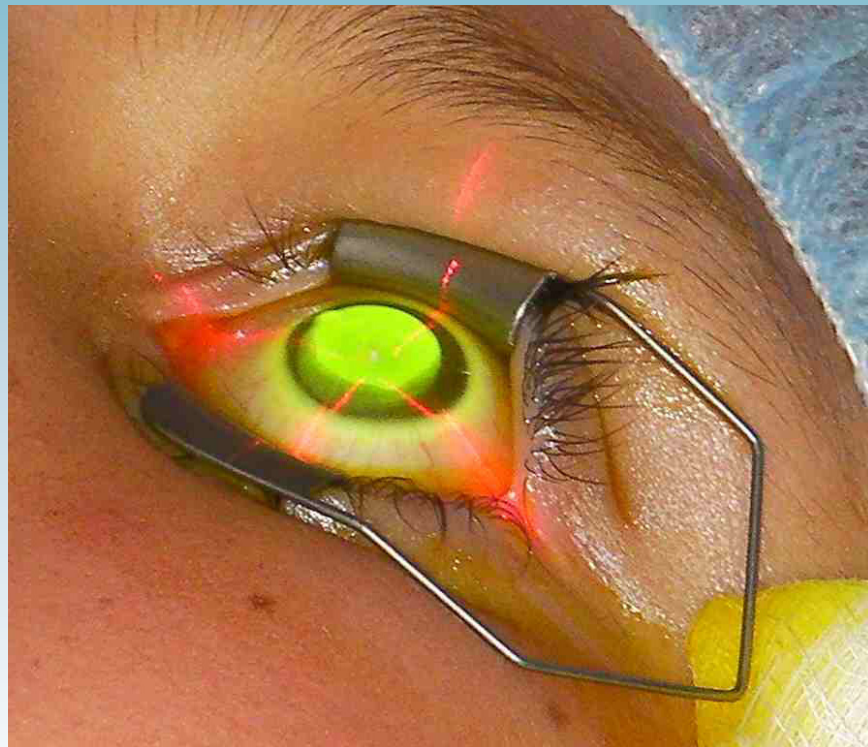


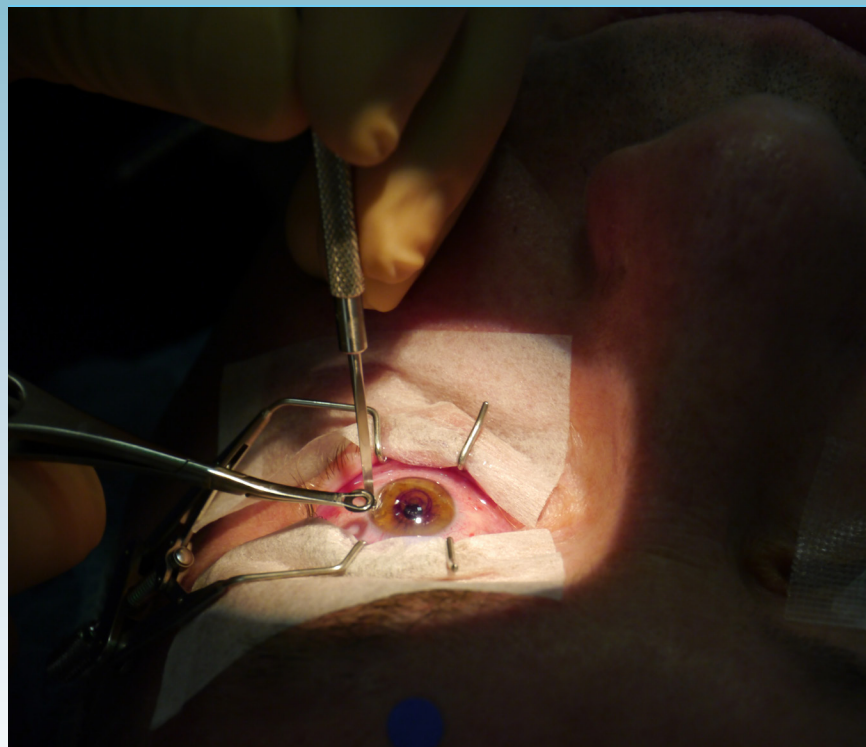
What's more minimally invasive than LASIK?

by Matt Young and Gloria D. Gamat EyeWorld Contributing Writers



Patient undergoing accelerated crosslinking with the KXL II system

Source: Peter Hersh, MD



Patient undergoing vision correction surgery with the KAMRA inlay

Source: Jeffery J. Machat, MD

PiXL, KAMRA, and—for extreme refractive error—the Visian ICL

Ophthalmologists will forever push the envelope to achieve a smaller surgical footprint.

