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ADVANCES IN POSTOPERATIVE ANTI-INFLAMMATORY TREATMENT

A CME activity provided by Evolve Medical Education LLC.

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Advances in Postoperative Anti-inflammatory Treatment

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CONTENT SOURCE

This continuing medical education (CME) activity captures content from a virtual roundtable discussion.

ACTIVITY DESCRIPTION

Despite the routine use of antibiotics, corticosteroids, and non-steroidal anti-inflammatory (NSAID) agents in postoperative ophthalmic surgical care, there are no controlled investigations to establish the optimal regimens for topical agents after cataract surgery. The individual surgeon decides whether to use any or all of these medications postoperatively.

Ongoing education about novel corticosteroids and technologies is warranted to ensure eye care providers can deliver the best patient care possible. Similarly, familiarity with the latest government regulations on reimbursement will be necessary to ensure practice profitability.

TARGET AUDIENCE

This certified CME activity is designed for ophthalmologists involved in the management of ocular inflammation following ophthalmic surgery.

LEARNING OBJECTIVES

Upon completion of this activity, the participant should be able to:

- **Identify** the issues surrounding patient compliance with postoperative topical medications.
- **Describe** the benefits of delivery of antiinflammatory medications during cataract surgery.
- **Summarize** the drug delivery properties of novel sustained-release medications.
- **State** how the latest federal government regulations on reimbursement will affect practices treating Medicare-eligible patients.

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DIGITAL EDITION

This activity is part of a curriculum that will include additional activities, including a webinar. To view the online version of the material, please visit go <http://evolvemeded.com/online-courses/1926-supplement>.



**PLEASE COMPLETE PRIOR TO ACCESSING THE MATERIAL AND SUBMIT WITH POSTTEST/ACTIVITY
EVALUATION/SATISFACTION MEASURES INSTRUCTIONS FOR CME CREDIT.**

1. PLEASE RATE YOUR CONFIDENCE ON YOUR ABILITY TO APPLY POSTOPERATIVE ANTIINFLMATORY TREATMENTS (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NOT AT ALL CONFIDENT AND 5 BEING EXTREMELY CONFIDENT).

- a. 1
- b. 2
- c. 3
- d. 4
- e. 5

2. PLEASE RATE HOW OFTEN YOU INTEND TO APPLY POSTOPERATIVE ANTI-INFLMATORY TREATMENTS (BASED ON A SCALE OF 1 TO 4, WITH 1 BEING NEVER AND 5 BEING ALWAYS).

- a. 1
- b. 2
- c. 3
- d. 4
- e. 5

3. WHAT PERCENTAGE OF PATIENTS UNDERGOING OPHTHALMIC SURGERY INSTILL THEIR MEDICATIONS CORRECTLY?

- a. 10%
- b. 25%
- c. 50%
- d. 75%

4. WHICH OF THE FOLLOWING IS AN ADVANTAGE OF SUSTAINED DELIVERY MEDICATIONS, SUCH AS THE DEXAMETHASONE 0.4 MG INTRACANALICULAR INSERT AND THE DEXAMETHASONE INTRAOCULAR SUSPENSION 9%?

- a. For many patients, there is no cost because of pass-through legislation.
- b. The preservative-free medications are better for the ocular surface.
- c. These medications remove the issue of compliance.
- d. All of the above.

5. WHICH OF THE FOLLOWING IS TRUE WITH REGARD TO CATARACT SURGERY IN YOUNG CHILDREN?

- a. There is an enhanced inflammatory response after surgery.
- b. Parents often struggle to place postoperative drops.
- c. Physician-applied medications could improve surgical outcomes.
- d. All of the above

6. THE DEXAMETHASONE OPHTHALMIC INSERT 0.4 MG IS (SELECT ALL THAT APPLY):

- a. An intracanalicular insert containing dexamethasone
- b. Preservative free
- c. Delivers steroid for up to 30 days
- d. Delivers steroid for only 7 days

7. WHICH TREATMENT FOR POSTOPERATIVE INFLAMMATION PROVIDES THE OPTION OF BEING USED EITHER PREOPERATIVELY OR IN THE OPERATING ROOM?

- a. Dexamethasone 0.4 mg intracanalicular insert
- b. Dexamethasone intraocular suspension 9%
- c. Both formulations of dexamethasone
- d. Neither formulation dexamethasone

8. WHICH FORMULATION OF LOTEPREDNOL ETABONATE HAS TWICE-DAILY DOSING?

- a. Loteprednol etabonate 0.5% gel
- b. Loteprednol etabonate 0.38% gel
- c. Loteprednol etabonate 1% suspension
- d. All of the above

9. WHICH OF THE FOLLOWING IS THE APPROVED DOSING REGIMEN FOR LOTEPREDNOL ETABONATE OPHTHALMIC SUSPENSION 1%?

- a. One to two drops into the affected eye four times daily beginning the day after surgery and continuing throughout the first 2 weeks of the postoperative period.
- b. One to two drops into the affected eye four times daily beginning two days before surgery and continuing throughout the first week of the postoperative period.
- c. One to two drops into the affected eye twice daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period.
- d. One to two drops into the affected eye twice daily beginning 2 days before surgery and continuing throughout the first 2 weeks of the posoperative period.

