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# Strategies to Improve Cataract Surgery Outcomes, Safety, and ★★★★★ PATIENT SATISFACTION

## FACULTY




**Eric D. Donnenfeld, MD (Chair)**
**John A. Hovanesian, MD**
**Cathleen M. McCabe, MD**
**Elizabeth Yeu, MD**

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## Activity Description and Purpose

Cataract surgery is recognized as one of the safest and most effective surgical procedures, yet preventing miosis, intraoperative and postoperative pain, and postoperative inflammation and cystoid macular edema is critical for optimizing the surgical experience and visual recovery of patients. The content of this activity is based on the proceedings of a live CME symposium that reviewed treatment strategies that can prevent or minimize these complications.

## Target Audience

This educational activity is intended for ophthalmologists.

## Learning Objectives

After completing this activity, participants will be better able to:

- Apply evidence on intraoperative miosis control to manage patients undergoing cataract surgery
- Evaluate recent data on pain management for patients undergoing cataract surgery
- Examine strategies to prevent postoperative inflammation in cataract surgery
- Identify strategies to optimize outcomes while reducing the risk of COVID-19 transmission in patients undergoing cataract surgery

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**John A. Hovanesian, MD,** is a consultant for Abbott Medical Optics, AcuFocus, Inc, Aerie Pharmaceuticals, Inc, Alcon, Allegro Ophthalmics, LLC, Allergan, BlephEx, Eyedetec Medical, Glaukos Corporation, Guardion Health Sciences, Inc, IOP Ophthalmics, Ivantis Inc, Kala Pharmaceuticals, Katena Products, Inc, Novartis Pharmaceuticals Corporation, Ocular Therapeutix, Inc, Omeros Corporation, Sarentis Ophthalmics, Inc, Sensimed AG, Shire, TearLab Corporation, TearFilm Innovations Inc, Valeant, and Veracity Innovations LLC; is an advisory board member of Abbott Medical Optics, Aerie Pharmaceuticals, Inc, BlephEx, Cord LLC, Eyedetec Medical, Glaukos Corporation, Guardion Health Sciences, Inc, Ingenoeye LLC, IOP Ophthalmics, Ivantis Inc, Kala Pharmaceuticals, Katena Products, Inc, Ocular Therapeutix, Inc, Omeros Corporation, Shire, Sight Sciences, TearLab Corporation, Tear Film Innovations Inc, Valeant, and Veracity; is a contracted researcher for Abbott Medical Optics, AcuFocus, Inc, Aerie Pharmaceuticals, Inc, Alcon, Allergan, Cloudbreak Therapeutics, Cord LLC, Eyedetec Medical, Glaukos Corporation, Ingenoeye LLC, IOP Ophthalmics, Katena Products, Inc, Novartis Pharmaceuticals Corporation, Ocular Therapeutix, Inc, Omeros Corporation, Shire, TearFilm Innovations Inc, and Valeant; and has individual stocks or stock options in Alcon, Allegro Ophthalmics, Allergan, BlephEx, Eyedetec Medical, Glaukos Corporation, Guardion Health Sciences, Inc, Ingenoeye LLC, Novartis Pharmaceuticals Corporation, Ocular Therapeutix, Inc, RxSIGHT, Sarentis Ophthalmics, Inc, Sight Sciences, and TearFilm Innovations Inc.

**Cathleen M. McCabe, MD,** is a consultant for Alcon, Allergan, Bausch & Lomb Incorporated, Dompé US, Inc, EyePoint Pharmaceuticals, Eyevance, Imprimis Pharmaceuticals, Inc, iSTAR Medical, Ivantis Inc, LENSAR, LLC, Novartis Pharmaceuticals Corporation, Ocular Therapeutix, Inc, Omeros Corporation, Orasis Pharmaceuticals, Quidel Corporation, ScienceBased Health, Sight Sciences, Tarsus Pharmaceuticals, Inc, Visus Therapeutics, and Zeiss; is on the speakers bureau for Alcon, Allergan, Bausch & Lomb Incorporated, EyePoint Pharmaceuticals, Ivantis Inc, LENSAR, LLC, Novartis Pharmaceuticals Corporation, Ocular Therapeutix, Inc, Omeros Corporation, and Sight Sciences; and is a contracted researcher for Alcon, Glaukos Corporation, Ivantis Inc, Ocular Therapeutix, Inc, Ora, Inc, Orasis Pharmaceuticals, and Sun Pharmaceutical Industries, Inc.

**Elizabeth Yeu, MD,** is a consultant for Alcon, Allergan, Avedro, Bausch & Lomb Incorporated, Beaver-Visitec International, BlephEx, Bruder Healthcare, CorneaGen, Dompé US, Inc, Expert Opinion, EyePoint Pharmaceuticals, Johnson & Johnson Vision Care, Inc, Kala Pharmaceuticals, LENSAR, LLC, Merck & Co., Inc, Minosys Cellular Devices Inc, Novartis Pharmaceuticals Corporation, Ocular Science, Ocular Therapeutix, Inc, OCuSOFT Inc, Omeros Corporation, Oyster Point Pharma, Inc, ScienceBased Health, Sight Sciences, Sun Pharmaceutical Industries, Inc, Surface Pharmaceuticals Inc, Tarsus Pharmaceuticals, Inc, TearLab Corporation, Thea Pharmaceuticals Limited, Topcon Medical Systems, Inc, Visus Therapeutics, and Zeiss; is on the speakers bureau for Glaukos Corporation; is a contracted researcher for Alcon, Bio-Tissue, Ocular Science, TearLab Corporation, and Topcon Medical Systems, Inc; and has individual stocks or stock options in BlephEx, CorneaGen, Ocular Science, Oyster Point Pharma, Inc, and Tarsus Pharmaceuticals, Inc.

