

Decreasing Vision and Cataracts After RK and AK

BY STEPHEN F. BRINT, MD; MITCHELL A. JACKSON, MD; AND J. BRADLEY RANDLEMAN, MD

CASE PRESENTATION

A 51-year-old male presents with a history of decreasing vision such that his current BCVA is about to cost him his pilot's license and thus his job. The patient's past ocular history is significant for bilateral RK and astigmatic keratotomy (AK) 25 years ago. No records are available on his previous refractive surgery or preoperative measurements.

An examination reveals a manifest refraction of $-5.00 +5.25 \times 164 = 20/50$ OD and $-1.75 +6.75 \times 158 = 20/60$ OS. A slit-lamp examination shows a 10-incision RK using a Ruiz procedure in both eyes, +2 nuclear sclerosis with a +2 posterior sub-

capsular cataract in his right eye, and +3 nuclear sclerosis with a +2 posterior subcapsular cataract in his left eye. The funduscopic examination is normal.

Computed topography reveals pertinent corneal information and the irregular astigmatism from the patient's previous refractive surgery (Figures 1 and 2). Figure 3 shows the radial and astigmatic incisions, several of which cross.

The patient wishes to be free of spectacles, but his only real requirement is a BCVA of 20/20 to avoid losing his job. How would you proceed?

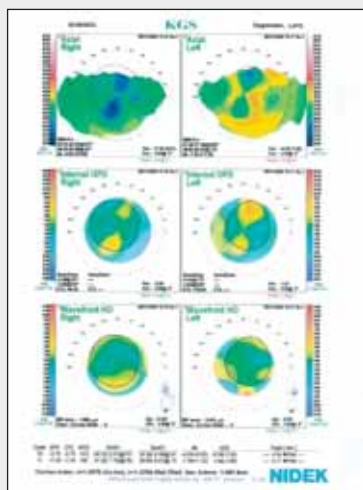


Figure 1. The patient has not only irregular corneal astigmatism but also marked lenticular astigmatism.

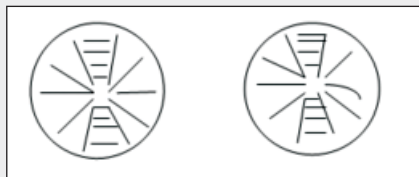


Figure 2. The patient has a history of RK and AK. In his left eye, the 3-o'clock incision is irregular and suspicious for microperforation.

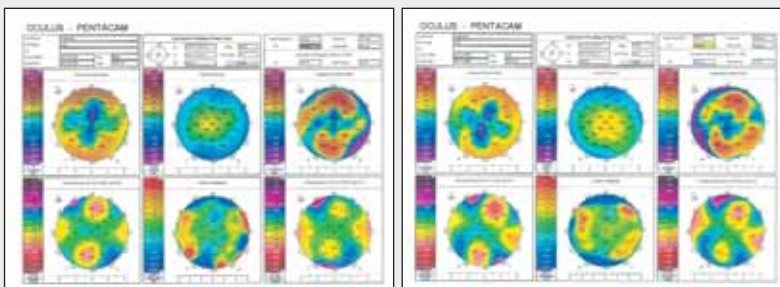


Figure 3. Imaging with the Pentacam Comprehensive Eye Scanner (Oculus, Inc., Lynnwood, WA) reveals the corneal irregularity related to the patient's previous refractive surgery.

STEPHEN F. BRINT, MD

First, I would inform the patient that 20/20 BCVA probably cannot be achieved, short of his possibly wearing a gas permeable contact lens or the SynergEyes A lens (SynergEyes, Inc., Carlsbad, CA). I would also explain that he faces a two-step (possibly a three-step) process for each

eye that will be time consuming in terms of surgery as well as healing.

To address the cataracts, I would implant the AcrySof IQ Toric IOL (Alcon Laboratories, Inc., Fort Worth, TX) in an effort to reduce as much of the residual cylinder as possible. Because the patient appears to have 4.00 to 5.00 D of

corneal cylinder, I would select the SA6AT5, which should correct approximately 2.50 D of the cylinder. I have no recent experience with the STAAR Toric IOL (STAAR Surgical Company, Monrovia, CA), which corrects more cylinder, but it would be another option. As there are no historical data, I would calculate the IOLs' power with the Holladay formula, both with the best of several auto keratometry readings and the Holladay simulated keratometry readings from the Pentacam. I would use the highest-powered IOL suggested for a postoperative target of -2.00 D. This is all guesswork, but I would expect the patient to be slightly myopic (in the range of -1.00 D with the residual cylinder) after surgery.

"My main advice on this case is to ensure that the patient maintains realistic expectations."