That's why LASIK isn't the endgame of refractive surgery, but rather the beginning of the beginning. As far as minimally invasive refractive surgery goes, this is especially true.

Advancements in technology and refractive surgical techniques have brought about a wide range of refractive correction procedures that are even more minimally invasive. Here we look at two of the latest advancements and a third (the Visian ICL, STAAR Surgical, Monrovia, Calif.) that is standing the test of time to provide a minimally invasive LASIK alternative for extreme refractive error.

Non-invasive, topography-guided crosslinking

In corneal refractive surgery, refrac-

tive errors are corrected through techniques that reshape the cornea either by surgery or by laser treatment. When corneal crosslinking with riboflavin and ultraviolet-A (UVA) was introduced, it provided an option that reshapes the cornea by changing its biomechanical structure. The standard technique was designed to stabilize the progression of ectatic corneal disorders such as keratoconus and corneal ectasia. However, basic science and clinical research have expanded the potential utilities of crosslinking. Today, accelerated crosslinking using higher power UV sources can reduce procedure time from 30 minutes to 3 minutes or less. In addition, Photorefractive Intraström Crosslinking (PiXL) using the KXL II System (Avedro, Waltham, Mass.) can address topography irregularities and refractive errors as well.

"PiXL is a topography-guided crosslinking," said **Peter Hersh, MD**, Cornea & Laser Eye Institute – Hersh Vision Group, Teaneck, N.J. "The KXL II System incorporates eye tracking to properly pattern and apply the UVA energy needed."

"PiXL has two goals," Dr. Hersh said. "In irregular corneas, such as in keratoconus, we can use topography both to guide the power and the pattern of the UV light on the cornea to obtain crosslinking individualized to the patient's corneal irregularity, and for refractive surgery, we are able to pattern the energy in order to correct lower degrees of nearsightedness, farsightedness, and astigmatism."

PiXL is extremely non-invasive, according to Dr. Hersh.

"Unlike LASIK or PRK, which are removing tissue, [PiXL] doesn't violate the tissue per se, but it changes the shape of the cornea on a biomechanical basis," he said. "It is a new kind of platform where we are changing the corneal biomechanics and corneal microarchitecture in order to correct refractive error."

While LASIK is most suitable for higher degrees of myopia, PiXL best suits patients with lower degrees of refractive error.

"It is a standalone procedure for lower degrees of hyperopia, myopia, or astigmatism," Dr. Hersh explained. "But we also see that it

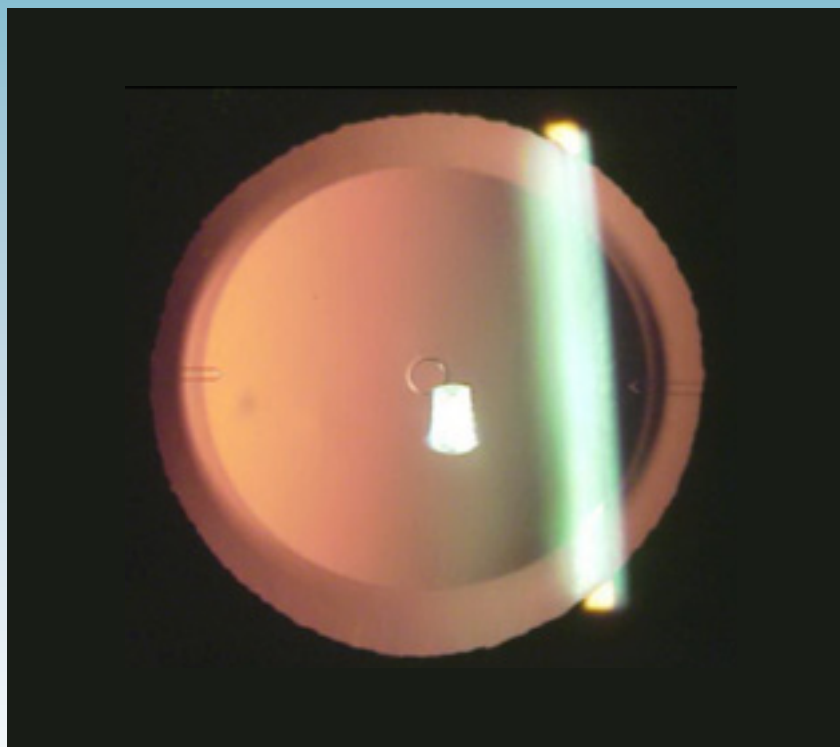
might have a good place as an enhancement procedure in post-cataract surgery, where there is a residual refractive error that can be corrected in a non-invasive way."