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## FACULTY

**Eric D. Donnenfeld, MD (Chair)**
Clinical Professor of Ophthalmology
New York University
Langone Medical Center
New York, New York
Founding Partner
Ophthalmic Consultants of Long Island
and Connecticut
Garden City, New York

**John A. Hovanesian, MD**
Specialist in Cataract, Refractive, Cornea,
and Pterygium Surgery
Harvard Eye Associates
Laguna Hills, California

**Cathleen M. McCabe, MD**
Cataract, Refractive, and
Anterior Segment Surgery
Chief Medical Officer, Eye Health America
Medical Director, The Eye Associates
Bradenton, Florida

**Elizabeth Yeu, MD**
Virginia Eye Consultants
Medical Director, CVP Mid-Atlantic
Medical Director, Virginia Surgery Center
Cornea, Cataract, External Disease,
and Refractive Surgery
Assistant Professor
Department of Ophthalmology
Eastern Virginia Medical School
Norfolk, Virginia

## Introduction

Cataract surgery is one of the safest and most effective surgical procedures. Yet the ability to attain surgical success and patient satisfaction requires attention to a variety of issues that can lead to complications, patient discomfort, and suboptimal visual outcomes.

In this educational activity, based on the proceedings of a live symposium held during the 2021 Annual Meeting of the American Academy of Ophthalmology, leading cataract surgeons focus on the importance of achieving and maintaining adequate pupil dilation, preventing intraoperative and postoperative pain and postoperative inflammation, managing ocular surface disease (OSD), and limiting topical drop burden. Through a series of didactic presentations and discussions, the expert faculty share strategies for attaining these goals, with a focus on the use of newer modalities.

## Managing and Preventing Small Pupils

A small pupil creates challenges during cataract surgery by limiting visualization and the area of the operative field. Operating through a small pupil (< 6 mm) can prolong the duration of the surgical procedure, lead to tissue touch causing pain, and increase the risk of complications, including posterior capsule tears, retained lens fragments, and vitreous loss.[1-3] Collectively, these sequelae can result in a worse visual outcome for patients and decreased satisfaction with the entire surgical experience. Therefore, achieving adequate pupil dilation preoperatively and maintaining it throughout the procedure is important for safe and successful surgery.

Factors associated with an increased risk for small pupils and/or intraoperative miosis include a history of intraoperative floppy iris syndrome (IFIS), α-blocker use, diabetes, uveitis, trauma, prior surgery, pseudoexfoliation syndrome, and glaucoma.[4] The risk for intraoperative miosis also increases during long, complicated surgeries, especially if there is iris touch. Intraoperative miosis, however, can occur unpredictably in the absence of recognized risk factors.

As discussed subsequently, various options exist for achieving adequate pupil dilation and managing intraoperative miosis. It is better, however, to avoid intraoperative miosis with the use of an effective preventive strategy than to face the need to intervene.

### *Preoperative Topical Medications*

Use of topical drops applied in the preoperative waiting area or even started by the patient at home is one approach for inducing pupil dilation and preventing intraoperative miosis. The medications used include agents with antimuscarinic activity, sympathomimetic/adrenergic drugs, and nonsteroidal anti-inflammatory drugs (NSAIDs) **(Table 1)**.[5-7] The topical treatments can also be effective for breaking existing posterior synechiae, and they are generally readily available. Yet, not all pupils respond adequately to topical treatment; the preoperative dilating regimen is

**Table 1.** Examples of Pharmacologic Agents Used for Pupil Dilation/Intraoperative Miosis Prevention[5-7]

| Topical | Intracameral |
|---|---|
| • Phenylephrine, 2.5% to 10.0%; tropicamide, 0.5% to 1.0%; cyclopentolate, 0.5% to 1.0%<br>• NSAIDs (eg, bromfenac, 0.09%; flurbiprofen, 0.03%; ketorolac, 0.5%; and nepafenac, 0.1%)<br>• Atropine, 0.5% to 1.0% | • Epinephrine in the irrigating solution<br>• Epinephrine 1:10,000 with nonpreserved lidocaine (epi-Shugarcaine)<br>• Phenylephrine, 1%/ketorolac, 0.3%, mixed in the irrigating solution |

Abbreviation: NSAIDs, nonsteroidal anti-inflammatory drugs.

time and resource intensive, and persistence of effect throughout the surgery can be limited by intraoperative medication washout.

## *Mechanical Strategies*

Viscodilation using a high-molecular-weight ophthalmic viscosurgical device (OVD) is a safe approach that can effectively expand the pupil in cases in which there is nearly sufficient pupil dilation or in mild cases of intraoperative miosis. Viscodilation has variable efficacy, however, and its benefit can also be transient secondary to material washout intraoperatively.[8]

Mechanical devices provide a reliably effective method for stretching and maintaining pupil size and include iris retractor hooks and various pupil expansion rings **(Figure 1)**. Use of a mechanical device, however, increases operative time and may risk iris injury.[9]

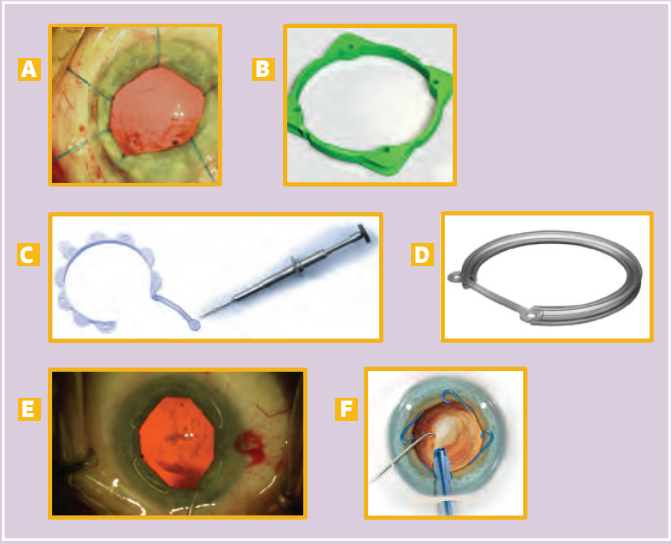


**Figure 1.** Mechanical devices for pupil expansion: (A) iris hooks, (B) I-Ring, (C) Perfect Pupil, (D) Graether Expander, (E) Xpand NT iris speculum, and (F) Malyugin ring

Figure 1A courtesy of Eric D. Donnenfeld, MD.