10. WHICH OF THE FOLLOWING IS NOT A CORRECT STATEMENT REGARDING THE DEXAMETHASONE 0.4 MG INTRACANALICULAR INSERT?

- a. It is indicated for the treatment of ocular inflammation and pain following ophthalmic surgery.
- b. It is preservative free, resorbable, and does not require removal.
- c. Dexamethasone is released for up to 30 days following insertion.
- d. It is contraindicated in patients with active corneal, conjunctival or canalicular infections or glaucoma.

Advances in Postoperative Anti-inflammatory Treatment

We have seen tremendous advancements in drug delivery over the last several years, but some unmet needs still exist in ophthalmology. I break it down to what I call the five Cs of drug delivery to control inflammation and reduce pain. We must have compliance; we must manage the cornea and prevent dry eye. We must provide medications that are comfortable, cost-effective, and that don't affect cosmesis (ie, cause red eyes).

Conventional eye drops to control inflammation have inherent shortcomings. The volume of a drop is about 20 to 50 μ L, while the precorneal space holds about 7 μ L. Only about 1% to 5% of an applied drop is absorbed into the eye, and most of the medication doesn't reach the anterior chamber. What's more, some excellent studies in glaucoma and cataract surgery show that patients don't use their medications properly and that compliance is an issue.¹⁻⁵ A study by An and colleagues showed that 92% of patients don't instill their drops properly, and many patients have manual dexterity problems and physical limitations that preclude the adequate use of these medications.⁶

With these facts in mind, I'm happy to report some exciting new opportunities have become available that enable us to provide better patient care.

— Eric D. Donnenfeld, MD

IMPACT OF POSTOPERATIVE INFLAMMATION

Q | DR. DONNENFELD: Let's first discuss the significance of inflammation following ophthalmic surgery. Dr. Aldave, as an anterior segment surgeon, why are you concerned about inflammation?

ANTHONY J. ALDAVE, MD: Inflammation can work against the goals we're trying to achieve with surgery. Surgeons who perform corneal transplants will tell you, prolonged inflammation causes significant damage to the corneal endothelium. Inflammation can also lead to anterior or posterior synechiae, which can result in increased IOP via primary or secondary angle closure. Inflammation also can indirectly affect patient compliance. Applying an eye drop to an already inflamed eye often causes more discomfort, making patients reluctant to use their drops as instructed.

DR. DONNENFELD: How important is controlling inflammation when managing pediatric cataract surgery?

M. EDWARD WILSON, MD: It's well-known that children experience more inflammation after surgery than adults. Children develop inflammatory membranes, synechiae, and cell deposits on the intraocular lens. Controlling inflammation from the very beginning is of the utmost importance. We've always struggled with placing that burden on the parents. We ask them to instill eye drops more frequently and for a longer duration for their children than we do for adults, and we find a tremendous variability in how well that's done. As a group, pediatric ophthalmologists are quite interested in any sort of physician-applied anti-inflammatory medication, rather than relying on parental compliance.

DR. DONNENFELD: Dr. Dhaliwal, as an anterior segment specialist focusing on cornea and cataract surgery, what is the impact of inflammation and pain on your patients?

DEEPINDER K. DHALIWAL, MD: I also worry about the development of cystoid macular edema (CME) due to inflammatory mediators released after anterior segment surgery. It's truly heartbreaking to see a patient develop decreased vision as a result of CME weeks after uncomplicated cataract surgery. The patient is rightfully concerned and disappointed and typically requires months of additional treatment. If we can decrease the incidence of inflammation and CME, our premium surgeries can have lasting premium results.

DR. DONNENFELD: Dr. Singh, what is the impact of inflammation on glaucoma surgery?

I. PAUL SINGH, MD: Inflammation is a concern after microinvasive glaucoma surgery (MIGS) combined with cataract surgery, as well as stand-alone MIGS and other glaucoma surgeries. Studies have found that in traditional glaucoma surgeries such as trabeculectomy or any filtering type of surgery, a higher risk of fibrosis and bleb scarring exists.⁷ Our biggest enemy is postoperative inflammation for a bleb type of surgery. In addition, when inflammation occurs after MIGS and the implantation of stents and other devices, there are risks for trabeculitis and intraocular pressure (IOP) spikes. The longevity and sustainability of success after these surgeries can be affected by inflammation.

One factor we haven't discussed yet is patient satisfaction, particularly after cataract surgery. Certainly, CME and inflammation are problematic, but patients may experience photophobia, redness, and pain postoperatively. If the inflammatory cascade is not controlled, patients are not happy, and they tell their friends and family members. From a patient-satisfaction standpoint, I think inflammation control, as well as pain control, is crucial.

DR. DONNENFELD: Dr. Bauman, what is the impact of CME on visual results after retina surgery?

CAROLINE R. BAUMAL, MD: CME can adversely affect visual results and lead to patient dissatisfaction, not only after retina surgery but also after cataract surgery. CME is often related to inflammatory mediators, and we typically control it with corticosteroid eye drops, but to be effective, prolonged use of eye drops and strict adherence to the dosing regimen are necessary. Poor control of inflammation after retina surgery can lead to other unwanted side effects, including failure of surgery, pain, scar tissue formation, and proliferative vitreoretinopathy.

