

Bimatoprost 0.3 mg/ml ophthalmic solution for lash growth – Pilot study, half side trail

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Abstract

Background: Bimatoprost is a prostamid analogon. It has been successfully used for many years in the treatment of glaucoma. Increased lash growth has been detected as an adverse reaction in using this drug. This implicates that treatment of the skin at the upper and lower lashlines with bimatoprost 0.3 mg/ml ophthalmic solution may lead to eyelash-length enhancement, resulting in a better appearance in aesthetic terms.

Material and methods: To prove its effectiveness on lash growth bimatoprost 0.3 mg/ml ophthalmic solution has been applied twice a day for a six-week period on the outer rim of the right upper eyelid in 15 volunteers. The untreated left eyelid was used as control. Lash growth was documented by clinical photography before and after the treatment period. Furthermore, there was a standardized patient-questionnaire to be answered.

Results: Within a six-week period of topical use of bimatoprost obvious enhancement in length of the eyelashes occurred. Photo-documentation showed the difference in lash lengths on the right and left upper eyelids in 9 of 12 participants (75%). In a standardized questionnaire almost 40% of participants reported short-term, reversible side effects like reddening of the eye, foreign body sensations, itching and enhanced growth of hair off the lashline. A statement regarding thickness and darkness of the lashes could not be given, 85% would recommend the product to others.

Discussion: Our results support the concept of using bimatoprost 0.3 mg/ml ophthalmic solution as an eyelash enhancing interval therapy for the treatment of eye lash hypotrichosis or for aesthetic purposes. Despite the clear positive effects on lash growth, there is still a certain risk of unwanted side effects. Users have to take this under consideration. Further controlled studies have to enlighten the effect of bimatoprost on the abbreviation of the telogen phase of the eyelashes.

Introduction

Long eyelashes have always been a symbol of beauty and attractiveness. There are many ways to increase lash length, thickness and darkness like using different types of mascara, false lashes, lash transplantation and a variety of sera.

The hair cycle of eyelashes lasts five to twelve months: anagen-phase one to two month, catagen-phase 15 days and telogen-phase four to nine months [1]. The length of the hair depends on the duration of anagen-phase [2,3]. Bimatoprost, a prostamid analogon ($C_{25}H_{37}NO_4$), has been used successfully for decreasing the intraocular pressure in chronic open-angle glaucoma and ocular hypertension for decades. Increased lash growth has been observed as an adverse drug reaction. This effect is supposedly related to a prolongation of the anagen phase, the growth phase of the hair cycle. According to the literature it may also lead to an increase of thickness and darkness of the eyelashes [1,4-8]. Therefore Latisse® (bimatoprost ophthalmic solution 0.03%) was FDA approved for the treatment of hypotrichosis of the eyelashes in the United States in December 2008 [4].

As this product is not available in Europe, we designed an off-label-use study utilizing bimatoprost 0.3 mg/ml eye drops (Lumigan®) for the enhancement of lash growth.

Material and methods

Recruiting

Healthy volunteers have been recruited by announcement in the polyclinic of the Department of Dermatology at the Medical University

of Graz. Fourteen female and one male test persons (age 20 to 34 years, mean 26) were included in consideration of the inclusion and exclusion criteria (Table 1). According to GCP-regulations they could reject their participation at any time. Before study start informed consent has been signed by each participant. The study was approved by the ethics committee of the Medical University of Graz.

Study design

Bimatoprost 0.3 mg/ml ophthalmic solution was tested for its effectiveness on lash growth on the upper eyelid of the right eye, the left upper eyelid served as a control (half-side-trail). Lash length was documented by clinical photography before and after the treatment period. Both eyes were photographed without and with black mascara, as well as without and with scale. For duration of six weeks all participants had to apply the study drug two times every day. At the end they had to answer a short questionnaire concerning side effects and patient satisfaction.

For the duration of the study no eyeliner or any sort of eye drops should be used.