—Mitchell A. Jackson, MD

When his refraction and visual acuity had been stable for at least 1 month, I would determine his refraction and BCVA. If his BCVA were 20/20, he would have the option of spectacles to correct the residual refractive error, or he might desire to undergo wavefront-guided PRK. If his BCVA were not 20/20, I would note the option of his going abroad for topography-guided PRK. As mentioned earlier, rigid contact lenses might be a final option.

MITCHELL A. JACKSON, MD

This case is quite challenging, and unfortunately, the surgeon who last operates on this patient will be remembered for any final visual outcome short of 20/20 BCVA. Meeting his unrealistic expectations will be problematic due to the irregular astigmatism from the previous RK and AK procedures. Furthermore, the complex cornea that now exists will make IOL power calculations even more prone to error than usual. My first step would be to set appropriate expectations for the patient. Specifically, I would explain that no single surgery will solve his problem and that he will most likely need gas permeable contact lenses after cataract surgery.

On its Web site, the ASCRS posts a format for determining IOL power after previous refractive surgery (<http://iol.ascrs.org/>) if the surgeon does not already use a specific formula (such as Masket, Haigis, Randleman, etc.) or have prior experience with such a formula. I would minimize any induced surgical astigmatism or spherical aberration as much as possible by using a microincisional

approach of a 1.8- to 2.0-mm clear corneal incision, performing phacoemulsification with the Stellaris Vision Enhancement System (Bausch & Lomb, Rochester, NY), and placing an aspheric Akreos AO Micro Incision Lens (MI60L; Bausch & Lomb) to yield the best lenticular result possible.

After a minimum of 6 months of refractive stability postoperatively, I would tackle any residual refractive error. Most likely, gas permeable contact lenses would yield the best result, but the patient would have other options such as topography-guided PRK with mitomycin C performed abroad. My main advice on this case is to ensure that the patient maintains realistic expectations.

J. BRADLEY RANDLEMAN, MD

This difficult scenario involves multiple separate variables, including challenges in terms of the IOL power calculations and cataract surgery, the management of both regular and irregular astigmatism, and a mandatory requirement of 20/20 or better BCVA postoperatively.

Step 1 for this patient is removing the cataract and implanting the IOL. With multiple RK incisions, irregular astigmatism, and no preoperative records, there is no single, accurate, consistent method for determining the appropriately powered IOL. In our clinic, my colleagues and I use the consensus K technique,¹ which involves as many methods as we can generate for determining the IOL's power and then choosing the most consistent values among techniques. Although cataract extraction should be relatively straightforward, I would pay extra attention to the placement of the cataract incision and the stability of the old RK and AK incisions, especially since some appear to be full thickness and are therefore more likely to open during surgery.

The choice of IOL for this patient includes monofocal or toric lenses. Given the inherent inaccuracy in IOL power calculations and the potential refractive fluctuations from multiple corneal incisions, I would hesitate to implant a toric IOL and would instead opt for bilateral monofocal IOLs. If I could obtain some history of clinical stability over time in the amount and orientation of the regular astigmatic component, a toric lens would be a possibility and might make the rest of the astigmatic management less challenging. I would not offer limbal relaxing incisions to this patient. After cataract extraction and the IOLs' implantation, the postoperative refraction will take longer than usual to stabilize. No further surgical interventions should be undertaken until the refraction is very consistent.

The next step for this patient would depend on his residual refraction and the degree to which irregular astigmatism was affecting his visual acuity. PRK might be an option (perhaps a topography-guided procedure would be optimal), but the overall amount of astigmatism and degree of irregular astig-

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loteprednol etabonate
ophthalmic suspension 0.5%

Rx only

Brief Summary

INDICATIONS AND USAGE:

LOTEMAX is indicated for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

STERILE OPHTHALMIC SUSPENSION

LOTEMAX is less effective than prednisolone acetate 1% in two 28-day controlled clinical studies in acute anterior uveitis, where 72% of patients treated with LOTEMAX experienced resolution of anterior chamber cells, compared to 87% of patients treated with prednisolone acetate 1%. The incidence of patients with clinically significant increases in IOP (≥ 10 mmHg) was 1% with LOTEMAX and 6% with prednisolone acetate 1%. LOTEMAX should not be used in patients who require a more potent corticosteroid for this indication.

LOTEMAX is also indicated for the treatment of post-operative inflammation following ocular surgery.

CONTRAINDICATIONS:

LOTEMAX, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. LOTEMAX is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

WARNINGS:

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Steroids should be used with caution in the presence of glaucoma.

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

PRECAUTIONS:

General: For ophthalmic use only. The initial prescription and renewal of the medication order beyond 34 days should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

If signs and symptoms fail to improve after two days, the patient should be re-evaluated.

If this product is used for 10 days or longer, intraocular pressure should be monitored even though it may be difficult in children and uncooperative patients (see WARNINGS).

