Peter J. McDonnell, MD | **EYE CLUES** CONJUNCTIVAL HEMORRHAGES A FORENSIC 'TELL'

Ophthalmology Times®

CUTTING-EDGE ADVANCEMENTS

March 15, 2020 VOL. 45, NO. 5

SPECIAL SECTION

Procedures set a new horizon in refractive surgery

Combined technique aims to increase stability of the visual outcome

By Roberto Pinelli, MD; Special to Ophthalmology Times

NOVEL PROCEDURES CONTINUE to provide refractive patients with surgical options that are safe, virtually painfree, and with reduced risk of postoperative complications.

The Switzerland Eye Research Institute, for one, is oriented toward less-invasive corneal techniques that reshape the corneal surface without penetrating the eye. Femtolasik and Femtolasik Xtra are established procedures worldwide,[1,2,3] and involve customized reshaping of the cornea to eliminate myopia, hyperopia, astigmatism, and presbyopia.

Continues on page 11 : Refractive surgery

▲An eye is shown four hours post-treatment.

SEE PAGE 11 THE SAME CORNEA AT SIX MONTHS POST-TREATMENT

(PHOTO COURTESY OF ROBERTO PINELLI, MD)

CLINICAL DIAGNOSIS

Sustained-release implant offers long-term IOP control, preserved visual function

Bimatoprost SR represents a paradigm shift in glaucoma treatment

By Lynda Charters;
Reviewed by Felipe Medeiros, MD, PhD

WITH THE FDA approval earlier this month of a new drug application (NDA) for the bimatoprost implant (Durysta, Allergan) 10 mcg for intracameral administration, the bimatoprost implant becomes the first intracameral, biodegradable, sustained-release (SR) implant indicated to reduce IOP in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT), according to the company.

Leading up to this approval, the bimatoprost SR implant met the primary endpoint of the ARTEMIS phase III study. It lowered IOP by about 30% and was found to be noninferior to timolol for reducing IOP through 12 weeks. In extended follow-up, more than three-quarters of eyes did not require additional treatment for one year following three administrations of the drug.

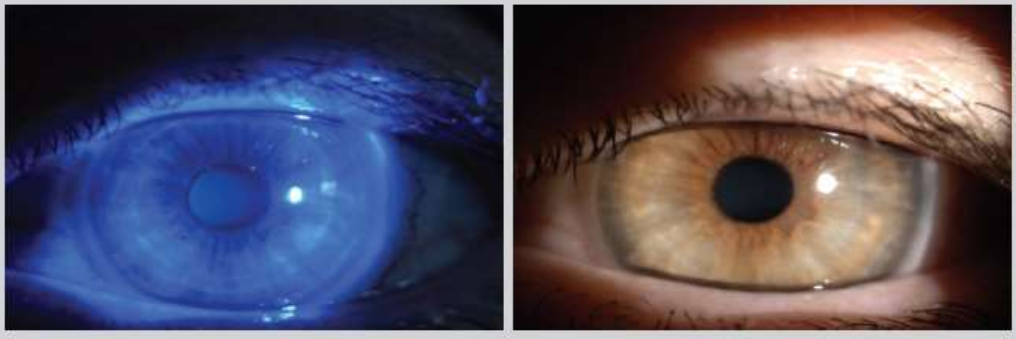
In the ARTEMIS phase III trials, patients were randomly assigned to treatment with bimatoprost SR versus timolol. Two concentrations of bimatoprost were evaluated, 10 and 15 mcg. The focus of the results reporting was on the lower dose, which will be the one that will be commercially available. Eyes randomly assigned to bimatoprost SR received implants every four months, for a total of three implants of the drug over the course of one year.

"Eighty percent of the eyes that received the three implants of bimatoprost SR had sustained IOP control for one year, without the need for additional treatment," said

Continues on page 16: Implant

Issue Highlights

▷ OphthalmologyTimes.com



(FIGURE 1)
At left, 4 hours post-treatment. At right, 6 months post-treatment.
(Images courtesy of Roberto Pinelli, MD)

REFRACTIVE SURGERY

(Continued from page 1)

Over the past six years, we have been approaching corneal surgery in Lugano using a novel procedure that unites Femtolasik and transepithelial crosslinking.

