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OCULAR Infection & Inflammation

Improving Surgical Outcomes

A continuing education newsletter for physicians, pharmacists, and nurses interested in infection & inflammation of the eye

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Activity Title

OCULAR Infection & Inflammation

This CME activity is supported by an unrestricted educational grant from

SIRION Therapeutics
One Vision ... for All to See

Objectives: Improving Surgical Outcomes

At the conclusion of this activity, participants should be able to:

- Compare & contrast treatments to control pain and inflammation
- Identify new antibiotic therapies for cataract surgery
- Describe steps to implement prophylaxis against post-LASIK infectious keratitis
- List causes and effects of cystoid macular edema

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Betty Danzi	None/USF Heath	CME Coordinator
Susan Easter, MS, CAE	None/Focus-ED	Project Manager

Accreditation

Target Audience:

General ophthalmologists
Cornea specialists
Pharmacists
Nurses (ANCC)

Physicians:

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of USF Health and Focus-ED. USF Health is accredited by the ACCME to provide continuing medical education for physicians.

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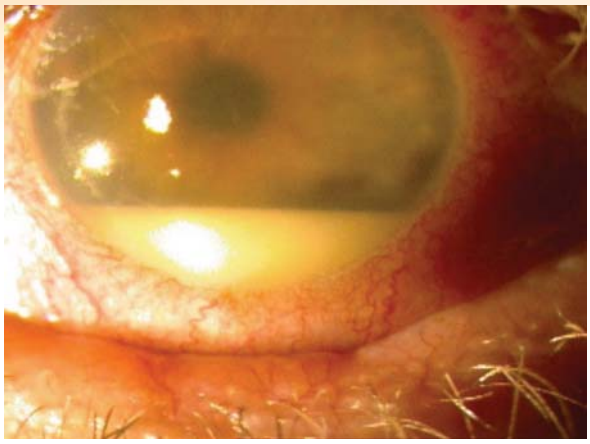
INTRODUCTION

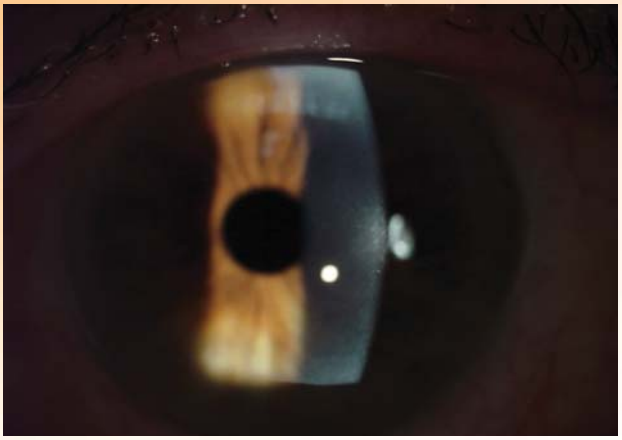
The cataract surgery patient of 2009 expects a rapid return of quality vision following a safe and painless procedure. Ophthalmic therapeutics used in the perioperative period are extraordinarily important to achieve these outcomes. We look at these therapeutics as preoperative and postoperative surgical tools which are as important as the surgeon's choice of phacoemulsification device, intraocular lens (IOL), or laser vision correction platform. The three therapeutics commonly used around cataract and refractive surgeries are anti-infectives, corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDS).

ANTIBIOTIC THERAPY FOR CATARACT SURGERY

Minimizing rates of infection, and therefore potential adverse outcomes with loss of best corrected acuity is imperative. In the United States, many clinicians have already adopted the routine use of both preoperative and immediate postoperative topical antibiotics. It has been well established in the literature that betadine used preoperatively effectively reduces the incidence of postoperative endophthalmitis.[1] More recent studies have suggested that the addition of use of preoperative fourth generation fluoroquinolones may help reduce the risk of postoperative ocular infection.[2] The fluoroquinolones are the newest class of ophthalmic antibiotics. They are based on the prototype, nalidixic acid (1,8-naphthyridine), which was synthesized in 1962.[3] In the 1980s, the fluoroquinolones were created from nalidixic acid by adding a fluorine atom to position 6 of the molecule. This addition widened the antibacterial spectrum of activity and resulted in decreased development of resistant organisms. The most recent generation of fluoroquinolones, gatifloxacin 0.3% (Zymar, Allergan, Inc., Irvine, CA), and moxifloxacin 0.5% (Vigamox, Alcon Laboratories, Inc., Fort Worth, TX), offer improved activity against methicillin-resistant Staphylococcus species (as compared to previous generation fluoroquinolones) which are the most common infections seen after cataract and refractive surgery.[4] A new fourth generation of ophthalmic fluoroquinolones which recently became available is besifloxacin 0.6% (Besivance, Bausch & Lomb Pharmaceuticals, Inc. Tampa, FL) . Unlike the previous fluoroquinolones in its generation, there is no systemic equivalent of the molecule and, therefore, no known systemic or ophthalmic resistance to the drug.