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

Information for Patients: This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the suspension. If pain develops, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician. As with all ophthalmic preparations containing benzalkonium chloride, patients should be advised not to wear soft contact lenses when using LOTEMAX.

Carcinogenesis, mutagenesis, impairment of fertility: Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic in vitro in the Ames test, the mouse lymphoma R assay, or in a chromosome aberration test in human lymphocytes, or in vivo in the single dose mouse micronucleus assay. Treatment of male and female rats with up to 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, (500 and 300 times the maximum clinical dose, respectively) prior to and during mating did not impair fertility in either gender.

Pregnancy: Teratogenic effects: Pregnancy Category C. Loteprednol etabonate has been shown to be embryotoxic (delayed ossification) and teratogenic (increased incidence of meringocele, abnormal left common carotid artery, and limb flexures) when administered orally to rabbits during organogenesis at a dose of 3 mg/kg/day (35 times the maximum daily clinical dose), a dose which caused no maternal toxicity. The no-observed-effect-level (NOEL) for these effects was 0.5 mg/kg/day (6 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at ≥ 5 mg/kg/day doses, and cleft palate and umbilical hernia at ≥ 50 mg/kg/day) and embryotoxicity (increased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with ≥ 50 mg/kg/day). Treatment of rats with 0.5 mg/kg/day (6 times the maximum clinical dose) during organogenesis did not result in any reproductive toxicity. Loteprednol etabonate was maternally toxic (significantly reduced body weight gain during treatment) when administered to pregnant rats during organogenesis at doses of ≥ 5 mg/kg/day.

Oral exposure of female rats to 50 mg/kg/day of loteprednol etabonate from the start of the fetal period through the end of lactation, a maternally toxic treatment regimen (significantly decreased body weight gain), gave rise to decreased growth and survival, and retarded development in the offspring during lactation; the NOEL for these effects was 5 mg/kg/day. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to pregnant rats at doses up to 50 mg/kg/day during the fetal period.

Nursing Mothers: It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemic steroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when LOTEMAX is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS:

Reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Ocular adverse reactions occurring in 5-15% of patients treated with loteprednol etabonate ophthalmic suspension (0.2%-0.5%) in clinical studies included abnormal vision/blurring, burning on instillation, chemosis, discharge, dry eyes, epiphora, foreign body sensation, itching, injection, and photophobia. Other ocular adverse reactions occurring in less than 5% of patients include conjunctivitis, corneal abnormalities, eyelid erythema, keratoconjunctivitis, ocular irritation/pain/discomfort, papillae, and uveitis. Some of these events were similar to the underlying ocular disease being studied.

Non-ocular adverse reactions occurred in less than 15% of patients. These include headache, rhinitis and pharyngitis.

In a summation of controlled, randomized studies of individuals treated for 28 days or longer with loteprednol etabonate, the incidence of significant elevation of intraocular pressure (≥ 10 mmHg) was 2% (15/901) among patients receiving loteprednol etabonate, 7% (11/164) among patients receiving 1% prednisolone acetate and 0.5% (3/583) among patients receiving placebo.

DOSAGE AND ADMINISTRATION:

SHAKE VIGOROUSLY BEFORE USING.

Steroid Responsive Disease Treatment: Apply one to two drops of LOTEMAX into the conjunctival sac of the affected eye(s) four times daily. During the initial treatment with the first week, the dosing may be increased, up to 1 drop every hour, if necessary. Care should be taken not to discontinue therapy prematurely. If signs and symptoms fail to improve after two days, the patient should be re-evaluated (See PRECAUTIONS).

Post-Operative Inflammation: Apply one to two drops of LOTEMAX into the conjunctival sac of the operated eye(s) four times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the post-operative period.

Storage: Store upright between 15°-25°C (59°-77°F). DO NOT FREEZE.

KEEP OUT OF REACH OF CHILDREN.

Revised April 2006

Bausch & Lomb Incorporated, Tampa, Florida 33637

U.S. Patent No. 4,996,335

U.S. Patent No. 5,540,930

U.S. Patent No. 5,747,061

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Based on full prescribing information revised April 2006

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REFRACTIVE SURGERY
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matism would likely limit the final outcome. Because the goal is a BCVA of 20/20 or better rather than best achievable UCVA or BSCVA, I would only offer additional corneal refractive surgery if cataract surgery had significantly decreased the refractive astigmatism and the patient could easily refract to 20/20, which is unlikely. The best option for final visual rehabilitation would probably be a strategy involving rigid gas permeable contact lenses, either alone or in combination with soft contact lenses (piggyback fit). ■

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1. Randleman JB, Foster JB, Loupe DL, et al. Intraocular lens power calculations after refractive surgery: the consensus K technique. *J Cataract Refract Surg*. 2007;33:1893-1899.