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Briefly, **iris hooks** are available in disposable and reusable versions. They can be used in different numbers and placed in various configurations, depending on where support for the iris is needed.[10]

Examples of pupillary expansion rings include the following:

- **Xpand NT iris speculum**[10]: A flexible nitinol ring designed with 4 pockets that cup the pupil margin and open the pupil to a diameter of 6.75 mm
- **Perfect Pupil**[11]: A grooved, incomplete plastic ring that is threaded along the pupillary margin using a metal injector. This device places tension on the iris root during insertion, and its trailing end, which remains externalized, can hinder instrument maneuverability.
- **Graether 2000 Pupil Expander**[12,13]: An incomplete silicone ring that engages the pupil in a circumferential groove. It requires bimanual expansion of the proximal segment.
- **I-Ring**[10,12]: A polyurethane device featuring 4 holes to aid in positioning. It provides gentle 8-point fixation, is easy to insert and remove, and does not cause pupil damage.
- **Malyugin ring**[10,12]: A 5-0 polypropylene device that is available in 2 sizes and provides 4 points of fixation. This device places more tension on the iris than does the I-Ring and therefore may be more prone to cause sphincter damage. Anecdotally, care must be taken when disengaging the Malyugin ring in order to avoid iris injury.

## *Intracameral Pharmacologic Agents*

Mixing preservative-free lidocaine and/or preservative- and bisulfite-free epinephrine into the irrigating solution or injecting the medication intracamerally can quickly increase pupil size and maintain dilation during the procedure. This approach, however, represents off-label medication use, may involve compounding with its related risks, and can be associated with prolonged pupil dilation postoperatively.[5,14]

Fixed-combination phenylephrine, 1%/ ketorolac, 0.3%, added into the irrigating solution offers an on-label option for preventing intraoperative miosis, and is also indicated for reducing postoperative ocular pain.[15] The fixed-combination solution is both preservative and bisulfite free, and its use avoids mixing or dilution calculation errors. Medicare covers its cost, but other patients may have a copay, depending on their insurance coverage.

Findings from premarketing and postmarketing trials document the effectiveness of intracameral phenylephrine/ketorolac for preventing intraoperative miosis, and also show that its use minimizes the risk of related complications and need for pupil expansion devices.[16,17] Results of a phase 2b study showed that the percentage of patients who developed a pupil diameter < 6 mm at any time during cataract surgery was significantly lower in the group operated on with fixed-combination phenylephrine/ketorolac than in controls receiving vehicle or either phenylephrine or ketorolac alone **(Figure 2)**.[16] In 2 pooled phase 3 studies, only 9.8% of 379 patients in the phenylephrine/ketorolac group experienced a pupil diameter < 6.5 mm at any time during surgery compared with 42.4% of 380 patients in the placebo control group ($P < .0001$).[17] During cortical cleanup, the percentage of patients with a pupil diameter < 6.0 mm was 4.0% in the phenylephrine/ketorolac group and 22.9% in the control group ($P < .001$). Pupillary constriction ≥ 2.5 mm at any time during surgery occurred in only 2.1% of patients in the phenylephrine/ketorolac group vs 27.1% of patients in the control group ($P < .0001$).

A single-center retrospective case review including 641 eyes operated on with epinephrine or phenylephrine/ketorolac added to the irrigating solution found that the fixed-combination group had a significantly lower rate of complications than the epinephrine group (4.5% vs 1.1%, respectively; $P = .018$) and a significantly shorter procedure duration after controlling for patient age ($P = .049$).[18] Data from other published trials similarly show that intracameral phenylephrine/ketorolac is effective at maintaining pupil dilation and also decreases surgical time, complication rates, and use of pupil expansion devices.[19-22]



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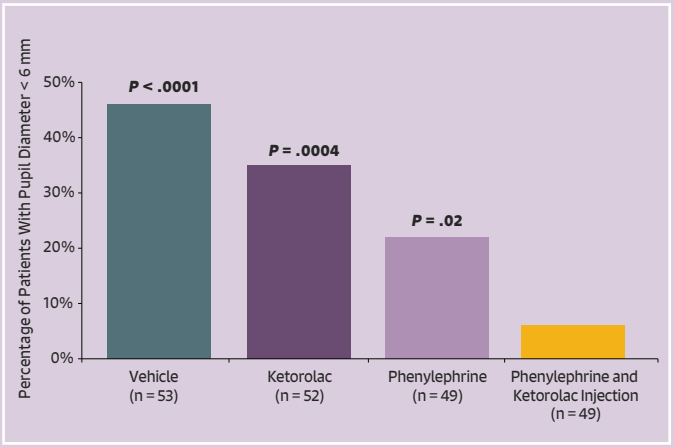


**Figure 2.** Percentage of patients with a pupil diameter < 6 mm at any time during cataract surgery[16]

## *Discussion*

**Dr Donnenfeld:** The results of the phase 2b study showing that the percentage of patients with a pupil size < 6 mm at any time during surgery was 5-fold lower with phenylephrine/ketorolac than with phenylephrine alone convincingly dispel the notion that epinephrine added to the irrigating solution is an equally effective alternative to phenylephrine/ketorolac.[16,18] If you consider that approximately 20% of cataract surgery patients have a small pupil, high-volume surgeons who perform approximately 100 cataract procedures per week would be faced with intraoperative miosis in 4 cases a week if they used phenylephrine/ketorolac and in 20 cases a week if they used epinephrine instead.[18]

**Dr McCabe:** I used epinephrine before phenylephrine/ketorolac became available, and those estimates on small pupils seem consistent with my personal experience.

**Dr Yeu:** Speaking anecdotally as well, I have found that pupil control is far better using phenylephrine/ketorolac in the irrigating solution compared with my previous approach of using a combination of lidocaine and epinephrine injected intracamerally at the beginning of the case and sometimes supplemented with an additional injection during surgery.

**Dr Donnenfeld:** Which OVD do you like to use for pupil dilation?

**Dr McCabe:** If I am trying to maintain pupil dilation, my preference is to place a ring of 2.3% hyaluronate around the pupil margin. Generally, I am already using sodium hyaluronate, 3%/chondroitin sulfate, 4%, as my OVD, so I use it for viscodilation if needed. In what situations do you use a mechanical device for pupil dilation?

