

AAD Exhibitor Guide
Autologous Fat Transfer
Natrelle Pre-Consultation Kit

Latisse Expands Aesthetic Treatment Market

Periodically a new product or technology emerges which has the power to transform the medical aesthetic market. Only months after FDA approval and a national consumer advertising launch campaign began, Latisse from Allergan Medical (Irvine, Calif.) has already proven its ability to create a massive and sustainable new category. This eyelash enhancement drug also brings new patients into medical aesthetic practices, which is certainly a welcome benefit in the midst of a prolonged economic crisis that has reduced patient spending in many established cosmetic surgery market segments.

continued on page 3

Novel FDA Approved Eyelash Growth Product Increases Patient Volume

By Amir Moradi, M.D.

Latisse (bimatoprost ophthalmic solution 0.03%) is the only product FDA cleared for the treatment of hypotrichosis of eyelashes, a congenital condition marked by lower than average length, thickness and/or number of eyelashes. As a relatively inexpensive therapy with broad appeal, even among potential patients who might otherwise be suspicious of aesthetic medicine, Allergan is positioning the product as an excellent practice building tool.

The unique aesthetic appeal of the eye has long been a focus of attention dating back to ancient Egyptian civilization. Eyelashes frame the eye; therefore, eyelash prominence has traditionally been regarded as a desirable aesthetic feature. Millions of dollars are spent each year on mascara, a product many women consider to be an essential component of their daily beauty regimen. Some women even use eyelash extensions or false eyelashes to increase volume.

While alternative therapies to Latisse exist, none have the same rigorous scientific examination of safety and efficacy, or FDA approval to support them. Due to its potential to pique the interest of any woman concerned with the look of her lashes, Allergan believes that Latisse could further redefine consumers' concept of aesthetic medicine, in much the same way that BOTOX Cosmetic (Allergan) did at the turn of the century.

Latisse features the same ingredient and concentration (bimatoprost ophthalmic solution 0.03%) as seen in Lumigan, a topical product that Allergan created to treat certain types of glaucoma and other causes of elevated pressure within the eye. Bimatoprost ophthalmic solution 0.03% is a synthetic prostamide analog. Prostamides, fatty

acid amides that regulate the outflow of aqueous humor, are found in the anterior chamber of the eye where intraocular pressure builds up. It is believed that the application of Lumigan stimulates prostamide receptors and clinical trials have revealed that this solution therapeutically reduces ocular pressure.

In addition to the intended effect of bimatoprost ophthalmic solution 0.03%, study participants also seemed to grow thicker, longer eyelashes as a direct result of use. When Allergan discovered this phenomenon they initiated a new multicenter, double blind, randomized parallel investigation to further examine this finding. When additional research studies confirmed this effect, Latisse was born.

"Ophthalmologists have long known that hair growth is a side effect of Lumigan therapy for glaucoma," said Steven G. Yoelin, M.D., an ophthalmologist in Newport Beach, Calif. "It was unclear if this side effect would have any value when used by individuals who simply wanted longer lashes."



Steven G. Yoelin, M.D.
Ophthalmologist
Newport Beach, CA

In the Fall of 2005 Dr. Yoelin initiated his own open label, proof-of-concept pilot study of bimatoprost ophthalmic solution 0.03% for eyelash growth. He recruited 28 patients from the aesthetic injectables portion of his practice. The protocol for Dr. Yoelin's initial trial was very similar to what would later be used in the pivotal FDA trial for Latisse. "The investigator initiated trial was designed to answer several questions. For example, would the product grow eyelashes



Week 0



Week 4



Week 8



Week 12



Week 16

“Everyone grew longer, more prominent eyelashes and the patients did not experience any major adverse events whatsoever.”

on a consistent basis? Would intraocular pressure drop? Would there be other adverse changes to the eye itself or to the eyelids,” he asked.

The results were remarkable. “Everyone grew longer, more prominent eyelashes and the patients did not experience any major adverse events whatsoever,” Dr. Yoelin continued. “Any minor adverse events that we did notice were transient and the treatment was well tolerated. I presented the results from this initial trial to the decision makers at Allergan, and the company decided to move forward with the Latisse program.”

