Achieving excellent visual outcomes from cataract surgery

by Richard Lindstrom, MD

To ensure successful outcomes from cataract surgery, it is critically important to recognize the influence of ocular inflammation on surgical results.

In this supplement, we will examine the impact of inflammation as well as therapeutic strategies to help you achieve the excellent visual outcomes your patients expect from cataract surgery.

Survey results
Results from the 2015 ASCRS Clinical Survey provided key insights regarding members’ clinical opinions and practice patterns. The survey collected responses from 2,047 unique respondents, based on 485 data points centered on the most compelling and controversial issues facing ophthalmologists.

The survey demonstrated that more than half (52%) of respondents who prescribe NSAIDs for the average cataract patient discontinue them.

Although other medical fields largely use generic medications, ophthalmologists still prescribe numerous branded drugs.

–Richard Lindstrom, MD
True impact of ocular inflammation and pain on outcomes in cataract surgery

by Terry Kim, MD

Because modern cataract surgery is now considered refractive surgery, 20/40 postoperative visual acuity is no longer an acceptable goal.

Today’s cataract patients usually work, are independent, and use mobile devices, requiring good functional vision as quickly as possible after surgery. They also have high expectations when paying out-of-pocket expenses for a premium IOL and/or femtosecond laser-assisted procedure.

Although technologic advances have enabled us to deliver better outcomes, it is critical to manage inflammation and pain and mitigate these risk factors to achieve greater visual outcomes and patient satisfaction after surgery.

“ Our advanced technology and techniques cannot address the inflammation and pain that can compromise visual, anatomic, and satisfaction outcomes after cataract surgery. ”

–Terry Kim, MD

weeks after surgery, and nearly a third (31%) discontinue them in 2 weeks or less.

Nearly 25% reported that 6% or more of their patients have 1+ cells/flare or greater 3 to 7 days after cataract surgery.

Respondents indicated that low to moderate intraocular inflammation can significantly affect variability in visual acuity and quality of results, vision recovery time, and patient comfort and satisfaction.

Fifty-two percent use steroids primarily to control anterior chamber inflammation, and 73% prescribe nonsteroidal anti-inflammatory drugs (NSAIDs) for CME prophylaxis.

Respondents think that less than 20% of their cataract surgery patients present for their preoperative consult with sufficient ocular surface disease (OSD) to require treatment beyond artificial tears. Furthermore, they think an average of 20% of patients develop OSD symptoms after cataract surgery even though they had no symptoms before surgery.

When asked whether they begin anti-inflammatory and pain control with intraoperative instillation of anti-inflammatory agents as an injection or by adding it to the irrigating solution during surgery, less than 15% reported that they always use intraoperative anti-inflammatories, and 38% indicated that they will consider intraoperative anti-inflammatories in the next 12 months.

Although other medical fields largely use generic medications, ophthalmologists still prescribe numerous branded drugs. The survey revealed that 44% of prescriptions are written for branded drugs.

Fifty percent write prescriptions for brand-name NSAIDs only; 41% of those who do not use brand names cited cost barriers for patients, and 11% of those who do not use brand names think there is not a difference in efficacy. Twenty-three percent think substituting a generic drug for a brand-name drug at the pharmacy does not impact patient outcomes and safety significantly.

On average, 5% of respondents’ patients have femtosecond laser-assisted cataract surgery; however, respondents predicted that this will increase to 12% in 3 years.

When participants were asked about barriers to adoption of femtosecond laser-assisted cataract surgery, some responded that it is not a viable economic model for their practices, there is not enough data to prove its clinical benefits, and adoption of the technology would interfere with patient flow, take additional time, and reduce efficiency.

Expert insights

In this supplement, our expert colleagues share their insights and experiences regarding the advanced therapeutic and surgical options that will help us reduce inflammation and achieve excellent visual outcomes from cataract surgery.

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Strategies to prevent inflammation and CME and relieve pain with anti-inflammatory agents

by Edward Holland, MD

New technology can help cataract surgeons reduce the risk of postoperative inflammation

Controlling inflammation is a key component of cataract surgery. Inflammation is associated with pain and cystoid macular edema (CME), a leading cause of decreased vision after intraocular surgery.

Although surgery triggers inflammation in normal and difficult cases, prolonged phacoemulsification and complications increase inflammation.

New anti-inflammatory vehicles will help decrease toxicity, increase solubility, increase ocular concentrations, and decrease dosing.

Managing inflammation
As inflammation increases in the eye, so does corneal edema, which delays visual recovery. Complicated procedures increase the risk of short-term edema and long-term risk of endothelial cell loss.