PiXL provides ophthalmic surgeons with an enhancement tool that can proceed without much intervention. However, experts are still defining the limits.

Corneal inlays over multifocal ablation

In the last 10 years, several generations of corneal inlays have been developed and refined. Made of an inert material called polyvinylidene fluoride (PVDF), the KAMRA corneal inlay (AcuFocus, Irvine, Calif.) is a disc-shaped inlay that is 6 microns thick, 3.8 mm in diameter and has a 1.6 mm opening.

"The KAMRA corneal inlay has 8,400 tiny perforations throughout the inlay in a pseudo randomized pattern," said **Jeffery J. Machat, MD**, chief medical director, Crystal Clear Vision, Toronto. "Weighing only as much as a crystal of salt, it is an incredibly refined type of inlay that works on extending the range



With the new V4c model of the Visian ICL that has a central hole, no iridectomies or iridotomies are needed. The surgery is faster, easier, and less traumatic compared to previous models that needed peripheral iridectomies/iridotomies.

Source: Alaa El Danasoury, MD

of focus of the eye using pinhole or small aperture optics."

In the clinical practice, it is more well known that changing the power of the eye means changing the shape of the cornea with lasers, like LASIK and PRK, or changing the power of the eye internally with a lens implant.

Corneal inlays work with a different mechanism.

"Instead of being a lens that changes the power of the eye, this is an optical principle that increases the depth of focus," said **Daniel S. Durrie, MD**, founder and president, Durrie Vision, Overland Park, Kan.

"You will have a large range [of vision]. That's what made this popular to patients and doctors," he said.

Its minimally invasive characteristic is another reason KAMRA is gaining popularity among patients and doctors. The procedure is straightforward, easy to put in and easy to remove as well.

"It takes 60 seconds or less to remove," Dr. Machat said.

Results of FDA clinical trials, which evaluated whether the KAMRA inlay can be removed from

the cornea and allow patients' vision to return to the preoperative state, have shown that patients did recover within one line of their best corrected vision after the inlay was removed.

"I think it is a comfort level for both surgeons and patients that it is removable and the patients' corneas tolerated the surgery to put it in and the surgery to take it out. The good news is that in well-selected patients, the removal rate is running 1% or less," Dr. Durrie said.

KAMRA provides a long-lasting, minimally invasive option to presbyopes who otherwise have healthy corneas.

"For this procedure, you need to have clear media," Dr. Machat said.

"Any sort of scarring or problem on the cornea, even a mere dry eye, any sort of irregularity or early cataract change in the lens disqualifies a patient from getting the inlay."

"[Patients] need to have a good tear film, and we need to make sure that they don't have a cataract," Dr. Durrie said. "The age group for

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this is patients in their 40s, 50s, and sometimes 60s—the same age group that could be developing a cataract. We are narrowing down the optics of the eye. We look through the small aperture optics. If patients have cataract or dry eye, they don't get nearly as good of a result."

With the KAMRA—an outpatient procedure that takes about 10 minutes with topical anesthetic—vision recovery can be quite rapid. However, patient reactions vary. While some can read fine print the next morning, others take about 4–6 weeks as their tear film stabilizes and any edema resolves centrally.

"In 15% of these patients, improvement of vision can be seen in 3–4 hours, and it does continue to improve after the first week," Dr. Durrie said. "There is an adaptation period to their vision whereby patients are more comfortable in their new vision after 1 month than 1 day after the surgery."

The surgical development of the KAMRA has been going on for a decade now. In the process, ophthalmic surgeons have learned who's a good candidate and have perfected how to do the surgery. The procedure performed well enough in the early studies done on patients to continue developing it.

"What is great about FDA clinical trials is that we can look at the long-term data (up to 5 years) and now know the best candidates and what the best surgical technique is," Dr. Durrie said. "We now know the best femtosecond laser settings and where to center the inlay. We did not know this when we started clinical trials."

The key to this procedure's success, Dr. Durrie said, is not just good patient selection and good technique, but also patient education.

"To make sure that expectations are aligned, patients need to understand that this procedure doesn't make them see instantly, and it doesn't make their eyes younger," Dr. Durrie said. "But it does give them the ability to have a broader function of vision for both near and distance. The main thing is that this is a new optical principle and that's what makes it exciting. We are now going to have a different tool when evaluating options for patients."

The Visian ICL for extreme—and low—refractive error

Patients with low to extremely high refractive errors, dry eyes and thin corneas do not qualify for LASIK. Instead, the Visian ICL could be more appropriate.