**Dr Hovanesian:** I feel it is best to avoid hooks and rings whenever possible, but I will use a device if the pupil is still too small after using nonmechanical approaches or to keep the tissue away from the phacoemulsification or irrigation/aspiration instrument tip in cases in which there is a lot of iris billowing. I tend to use iris hooks, but surgeons should choose whatever device they feel induces the least trauma to the iris in their hands.

**Dr McCabe:** What do you do to prevent injury and inflammation when using a mechanical device to open the pupil?

**Dr Yeu:** I use a little extra steroid at the end of the case, or I might increase the intensity of the postoperative steroid regimen.

**Dr Donnenfeld:** Here are a few pearls for using mechanical devices and dealing with a floppy iris. Pupil expansion rings can only be used if the pupil is intact. Otherwise, iris hooks will have to be used, but I avoid iris hooks in IFIS cases because they seem to worsen iris floppiness.

If IFIS is anticipated, the incision should be placed more anteriorly because the iris will extrude from a posteriorly placed wound. If the iris extrudes, I would stop what I am doing, withdraw the instruments from the eye, suture the incision, and create a new incision at a different location.

**Dr Yeu:** In my experience, continuous irrigation when phenylephrine/ketorolac has been added to the irrigating solution also seems to prevent iris billowing.

# Treatment for Pain and Inflammation

Effective control of pain and inflammation is essential for achieving patient satisfaction and good visual outcomes after cataract surgery. In particular, patients who choose a premium intraocular lens (IOL) expect rapid visual recovery, and all patients want their procedure and postoperative period to be pain free. The following cases highlight considerations for controlling pain and inflammation to provide all patients with a premium cataract surgery experience.

## *Case 1: Pain Control in a Patient With a History of Opioid Addiction*

### From the Files of Eric D. Donnenfeld, MD

*A 73-year-old male Vietnam war veteran presented for cataract surgery evaluation for his left eye. Another surgeon previously removed a cataract in his right eye. The patient now reported progressively worsening vision and difficulty driving at night.*

*His medical history included hypertension, benign prostatic hyperplasia that was being treated with tamsulosin, and opioid addiction. The patient denied using opioids at present, but said he became addicted to opioids after being hospitalized for a shrapnel injury in Vietnam. He eventually stopped using opioids, but became addicted again after starting on acetaminophen and hydrocodone for hip pain. He said his addiction worsened after the cataract surgery in his right eye, which was performed with intraoperative fentanyl.*

*The patient also developed IFIS with vitreous loss during his previous cataract surgery. He experienced intraoperative and postoperative pain and now had glare and poor vision in the right eye.*

*Findings on examination were +0.50 -1.25 × 95 (20/30) OD and +2.50 sph (20/50) OS; 2+ nuclear sclerotic cataract OS; an anterior chamber IOL; iris atrophy; epiretinal membrane; and chronic mild cystoid macular edema that is being treated with a topical NSAID OD.*

*The patient was extremely unhappy after his previous cataract surgery and posted a negative online review about the surgeon. He was very concerned that he would have a similar experience with the cataract surgery in his left eye, including severe postoperative pain.*

Studies investigating pain associated with cataract surgery report incidence rates of 35% to 85% intraoperatively, up to 95% in the early postoperative period, and up to 42% during the first 72 hours postdischarge.[23,24] As many as 35% of patients may experience moderate to severe pain in the immediate postoperative period.[24]

Anesthesiologists may use an opioid, such as fentanyl, to control pain during cataract surgery and in the early postoperative period, and cataract surgeons may also prescribe an opioid for postoperative pain management.[25-27] These practices are concerning, considering the finding of an approximately 6-fold increased risk for new persistent opioid use among opioid-naïve cataract surgery patients who filled a prescription for an opioid vs those who did not, data showing a rising rate of filled opioid prescriptions by patients undergoing incisional ocular surgery, and the fact that several risk factors for opioid misuse are prominent among older individuals who are representative of the cataract surgery population.[27-33] Recognizing the millions of cataract surgeries performed each year, cataract surgeons can take a stewardship role in curtailing the growing opioid epidemic by using measures to minimize or eliminate opioids from intraoperative and postoperative cataract surgery care.

Results from 2 placebo-controlled pivotal phase 3 studies showed that intracameral phenylephrine/ketorolac was effective for increasing the percentage of patients who were pain free during postoperative follow-up and for decreasing use of oral analgesics on the day of surgery.[17] In addition, findings from 2 single-center, prospective studies show that use of phenylephrine/ketorolac decreases intraoperative and postoperative pain scores and intraoperative fentanyl use compared with cataract surgery performed with epinephrine in the irrigating solution.[25,34] The more recent study included 56 patients undergoing bilateral, sequential, cataract surgery with topical anesthesia.[34] Participants were randomly assigned to undergo first-eye surgery with either epinephrine or phenylephrine/ketorolac added to the irrigating solution and had second-eye surgery 2 weeks later with the alternate choice. Intravenous fentanyl could be used for intraoperative pain control according to the surgeon's and anesthesiologist's clinical judgment and the patient's request for pain medication. The need for fentanyl was assessed as the primary outcome measure, and the results showed that patients were 3.6-fold more likely to require fentanyl when operated on with epinephrine than with phenylephrine/ketorolac (33.9% vs 12.5%, respectively; $P = .013$) **(Figure 3)**.[34]

Additional end point analyses showed that use of phenylephrine/ketorolac was associated with significantly lower pain severity scores intraoperatively, at 10 minutes postoperatively, and at 1 day after surgery compared with use of epinephrine ($P < .001$ for all comparisons).[34] Furthermore, total operating room time was significantly shorter for procedures performed with phenylephrine/ketorolac than for those performed with epinephrine (6.9 vs 7.6 min, respectively; $P = .004$).