DR. DONNENFELD: The old postoperative paradigm had patients using steroid and nonsteroidal anti-inflammatory drug (NSAID) eye drops to reduce inflammation and pain associated with cataract surgery, but we didn't consider pain much of an issue. Today, there's a new paradigm. Rather than control inflammation, we want to prevent it. To accomplish this, we need to be extraordinarily aggressive, because any inflammation is detrimental to visual outcomes.

What's more, patients perceive their results differently than ophthalmologists do. We think in terms of visual acuity, but patients think in terms of their experience. When a patient is uncomfortable and having pain, a perfect result will be viewed by the patient as an unacceptable result. In a patient's mind, controlling pain sometimes is just as important as the visual result.

Nothing is more devastating to me as an ophthalmologist than performing a surgery well but having a suboptimal result because the patient didn't use the medications properly. A new paradigm that removes the burden from patients and gives control to surgeons via sustained release medications is a better model than the old ones we've dealt with in the past.

DR. DHALIWAL: I couldn't agree with you more. Cataract surgery has evolved so much over the past decade, yet our postoperative medication regimen has not. If we could remove patient compliance from the equation in terms of postoperative results, it would be truly phenomenal.

I think it's somewhat unfair to ask patients to instill some 70 or more drops into their eyes, exactly on time, to achieve the proper peak and trough effect. Our patients have busy lives. If we could implant a sustained-release product, I believe patient satisfaction and postoperative results would improve.

DR. BAUMAL: So many of our patients are elderly, and some have memory issues or physical impairments that make it difficult to instill eyedrops properly. Relieving them of this task would be advantageous, as uncontrolled inflammation can adversely affect the results of our surgeries, which is the reason why patients come to us in the first place.

DR. SINGH: Compliance is a difficult issue for us in the glaucoma world. Studies have shown that as many as 60% of patients don't use their glaucoma medications as prescribed.⁸⁻¹⁰ Compliance is poor even for a single drop, let alone three or four drops a day. With different regimens and tapering dosages, it's confusing and frustrating for patients.

CASE 1: NOVEL DRUG DELIVERY HELPS TO OVERCOME BARRIERS

By Eric D. Donnenfeld, MD

I was recently referred a 54-year-old man with best corrected bilateral hand-motion cataracts. The patient was a functioning schizophrenic who just could not bear the thought of having surgery. His consultation revealed a clear cornea, 4+ bilateral nuclear cataracts, IOPs of 15/16 mm Hg, a hazy fundus view that appeared normal, and a normal B-scan ultrasound.

After my examination and an extensive conversation with the patient's family, we decided it was best to perform bilateral, same-day, sequential cataract surgery. Once this had been determined, the only remaining obstacle was the patient's inability to use eye drops. Not only was he not able to instill drops himself, he was extremely resistant to having family members give drops. Drug delivery was our major unmet need.

The patient underwent uneventful bilateral cataract surgery under peribulbar anesthesia with IV sedation. We used phenylephrine and ketorolac intraocular solution 1%/0.3% in both eyes. At the conclusion of surgery, the patient received anterior chamber moxifloxacin and bilateral dexamethasone intracanalicular inserts 0.4 mg into his inferior puncta.

Postoperatively, the patient has done extremely well, with return of uncorrected 20/20 visual acuity. He received no postoperative medications other than what was outlined above, and both eyes have had clear corneas with no anterior chamber iritis. Most importantly, he has had a remarkable improvement in his mental status, and the family views his quality of life as markedly improved.

Drug delivery is a common problem for many patients, and their ability to comply with a regimen of postoperative topical medications is a concern for me. They may have physical or mental barriers to instilling drops, the cost of the medications may be prohibitive for them, they may be forgetful or simply noncompliant. In this case, the use of dexamethasone intracanalicular inserts enabled me to perform life-changing surgery safely and effectively.

The issues are similar for cataract surgery. In my practice, we performed a study (unpublished) in which we asked patients 3 months after they'd undergone uneventful cataract surgery with good outcomes what their biggest challenge was with the surgery. More than 90% of the patients (30 patients) said their biggest challenge, the most frustrating aspect, was using the eye drops. Not only is noncompliance problematic from the scientific perspective of controlling inflammation but also from a patient satisfaction standpoint, particularly when expectations are so high. For me, one solution is to avoid using eye drops as much as possible, and a drug delivery system is a great option.

DR. ALDAVE: Keratoplasty outcomes are also critically dependent upon controlling inflammation. In these cases, we're asking patients

to use anti-inflammatory medications for a prolonged period, and compliance is definitely going to be reduced.

Another situation where anterior segment surgeons ask patients to use steroid or anti-inflammatory drops for a month or more is following pterygium surgery (Figure 1). When we talk about the success of a surgery being dependent upon controlling inflammation, nowhere is that as true as it is with pterygium surgery. In my practice, I'm asking the most of that population and the keratoplasty population, as they must use a topical anti-inflammatory for weeks or months on end. These are also the groups in which poor compliance is my biggest concern regarding long-term success of the surgery.