"The Visian ICL can correct a wide range of refractive errors, between –18.0 and +6.0 D," said Alaa El Danasoury, MD, medical director and chief of the refractive surgery department, Magrabi Hospitals & Centers. "It also corrects astigmatism up to 6.0 D. This range covers most patients with ametropia. The main prerequisite for ICL implantation is an anterior chamber depth of

3.0 mm or more, measured from the endothelium. Other criteria include stable refraction and healthy endothelium."

Although glaucoma, keratoconus, and retinal dysfunction are relative contraindications for the procedure, the most important exclusion criterion for Visian ICL is a shallow anterior chamber (less than 3.0 mm), Dr. El Danasoury said.

Considered a minimally invasive procedure, the Visian ICL is performed routinely under topical anesthesia.

"The implant can be inserted through a small incision, less than 3 mm, and it entails minimal manipulation of the intraocular tissue," he said. "With the new V4c model that has a central hole, no iridectomy or iridotomies are needed. It is an

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use Zylet safely and effectively. See full prescribing information for Zylet.

Zylet® (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension)
Initial U.S. Approval: 2004

DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

Apply one or two drops of Zylet into the conjunctival sac of the affected eye every four to six hours. During the initial 24 to 48 hours, the dosing may be increased, to every one to two hours. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

2.2 Prescription Guideline

Not more than 20 mL should be prescribed initially and the prescription should not be refilled without further evaluation [see Warnings and Precautions (5.3)].

CONTRAINDICATIONS

4.1 Nonbacterial Etiology

Zylet, as with other steroid anti-infective ophthalmic combination drugs, 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.

WARNINGS AND PRECAUTIONS

5.1 Intraocular Pressure (IOP) Increase

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

If this product is used for 10 days or longer, intraocular pressure should be monitored.

5.2 Cataracts

Use of corticosteroids may result in posterior subcapsular cataract formation.

5.3 Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as a slit lamp biomicroscopy and, where appropriate, fluorescein staining.

5.4 Bacterial Infections

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

5.5 Viral Infections

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

5.6 Fungal Infections

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.

5.7 Aminoglycoside Hypersensitivity

Sensitivity to topically applied aminoglycosides may occur in some patients. If hypersensitivity develops with this product, discontinue use and institute appropriate therapy.

ADVERSE REACTIONS

Adverse reactions have occurred with steroid/anti-infective combination drugs which can be attributed to the steroid component, the anti-infective component, or the combination.

Zylet:

In a 42 day safety study comparing Zylet to placebo, ocular adverse reactions included injection (approximately 20%) and superficial punctate keratitis (approximately 15%). Increased intraocular pressure was reported in 10% (Zylet) and 4% (placebo) of subjects. Nine percent (9%) of Zylet subjects reported burning and stinging upon instillation.

Ocular reactions reported with an incidence less than 4% include vision disorders, discharge, itching, lacrimation disorder, photophobia, corneal deposits, ocular discomfort, eyelid disorder, and other unspecified eye disorders.

The incidence of non-ocular reactions reported in approximately 14% of subjects was headache; all other non-ocular reactions had an incidence of less than 5%.

Loteprednol etabonate ophthalmic suspension 0.2% - 0.5%:

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

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 mm Hg) 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.

Tobramycin ophthalmic solution 0.3%:

The most frequent adverse reactions to topical tobramycin are hypersensitivity and localized ocular toxicity, including lid itching and swelling and conjunctival erythema. These reactions occur in less than 4% of patients. Similar reactions may occur with the topical use of other aminoglycoside antibiotics.

Secondary Infection:

The development of secondary infection has occurred after use of combinations containing steroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids.

The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used.

Secondary bacterial ocular infection following suppression of host responses also occurs.

USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic effects: Pregnancy Category C. Loteprednol etabonate has been shown to be embryotoxic (delayed ossification) and teratogenic (increased incidence of meningocele, abnormal left common carotid artery, and limb fixtures) 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 at 0.5 mg/kg/day (6 times the maximum daily 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.

Reproductive studies have been performed in rats and rabbits with tobramycin at doses up to 100 mg/kg/day parenterally and have revealed no evidence of impaired fertility or harm to the fetus. There are no adequate and well controlled studies in pregnant women. Zylet should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 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 that appear in human milk could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when Zylet is administered to a nursing woman.

8.4 Pediatric Use

Two trials were conducted to evaluate the safety and efficacy of Zylet® (loteprednol etabonate and tobramycin ophthalmic suspension) in pediatric subjects age zero to six years; one was in subjects with lid inflammation and the other was in subjects with blepharoconjunctivitis.