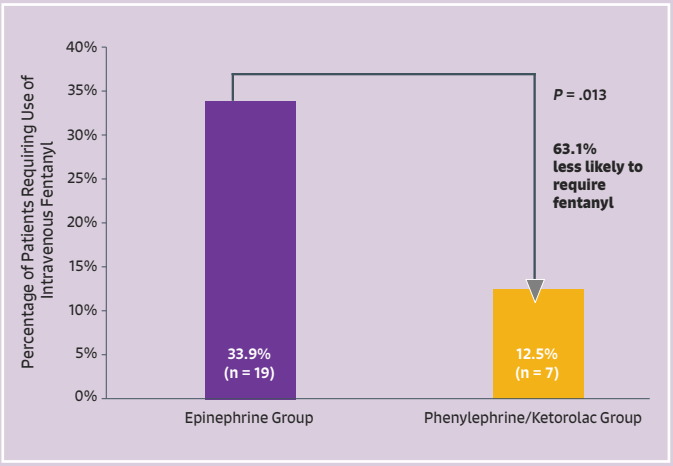


**Figure 3.** Percentage of patients requiring intravenous fentanyl for cataract surgery when operated on with epinephrine or phenylephrine/ketorolac added to the irrigating solution[34]

*The patient underwent cataract surgery with intraoperative phenylephrine/ketorolac. The procedure was uneventful, and the patient said he had no pain. His uncorrected visual acuity was 20/20 on postoperative day 1.*

**Dr Donnenfeld:** Recently, we began to use a compounded sublingual troche for conscious sedation during cataract surgery.[35] This approach avoids both opioid exposure and the need to start an intravenous line. Each lemon-flavored "melt" contains midazolam 3 mg, ketamine 25 mg, and ondansetron 2 mg. In addition to its sedating action, midazolam has anxiolytic and amnestic effects. Ketamine provides analgesia and eliminates blinking.[36]

**Dr Hovanesian:** We also use the sublingual troche for sedation. The anesthesiologist or anesthetist determines whether to give 1 or 2 melts. Younger patients tend to get 2 melts, but body weight is also a factor for determining the dose. Time to onset of effect is approximately 15 minutes. Although patients are well sedated, they are still cooperative.

## *Case 2: Providing a Premium Experience by Controlling Pain and Managing Ocular Surface Disease*

### From the Files of Elizabeth Yeu, MD

*A 69-year-old female presented because of progressively worsening glare and vision that she said fluctuated with reading. She also complained of mild discomfort/foreign body sensation that was constant throughout the day, but worse in the morning. Her husband had undergone cataract surgery, and she was wondering if she needed it as well.*

*The patient was generally healthy. Her medications included a statin, calcium, and vitamins C and D2. Findings on examination were -1.50 sph (20/30) BATmed (20/70) OD, -2.50 sph (20/30) BATmed (20/80); SPEED (Standard Patient Evaluation of Eye Dryness Questionnaire) score of 15; tear osmolarity of 291/282 mOsm/L OD/OS; matrix metalloproteinase-9 (MMP-9) lightly positive OU; 2-3+ meibomian gland dysfunction (MGD), 2+ telangiectasis, and 50% meibomian gland dropout OU*



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*(**Figure 4**); trace inferior punctate epithelial erosions OU; 2+ nuclear sclerotic cataract/3+ cortical spokes OU; and dilated pupil diameter 5 mm OU.*

*The patient was 167.64 cm (5 ft 6 in) tall. She was an architect without any desire to retire. She used 3 computer monitors for work, which were positioned at a distance of approximately 80 cm (farther than arm's length). She said she did not use glasses to see the screens, but was needing to lean closer. She also read analog blueprints for work, and enjoyed playing tennis and being outdoors.*

*The patient wanted to be able to see without glasses at close distance and have better uncorrected distance vision to improve her line of sight with the tennis ball. She drove at night and was concerned about glare, halos, and flares. She was willing to start chronic treatment for OSD as needed to provide visual stability.*

*The patient was diagnosed with MGD and ocular rosacea and started on treatment, including oral omega supplementation, lid hygiene and exercises, hypochlorous acid, 0.01%, lid spray 3 times per week, microblepharoexfoliation, and vectored thermal pulsation. She was prescribed topical loteprednol, 0.2%, to be used 4 times daily for 2 weeks, then as needed for flare-ups, and lifitegrast, 5%, twice daily to be started once her symptoms began to improve.*

**Dr Yeu:** This patient is able to see without glasses at distances from approximately 40 to 66 cm because of her naturally occurring myopia. She wants to maintain that function after cataract surgery and have good uncorrected vision from far intermediate to distance. Despite this, she has significant OSD that will need to be addressed preoperatively.

Studies show that objective signs of dry eye disease (DED), including staining, abnormal osmolarity, and/or a positive MMP-9 assay, are present in most patients undergoing cataract surgery and often exist in the absence of symptoms.[37-39] Detecting and treating DED is important in patients undergoing cataract surgery because DED reduces the accuracy of the measurements that are used for surgical planning and negatively affects visual acuity and quality both preoperatively and postoperatively.[40,41] Preexisting DED/MGD is a risk factor for postoperative DED, but DED can also develop de novo after surgery and can persist for months or longer.[42-46]

To treat MGD, I like to address gland obstruction with a mechanical and/or thermal type of intervention and recommend an oral omega supplement because it may improve meibum quality and expressibility.[47,48] If meibum is still moderately expressible from the glands, I like to use microblepharoexfoliation, which I believe will further open the glands by removing biofilm and debris from the lashes and lid margin. I think that microblepharoexfoliation in this setting might even reverse gland truncation instead of just preventing it from worsening **(Figure 4)**.

I also consider the patient's vision goals and the severity of the MGD when deciding on treatment. If a patient is not getting a presbyopia-correcting IOL and if the meibomian gland architecture is good, I might use microblepharoexfoliation alone. I would, however, combine it with thermal pulsation if I see any level of glandular architectural damage or if the patient wants a presbyopia-correcting IOL.

