks. The study demonstrated the effectiveness of the product, with all women who responded to questions about efficacy reporting at least some improvement in their eyelashes. None of the patients discontinued treatment as a result of adverse events, and only minor, transient adverse events were reported. Additionally, changes in intraocular pressure were not statistically significant, Dr. Zachary said.

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A confirmatory phase III trial of 278 patients used a global eyelash assessment, digital image analysis, and patient-reported outcome measures to assess the efficacy of the product. At the end of 16 weeks, a statistically significant percentage of patients in the bimatoprost group had improvements in eyelash prominence, length, thickness, and darkness, compared with the vehicle group. The results of the randomized, double-blind, placebo-controlled study were consistent across age and race.

In terms of safety, four patients in the bimatoprost group and four patients in the control group discontinued due to adverse events. All of the treatment-related events were minor: eczematous change, irritant dermatitis, dry eye, eyelid erythema, and low intraocular pressure.

When used by glaucoma patients over long periods, bimatoprost resulted in darkening of the iris in some, Dr. Zachary said. Although this effect was not found in any of the cosmetic trials, patients should be informed of this possibility.

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Treatment results can be seen in these photos from Allergan's clinical trial.

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