CONVENTIONAL THERAPY: AN OVERVIEW

Q | DR. DONNENFELD: What medications do you commonly use to control pain and inflammation following intraocular surgery?

DR. DHALIWAL: For pain and inflammation, I prescribe a topical steroid and an NSAID postoperatively. The steroid regimen is typically four times daily (QID) for the first week followed by a taper by one drop each week. In a low-risk patient, the topical NSAID is started the hour before surgery and then held until the 1-week postoperative visit. There are two reasons I hold the NSAID during the first postoperative week: one is that I want the corneal epithelium to be intact to minimize the risk of corneal melt (Figure 2); and the other is that I want patients to use only two medications at a time. I don't want to overwhelm them. At the 1-week postoperative visit, I stop the antibiotic and start the NSAID. I believe in using NSAIDs combined with the steroids for optimal control of pain and inflammation after surgery.

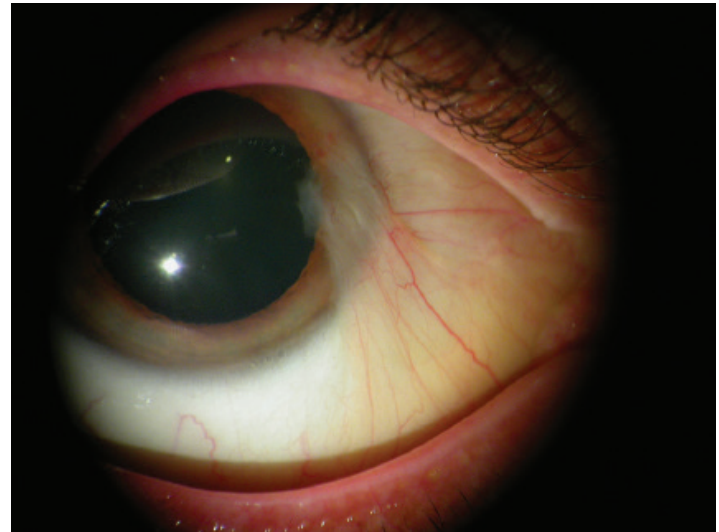
DR. SINGH: I prescribe concomitant NSAIDs and topical steroids, as well. I typically start these drops 3 days before cataract surgery, and, depending on the type of steroid, I continue them postoperatively.

One challenge is that we have many options for the type of steroid we can use—generic versus branded, with differences in solutions and vehicles—and these factors change the number of doses and the number of drops per day, not to mention the efficiency of controlling inflammation. I try to minimize the amount of tapering required. For most standard cases, I usually prescribe twice daily (BID) dosing of a topical steroid and once-a-day dosing of the NSAID. I don't do any tapering, and I stop at 4 to 6 weeks, depending on the patient.

One of the biggest issues with topical drops is that they often contain preservatives. If a patient is already using topical glaucoma medications and I'm performing combination cataract surgery and MIGS, the topical medications are likely to irritate the cornea over time. That's why I try to minimize the amount of topical medications.

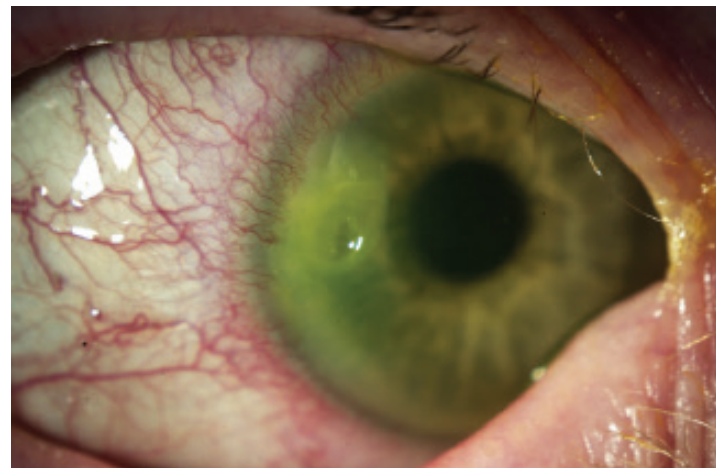
DR. DONNENFELD: Dr. Bauman, how important is it to use steroids and nonsteroidals to prevent CME following cataract surgery?

DR. BAUMAN: Individuals with a history of retinal surgery, intravitreal injection or posterior segment trauma may be at higher



(Image courtesy of Anthony J. Adave, MD)

Figure 1. Recurrent pterygium involving the nasal and inferonasal bulbar conjunctiva following prior excision.



(Image courtesy of Deepinder K. Dhaliwal, MD, LAC)

Figure 2. Corneal melt following uncomplicated phacoemulsification in a patient with Sjogren syndrome and very dry preoperative ocular surface. This patient was using a combination of a steroid and antibiotics drop (dexamethasone; neomycin; polymyxin b) and NSAID together.

risk for complicated cataract surgery and CME after cataract surgery, so utilizing topical steroids and nonsteroidals may have an additive preventive effect. Treatment of CME may require prolonged use of eye drops or even periocular or intravitreal steroid injection. Therefore, prophylactic therapy to prevent CME, particularly in high-risk eyes, would be ideal. Patients with diabetes are particularly prone to developing CME post cataract surgery, and the steroid and nonsteroidal eye drop regimen has demonstrated efficacy to prevent development of CME in this group.