Endophthalmitis one week post-CEIOL.



Mild corneal edema following cataract surgery.

ANTIBIOTIC THERAPY FOR LASIK PROCEDURES

The incidence of post-LASIK infectious keratitis is unknown and varies widely depending on the study. One large, retrospective investigation of the complications associated with LASIK surgery found an incidence of two infections in 1,062 eyes,[5] and a similar study found one infection in 1,019 eyes.[6] Recently, however, a case series of LASIK-associated infections encountered at a single institution quoted an estimated occurrence of between 1:1000 and 1:5000.[7] Based on a comprehensive review and analysis of the published literature, Chang and colleagues confirmed that the numbers of infection post-LASIK can vary widely (0%-1.5%).[8]

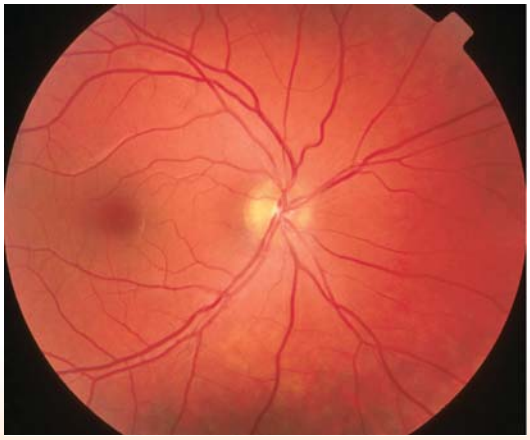
For prophylaxis against post-LASIK infectious keratitis, surgeons need to implement several steps. Preoperatively, all patients considering refractive surgery should have a thorough examination of their eyelids and lacrimal apparatus. In a case where there is significant Staph marginal lid disease, a course of topical azithromycin (Azasite, Inspire Pharmaceuticals, Inc., Durham, NC) should be seriously considered as it has good activity against Staph species, penetrates into lid tissue and due to its mucoadhesive matrix

adheres to the lid margin.[9,10]

In general, the antibiotic should provide a broad spectrum of coverage with an emphasis on gram-positive organisms. The antibiotic should also provide coverage against atypical mycobacteria and should be nontoxic to the cornea to promote corneal epithelial healing. Finally, the appropriate antibiotic should penetrate effectively into the cornea and achieve therapeutic levels in the middle of the corneal stroma. Fourth-generation fluoroquinolones (gatifloxacin 0.3% and moxifloxacin 0.5% and possibly besifloxacin 0.6%) are recommended as prophylaxis against infection following LASIK and photorefractive keratectomy (PRK), because they are best suited to meet the aforementioned criteria.[11]

Based on personal experience, topical therapy may begin one hour prior to surgery and, at the conclusion of LASIK, the cornea is dehydrated for 1 to 2 minutes to improve the flap's adherence. Next, apply the antibiotic directly to the dehydrated flap to improve drug absorption into the cornea. With PRK, place the antibiotic directly onto the stromal bed and soak the bandage contact lens in the antibiotic for 30 seconds prior to placing it on the eye. Postoperatively, LASIK patients receive a fourth-generation fluoroquinolone q.i.d. for 5 days whereas PRK patients commence this regimen 1 day after their epithelial defect has closed.[12]

Postoperative inflammation is a well-described entity which must be treated aggressively not only for short-term visual and symptomatic benefit, but more importantly perhaps in order to minimize long-term risk of chronic cystoid macular edema (CME) which may permanently jeapordize visual outcome. Non-steroidal and corticosteroid medical management are valuable prophylactic and therapeutic options available to the surgical patient.



Blunted retinal reflex in patient with cystoid macular edema

CORTICOSTEROIDS AND NONSTEROIDAL ANTI-INFLAMMATORY DRUGS

Ocular inflammation may be characterized by redness, swelling, and/or pain associated with irritation or trauma to the eye. Common triggers of ocular inflammation include allergies, meibomian gland dysfunction, ocular diseases (e.g., traumatic iritis, peripheral corneal inflammatory keratitis, episcleritis) and surgical procedures. The strict regulation of inflammatory reactions within the eye is vital in maintaining both anatomical integrity and visual function. Left unregulated, inflammation within the eye may lead to extensive ocular damage, resulting in pain, impaired vision and increased risk for the development of CME.