This combined technique is known as Femtolasik Lux, and aims to increase the stability of the visual outcome in patients, thereby maintaining a healthy and robust cornea.

Femtolasik Lux is a non-invasive, "no-touch" procedure, which—at no point touching the eye with any instrument—uses three different light sources to resolve any visual defect in a few minutes without pain.

> 'Although the chances of ectasia occurring have become very much reduced over the past decade, it nonetheless remains a very remote possibility to be avoided.'
>
> – Roberto Pinelli, MD

This procedure leads to a final sharp refractive result, provides a stronger corneal tissue that is less vulnerable to curvature change, and reduces refractive error regression and incidence of corneal ectasia.

Safety, effectiveness, and excellent long-term results have been demonstrably achieved.

There is a protocol for this technique called the Lugano Protocol. ParaCel eye drops are used to soak the corneal epithelium for a time that cn range from 30 to 50 seconds after the repositioning of the flap.

Soaking is thus customized and a very minimal quantity of riboflavin is delivered to the cornea in a short time, which is possible due to its osmotic properties.[4]

Exposure to UV-A is performed with Avedro technology at 30 mW/cm^2. This quantity of ParaCel and timing of exposure are enough to permit ParaCel to penetrate the flap and spread into the stroma.

Unlike other data reported in the current literature, we osmotically soak the cornea over the flap leaving the interface free from any possible irregularity due to riboflavin on the cornea.

The purpose is to take advantage of CXL treatment, usually performed to strengthen corneal tissue, in order to stiffen a prospective weakened cornea and prevent corneal ectasia, which is every refractive surgeon's nightmare.

Though the chances of ectasia occurring have become very much reduced over the past decade, it nonetheless remains a remote possibility to be avoided. I am pleased to report that after our six years with this procedure, we have not experienced one case of ectasia.

As far as side effects are concerned, I believe that there are no adverse events to report and no flap wrinkles. (Figure 1)

It seems that the riboflavin penetration did not induce any refractive change. On the contrary, a greater stability and a better and softer crosslinking of the cornea were observed, and less regression, particularly regarding myopic astigmatism.

With ParaCel being osmotic, its penetration through the cap to the corneal stroma probably restores biomechanical strength to the cornea. This aspect enables the flap to become better reintegrated into the cornea, becoming one with the other corneal layers, and thereby more stable and less susceptible to dislodging, unlike the situation in the past. I believe that this is why we don't see any ectasia.

In addition to the assessment of postoperative visual data, the self-perceived satisfaction with the procedure was evaluated by our Psychology of Vision Unit: objective/subjective outcomes were found to be equally positive.

Researchers said their experience with Femtolasik Lux with the Lugano Protocol has also been positive, and they fully intend to continue with this technique in order to restore vision and improve the overall quality of life in our patients

Miorica Bertelli, OD, Caterina Berti, OD, and Elena Scaffidi, MS, contributed to this report. ■

take-home

The primary purpose of refractive surgery is to improve the patient's natural vision and free them from their dependence on glasses and contact lenses with the ultimate goal of improving their quality of life.

REFERENCES

1. Aslanides IM, Mukherjee AN. Adjuvant corneal crosslinking to prevent hyperopic LASIK regression. *Clin Ophthalmol.* 2013;7:637-641.
2. Wu Y, Tian L, Wang LQ, Huang YF. Efficacy and Safety of LASIK Combined with Accelerated Corneal Collagen Cross-Linking for Myopia: Six-Month Study. Biomed Res Int. 2016;2016: Article number: 5083069.
3. Rajpal RK, Wisecarver CB, Williams D, Rajpal SD, Kerzner R, Nianiaris N, Lytle G, Hoang K. Lasik Xtra Provides Corneal Stability and Improved Outcomes. *Ophthalmol Ther.* 2015;4:89-102.
4. Raiskup F, Pinelli R, Spoerl E. Riboflavin osmolar modification for transepithelial corneal cross-linking. *Curr Eye Res.* 2012;37:234-238.

ROBERTO PINELLI, MD
E: *pinelli@seri-lugano.ch*
Dr. Pinelli is founder of the Switzerland Eye Research Institute