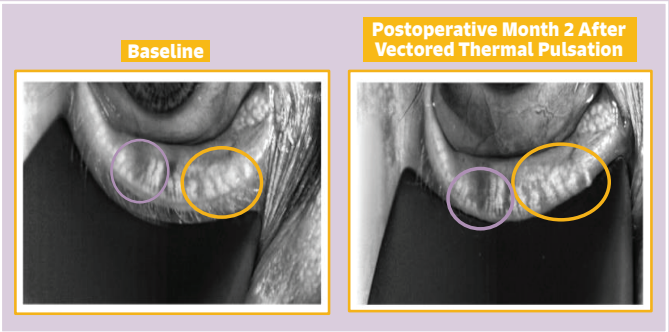


**Figure 4.** Meibography of patient in Case 2 before and after thermal pulsation treatment

**Dr Donnenfeld:** I like microblepharoexfoliation as well. I think of its benefit for MGD as analogous to a dental cleaning for dental health. Microblepharoexfoliation is a quick procedure that takes just 5 to 10 minutes and can be done by an optometrist.

**Dr McCabe:** I also recommend long-term use of an oral omega supplement for patients with MGD along with microblepharoexfoliation, which is done by an optometrist in our practice. I find that patients may be good about doing lid hygiene at home when they are eager to be ready for cataract surgery, but their compliance tends to fall off postoperatively.

**Dr Hovanesian:** When needed, I also prescribe a short course of a mild steroid to improve the condition of the ocular surface preoperatively. Newer formulations of loteprednol are now available, including loteprednol, 0.25%, which is indicated specifically for short-term treatment of the signs and symptoms of DED.[49]

**Dr Donnenfeld:** I also prescribe a topical steroid for patients to use after microblepharoexfoliation to reduce inflammation and increase comfort.

**Dr Yeu:** How do you manage a situation in which you find significant OSD, but the patient has no symptoms and wants to have surgery as soon as possible? I explain the importance of waiting until the ocular surface condition has improved. To avoid patients becoming too disappointed by the delay, which usually ranges from 5 to 7 weeks, I say that we can get them onto the schedule now. I also explain that they will have to return for another evaluation in 3 to 4 weeks to see if the ocular surface improved sufficiently with the treatment I am recommending.

**Dr McCabe:** A short course of loteprednol, 0.25%, twice daily is my go-to treatment for rapidly improving the condition of the ocular surface. I combine it with maximal use of preservative-free artificial tears, and I also start an oral omega supplement that is intended for maintenance treatment, recognizing that it takes a while to see onset of benefit from the supplement.

**Dr Donnenfeld:** I also start an oral omega supplement that will be continued after surgery. I sometimes insert a punctal plug preoperatively so long as the patient is using an anti-inflammatory medication. For loteprednol treatment in patients who are not old enough to have Medicare coverage, I find that the new 0.25% suspension can be a reasonably priced option. I delay cataract surgery for any patient who has DED-related corneal staining in the visual axis; I see this in approximately 5% of patients.

**Dr Yeu:** The patient in this case has high expectations for her visual outcome, which will depend on controlling postoperative inflammation, but her overall satisfaction will also likely depend on the comfort of her experience. In a study of 306 patients undergoing cataract surgery, 34% of the participants reported postoperative moderate pain, and postoperative pain was one of the most significant predictors of patient dissatisfaction.[50]

Cataract surgeons have multiple medications they can use to control postoperative inflammation and pain. Traditionally, patients are prescribed a topical NSAID and/or a topical steroid. The newer options include intracameral phenylephrine/ketorolac added to the irrigating solution, which is indicated for postoperative pain[15]; the intracanalicular dexamethasone insert, 0.4 mg, which is inserted into the inferior punctum and is indicated for treating both pain and inflammation[51]; and dexamethasone intraocular suspension, 9%, which is injected into the posterior chamber behind the iris at the end of the surgery and is approved for treating postoperative inflammation.[52]

The intracanalicular dexamethasone insert is a firm hydrogel rod that swells and softens after it is inserted into the lower punctum.[53] It is preservative free and dissolves slowly, providing tapered release of dexamethasone into the tear film over a period of approximately 30 days. A placebo-controlled phase 3 study demonstrated its efficacy and safety for controlling postoperative pain and inflammation **(Figure 5)**.[53,54] By delivering the steroid onto the ocular surface and by blocking the punctum, this product also has a benefit for treating DED.

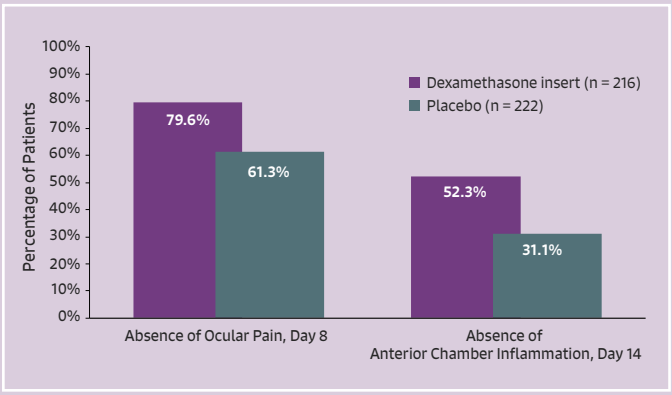


**Figure 5.** Intracanalicular dexamethasone insert met its coprimary efficacy end points in a phase 3 study, demonstrating statistical superiority vs placebo in analyses of the percentages of patients with absence of ocular pain at postoperative day 8 and absence of anterior chamber inflammation at day 14 ($P < .0001$ for both end points)[53,54]

Reprinted with permission from Tyson SL, Bafna S, Gira JP, et al. Multicenter randomized phase 3 study of a sustained-release intracanalicular dexamethasone insert for treatment of ocular inflammation and pain after cataract surgery. *J Cataract Refract Surg.* 2019;45(2):204-212. Copyright 2018 by The Authors.