Nonsteroidal anti-inflammatory drugs (NSAIDs)

Ophthalmic nonsteroidal anti-inflammatory drugs (NSAIDs) are becoming a cornerstone for the management of ocular pain and inflammation associated with cataract and refractive surgeries. Nonsteroidal anti-inflammatory drugs have well-characterized anti-inflammatory and analgesic properties, as well as an established safety record. This drug profile makes NSAIDs an important tool when optimizing surgical outcomes. Nonsteroidal anti-inflammatories inhibit the production of prostaglandins; they do not affect prostaglandins that have already been formed. It is important to begin NSAID treatment sufficiently in advance of surgery to inhibit the formation of prostaglandins in response to surgical insult.

Ophthalmic NSAIDs currently play four principle roles in ophthalmic surgery including:

1. The prevention of intraoperative miosis during cataract surgery. Miosis may restrict the surgeon's field of view during cataract surgery, thereby hindering the progression of the procedure, and increasing the risk of complications and posterior capsule rupture. The NSAIDs prevent miosis by limiting prostaglandin synthesis within the tissues by inhibiting cyclooxygenase and reducing inflammation. They also help to maintain better intraoperative dilation thereby reducing complication rates.
2. The management of post-operative inflammation.
3. The reduction of pain and discomfort following cataract and refractive surgery.
4. The prevention and treatment of CME following cataract surgery.

Cystoid macular edema is potentially the most adverse ocular outcome of prostaglandin production. CME is caused by cystic accumulation of intraretinal fluid in the outer plexi-

form and inner nuclear layers of the retina, as a result of breakdown of the blood-retinal barrier. It is most common following intraocular surgery, and in patients with venous occlusive disease, diabetic retinopathy, and posterior segment inflammatory conditions. However, CME can develop in surgeries with no obvious complications. The condition is often asymptomatic and may only be detected with fluorescein angiography or optical coherence tomography.

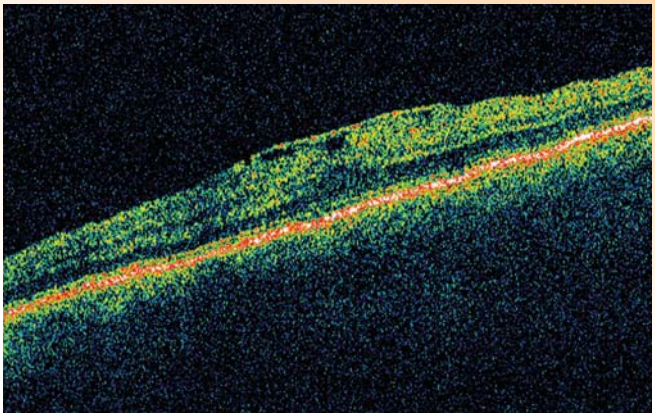
While postoperative NSAID use is important to control pain and inflammation, preoperative treatment is essential to improve the results of surgery. Cystoid macular edema usually presents with blurred vision, retinal swelling, or loss of vision. While most CME is self-limited, consequences of CME can include irreversible cystic damage, which can lead to decreased visual acuity and impaired contrast sensitivity. Clinical CME was previously felt to be a rare occurrence, but

CLASSES OF NSAIDS FOR TOPICAL USE

INDOLE			
Indomethacin	Indole derivative	1% aqueous suspension	Available outside of U.S.
PHENYLACETIC ACIDS			
Diclofenac	Phenylacetic derivative	1% water-soluble	FDA-approved to minimize inflammation related to cataract surgery, & for reduction of pain & photophobia after cataract surgery
Bromfenac	Phenylacetic derivative	0.09% 2x daily topical	Indicated for treatment of post-operative cataract surgery; available in Japan; removed from U.S. market due to liver toxicity as a systemic medication
ARYLACETIC ACID PRO-DRUG			
Nepafenac	Arylacetic acid pro-drug	0.1% 3x daily	For pain & inflammation associated with cataract surgery
PHENYLALKANOIC ACIDS			
Flurbiprofen	Water-soluble	0.03%	FDA-approved for intraoperative use during cataract surgery for inhibition of excessive miosis
Suprofen	Water-soluble	1%	FDA-approved for intraoperative use during cataract surgery for inhibition of excessive miosis
Ketorolac tromethamine	Water-soluble	0.4%	FDA-approved treatment for reduction of ocular pain & burning-stinging following corneal refractive surgery; also approved for relief of itching associated with seasonal allergic conjunctivitis

new information shows that CME is actually extremely common and can occur even with the use of a postoperative corticosteroid. Any CME degrades quality of vision which may reduce the quality of vision with monofocal IOLs, but can be devastating in patients receiving multifocal IOLs due to the inherent loss of quality of vision associated with the use of these lenses.