The exact mechanism of action of the drug as a treatment for hypotrichosis of eyelashes is not yet well understood. Everyone’s hair is different in color, character, thickness, density and placement on the body. While many factors concerning the character and behavior of an individual’s hair are heavily dependent on genetics, the cyclic growth and loss of hair all over the body occurs similarly for everyone. This happens in three phases: the telogen phase, which is a dormant or resting phase four to nine months long; the anagen phase, a period of active growth lasting one to two months during which growth takes place; and the catagen phase, a transition between growth and dormancy which may last about 15 days.

Study results suggest that Latisse therapy stimulates eyelashes to progress more rapidly from the telogen phase to the anagen phase, and to maintain the anagen phase for a longer period of time. So at any given moment, more lashes are in this active growth phase, which promotes thicker, longer eyelashes and increased eyelash density, leading to the intended overall effect. “Latisse is a great product,” said Mary Lupo, M.D., a dermatologist in New Orleans, La. “I often say, ‘in my world,



Mary Lupo, M.D.
Dermatologist
New Orleans, LA

nothing works 100% of the time,’ but in my experience Latisse actually does. There may be some variability in the outcomes but everyone responds to some degree, and any incidence of minor adverse events is extremely rare.”

The physicochemical properties of bimatoprost ophthalmic solution 0.03% seem to promote its absorption by the lashes. Studies have shown that when applied correctly with the disposable applicators, about 5% of the active ingredient is taken up by the eyelashes. When applied, the drug travels down the hair shaft to the base of the hair and is absorbed by the follicle. Many topically applied drugs are absorbed into the body in this manner.

The FDA approved disposable sterile applicators for Latisse were designed to standardize the dosage administered to the upper eyelid margin, as well as reduce the likelihood that the eye or other skin surfaces would be unnecessarily exposed to the product during self treatment. Since this drug may influence hair growth anywhere on the skin or may cause changes in skin pigmentation, is not for use on the lower eyelid or anywhere else on the body.

Some attention has been paid to the incidence of increased brown pigmentation of the iris as a result of treatment with bimatoprost ophthalmic solution 0.03%. This effect has actually not been seen with Latisse in clinical trials, but was noted in approximately 1.5% of subjects during the initial two year studies with Lumigan, presumably because the latter is applied directly to the eye itself. However, the Latisse applicator is

designed to limit contact of the drug with the eye and prevent pigmentation problems from occurring.

The dosage applicators were used during the 20 week multicenter, double blind, randomized parallel study. This study examined the safety and efficacy of bimatoprost ophthalmic solution 0.03% for hypotrichosis of the eyelashes compared to an application vehicle (control). Study patients (n=278) were randomized into two groups: vehicle only and Latisse treatment. After extensive instruction, each subject treated themselves with either Latisse or the vehicle nightly for four months, with one month of follow-up. The study was completed by 257 patients, with 131 in the Latisse group and 126 in the control group.

Efficacy was primarily evaluated using a global eyelash assessment (GEA) scale. This GEA scale is a validated four point numerical grading of eyelash prominence representing a combination of factors rated by clinicians such as length, fullness and color of the upper eyelashes. Subjects were considered to have responded if their condition improved at least one grade from baseline. Digital image analysis was employed as a secondary method to measure efficacy. Safety was studied through the recording of adverse events, as well as by the monitoring of ocular (intraocular pressure, pupil dilation, visual acuity) and non-ocular (pulse, blood pressure) signs.

Treatment was well tolerated and the results were very clear. More than 75% of subjects showed GEA improvement of at least one grade by the end of the follow-up period. Digital recording and measurement of results visibly demonstrated obvious positive outcomes. Individual measurements of eyelash length, fullness or thickness and darkness also showed marked improvement in the Latisse group over the control

group. Furthermore, study subjects themselves noted increases in eyelash length, thickness and density. The incidence of treatment related adverse events was less than 4%, and largely limited to itching and redness.

One important aspect of this study, not to be overlooked, was that the patient population was well rounded, with basically equal distribution of subjects by demographic parameters (e.g. age, gender and ethnicity) between the two patient groups. However, there were a high number of lighter skinned subjects, likely a result of technicalities from the inclusion / exclusion criteria for imaging and GEA score measurement.