Dexamethasone intraocular suspension, 9%, is formulated in a preservative-free, bioabsorbable delivery system that releases the steroid in a tapering dose, maintaining therapeutic levels for up to 21 days.[52,55] In phase 3 studies, it was superior to placebo **(Figure 6)** and comparable to topical prednisolone for eliminating inflammation on postoperative day 8 and had a safety profile similar to that of prednisolone.[55,56]

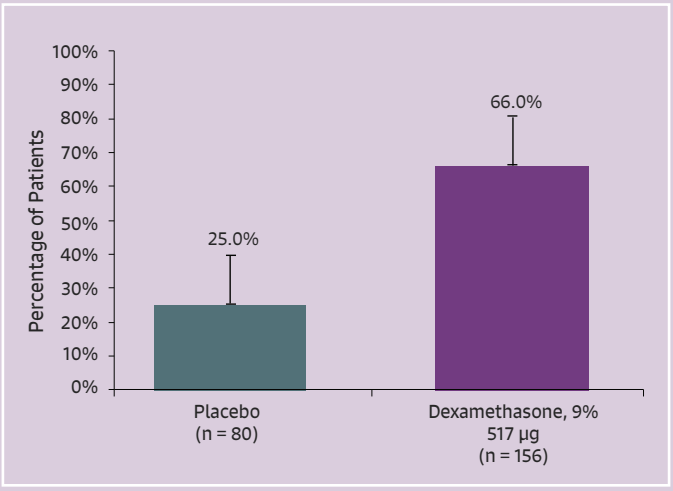


**Figure 6.** Intraocular dexamethasone suspension, 9%, met its primary efficacy end point in a phase 3 study, demonstrating statistical superiority vs placebo in the analysis of percentage of patients with anterior chamber cell clearing on postoperative day 8 ($P \leq .001$)[55,56]

**Dr Yeu:** What is your main strategy for mitigating inflammation and pain after cataract surgery?

**Dr McCabe:** Because the condition of the ocular surface affects pain after cataract surgery, managing OSD preoperatively and postoperatively is one aspect of mitigating pain after cataract surgery. I like to use intracameral phenylephrine/ketorolac intraoperatively and one of the newer sustained-release dexamethasone products for postoperative control of pain and inflammation.

**Dr Donnenfeld:** Pain and inflammation go hand in hand. Therefore, to control pain, surgeons should aim to eliminate inflammation rather than just to suppress it. Surgical trauma initiates an inflammatory cascade that results in the production of prostaglandins and other proinflammatory mediators. Starting treatment preoperatively with a topical NSAID that will block the pathway, leading to prostaglandin release, is one strategy for preventing inflammation. In addition, steroids, which control inflammation by a different mechanism, should be used aggressively in the early postoperative period, but tapered quickly. Both the intraocular dexamethasone suspension and the intracanalicular dexamethasone insert provide the desired pattern of tapered-dose delivery.

**Dr Hovanesian:** When using the intraocular dexamethasone suspension, I place it in the capsular bag just peripheral to the IOL optic by using a little sweeping motion. I find that when the medication is placed in this location, it stays in the posterior chamber and away from the iris, where excessive exposure to the steroid might cause stromal tissue atrophy.[57] The safety and efficacy of the intraocular steroid is not adversely affected if the spherule of dexamethasone fragments and a droplet migrate into the anterior chamber. Patients should be informed about this possibility so they do not become concerned if they see the material in the eye.

*After treatment to improve her ocular surface, the patient underwent sequential bilateral cataract surgery with implantation of refractive extended depth-of-focus IOLs. The procedures were performed using intracameral phenylephrine/ketorolac to*

*maintain pupil size and with intracameral moxifloxacin injected at the end of the case. Postoperative medications included compounded fixed-combination products to decrease drop burden. The patient was instructed to continue taking an oral omega supplement, to return once yearly for in-office treatment for MGD, and to use loteprednol, 0.25%, suspension for symptomatic flares.*

## Drug Delivery: Reducing Burden and Risk

The efficacy of any medication depends on proper use. For topical ophthalmic medications, not only is poor treatment adherence an issue, but difficulty with instillation is also a concern, as highlighted by a study that reported incorrect instillation of medications after cataract surgery by 93% of patients.[58]

Drug delivery methods that reduce the need for topical drops can limit or avoid these problems and therefore have the potential to increase treatment success. Furthermore, interest in strategies that provide effective control of postoperative pain and inflammation with reduced need for topical drops is heightened in the setting of the COVID-19 pandemic, in which patients may have less access to family or caregiver assistance with drop administration and in which there is a desire to minimize situations that risk infection with the coronavirus, such as trips to the pharmacy to pick up a prescription, unscheduled follow-up visits for evaluation of uncontrolled inflammation or pain, and hand-to-eye contact.

Reducing drop burden can be achieved using topical medications that were developed for improved bioavailability to decrease dosing frequency. For controlling inflammation, these products include loteprednol etabonate gel, 0.38%, which is formulated with submicron particles of loteprednol and administered 3 times a day, and loteprednol etabonate suspension, 1%, which uses mucus-penetrating particle technology and is administered twice daily.[49,59]

Surgeon-administered medications that provide sustained-release delivery of dexamethasone for up to 30 days represent another option. This category includes dexamethasone intraocular suspension, 9%, and intracanalicular dexamethasone insert, 0.4 mg.

Patients' perspectives on a medication regimen that reduces eye drop burden by incorporating surgeon-administered steroid and antimicrobial medications were explored in an open-label randomized study that included 30 patients undergoing bilateral routine cataract surgery.[60] In this investigation, known as the D3 study (Drug Delivery vs Drops), the first eye of each patient was randomly assigned to receive a "less drops" regimen consisting of the intraocular dexamethasone suspension and intracameral moxifloxacin 500 µg injected at the end of surgery or the control regimen using topical prednisolone acetate, 1%, on a 28-day tapering regimen, and moxifloxacin, 0.5%, 4 times daily for 10 days. Both regimens included topical bromfenac, 0.07%, once daily for 28 days. Patients received the alternate regimen for the second eye surgery.

Patient preference for medication protocol was assessed as the primary end point, and the data showed a highly statistically significant difference favoring the less drops regimen over the 3-drop control regimen (97% vs 3%; $P < .0000001$).[60] Ease was the most common reason that patients cited for preferring the less drops approach.

The study also found other advantages for the less drops regimen compared with the control protocol, including significantly lower values for mean out-of-pocket cost ($40.86 vs $139.16, respectively; $P < .0004$), postoperative pain severity **(Figure 7)**, and summed ocular inflammation scores.[60] There were no statistically significant differences between the 2 treatments in mean IOP values measured on postoperative days 1, 7, 14, and 28, which is consistent with results from a phase 3 trial comparing dexamethasone suspension with topical prednisolone.[56,60] There was also no difference between groups in change in macular thickness.[60] Significantly more patients in the less drops group, however, achieved 20/20 uncorrected visual acuity at all time points after surgery.

