Postsurgical Pearls
for Managing Ocular Inflammation With Lotemax Gel
Legacy and Benefits of Lotemax Gel

A look at the history and safety profile of Lotemax Gel for the treatment of inflammation and pain following ocular surgery.

**HERITAGE OF THE MOLECULE**

The loteprednol etabonate molecule has been extensively studied, with demonstrated postoperative control of inflammation and pain following ocular surgery as well as a low incidence of IOP elevation. It has been on the market for 15 years, has been used in thousands of patients, and has evolved to include suspension, ointment, and gel formulations.

“The history of loteprednol etabonate, both in terms of clinical studies and in terms of clinical use, is important to me because I know that what I am giving to my patients to control their inflammation and pain after ocular surgery is a product with a demonstrated efficacy and safety profile,” says Marguerite McDonald, MD.

**CLINICAL EXPERIENCE**

It is widely known that prolonged use of corticosteroids may result in elevated IOP. In phase 3 trials, Lotemax Gel (loteprednol etabonate; Bausch + Lomb) showed an incidence of increased IOP similar to vehicle, as far out as day 14. In the same phase 3 trials, only two of 408 patients treated with Lotemax Gel experienced a significant IOP elevation (Figure 1).1

In phase 3 trials, Lotemax Gel also demonstrated statistically significant inflammation and pain control (Figure 2). More patients achieved complete resolution of anterior chamber cells and grade 0 pain with Lotemax Gel (n = 409) versus vehicle (n = 404) at day 8 (anterior chamber cell resolution: 31% vs 15%; grade 0 pain: 74% vs 44%), with continued efficacy at day 15 (anterior chamber cells resolution: 53% vs 26%; grade 0 pain: 77% vs 41%).1

“My clinical experience with Lotemax Gel aligns with these data,” says John D. Sheppard, MD. “Lotemax Gel provides the inflammation control I am looking for and the pain control my patients appreciate following ocular surgery.”

**FEATURES OF GEL FORMULATION**

There is no one patient type for using Lotemax Gel. It is an effective option for inflammation and pain following any ocular surgery, including refractive, cataract, and corneal surgeries.1,2

It is also easy to use. The gel formulation of Lotemax provides a consistent concentration of loteprednol in every drop.3 A study revealed that 63% of patients (n = 100 patients) do not shake their ocular medications at all, even though the...
Labels will clearly emphasize in red to “shake well.” Lotemax Gel’s nonsettling formulation was compared to Lotemax Suspension (centrifuging for 24 hours at 120x gravity); the results showed that the suspension settled in less than 20 minutes, whereas Lotemax Gel did not settle over 24 hours (Figure 3).

“I want to be confident that, when my patients are at home, administering their own drops, they are getting a consistent concentration in every drop to control their pain and inflammation around the clock,” says Christopher E. Starr, MD. “It is one less thing patients have to think about when following their postsurgical protocol.”

Lotemax Gel has mucoadhesive technology that is engineered to adhere to the ocular surface. Adaptive viscosity technology allows it to be a gel at rest and transforms it into a viscous liquid under shear stress (ie, blinking) and due to electrolytes in the tear fluid, making it more than 10x more viscous than Lotemax Suspension (data on file with Bausch + Lomb Incorporated). It also has a lower preservative concentration (30 ppm benzalkonium chloride) than its suspension counterpart; it includes a proprietary blend of moisturizers (glycerin, propylene glycol); and it is close to the physiologic pH of tear fluid (buffer keeps pH centered at 6.5).

NO GENERIC SUBSTITUTION

Ocular surgery, including cataract surgery, is an investment. Postsurgical management is important. Lotemax Gel has a proven efficacy and safety profile in clinical trials. There is no generic substitute for it.

“I always encourage my patients to fill their prescriptions exactly as I have written them, and my office staff is trained to let pharmacies know to follow my prescriptions as written,” says Karl G. Stonecipher, MD.

If patients need help paying for their prescription, Bausch + Lomb provides copay programs that may help them get the medicines they need. Final costs will depend on insurance coverage, but there are multiple programs in place.