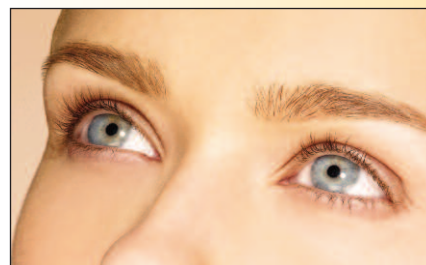
Drawing on these positive study results and FDA approval of Latisse, Allergan has launched a major consumer marketing campaign to raise awareness and drive momentum for the product's growth, and eventually, the aesthetic market as a whole. This effort includes a national media blitz across television, print and the Internet, and is expected to reach more than one billion consumers. Brooke Shields, a high-profile celebrity known for her beautiful eyes, is the face of this campaign and is already creating brand awareness.

Aesthetic medicine is driven forward by the development of newer, safer, more tolerable and effective treatments with reduced downtime, as well as positive public perception. Awareness and basic exposure has always been the best way to awaken the interest of potential patients who may be intimidated by aesthetic procedures or their cost, and those that have preconceived ideas about treatments.

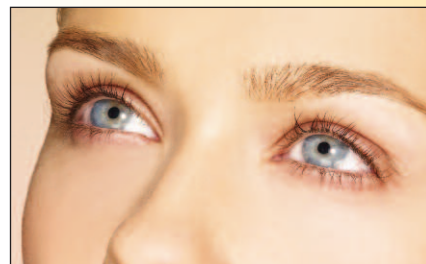
As a proven safe, tolerable, easy-to-use, effective and relatively inexpensive aesthetic treatment with broad appeal, Latisse has tremendous potential to grow



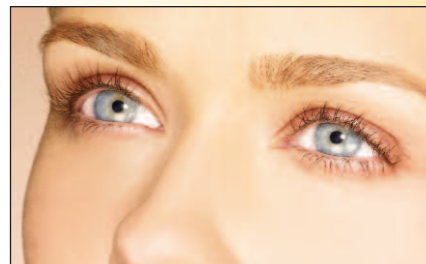
Week 0



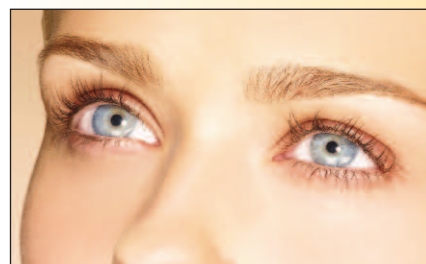
Week 4



Week 8



Week 12



Week 16



Before Tx



After Latisse treatments

Photos courtesy of Joel L. Cohen, M.D.



Before Tx



After Latisse treatments

Photos courtesy of Joel L. Cohen, M.D.

the aesthetic medicine market. Virtually anyone can use and expect visible results with Latisse, with the exception of those sensitive to the product's ingredients and those already using Lumigan to regulate intraocular pressure, for example. Although it is essential that patients check with their ophthalmologist before using Latisse, there are no limitations due to skin type or hair color.

Latisse is applied once nightly to the upper eyelid. Increased eyelash prominence will become evident in four to eight weeks; however, without regular application the results will fade and hypotrichosis will return. This contributes to the revenue generating potential of Latisse – as demonstrated with BOTOX, highly satisfied patients will return for more product regularly.

Latisse's market potential crosses age and socio-economic boundaries as well, exposing potential patients to the realities of modern aesthetic medicine. This visibility brings increased comfort and familiarity with products and services offered by aesthetic practices, in patients who otherwise would never set foot in the office. Latisse also generates revenue from a practice's existing patient base.

A market study by Allergan revealed startling numbers that strongly support these suppositions. According to the findings, approximately 75% of Latisse patients expect to use the product long-term, suggesting satisfaction with results and a willingness to pay for them, while 87% of users told friends and family about the product. Physicians reported that 75% of Latisse users are existing patients and 58% of their new and existing patients received other products or services in addition to Latisse. Furthermore, 25% reported that Latisse has brought new business to their practice.

According to additional research by Allergan, nine million women between the ages of 30 and 60 that have been treated with or are considering treatment with facial injectables may be interested in Latisse. This product also appeals to the 27 million women between the ages of 18 and 65 who consider eyelashes an important part of their beauty regimen – potentially tripling the market size. Lastly, 95% of physicians surveyed felt that these patients may be interested in at least one other procedure.