References

Dr. Kim is professor of ophthalmology, Duke University School of Medicine, chief of the cornea and external disease division, and director of the refractive surgery service, Duke University Eye Center, Durham, North Carolina. He can be contacted at terry.kim@duke.edu.
In a multicenter study, patients having bilateral phacoemulsification received pulsed initial doses of difluprednate 0.05% in 1 eye and prednisolone acetate 1% in the other immediately before and after surgery. On postoperative day 1, 62% of eyes receiving difluprednate vs. 38% of those receiving prednisolone were free of corneal edema as defined by pachymetry. Those receiving difluprednate also had better visual acuity on day 1, less retinal edema at day 15, and greater endothelial cell density at day 30.

The incidence of postoperative CME is considered to be up to 6% of cataract patients as identified by fluorescein angiography and visual acuity; however, optical coherence tomography has shown an incidence of 9% to 19%. It is important to proactively prevent CME; treatment does not have the same outcome as prevention.

Topical nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroids work synergistically to reduce inflammation, and they have their own advantages and disadvantages.

Surgeons in Europe use nepafenac 0.1% to prevent CME. This use is off-label in the United States, where NSAIDs are approved to control inflammation and reduce postoperative pain.

We know NSAIDs prevent CME more effectively than corticosteroids. In patients at high risk of CME (e.g., patients with diabetes or a history of inflammation or CME), NSAIDs are used as long as 90 days, as well as preoperative loading of the cornea.

NSAIDs are safe in most patients; the vast majority of corneal melts with NSAIDs occurred in patients with dry eye and those using generic NSAIDs.

New vehicles
New anti-inflammatory vehicles offer decreased toxicity, increased solubility, increased ocular concentrations, and easier dosing.

Some medications have added guar gum, which acts as a stabilizer and thickening agent (e.g., nepafenac 0.3%). Micro-adhesive technology adheres to the ocular surface and has adaptive viscosity (e.g., loteprednol gel 0.5%). Lipid-emulsion technology increases the bioavailability of the drug (e.g., difluprednate 0.05%).

The future trend will be to instill medications during surgery. An injectable, preservative-free, bisulfate-free form of phenylephrine 1% and ketorolac 0.3% is added to the irrigating solution, maintaining pupillary dilation and reducing pain.

Compounding pharmacies provide proprietary antibiotic and steroid formulations for single injectable intraocular doses, allowing surgeons to load the eye with medication and reduce the need for postoperative drops.

As well as treating inflammation, NSAIDs are indicated for pain control. In separate clinical studies, pain-free days have been reported with both bromfenac and nepafenac. Use of bromfenac 0.07% demonstrated a statistically significant percentage of subjects with ocular pain scores of grade zero compared with placebo.

Nepafenac 0.3% and 0.1% had more pain-free days, which was statistically significant, compared with the vehicle arms.

When weighing branded medications versus generics, we need to remember that branded drugs pass a rigorous approval process, but generics have an abbreviated process. Furthermore, the vehicles and formulations are not the same.

Conclusion
Controlling inflammation is essential to achieve optimal outcomes and reduce the risk of complications after cataract surgery. Surgeons need to make the most of available technology to reduce the risk of inflammation.

References

Dr. Holland is director of the cornea service, Cincinnati Eye Institute, and professor of clinical ophthalmology, University of Cincinnati, Ohio. He can be contacted at eholland@holprovision.com.

Dr. Holland’s perioperative inflammation regimen

Preoperatively:
- Pretreat with nepafenac 0.3% QD—routine cases: 1 day preoperatively; high-risk cases: 7 days preoperatively
- Topical moxifloxacin 0.5%, nepafenac 0.3%, and difluprednate 0.05% day of surgery

Intraoperatively:
- Phenylephrine 1%/ketorolac 0.3% injection (in balanced salt solution)

Postoperatively:
- Topical moxifloxacin 0.5% BID for 1 week
- Topical difluprednate 0.05% BID for 2 weeks and QD for 1 week
- Topical nepafenac 0.3% QD—routine cases: 1 day; high-risk cases: 8 weeks
Innovative ophthalmic drug-delivery approaches, intraoperative anti-inflammatories, and future development

by Francis Mah, MD

Emerging drug-delivery options may improve patient compliance and outcomes

Although anti-inflammatory eye drops reduce inflammation and pain after cataract surgery, a number of issues may limit their efficacy. Innovative new drug-delivery options are emerging that may help us control pain and inflammation more effectively.

Limitations of current options

Problems with topical drops may include noncompliance, manual dexterity difficulties, ocular surface toxicity from traditional preservatives, inconsistent penetration into the eye, and cost.