Marguerite McDonald, MD, is a cornea/refractive specialist with Ophthalmic Consultants of Long Island, New York. She is also clinical professor of ophthalmology, NYU School of Medicine, New York, and adjunct clinical professor of ophthalmology, Tulane University Health Sciences Center, New Orleans. She does not have a retainer or royalty relationship with any company mentioned but occasionally receives honoraria for promotional talks. Dr. McDonald may be reached at margueritemcdmd@aol.com.

John D. Sheppard, MD, MMSc, is a professor of ophthalmology, microbiology & immunology, clinical director of the Thomas R. Lee Center for Ocular Pharmacology, and ophthalmology residency research director at the Eastern Virginia Medical School in Norfolk, Virginia. He is also the president of Virginia Eye Consultants and the medical director of the Lions Eye Bank of Eastern Virginia. He is a consultant to Bausch + Lomb. Dr. Sheppard may be reached at docshep@hotmail.com.

Christopher E. Starr, MD, is associate professor of ophthalmology at Weill Cornell Medical College in New York. He is also director of the Refractive Surgery Service, director of ophthalmic education, and director of the Cornea, Cataract, and Refractive Surgery Fellowship at Weill Cornell Medical College. He is a consultant to Allergan, Bausch + Lomb, TearLab, Rapid Pathogen Screening, and Shire. Dr. Starr may be reached at cestarr@med.cornell.edu.

Karl G. Stonecipher, MD, is director of refractive surgery at TLC in Greensboro, North Carolina. He is a consultant to and speaker for and has received grant support and travel reimbursement from Abbott Medical Optics Inc. and Alcon Laboratories, Inc. Dr. Stonecipher may be reached at stonenc@aol.com.

3. Coffey MJ, Davio SR. Viscoelastic and sedimentation characterization of loteprednol etabonate ophthalmic gel, 0.5%. Poster presented at: 2012 Annual Meeting of the Association for Research in Vision and Ophthalmology, May 2012; Ft. Lauderdale, FL.
**An Effective Option Following Any Ocular Surgery**

Physicians share their experiences using Lotemax Gel for postoperative control of inflammation and pain following ocular surgery, including LASIK, pterygium, MIGS, and PRK.

**CASE 1**

**LASIK After Unsatisfactory Cataract Surgery With Multifocal IOL**

By Douglas Katsev, MD

A 63-year-old man presented to our clinic dissatisfied with his visual acuity. He had undergone bilateral cataract surgery 4 months prior and had received a refractive multifocal IOL. Having invested in a premium IOL, and hoping to limit his dependence on spectacles, the patient remained not quite satisfied with his vision after cataract surgery.

At the time of his visit, the patient’s refraction was 0.75 D with 0.75 D of against-the-rule astigmatism in both eyes. In addition to being unhappy with his vision, this patient complained of occasional ocular dryness symptoms, particularly after prolonged tasks like reading and working at the computer. At the slit lamp, a lowered tear meniscus and shortened tear breakup time were noted. His eyelids appeared normal without significant infection, scurvy, or capped glands. However, diagnostic gland expression revealed slightly opaque meibum.

In order to give this patient the quality of distance and near vision he desired, we discussed the option of LASIK, which he strongly favored. As part of this conversation, I let the patient know that, without some preoperative intervention, performing the LASIK procedure might temporarily exacerbate his mild dry eye and possibly affect not only his comfort but also the quality of his vision. With this in mind, I prescribed preservative-free artificial tears for him to use as needed for a few weeks leading up to his surgery. When the patient presented on the day of surgery, he reported symptomatic relief from the artificial tears. His tear film and ocular surface looked normal. Therefore, I was comfortable confirming his measurements and proceeded as planned.

I identified the LASIK flap’s edge and lifted it with the superior hinge. With the flap thus protected and the stromal bed dry, I obtained centration and performed the hyperopic correction (Figure). I then replaced the flap and irrigated the cornea.