DR. DONNENFELD: In the PREMED study, investigators looked at the use of corticosteroids alone versus nonsteroidals alone versus both.¹¹ They found that nonsteroidals were somewhat more important than steroids in preventing CME, but the two medications combined were the best option to prevent CME, and they were

overwhelmingly the best combination for preventing inflammation following surgery.

DR. BAUMAL: When patients have CME, those two medications may have an additive mechanistic effect. Heier and colleagues evaluated prednisolone and ketorolac alone versus combined and found that the combination of these agents was more helpful in treating CME when it's already established.¹²

INTRACANALICULAR INSERT

Q | DR. DONNENFELD: I believe controlling inflammation is the old paradigm. Preventing inflammation is the new paradigm. Eye drops have significant drawbacks associated with them, namely, toxicity and compliance issues. What's more, they remain in the tear film for only 5 to 10 minutes, which creates a significant problem. Many new treatment options have become available recently, including two prolonged delivery systems approved this year.

Dr. Singh, you were involved in the US trials of the dexamethasone 0.4 mg intracanalicular insert (Ocular Therapeutix). Please tell us about this medication and your experience with it.

DR. SINGH: The dexamethasone 0.4 mg intracanalicular insert is made of a polyethylene glycol-based hydrogel that naturally reabsorbs. It can be implanted preoperatively or intraoperatively after the surgery is completed. The insert is placed within the canaliculus to provide a sustained and tapered delivery of drug to the ocular surface. The highest concentration is released during the first 2 weeks and then slowly tapers over about a month. Because it's inserted in the canalicula, there's no need to worry about it being inside the eye.

Regarding IOP, phase 3 studies showed the dexamethasone 0.4 mg intracanalicular insert is safe.¹³ Compared with placebo, there were no significant issues with IOP spikes from using the intracanalicular insert. Hypothetically, if there is a concern about a pressure spike, the insert can be removed with a forceps or it can be flushed down the lacrimal system.

Regarding pain and inflammation in the phase 3 studies, a significantly greater proportion of eyes in the dexamethasone 0.4 mg intracanalicular insert group had an absence of ocular pain and an absence of anterior chamber cells, compared with the placebo group.¹⁴

As for my experience, I've used the intracanalicular insert in about 50 cases to date, and I've already seen a huge benefit from an office and patient perspective.

DR. DONNENFELD: Dr. Wilson, have you used the dexamethasone 0.4 mg intracanalicular insert?

DR. WILSON: Yes. I've had some experience with the intracanalicular insert in children. The sustained-release aspect is interesting. I think pediatric ophthalmologists were somewhat concerned early on that it might not be strong enough for the

CASE 2: NONCLEARING RECURRENT VITREOUS HEMORRHAGE

By Caroline R. Baumal, MD

A 72-year-old man with poorly controlled type 2 diabetes mellitus presented for evaluation of a nonclearing recurrent vitreous hemorrhage in his right eye. This eye had previous surgery elsewhere with vitrectomy for a complicated tractional diabetic retinal detachment.

The patient is confined to a wheelchair and lives alone. He depends on a social worker to take him to appointments and to his surgeries. A nurse visits once a day to help with medications. The patient stated that he did not use any eye drops after his first vitrectomy surgery because he was unable to instill them owing to physical impairment and memory issues. Based on this information, I decided to use the dexamethasone intracanalicular insert 0.4 mg for his reoperation.

I performed a repeat vitrectomy with laser and placed a dexamethasone intracanalicular insert at the end of surgery for its 30-day slow release of steroid. The patient also received a single dose of subconjunctival antibiotic.

The patient recovered well after surgery without inflammation or pain.

inflammation that we see, and they thought we would need rescue drops more often. My experience, so far, has been surprising to me. The dexamethasone 0.4 mg intracanalicular insert has been able to stand alone without steroid drops much better than I expected. I've used it in patients as young as 5 months old. Even when the canalicular opening is small, it stretches nicely and the insert fits well. In the 15 cases I've treated so far, only a few of them have needed supplemental prednisolone acetate drops.

DR. DONNENFELD: I have limited experience performing surgery on children, but my experience has been that not only is it difficult to administer eye drops, but once you do, children often cry and wash out the medications immediately, thus limiting their efficacy. What is the advantage of the dexamethasone 0.4 mg intracanalicular insert in managing children postoperatively?

DR. WILSON: With the intracanalicular insert, the steroid is released evenly and the eye is receiving the medication even when the child's asleep. I also appreciate that it has a built-in taper. I think that's a nice added feature.

DR. DONNENFELD: Dr. Baumal, what is your experience with the dexamethasone 0.4 mg intracanalicular insert?

DR. BAUMAL: In my experience, I have noted beneficial effects for my patients with the dexamethasone intracanalicular insert. I find it particularly useful for treating complicated cases when patients are at high risk for postoperative inflammation and are limited in their ability to self-instill eyedrops secondary to physical or cognitive issues.

I recently used the dexamethasone intracanalicular insert after surgery in a monocular, highly myopic woman who had extensive retinal surgery for a tractional retinal detachment related to proliferative diabetic retinopathy as well as a macular hole. The patient was concerned about eye drop placement, as intraocular gas will limit her vision postoperatively.