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Table 1. Inclusion and exclusion criteria.

Inclusion criteria	<ul style="list-style-type: none"> • Persons of both sexes between 18 and 99 years • Signed informed consent before the start of the study • Effective contraception in women of child-bearing potential [as per description of the ethics commission Austria]
Exclusion criteria	<ul style="list-style-type: none"> • Use of contact lenses during the study • Use of eye drops (indication and product irrelevant) during the last six month • Pregnant women or women of child-bearing potential without an effective contraception • Known hypersensitivity or allergy to Bimatoprost or one of the other ingredients of Lumigan® 0,3 mg/ml ophthalmic solution

Table 2. Analysis of the Images.

Rating	Number of Participants – Baseline	Number of Participants – End Date*
+ 1	0	9
0	12	3

* Six weeks after the start of the study

Results

Fifteen healthy volunteers were included, two dropped out because of a non-itching reddening of the eye, one after two, the second after four days. One person confessed irregular use, her questionnaire was evaluated, and her pictures were not.

Therefore we analysed the clinical photography of 12 participants and the questionnaires of 13.

Images

The overview pictures (both eyes) were taken for the analysis with the naked eye.

No statement concerning a change in thickness or darkness could be given.

Scoring was performed by comparing the length enhancement of the lashes on the right and left eyelid: 0 meaning no change and + 1 meaning visible longer lashes on the treatment side (right upper eyelid). Images were evaluated by three independent physicians from the Department of Dermatology. There was a 100%-match of the results (Table 2).

As expected at the beginning of study there was no difference in the length of the lashes. After the six-week period of topical use of bimatoprost on the right upper eyelid there was an obvious difference in length of the eyelashes in 75% of the participants, 25% showed no assessable difference. Examples of rated images can be seen in Table 3.

Standardized patient questionnaire

11 of 13 participants (84.7%) were satisfied or very satisfied with the product. All test persons were satisfied or very satisfied with the mode of application of the product. 9 of 13 participants (69.2%) claimed that there was an increased lash growth. 84.7% of the participants would recommend the product to others.

38.5% of them reported short-term, reversible but unwanted side effects like reddening of the eye, foreign body sensations, itching and enhanced growth of hair underneath the lashline. These effects were part of the expected side effect profile (Table 4).

A statement regarding thickness and darkness of the lashes could not be given.

Discussion

Bimatoprost, used for the treatment of chronic open-angle glaucoma and ocular hypertension, has shown undesired eye-lash growth as a side effect [1,4,5,7,9-13]. Harii *et al.* (2014) demonstrated increased eyelash growth for aesthetic purposes in 29.5% of the participants after one month, 48.9% after two, 77.3% after three and 78.6% after four month [9].





Our study underlines that topical use of bimatoprost on the eyelids leads to an obvious enhancement in length of eyelashes in 75% of the participants after a six-week period. In our study almost 40% of the participants showed side effects. This number is similar to comparable studies from Harii *et al.* and Smith *et al.* [10,12].

As the anagen-phase lasts one to two months [6] bimatoprost leads to a prolongation of this phase of the hair cycle [4,5,12]. Randall *et al.* stated that the telogen-phase of eyelids lasts four to nine months [3]. So far, bimatoprost-induced changes of the duration of the telogen phase have not been explored yet. Our findings suggest that the prolongation of the anagen phase could perhaps cause a shortening of the telogen phase of the eyelash growth cycle. Thus, further studies have to be conducted to newly define the duration of the growth cycle phases of eyelashes under topical treatment with prostamid analoga.

Authors' contribution

Dana Moore, M. D., Erika Richtig, M. D., and Daisy Kopera, M. D. had full access to all of the data in this work and take responsibility for the integrity of the data and accuracy of the data analysis.

Table 3. Examples of rated Images (End Date).

ID	Image	Score
OS94		+ 1
MD90		+ 1
LS87		+ 1
BS80		+ 1

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