Multiple studies have reported noncompliance and self-administration difficulties with topical medications among cataract surgery patients.1,2 A 2014 study showed that 92.6% of patients incorrectly administered topical medications after cataract surgery.3

Drug-delivery advances

A new phenylephrine 1%/ketorolac 0.3% Food and Drug Administration-approved drug-delivery option is available. Studies have shown that it helps prevent miosis during cataract surgery, reduces postoperative pain, and is safe and well-tolerated.4,5

In a retrospective case review of 641 cataract procedures, 260 procedures were performed with intracameral phenylephrine/ketorolac and 381 were performed with intracameral epinephrine 1 mg/mL.6 Intracameral phenylephrine/ketorolac decreased intraoperative and postoperative complications and pupillary dilating device dependence, improved best corrected visual acuity, and reduced procedural time compared with intracameral epinephrine alone.

We also have a number of other intracameral and injectable compounded medications from compounding pharmacies. A study of 2,300 eyes was performed to review transzonal injection of the steroid/antibiotic combination of triamcinolone and moxifloxacin with and without vancomycin to reduce the use of drops postoperatively; 19% of the patients also received supplemental topical NSAIDs, no patients developed endophthalmitis, and cystoid macular edema (CME) developed in 2%.7 This work was confirmed by a study from James Lewis, MD, who also found a CME rate of 2% when transzonal triamcinolone was used in place of topical anti-inflammatory medications.8

Novel drug-delivery platforms are proceeding through the approval process. One product is a sustained-release, resorbable dexamethasone depot that is placed in the canaliculus of the eyelid. The hydrogel delivery vehicle with dexamethasone is inserted in the vertical canaliculus. It swells on contact with moisture and expands until firmly secured in the canaliculus. It is designed to remain for 30 days and beyond.

In phase 2 and both phase 3 trials, there was a significant difference in the absence of pain on postoperative day 8 with the treatment compared with the placebo; in the phase 2 trial and first phase 3 trial, there was a significant difference in the absence of inflammatory cells on day 14 with the treatment compared with placebo.9

A recently approved bromfenac 0.075% preparation was released.

Emerging drug-delivery options may improve patient compliance and outcomes

We have a variety of excellent choices to help improve patient compliance and surgical outcomes.”

Francis Mah, MD

Dr. Mah’s perioperative inflammation regimen

High-risk CME patients
• Topical nepafenac 0.3% 3 days preoperatively
• Topical difluprednate 0.05% and nepafenac 0.3% for 3 months

Routine cataract
• Intracameral compounded dexamethasone and moxifloxacin
• Topical difluprednate 0.05% QD and nepafenac 0.3% QD for 4 weeks
• If cost is an issue, compounded drops
• Prednisolone phosphate/ketorolac taper

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Reducing inflammation: clinical impact of ultrasound energy applied during cataract surgery

by Eric Donnenfeld, MD

With the femtosecond laser, tightly focused, ultrashort light pulses cause photo-disruption by creating high-energy densities in the cornea, capsule, or lens. It creates a plasma-induced ablation of only a few microns, functioning too quickly to cause thermal effects in the tissue.

Comparing with standard phacoemulsification, the femtosecond laser delivers energy more efficiently into the eye, with less heat and collateral damage, reducing trauma and inflammation from the outset.

Current femtosecond laser platforms are highly automated and precise, replacing manual techniques for capsulotomy, fragmentation, and corneal incisions and significantly reducing effective phacoemulsification time and energy.

**Future of cataract surgery**

I think future cataract surgery will focus more on fluidics control and less on ultrasound energy. Irrigation/aspiration (I/A) and phacoemulsification systems may offer larger-bore I/A, better fluidics, and less beveled phacoemulsification tips to complement laser-assisted cataract surgery (LACS).

I think we can perform ultrasound-free procedures today in approximately half of cases, even with more significant cataracts. I have minimized my ultrasound energy substantially by using the femtosecond laser for softening.

A multicenter international field study assessed standard coaxial phacoemulsification, coaxial microincision cataract surgery, and bimanual (bixial) microincision cataract surgery. The mean effective phacoemulsification time and mean power usage for microincision surgery with femtosecond laser assistance were similar to or less than the values for standard coaxial small incision cataract surgery.

Research has shown that LACS may cause less endothelial cell loss, less corneal swelling, and less trauma to the endothelial cells compared with manual phacoemulsification.2

Nagy et al. reported significantly less macular edema with the femtosecond laser.3

**Zero tolerance**

We should have zero tolerance for inflammation. It increases

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**References**


6. Rosenberg E, et al. Initial experience, visual outcomes and efficacy of intracameral phenylephrine and ketorolac (1%/0.3%) during cataract surgery. Presented at the 2016 ASCRS•ASOA Symposium & Congress.