Until recently, there have been few large scale studies demonstrating the efficacy of currently available NSAIDs in the prevention of CME following phacoemulsification. A large-scale study by John R. Wittpenn Jr., MD, and colleagues concluded that the non-steroidal anti-inflammatory, ketorolac 0.4% (Acular LS, Allergan, Inc., Irvine, CA)[13], improved visual result and minimized the risk of CME. They demonstrated a statistically significant difference in the incidence of CME in patients treated prophylactically for 3 days before



Foveal thickening in a patient with cystoid macular edema.

cataract surgery with ketorolac tromethamine plus steroids compared with patients receiving steroids only. Those investigators also showed an association between retinal thickening and postoperative quality of vision as measured by contrast sensitivity.

Corticosteroids

The final therapeutic option to discuss is the use of corticosteroids. Following cataract surgery, it is extremely important to remember that topical corticosteroid agents remain the gold standard for treating inflammation, reducing complications, and restoring visual acuity. There are many corticosteroids that may be used after surgery.

Increased intraocular pressure (IOP) is sometimes an adverse effect of this treatment. 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 used for 10 days or longer, intraocular pressure should be monitored.

The most commonly employed corticosteroid is prednisolone acetate 1% (Pred Forte, Allergan, Inc., Irvine, CA). QID dosing is recommended for long-term use. Prednisolone decreases inflammation by suppressing migration of polymorphonuclear leukocytes and reversing increased capillary permeability.

The second most prescribed corticosteroid is loteprednol. Loteprednol Etabonate (Lotemax, Bausch & Lomb, Tampa, FL) is a structurally similar compound to prednisolone, the difference being the lack of a ketone group. Clinical trials have found loteprednol to be effective in the treatment of anterior chamber inflammation. 72% of patients treated with loteprednol compared to 87% patients treated with prednisolone demonstrated resolution of anterior chamber cell and flare, however the loteprednol-treated patients experienced a lower incidence of significant IOP increase (1% in loteprednol group compared to 6% in prednisolone group.) [14]

Both of these steroids are effective at controlling inflammation but do not appear to be as potent as the newest topical corticosteroid anti-inflammatory, difluprednate ophthalmic emulsion, 0.05%, (Durezol, Sirion Therapeutics, Inc., Tampa, FL). This emulsion is the first and only steroid with an indication for both inflammation and pain. In a trial of anterior uveitis patients, difluprednate given 4 times a day was numerically better at controlling inflammation than prednisolone acetate 8 times a day.[15]

Difluprednate achieves its efficacy and strength in part due to the fact that it is fluorinated at both the C6 and C9 positions, making it a difluorinated prednisolone derivative. Fluorinated corticosteroids have been used in dermatology for decades and are well established as the most potent topical anti-inflammatory medications available. In addition, it does not contain the preservative benzalkonium chloride (BAK), but rather, is preserved with sorbic acid which is particularly preferable in patients with sensitive eyes. The difluprednate emulsion, which unlike a suspension, does not require shaking and maintains an even distribution of active ingredient.

SUMMARY

In today's world of cataract and refractive surgery, patient expectations are significantly higher than in the past. Prevention of ocular infections, and rapid return of quality vision, is the key to successful outcomes. Prophylaxis against inflammation can make the difference between a successful and poor outcome. The modern day surgeon should be familiar and comfortable with all of the currently available agents.

Clinical Studies Outcomes

Several pre-approval studies were performed with Durezol evaluating its ability as an anti-inflammatory agent in the treatment of post-operative inflammation and pain associated with routine, uncomplicated cataract surgery in low-risk patients. One of the pre-approval post-operative studies was conducted employing a standard FDA protocol, measuring Durezol against placebo. In the two identical pivotal studies, which were the basis of the FDA approval for post-operative inflammation and pain, the patients were not enrolled until post-operative day 1 (no anti-inflammatory medication administered prior to surgery), at which time the patient was required to have an inflammation score of at least 2+ cells in the anterior chamber. In each study, there were two treatment arms, addressing the use of this medication both BID and QID, compared to the same dosing frequency for placebo. The conclusion drawn from this research showed that, Durezol used twice a day was as efficacious as when it was used four times a day. Of particular interest, Durezol achieved a more rapid clearing of the cornea than seen with placebo, with significant results seen as early as Day 3 after surgery. There were no serious ocular adverse events.[15]