In the lid inflammation trial, Zylet with warm compresses did not demonstrate efficacy compared to vehicle with warm compresses. Patients received warm compress lid treatment plus Zylet or vehicle for 14 days. The majority of patients in both treatment groups showed reduced lid inflammation.

In the blepharoconjunctivitis trial, Zylet did not demonstrate efficacy compared to vehicle, loteprednol etabonate ophthalmic suspension, or tobramycin ophthalmic solution. There was no difference between treatment groups in mean change from baseline blepharoconjunctivitis score at Day 15.

There were no differences in safety assessments between the treatment groups in either trial.

8.5 Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate or tobramycin.

Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma TK assay, a chromosome aberration test in human lymphocytes, or in an *in vivo* mouse micronucleus assay.

Oral treatment of male and female rats at 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, (500 and 250 times the maximum clinical dose, respectively) prior to and during mating did not impair fertility in either gender. No impairment of fertility was noted in studies of subcutaneous tobramycin in rats at 100 mg/kg/day (1700 times the maximum daily clinical dose).

PATIENT COUNSELING INFORMATION

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 Zylet.

MANUFACTURER INFORMATION

BAUSCH & LOMB INCORPORATED

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additive procedure so it can be partially reversed and the lens can be easily exchanged if needed."

Similar to laser vision correction, the procedure is done in an outpatient setting.

"In experienced hands the whole procedure takes less than 3 minutes, which minimizes the risk of infection," Dr. El Danasoury said.

Ophthalmologists will forever push the envelope to achieve a smaller surgical footprint. That's why LASIK isn't the endgame of refractive surgery, but rather the beginning of the beginning.

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INDICATIONS AND USAGE

ZYLET® (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension) is a topical anti-infective and corticosteroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

Ocular steroids are indicated in 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, and where the inherent risk of steroid use in certain infective conjunctivitis is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

The particular anti-infective drug in this product (tobramycin) is active against the following common bacterial eye pathogens: *Staphylococci*, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains, *Streptococci*, including some of the Group A-beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Proteus mirabilis*, *Morganella morganii*, most *Proteus vulgaris* strains, *Haemophilus influenzae*, and *H. aegyptius*, *Moraxella lacunata*, *Acinetobacter calcoaceticus* and some *Neisseria* species.

IMPORTANT SAFETY INFORMATION

• ZYLET® 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.

IMPORTANT SAFETY INFORMATION (continued)

- Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If this product is used for 10 days or longer, intraocular pressure should be monitored.
- Use of corticosteroids may result in posterior subcapsular cataract formation.
- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as a slit lamp biomicroscopy and, where appropriate, fluorescein staining.
- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infections. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
- Employment of corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and exacerbate the severity of many viral infections of the eye (including herpes simplex).
- 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.
- Most common adverse reactions reported in patients were injection and superficial punctate keratitis, increased intraocular pressure, burning and stinging upon instillation.

Please see Brief Summary of Prescribing Information for ZYLET® on adjacent page.

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Zylet®
loteprednol etabonate
0.5% and tobramycin 0.3%
ophthalmic suspension



Compared to other refractive correction procedures, the Visian ICL may be a better option for patients with myopia above 7.0 D because of the better quality of vision, elimination of the risk of ectasia and flap complications, refractive stability, and preservation of the crystalline lens and accommodation.

"For moderate myopia (between 5.0 and 7.0 D) I personally prefer the Visian ICL because of better predictability, less night vision complaints, and less postoperative chair time," Dr. El Danasoury said. "In many cases with low myopia (between 1.0 and 4.0 D) I still prefer the Visian ICL if the topography and/or tomography show any degree of suspicion or in cases of borderline corneal thickness. With the ICL there is no risk of surprises that we sometimes see with laser correction."

Although there are some areas warranting refinement (i.e., ICL sizing), the current available methods, according to Dr. El Danasoury, are good enough for about 95% of the cases. Further, in the rare cases with oversizing or undersizing, the ICL can be easily exchanged for a smaller or larger lens.

"Modern phakic IOLs gained a solid place in refractive surgery over the last 3 decades; the main debate that was ongoing for the last 10–15 years—which phakic IOL is better?—is now resolved, and most of the phakic IOL surgeons agree that posterior chamber IOLs are the closest to ideal because of their long-term safety, stability inside the eye, ability to correct astigmatism, better cosmesis, and higher patient satisfaction," he said. **EW**

Editors' note: Dr. Hersh has financial interests with Avedro. Drs. Machat and Durrie have financial interests with AcuFocus. Dr. El Danasoury has financial interests with STAAR Surgical.

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