I also used the intracanalicular insert in an individual with retinitis pigmentosa after surgical placement of an Argus retinal implant. This complicated procedure has both intraocular and extraocular components and has potential to produce significant inflammation around the eye. In addition, an individual receiving an Argus implant has severe visual impairment and may have a great deal of difficulty instilling eye drops, and it may not be apparent that the drops are reaching the desired location. When I use the intracanalicular insert, I am confident the individual is receiving the steroid, and this is reflected by reduced inflammation after surgery.

DR. DONNENFELD: What do you think about the use of the dexamethasone 0.4 mg intracanalicular insert for pterygium surgery?

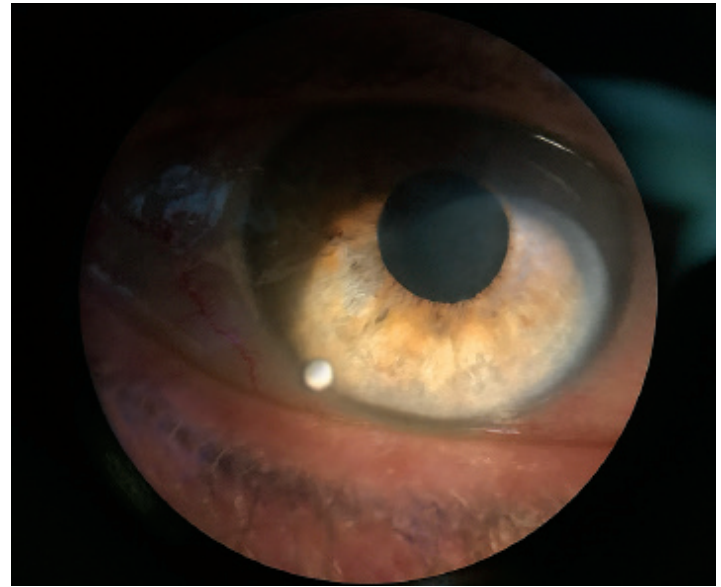
DR. ALDAVE: If we can achieve therapeutic concentrations on the ocular surface for an extended period following pterygium surgery, I believe the intracanalicular insert could relieve the need for eye drops. With that, hopefully, we would see a decrease in the recurrence of pterygia following surgery. A study needs to be done, but the data from the phase 3 study indicated that it may have utility for ocular surface surgery, as well.¹³

DR. DHALIWAL: Two things about the dexamethasone 0.4 mg intracanalicular insert excite me. First, it's preservative-free. For cornea specialists and glaucoma specialists, decreasing the preservative contact on the ocular surface is important, because preservatives can be quite damaging. Second, the intracanalicular insert occludes the punctum. In the postoperative period, many patients experience dryness and irritation. This insert will act as temporary punctal occlusion, and patients should be more comfortable.

DEXAMETHASONE INTRAOCCULAR SUSPENSION

Q | DR. DONNENFELD: Dr. Singh, you've had experience with the dexamethasone intraocular suspension 9% (EyePoint Pharmaceuticals). What can you tell us about it?

DR. SINGH: The dexamethasone intraocular suspension 9% is administered intracamerally at the end of surgery via a proprietary sustained-release drug delivery technology. It's introduced into the anterior chamber under the iris through a paracentesis. Because it's a hydrophobic material, it sometimes adheres to the cannula, and it can move above the iris into the anterior chamber, but I've found that's not a significant issue. The medication is released in a controlled fashion, with peak concentrations in the first couple of weeks, slowly tapering over about a month's time. It has shown significant efficacy in clearing anterior chamber cell and flare compared to placebo.¹⁰



(Image courtesy of Eric D. Donnemfeld, MD)

Figure 3. Dexamethasone intraocular suspension 9% intracamerally administered at the end of cataract surgery.

DR. DONNENFELD: I've looked at two studies of dexamethasone intraocular suspension 9%. One showed that it was significantly better than placebo, and the second showed noninferiority versus prednisolone acetate 1% QID.^{10,11} The dexamethasone suspension was as good as a standard of care with the additional benefit of 100% compliance. This is another good alternative to consider for patients who are having intraocular surgery (Figure 3).

DR. WILSON: The FDA has requested a randomized trial comparing prednisolone acetate QID to dexamethasone intraocular suspension 9% in the 0 to 3-year-old age group. Our center is involved, and recruitment will begin shortly. The FDA will be watching for safety, primarily, but efficacy as well. The 0- to 3-year-old age group is fairly difficult to study, and we'll be using dexamethasone intraocular suspension 9% without any drops in one arm of the study and comparing it to standard prednisolone acetate. A similar FDA-directed study is planned for the dexamethasone 0.4 mg intracanalicular insert, again as a randomized trial in the 0- to 3-year-old age group.

ADVANTAGES OF PREOPERATIVE SUSTAINED-RELEASE STEROID

Q | DR. DONNENFELD: One of the advantages of the dexamethasone 0.4 mg intracanalicular insert is that it can be placed preoperatively or in the OR, as opposed to the dexamethasone intraocular suspension 9%, which must be administered in the OR. What are the advantages of placing the intracanalicular insert preoperatively?

