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Abstract Title:	**Efficacy and Safety of Long-Term Bimatoprost Treatment in Glaucoma and Ocular Hypertension**
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Background: In its pivotal trials for drug approval, bimatoprost reduced IOP by 2-3 mm Hg more than timolol. In other trials, bimatoprost reduced IOP by up to 2.2 mm Hg more than latanoprost. Mild conjunctival hyperemia was the most frequent side effect.
Purpose: Evaluate the efficacy and safety profile of bimatoprost over long-term use.
Methods: The pivotal trials comparing bimatoprost with timolol were extended to 3 years. A total of 183 patients were enrolled for the 3rd year of treatment: 43 patients from the original timolol treatment group were continued on timolol b.i.d., 90 from the original bimatoprost q.d. group were continued on bimatoprost q.d., and 50 from the original bimatoprost b.i.d. group were switched to a once-daily regimen of bimatoprost in a masked fashion. Efficacy was evaluated by the mean IOP reduction from baseline IOP. Safety evaluations included adverse events reported during the 3rd year that were not ongoing at month 24, and adverse events that were ongoing at month 24 and increased in severity during the 3rd year.
Results: Bimatoprost q.d. continued to show superior efficacy to timolol throughout the 3rd year of treatment. Mean IOP reductions from baseline at 10 AM (peak drug effect) ranged from 7.1-7.9 mm Hg in the bimatoprost q.d. group compared with 4.9-5.2 mm Hg in the timolol group ($P \leq .009$). In patients switched from b.i.d. to q.d. dosing of bimatoprost, mean IOP reductions at 10 AM ranged from 5.8-6.0 mm Hg. There were no serious treatment-related adverse events during the 3rd year. Treatment-related conjunctival hyperemia was reported for 12.9% (18/140) of bimatoprost-treated patients. These cases were graded as mild or moderate; none were severe. On biomicroscopy, 48.6% (68/140) of patients had at least a trace increase in conjunctival hyperemia from untreated baseline at one or more study visits during the 3rd year. No patients, however, discontinued from the study during the 3rd year due to conjunctival hyperemia or due to any other side effect of treatment. There were no reports of increased iris pigmentation or CME during the 3rd year.
Conclusions: The long-term efficacy and safety profiles of bimatoprost are favorable. Once-daily bimatoprost provides sustained, superior IOP lowering, and glaucoma patients that tolerate bimatoprost initially continue to do so over long-term treatment.

Commercial Relationship:	**J.S. Cohen**, Allergan, Inc. C, R; Merck R; Pfizer R; **L. Greff**, None.