For all my patients, my top priorities in the immediate postoperative period are to control any inflammation and maintain the stability of the patient’s tear film. I instructed this patient to continue with the preservative-free artificial tears. To control postoperative pain and inflammation, I prescribed Lotemax Gel (loteprednol etabonate; Bausch + Lomb) four times daily for 2 weeks following his surgery as well as an antibiotic (Besivance; Bausch + Lomb). Lotemax Gel is an effective corticosteroid with a proven safety profile, including a low risk of a significant IOP increase, and it was a suitable choice for this individual, as it is for many of my patients after LASIK.1 The formulation of Lotemax Gel ensures a consistent delivery of the drug with every dose and helps it remain on the surface of the eye, where it is needed.2 Lotemax Gel also contains demulcents, including propylene glycol and glycerin.3 Lotemax Gel is indicated for postoperative inflammation control following ocular surgery.1 Lotemax Gel should not be used intraoperatively beneath the LASIK flap.

Figure. Obtaining centration and performing the hyperopic correction during LASIK surgery.
I have had a great experience using Lotemax Gel postoperatively for inflammation control in my LASIK patients. Indeed, this patient experienced a fantastic visual outcome with a final refraction of -0.25 +0.25 x 90. He seldom has to use glasses, even for reading, and he has referred many new patients to our practice.

Douglas A. Katsev, MD, is in private practice at the Sansum Clinic in Santa Barbara, California. He is a consultant to Bausch + Lomb. Dr. Katsev may be reached at katsev@aol.com.

CASE 2
Primary Pterygium Surgery in a 32-Year-Old Patient
By Barry A. Schechter, MD

A 32-year-old woman presented to our clinic with a primary pterygium on the nasal side of her left eye. She complained of a persistent foreign body sensation and blurred UCVA when compared to her fellow eye.

During surgery, I approach the pterygium with forceps and a syringe of Xylocaine 2% (lidocaine; AstraZeneca) with epinephrine, and I perform the injection just underneath the pterygium to balloon up the fibrotic tissue. Then, using blunt scissors, I remove the pterygium tail. It is very important to preserve yet undermine the conjunctiva and remove as much fibrovascular Tenon tissue as possible to limit recurrence, improve cosmesis, and reduce postoperative inflammation.

Having removed most of the pterygium, I irrigate the surface and avulse the remaining tissue from the limbal area with toothed forceps. I then polish the limbal area with a diamond burr to further reduce the load of remaining fibrovascular tissue. Next, I lightly cauterize the area. Using calipers, I measure the area of the excision site in order to prepare the graft. I dry an area of the superior conjunctival surface and mark the graft area, marking just forward of the superior limbal arcade of vessels in order to harvest stem cells, oversizing it by about 1 millimeter in the lateral and posterior directions to ensure coverage of the bed. Then, once more using Xylocaine 2% with epinephrine I create a small balloon and dissect a very thin graft from the superior bulbar conjunctiva, leaving Tenon tissue behind. Obtaining a thin, slightly oversized graft is helpful to optimize the cosmetic outcome of pterygium surgery.

With blunt scissors and forceps, I free the conjunctival graft, taking care to include the limbal corneal epithelium that contains stem cells. My demarcation line is just in front of the limbal vascular arcade. I consider this step essential to keeping my rate of pterygium recurrence very low because stem cells form the new limbus and act as a barrier to regrowth. I use a crescent blade to complete the dissection into the peripheral cornea, harvesting those stem cells. I place the graft onto the cornea, epithelial side down, align the limbal edge of the graft with the area of the limbus adjacent to the excision site, and I dry the scleral bed. Keeping the graft properly oriented is vital, and we always mark the limbal side of the graft accordingly. Into the subconjunctival space adjacent to the excision area, I tuck a piece of amniotic membrane to aid postoperative healing by inhibiting fibrovascular proliferation, neovascularization, and inflammation. I place the amniotic membrane at the distal edge of the conjunctival bed, the place where recurrence of fibrotic tissue is likely to develop first, which I believe also helps to limit recurrence and gives a nice cosmetic outcome.

My amniotic membrane is in dehydrated form. It is easy to use and cut to the appropriate size, and yet it retains a dense extracellular matrix that hinders fibrovascular growth and activity. To affix the autograft, I use fibrin adhesive. Its two components—thrombin and fibrinogen—mimic natural clot formation when combined. I place a very small amount of thrombin onto the bare sclera, add a small amount of fibrinogen to the underside of the conjunctival graft, and quickly evert the graft to combine them (Figure). Using forceps, I quickly position and squeegee the graft in place, and I pinch the periphery to make sure the edges are sealed. At this stage, I go back to lightly cauterize the donor site. As a final step, I place a bandage contact lens, which helps maintain the patient’s comfort by covering the epithelial defect and serves to help keep the graft of limbal stem cells in place during the first postoperative week.