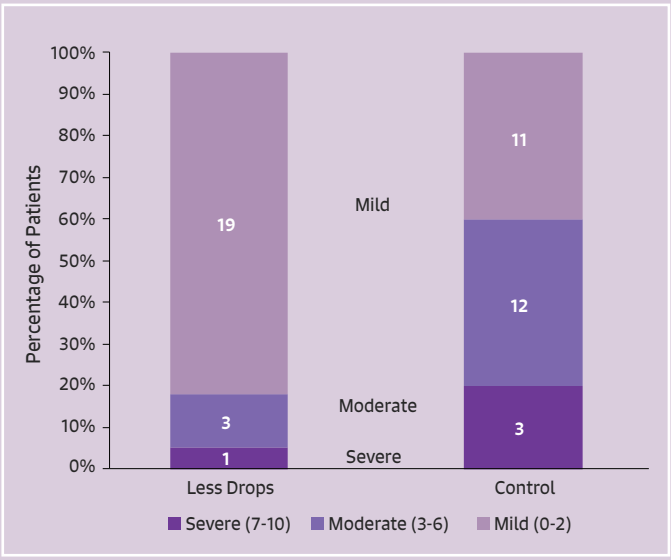


**Figure 7.** Reported pain severity was lower using the less drops regimen[60]

Additional research suggests that in appropriately selected patients (eg, individuals not at increased risk for inflammation or cystoid macular edema after cataract surgery), it might be possible to reduce the postoperative topical medication burden when using phenylephrine/ketorolac intraoperatively.[61] Investigators measuring ketorolac concentrations in the aqueous and vitreous humor, retina, choroid, and iris/ciliary body in animals undergoing cataract surgery with intracameral phenylephrine/ketorolac found that ketorolac was present at therapeutic concentrations in these tissues and fluids for up to 10 hours postoperatively. The researchers concluded that use of the fixed combination in the irrigation solution may preclude the need for postoperative topical NSAID treatment. Findings of a large retrospective study comparing groups of eyes receiving either intracameral phenylephrine/ketorolac plus a topical NSAID postoperatively or the same topical NSAID plus a topical steroid postoperatively showed the phenylephrine/ketorolac group had significantly lower rates of clinical cystoid macular edema ($P = .021$), breakthrough iritis ($P < .001$), and postoperative pain ($P < .001$).[62]

## Take-Home Messages

**Performing cataract surgery through a small pupil increases the risk of intraoperative pain and complications.**

- Multiple pharmacologic and mechanical options are available for achieving and maintaining adequate pupil dilation

**Pain is a critical aspect of patient satisfaction after cataract surgery.**

- Up to 85% of patients experience pain intraoperatively, and up to 35% of patients experience moderate to severe pain in the early postoperative period
- Inflammation induced by surgical trauma leads to pain and should be eliminated, not just suppressed
- Intraoperative fentanyl use and opioid prescribing increase the risk for persistent opioid use
- Intracameral phenylephrine/ketorolac is a viable nonopioid alternative for managing both intraoperative and early postoperative pain and may decrease the use of intraoperative fentanyl

**Ocular surface disease (DED/MGD) limits accurate planning and visual outcomes after cataract surgery.**

- Screening and evaluation for OSD is important because it is common in the cataract surgery population, and patients are often asymptomatic
- Rapid rehabilitation of the ocular surface is often attainable with a short course of a topical corticosteroid, and will improve patient comfort after surgery
- Continued treatment for DED after cataract surgery enables optimal visual performance

**The efficacy of topical medication regimens is challenged by problems with patient adherence and difficulty with drop instillation.**

- Perioperative medication regimens that reduce topical drop burden through the use of surgeon-administered treatments, including intracameral phenylephrine, intracanalicular dexamethasone, and intraocular dexamethasone, have been shown to be equally or more effective than conventional topical protocols for controlling postoperative pain and inflammation, may be preferred by patients, and have potential benefits for overcoming issues that have arisen in association with the COVID-19 pandemic

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See detailed instructions at **Instructions for Obtaining Credit** on page 2.

1. Which of the following strategies for preventing postoperative inflammation would be optimal in a patient with OSD?
   a. Intracameral dexamethasone
   b. Intracanalicular dexamethasone insert
   c. Intracameral phenylephrine/ketorolac
   d. Topical ketorolac, 0.4%

2. Which of the following outcomes were experienced by a greater number of patients receiving phenylephrine/ketorolac than those receiving placebo in phase 3 trials?
   a. Pupil diameter < 6.5 mm at any time during surgery
   b. Pupil diameter > 6.0 mm during cortical cleanup
   c. Pupillary constriction ≥2.5 mm at any time during surgery
   d. None of the above

3. Among opioid-naïve patients undergoing cataract surgery, the risk for new persistent opioid use increased by approximately _____.
   a. 2-fold
   b. 4-fold
   c. 6-fold
   d. 10-fold

4. Dexamethasone intraocular suspension, 9%, and intracanalicular dexamethasone insert share all the following features, EXCEPT:
   a. Indication for treating postoperative pain
   b. Indication for treating postoperative inflammation
   c. Preservative-free formulation
   d. Tapered-dose delivery

5. Which medication is NOT an active ingredient in a compounded sublingual troche that can be used for conscious sedation during cataract surgery?
   a. Fentanyl
   b. Ketamine
   c. Midazolam
   d. Ondansetron

6. Which potential benefit results from substituting surgeon-administered medications for postoperative topical medications in the setting of the COVID-19 pandemic?
   a. Minimizing hand-to-eye contact
   b. Overcoming any need for outside individuals to assist with drop instillation
   c. Providing reliable efficacy that can minimize unscheduled follow-up visits for uncontrolled pain or inflammation
   d. All the above

7. In the D3 study, for which end points were differences seen favoring the group receiving the less drops regimen, including intracameral phenylephrine/ketorolac and moxifloxacin?
   a. Patient protocol preference and macular thickness change
   b. Patient protocol preference and endophthalmitis rate
   c. Patient protocol preference and medication cost
   d. Pain severity and macular thickness change