Joel L. Cohen, M.D., medical director of AboutSkin Dermatology and DermSurgery Centers in the Denver, Colorado area, had his practice participate in the multicenter clinical trials for Latisse. "Once Allergan secured FDA approval for the drug, we were able to attract patients through newsletters and the Internet, which set us up as having special expertise," he explained. "Little by little new patients have come in over the course of the year, driven by word-of-mouth and Latisse's brand awareness. I find it remarkable that patients seem to understand that Latisse is a scientifically validated, FDA approved product, while the alternatives available in spas are not."



Joel L. Cohen, M.D.

Medical Director
AboutSkin Dermatology and DermSurgery
Centers
Denver, CO

According to Dr. Yoelin, Latisse has played a valuable role in the overall success of his practice. "Patients who would not normally come into my practice now frequently visit the office in order to get a prescription for Latisse. Since I practice in California, I am able to dispense it directly out of my office. So even though these

patients may not initially be interested in other procedures, the consultation is important because they are introduced to my practice and exposed to other aesthetic treatments that I offer." Latisse has allowed Dr. Yoelin to expand his patient base and grow his aesthetic and injectable practice. "I am booked through the middle of 2010," he added.

Practices can entice potential Latisse patients in many ways, including prominently displayed posters and literature, as well as value or bundle pricing. In Dr. Cohen's practice the office staff is his best advertisement. "More than anything else it's our existing patients who have already come into the office for something else that end up interested in Latisse." Part of Dr. Cohen's marketing efforts includes the staff, with their great lashes, wearing buttons that call attention to their use of Latisse, which elicits questions from patients. This helps them capitalize on the many opportunities to maintain demand for Latisse. "Patients who come in for more BOTOX or other injectables may decide to get their next allotment of Latisse at the same time," he noted. "It's a great scenario for generating revenue that wouldn't exist if Latisse didn't deliver on its promises. We use value pricing and seasonal promotions to drive demand, much as we do with BOTOX. This has proven successful for us."

Dr. Lupo has applied a similar approach in her practice, "Since my aesthetic practice is primarily injectables, Latisse was a natural fit, as we're mostly concerned with non-surgical rejuvenation. We don't advertise Latisse, but once a patient is in the office, they see the posters and all of us with great eyelashes and then they become interested."

Latisse also has the unique ability to reach a specific segment of Dr. Lupo's

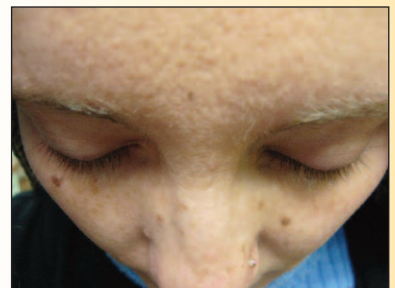
patient population. "In addition to the usual cosmetic patients, Latisse has gotten attention from my medical patients who do not come in for elective, aesthetic procedures like dermal fillers and BOTOX," she noted. "The marketing of purely cosmetic procedures and products to this particular segment is a very touchy subject with obvious ethical implications. It's one thing to actively market BOTOX to a patient who is receiving a chemical peel, but it's a completely different prospect when dealing with an acne patient." Dr. Lupo feels that Latisse has opened the door for crossover. "It's surprising and refreshing to see medical patients making it a priority to ask about Latisse. As with any patient, once they have consistent success with one modality, they are more interested in other procedures we offer. It's a paradigm shift for them and before you know it, they believe in the reality of modern aesthetic medicine." ■



Amir Moradi, M.D.

Amir Moradi, M.D. is a board certified facial plastic surgeon with a private practice in San Diego, Calif. He graduated summa cum laude from the University of California, San Diego and went on to receive his Medical Degree from the same institution. Dr. Moradi then completed his surgical training at Duke University Medical Center (Durham, N.C.). Dr. Moradi serves on multiple committees and panels, as well as representing several medical companies in training, speaking and consulting. He also travels to Mexico quarterly with the Thousand Smiles Foundation where he performs cleft lip and palate repair.

"Even though these patients may not initially be interested in other procedures, the consultation is important because they are introduced to my practice and exposed to other aesthetic treatments that I offer."



Before Tx



After Latisse treatments

Photos courtesy of Joel L. Cohen, M.D.