Surgical techniques that induce less postoperative inflammation—for example, the use of fibrin glue rather than sutures—are associated with lower rates of pterygium recurrence. Pharmacologic inflammation control in the postoperative period is also an essential part of pterygium management. For this patient, I prescribed Lotemax Gel (loteprednol etabonate; Bausch + Lomb), dosed four times per day, and an ophthalmic nonsteroidal anti-inflammatory drug such as Prolensa (bromf-
enac; Bausch + Lomb) dosed once per day for the first 10 to 14 postoperative days. I favor Lotemax Gel in particular for these cases because it offers excellent anti-inflammatory efficacy coupled with a low risk of significant IOP spikes.⁴ I routinely see pterygium patients at 1 day, 1 week, and 5 weeks postoperatively. At this patient’s 1-day and 1-week visits, her eye looked great, and she was healing well. I removed the bandage contact lens at the 1-week visit and instructed her to continue with the postoperative medication regimen.

In pterygium surgery, I find that using advanced technology, including fibrin glue and prepared amniotic tissue, as well as meticulous surgical technique to harvest limbal stem cells and following the case with effective and safe anti-inflammatory drugs all lead to excellent outcomes and happy satisfied patients.

Barry A. Schechter, MD, is director, Department of Cornea and External Diseases, Florida Eye Microsurgical Institute, Boynton Beach, Florida. He serves as a consultant to Abbott Medical Optics and Bausch + Lomb, and he is a member of the speakers board for Omeros. Dr. Schechter can be reached at baschechter@gmail.com.

CASE 3
iStent Implantation in Cataractous Eye With Early Open-Angle Glaucoma

By Inder Paul Singh, MD

In recent years, I have seen an exciting proliferation of options for performing microinvasive glaucoma surgery (MIGS). Most MIGS procedures involve the use of microstent devices, which improve aqueous outflow through a physiologic pathway. MIGS can be highly successful in patients with mild to moderate glaucoma,⁵ and because they spare the conjunctiva, these procedures preserve the tissue for more aggressive filtering surgery as a future treatment option, should it become necessary, as is demonstrated by this case.

Even as MIGS devices and procedures continue to evolve, outcomes still depend on careful surgical technique and postoperative management. This case involves a 64-year-old woman who presented to my practice complaining of decreased vision, especially at night. An examination revealed significant cataract, and the patient also had glaucoma, which was controlled using two topical glaucoma medications. As the patient was motivated to reduce her reliance on glaucoma drops, we discussed the implantation of the iStent Trabecular Micro-Bypass Stent (Glaukos) in conjunction with her cataract surgery.

The first-generation iStent is a 1-mm long, 0.3-mm tall L-shaped titanium implant designed to allow aqueous to flow from anterior chamber directly to Schlemm canal, bypassing the trabecular meshwork. The iStent is FDA approved for use in conjunction with cataract surgery in patients with mild to moderate open-angle glaucoma. The iStent is typically not implanted as a stand-alone procedure but is performed in conjunction with cataract surgery; the device is inserted into Schlemm canal via the trabecular meshwork using a preloaded inserter.

This patient made an ideal candidate for the combined procedure, because she had symptomatic cataract and early open-angle glaucoma. She was already on one glaucoma drop and wished to decrease the burden of medication for managing her glaucoma. After I completed the cataract procedure, I was ready to insert the iStent. I added more viscoelastic to deepen the chamber, and I entered the eye through the same clear corneal incision used in the primary procedure. Using a gonio lens, I was able to visualize the angle and can see Schwalbe line, pigmented trabecular meshwork, the scleral spur, and the ciliary body. I approached the upper part of the trabecular meshwork at an angle of 15º, engaged the meshwork tissue, and entered Schlemm canal. The iStent moved forward into the canal. I released the iStent, and then I used the tip of the inserter to gently tap the snorkel end of the implant to make sure it was properly and securely placed (Figure 1). The implant fit nicely in the canal. Then, I removed the viscoelastic in the anterior chamber. There was a little reflux of blood in the area where the iStent was implanted. This was a good sign, as it showed me that the iStent is well positioned and already communicating with the venous drainage system. The surgery went well, and the iStent remained in good position.