DR. DHALIWAL: By implanting the dexamethasone 0.4 mg intracanalicular insert preoperatively, we are taking a step toward preventing inflammation instead of just controlling it. In addition,

our dry eye patients will start feeling better, the tear film will be optimized, and we may be able to obtain better keratometry readings. In patients with uveitis and in the corneal transplant population, this would be fantastic, because we could control inflammation before we enter the eye.

DR. SINGH: I appreciate being able to implant a dexamethasone 0.4 mg intracanalicular insert a week or two before surgery (Figures 4 and 5) to calm the eye and have a healthier conjunctiva going into surgery and helping to allow for a quieter conjunctiva after a trabeculectomy or a 6-mm gel stent (Allergan) surgery. With the insert, I can decrease the amount of topical steroid postoperatively. Instead of using a steroid every few hours as I usually do for the first week, I can reduce the frequency to two or three times a day with a topical steroid. That preoperative in-office dose is a crucial advantage not only for glaucoma surgeons, but also for general ophthalmologists to help heal the ocular surface and therefore allow for better pre- and postoperative measurements.

DR. BAUMAL: Another differentiating feature is the location of the sustained release steroid implants. The dexamethasone 0.4 mg implant is an intracanalicular insert with extremely low risk. In contrast, the dexamethasone intravitreal implant 0.7 mg (Allergan) is an intravitreal injection, and the dexamethasone intraocular suspension 9% must be administered intraocularly. Steroids may also be placed in the sub-Tenon or suprachoroidal space. Thus, the other modalities of steroid delivery are more invasive than the intracanalicular route.

Implanting the dexamethasone 0.4 mg intracanalicular insert is a relatively easy and painless in-office procedure with a whole host of benefits, such as healing the ocular surface, calming the eye, and preventing inflammation. The beauty is that it lasts 30 days, just long enough to avoid IOP spikes, and we can see if the steroid has a beneficial effect.

DR. DONNENFELD: A J-code is a milestone in that it simplifies reimbursement for a specific use of these medications.* Another advantage of the dexamethasone 0.4 mg intracanalicular insert is that it occludes the punctum and physicians can bill for punctal plug placement. Not only does the patient receive the intracanalicular insert for free, but the physician is reimbursed for implanting it.

**Editor's note: The Centers for Medicare and Medicaid Services (CMS) issued a permanent product-specific J-code for dexamethasone ophthalmic insert 0.4 mg for intracanalicular use. The J-code (J1096) became effective October 1, 2019, and replaced the previously issued C-code. The company will retain transitional pass-through status granted for dexamethasone ophthalmic insert 0.4 mg from CMS.*

UPDATE ON TOPICAL STEROIDS

Q | DR. DONNENFELD: There are two new topical loteprednol etabonate medications: a 0.38% gel (Bausch + Lomb) and a 1% suspension (Kala Pharmaceuticals). What is your experience with these medications?



Figure 4. Insertion of dexamethasone ophthalmic insert 0.4 mg.



Figure 5. Dexamethasone ophthalmic insert 0.4 mg placed into the punctum.

DR. SINGH: The inactive ingredients play a huge role in the effectiveness and safety of any medication, particularly for glaucoma. Loteprednol etabonate 0.38% gel has a polycarbophil vehicle that allows it to stay on the ocular surface longer. The 0.38% loteprednol gel also has a smaller, submicron particle size of steroid that allows it to penetrate through and adhere to the ocular surface, so that more of the active medication gets into the anterior chamber. The increased residence time on the ocular surface and the smaller particle size enable the manufacturer to decrease the concentration of the loteprednol to 0.38%. Despite this lower concentration of active steroid, investigators found good efficacy compared to loteprednol etabonate ophthalmic gel 0.5%.¹⁵ With a lower concentration of steroid, there is less potential for adverse events while maintaining similar efficacy. The dosing regimen is also decreased to three times daily (TID).

DR. DONNENFELD: Dr. Dhaliwal, what is your experience with loteprednol etabonate 1% suspension?

DR. DHALIWAL: I have had a positive experience with loteprednol etabonate 1% suspension. This medication has a mucus-penetrating technology, and it is labeled for BID dosing to control pain and inflammation after cataract surgery.

Compliance, Confusion, Costs

Dr. Donnenfeld: Dr. Singh, what problems do your patients have when using medication to manage inflammation, even when they're trying to do their best?

Dr. Singh: It's frustrating for patients and for the family especially. Some older patients who can't manage the drops physically have family members come in to live with them, or they visit three, four, or five times a day to instill the medications, and they're not waiting 5 minutes between drops. A tapering dosing schedule is particularly difficult. For cataract surgery, the two eyes are scheduled for surgery a week or two apart, thus, the schedules are not the same for each eye. Patients and family members get confused and frustrated.

The first dexamethasone 0.4 mg intracanalicular inserts I implanted were in patients who were prescribed topical steroid drops after surgery on their first eye and received the dexamethasone 0.4 mg intracanalicular insert for their second eye. Even though the outcomes were the same for both eyes, the satisfaction level was through the roof for the patients who received the intracanalicular insert and didn't have to use the topical steroid drops.