In a double masked uveitis trial, Durezol was found to be as effective when administered 4 times per day as Pred Forte 1% administered 8 times per day.[16] Durezol was numerically superior to Pred Forte in almost every efficacy measure, even though it was only dosed half as often. Interestingly, 12.5% of patients in the Pred Forte group were withdrawn from the study due to "lack of efficacy", while no patients were withdrawn from the Durezol group for this reason. One of the salient finding of this study was a faster return of visual acuity in the patients treated with Durezol as compared to Pred Forte.

OCULAR Infection & Inflammation

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Erratum

For *Ocular infection & Inflammation, Uveitis, vol. 1, issue 2,* the Disclosure of Relevant Financial Relationships with Commercial Interest is revised as follows:

Charles Slonim, MD, FACS		Editor-in-Chief
	Bausch & Lomb, Santen, Medea, Johnson & Johnson & Sirion Therapeutics	Advisory Board/Panel, Speakers Bureau, & Consultant
Michael B. Raizman, MD		Editor
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OCULAR Infection & Inflammation

IMPROVING SURGICAL OUTCOMES POST TEST

1) The most likely adverse ocular outcome of prostaglandin production is:
   a) cataracts
   b) glaucoma
   c) cystoid macular edema
   d) squint

2) Minimizing rates of surgical infection and adverse outcomes is:
   a) uncommon
   b) occasional
   c) preferred
   d) imperative

3) The newest ophthalmic antibiotic is:
   a) aminoglycosides
   b) fluoroquinolones
   c) sulfa
   d) neomycin

4) The improved mechanism of 4th-generation fluoroquinolones is:
   a) a broader antibacterial spectrum of activity
   b) decreased prostaglandin production
   c) its soothing properties
   d) it decreases pain

5) The gold standard for treating inflammation, reducing complications, and restoring visual acuity following cataract surgery is:
   a) topical corticosteroid agents
   b) beta blockers
   c) antibiotics
   d) NSAIDS

6) Which of the following has been shown to effectively reduce postoperative endophthalmitis when used preoperatively?
   a) aminoglycosides
   b) neomycin
   c) sulfas
   d) betadine

7) Which of the following is not a common cause of ocular inflammation:
   a) meibomian gland dysfunction
   b) allergies
   c) macular degeneration
   d) episcleritis

8) Nonsteroidal anti-inflammatory drugs (NSAIDS):
   a) produce prostaglandins
   b) attack formed prostaglandins
   c) remove prostaglandins
   d) inhibit prostaglandins

9) Which of the following is not a consequence of cystoid macular edema:
   a) impaired contrast sensitivity
   b) decreased visual acuity
   c) irreversible cystic damage
   d) retinal detachment

10) Postoperative inflammation should be treated:
   a) aggressively
   b) gently
   c) not at all
   d) only when CME is present

Evaluation/Post Test, Ocular Infection & Inflammation
Volume 1, Issue 3, Improving Surgical Outcomes. Program # MU 2008 104 C/1170

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Objectives:

1) Compare & contrast treatments to control pain and inflammation
2) Identify new antibiotic therapies for cataract surgery
3) Describe steps to implement prophylaxis against post-LASIK infectious keratitis
4) List causes and effects of cystoid macular edema

Registration Information and Evaluation Response Form

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Type of credit desired: ❍ CME ❍ Nursing Contact Hours ❍ Pharmacist

Test response: Circle the most appropriate response matching test question number and response number.

1. A B C D	4. A B C D	7. A B C D	10. A B C D
2. A B C D	5. A B C D	8. A B C D	
3. A B C D	6. A B C D	9. A B C D	

General Evaluation: Please use the scale below to evaluate this educational activity and objectives. Circle your response.

As a result of completing this offering, I am able to meet the following objectives.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
1. Compare & contrast treatments to control pain and inflammation	4	3	2	1
2. Identify new antibiotic therapies for cataract surgery	4	3	2	1
3. Describe steps to implement prophylaxis against post-LASIK infectious keratitis	4	3	2	1
4. List causes and effects of cystoid macular edema	4	3	2	1
5. Commitment to change	4	3	2	1
6. The content matches the objectives	4	3	2	1
7. Independent study was an effective teaching method	4	3	2	1
8. Is the article free of commercial bias?	4	3	2	1
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