Following the surgery, the patient was placed on topical ophthalmic corticosteroid drops and a topical nonsteroidal anti-inflammatory drug to control inflammation and ocular pain. On postoperative day 1, the patient’s IOP was in the midteens. At her visit 1 week later, the IOP was 35 mm Hg in...
the operated eye and 18 mm Hg in the fellow eye. Because the patient had no optic nerve head changes or visual field loss, to address the elevated IOP, I instructed her to discontinue the corticosteroid eye drop she had been using and replace it with Lotemax Gel (loteprednol etabonate; Bausch + Lomb). I asked her to return a week later, and when she did, her IOP had come down to 20 mm Hg. A month later, the patient’s IOP was stable at 16 mm Hg in that eye.

Lotemax Gel is engineered to facilitate adequate residence time on the ocular surface and, in contrast to its suspension formulation, does not require shaking to ensure dose-to-dose uniformity of drug delivery. Lotemax Gel is indicated for the treatment of postoperative inflammation and pain following ocular surgery. Importantly, for this patient’s case, the drug offers a proven safety profile and a low propensity to cause significantly elevated IOP. For this patient, Lotemax Gel offered continued inflammation control without the worries of an IOP spike. When I removed the cataract and implanted an iStent in this patient’s fellow eye, I began with Lotemax Gel, and the patient experienced an uneventful postoperative course and a rapid visual recovery. Her second eye did not exhibit any significant IOP spike, and the pressure measured 18 mm Hg at postoperative week 1. After a month, the IOP in the eye had settled at 16 mm Hg.

Inder Paul Singh, MD, is a glaucoma specialist at The Eye Centers of Racine and Kenosha in Racine, Wisconsin. He acknowledged no financial interest in the products or companies mentioned herein. Dr. Singh may be reached at ipsingh@amazingeye.com.

CASE 4

PRK: Rapid Epithelial Removal With an “Epi-rhexis” Technique

By Christopher E. Starr, MD

Although LASIK has garnered a reputation for being associated with less pain and faster recovery, I perform mostly advanced surface ablation on my refractive surgery patients. I find modern PRK to be simple, safe, and reliable. Visual outcomes are comparable to those with LASIK, and the patient’s experience with PRK has vastly improved in the modern era and now really rivals that of patients undergoing LASIK.

I would like to present a clinical case from my practice that illustrates my approach to PRK and perhaps my rationale for using it. A 30-year-old woman presented to my clinic seeking laser vision correction for myopia. Her refractive error was -4.00 D sphere in both eyes. She was intolerant of contact lenses and complained of symptoms consistent with mild dry eye disease. An evaluation revealed central corneal staining and high tear osmolarity. Prior to scheduling surgery, we took steps to optimize the condition of her ocular surface. She was advised to discontinue contact lens wear and wear glasses instead. She was placed on a 30-day regimen for the treatment of dry eyes. On follow-up at 6 weeks, the patient’s corneal surface appeared normal and revealed no staining. Her corneal topography and osmolarity were also normal. We were then able to proceed to PRK.

I think sterile technique is essential to the safety and success of any outpatient procedure, including PRK and LASIK. I wear a mask, a cap and gown, and sterile gloves, and I use a sterile drape over the patient’s head and lashes. A sterile drape is placed over the joystick and buttons as well before every case. I always make sure to change my gloves in between eyes. To start off, a sponge soaked in topical tetracaine is applied to the cornea, conjunctiva, and lid margin for about 30 seconds. This reduces pain and weakens the corneal epithelium. To further soften the epithelium, alcohol is instilled in a 9-mm well placed against the cornea for about 25 seconds. If alcohol leaks out, the patient will experience more redness and pain postoperatively. Therefore, it is important to hold the well firmly against the cornea, actually retropulsing the eye slightly. Before releasing the ring, I use a sponge to absorb excess alcohol and gently score the epithelium.