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discomfort, slows postoperative recovery, and increases the risk of complications.

I think the best way to achieve this goal is to prevent inflammation from occurring at all, which is my personal goal.

I offer femtosecond laser surgery to all of my patients with visually significant astigmatism or premium intraocular lens selections. In addition, I think new drug-delivery devices will be good adjuncts as we move forward.

References
1. Data on file, Bausch + Lomb.

Dr. Donnenfeld practices with Ophthalmic Consultants of Long Island and Connecticut, and is clinical professor of ophthalmology at New York University. He can be contacted at eric@donnenfeld@gmail.com.

Panel discussion

Richard Lindstrom, MD: In your opinion, in 5 years, which of the 3 medications we currently use (antiinflammatory, antibiotic, steroid, and nonsteroidal) will be delivered with a method other than drops?

Edward Holland, MD: All of them. I think physicians and patients want other drug-delivery systems. Several medications are under evaluation. I think in 5 years all of them will be delivered into the eye, and patients will not be using drops after surgery.

Terry Kim, MD: With ongoing innovations, we are looking at punctal plug-delivery systems, depots that will be placed in the eye, and intraoperative use of medications. Many surgeons have discussed the frustrations associated with topical medications: cost, compliance, and callbacks. We need to reduce these because they drain our time and resources. I think these innovations will make surgeons and patients happier.

Francis Mah, MD: I also think we will be using other delivery systems within 5 years. We already have an approved agent with a nonsteroidal that is going into the eye. We also have agents that are on the doorstep, such as the punctal plug that is working through the approval process. Therefore, I think within 5 years, drops will be available for resistant cases or to treat cystoid macular edema, but I think our routine cases will be dropless.

Eric Donnenfeld, MD: Economic and compliance issues are changing pharmaceutical delivery at a pace I have never seen in ophthalmology, so I think the transition to dropless procedures will occur rapidly. Corticosteroids may be used intracameral to treat inflammation and topically to optimize the ocular surface. However, I think nonsteroids and antibiotics will be used inside the eye, without a doubt.

Dr. Lindstrom: In your practice, what percentage of your cataract surgeries are performed with femtosecond laser-assisted cataract surgery (LACS)? In addition, looking ahead 5 years to other innovative alternatives to perform capsulotomies and fragment lenses, will LACS continue to grow in your practice, or do you think it will be challenged?

Dr. Kim: I’ve been surprised at the successful integration of LACS into my practice and the patient acceptance of this technology. Approximately 70% of my cataract surgeries are performed with the femtosecond laser. Patients typically like the concept of a laser and understand the connotations of precision and safety. Therefore, it has been very easy to adopt and discuss with patients. I think it is here to stay, and adoption will certainly continue to increase during the next 5 years.

Dr. Lindstrom: In your eyes, do you think it will be challenged?

Dr. Mah: We just adopted the femtosecond laser in October. I am using it in approximately 20% of my cataract patients, but that is growing quickly. I am using 40% premium IOLs; I am sure that number will continue to grow, probably to roughly 70%.

Dr. Donnenfeld: I use the femtosecond laser in 70% of cataract surgeries in our practice. I think it will continue to grow. Charles Kelman, MD, said it best: “Doctors debate; patients decide.” In my practice, patients have decided this is what they want. I think the results justify it, and it is certainly something I would want a surgeon to perform on my eyes.
1. Dr. Kim explained that ______ may predispose patients to cystoid macular edema.
   a. Diabetes
   b. Uveitis
   c. Previous ocular surgery
   d. All of the above

2. According to Dr. Holland, mucoadhesive technology __________
   a. Acts as a stabilizer
   b. Adheres to the ocular surface and has adaptive viscosity
   c. Acts as a thickener
   d. Contains guar gum

3. According to Dr. Donnenfeld, cataract surgeons can help reduce inflammation by __________
   a. Using LACS vs. manual phacoemulsification
   b. Using smaller-bore I/A
   c. Using more beveled phacoemulsification tips
   d. All of the above

4. In a retrospective case review discussed by Dr. Mah, intracameral phenylephrine/ketorolac __________ compared with intracameral epinephrine alone.
   a. Increased intraoperative and postoperative complications
   b. Increased procedural time
   c. Reduced best corrected visual acuity
   d. Decreased intraoperative and postoperative complications

5. Topical eye drops have been associated with:
   a. Reduced patient costs
   b. Inconsistent penetration into the eye
   c. Increased penetration into the eye
   d. Ease of application

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