Now, I am ready to perform what I call the “epi-rhexis” using a dry Weck-Cel spear (Beaver-Visitec International). I try to remove the epithelium fairly rapidly in one sheet to prevent hydration changes in the stroma. Trying to limitstromal dehydration protects against excessive laser ablation and overcorrection. Ablation is performed using a laser equipped with iris registration and eye-movement tracking for optimal accuracy. In cases of moderate or high myopia, a mitomycin C-dampened sponge is applied to the ablated corneal surface for 12 seconds, and I take care to avoid any exposure to the limbal stem cells. The eye is then irrigated with two bottles of chilled balanced salt solution. One drop of prednisolone acetate is instilled; then the epithelial edge is visualized, any scrolled edges are flattened, and any alcohol-soaked tags are removed. I then apply a bandage contact lens. I want it to fit relatively tightly to facilitate healing and minimize postoperative pain.

The procedure is then repeated on the fellow eye. Tetracaine is applied to the cornea, conjunctiva, and lid margin, alcohol is placed in the well, excess is absorbed, and the epithelium is scored. Epithelium is then removed using a dry Weck-Cel spear. Again, I am aiming for rapid and consistent epithelial removal. Laser ablation is performed, mitomycin C is applied, and the eye is irrigated with chilled balanced salt solution. A drop of corticosteroid is then instilled. Imperfections along the epithelial edge are cleaned up, and a bandage contact lens is applied.
My standard practice for postoperative care includes short-term topical corticosteroids and long-term topical cyclosporine for about 6 months. Pain control is achieved by oral nonsteroidal anti-inflammatory agents, chilled preservative-free artificial tears, and cold compresses. In my practice, I have not found it necessary to prescribe oral corticosteroids, oral narcotics, neuroleptic agents, topical anesthetics, or comfort drops. I prescribe two oral supplements in the week following surgery: ascorbic acid (vitamin C) and omega-3 essential fatty acids. Ascorbic acid is used to prevent late-onset corneal haze associated with exposure to solar ultraviolet radiation. Omega-3 fatty acids have been associated with improved speed of healing, tear breakup time, and visual acuity recovery following PRK.

The patient was placed on Lotemax Gel four times daily following surgery. Lotemax Gel reduces pain and inflammation following ocular surgery. I find it to be effective for most of my patients undergoing mild to moderate refractive error correction with PRK. This is important for patients who chose to have PRK with me rather than LASIK somewhere else. In a wholly elective surgery like PRK, where patients have extremely high expectations, I need to have faith in the agents I prescribe as well as in my own surgical skills.

This patient had an uneventful surgical and postsurgical course, with a good visual outcome of 20/15 without haze, which is a typical outcome. The table shows my first 10 consecutive patients of 2013 who underwent bilateral PRK in my practice. By postoperative month 1, the mean visual acuity was 20/16 OU. By postoperative month 6, mean visual acuity was 20/15. On a pain scale from 0 to 5, the mean score on the night of surgery was 1.3 and on the first postoperative day was 1.2, which is quite low and not significantly worse than LASIK pain scores. Forty percent of patients reported no pain at all on postoperative day 1. These data reflect 20 eyes of 10 patients but are largely representative of my global experience with PRK in the past 10 years of practicing. Careful screening and conservative patient selection most certainly play an important role in my outcomes.

PRK is highly effective, and long-term visual outcomes are comparable to those with LASIK. It is easier, quicker, and cheaper to perform than LASIK, and potential flap complications are eliminated entirely. The patient’s experience has improved dramatically in recent years with less pain and faster visual recovery. Many patients experience a “wow” factor similar to that commonly seen with LASIK surgery. For all of these reasons, I favor advanced surface ablation for laser vision correction surgery.

Christopher E. Starr, MD, is associate professor of ophthalmology at Weill Cornell Medical College in New York. He is also director of the Refractive Surgery Service, director of ophthalmic education, and director of the Cornea, Cataract, and Refractive Surgery Fellowship at Weill Cornell Medical College. He is a consultant to Allergan, Bausch + Lomb, TearLab, Rapid Pathogen Screening, and Shire. Dr. Starr can be reached at cestarr@med.cornell.edu.