Dr. Donnenfeld: Do patients sometimes not use medications because of the cost?

Dr. Singh: Absolutely. We see it in glaucoma treatment, and we see it in topical steroid drops.

Dr. Donnenfeld: What is the cost to patients for using the dexamethasone 0.4 mg intracanalicular insert or the dexamethasone intraocular suspension 9% under current guidelines?

Dr. Singh: Both products have pass-through status. That means patients insured by Medicare can have the intracanalicular insert or the intracameral suspension without paying out of pocket. In addition, the ambulatory surgery center doesn't lose any money. In fact, the ambulatory surgery center can charge an up-charge for processing the medicine. Patients don't have to pay, and the cost doesn't come out of the same fund.

There's some confusion that we're adding more cost to our Medicare budget, but actually the cost comes from a special, novel-technologies fund. Therefore, it's not the same pool of money that's used for typical Medicare payouts. Patients don't have to pay out of pocket for the medication, the facilities don't have to pay out of pocket for it, and, hopefully, patients save money because they don't have to buy postoperative drops, and we avoid the compliance issues.

Dr. Donnenfeld: Pass-through is a pathway for doctors, not only in ophthalmology but all specialties, to use innovative drugs. A fund has been established that is separate from the Medicare funds, and that

money is available for new technology. For patients with Medicare, specifically those with coinsurance, there's no cost to the surgeon or to the surgery center, and the patient receives a medication gratis—in this case, we're talking about the intracanalicular dexamethasone insert or the intracameral dexamethasone suspension—and the patient doesn't have to use the topical eye drops. It's a win-win situation. This seems to be an obvious advantage for our patients, and it's something that patients will be asking for, because if you can eliminate one medication and you can eliminate the cost of a medication, it's a tremendous advantage.

Let's talk about what happens in your offices when your staff must handle inquiries from pharmacies and from patients regarding drop regimens and cost of medications. Dr. Aldave, do you have these issues in your practice?

Dr. Aldave: Yes, and they consume a significant amount of time for me and my staff. I estimate that for one of every five prescriptions I write or e-prescribe for topical steroids, I receive a call from the patient, the pharmacy, or my staff, usually about the cost and coverage, and sometimes about availability. Even patients who have been using a specific medication for years have told me the cost of their refills was double what it was before.

As we've discussed, one of the benefits of the dexamethasone 0.4 mg intracanalicular insert and the dexamethasone intraocular suspension 9% is that you know the patient receives the medication, whereas if you give the patient a prescription or send it to a pharmacy, you don't know if the patient gets it or not. Often, patients return to my office and tell us they didn't pick up a prescription because of X or Y. It's really time-consuming and interferes with my ability to make sure my patients are using the medications they need to be using.

Dr. Singh: When trialing our first dexamethasone 0.4 mg intracanalicular inserts, we compared time expended versus the standard postoperative regimen. We saved almost 5 minutes of technicians' time by not having to review all of the instructions, the drops, and the verification. If you have 20 postoperative visits a day and you're saving 3 to 5 minutes per case, that's a significant savings of time. From an efficiency standpoint, using the intracanalicular insert can make a big difference.

Dr. Donnenfeld: Those are excellent points. I couldn't agree with you more. It's really frustrating when you prescribe a medication and either the patient doesn't get it, or there are endless calls to the office or to you to navigate the vagaries of insurance. In addition, you can prescribe a medication and, at least in New York, the pharmacist can substitute another medication, so what I'm prescribing isn't always what the patient gets. When you administer the dexamethasone intercanalicular insert or the intracameral dexamethasone suspension, you know the patient is receiving the medication that you want the patient to have.

Unfortunately, topical medications work only if patients place them in their eyes. Some patients cannot remember to use their drops. Others are physically challenged and cannot get the bottle to their eye and squeeze out the drops. It's sad when patients are unable to comply with the postoperative regimen, and they often do not want to burden friends and family members with this responsibility. So, the drops work, but compliance is still a factor.

DR. DONNENFELD: Loteprednol is an ester-steroid that is neutralized in the eye by esterases, so it doesn't cause as much cataractogenesis or pressure spikes as other corticosteroids do. These new topical steroids are in submicron levels, so they provide better penetration, particularly the 1% loteprednol, which is a mucus-penetrating medication. This medication gets very high drug levels in the anterior chamber and is significantly more efficacious than older generations of loteprednol.

DR. WILSON: For patients who must use steroids for prolonged periods, such as those with juvenile idiopathic arthritis, going from QID to BID dosing is incredibly important, because in my experience, the most frequently missed doses are those in the middle of the day.

REAL-WORLD EXPERIENCE

Q | DR. DONNENFELD: What's been your experience using these new medications in real-world practice?

DR. SINGH: I think there's a place for all of these devices, procedures, and drops, and I'm currently evaluating all of them.

Some physicians are concerned about using sustained-release steroids in the glaucoma population, but I've used the dexamethasone injectable suspension 9% and the dexamethasone 0.4 mg intracanalicular insert in a number of combination MIGS and cataract surgeries and I've seen no pressure spikes to date. My concern of an IOP spike has gone down when performing a MIGS surgery, since we're helping to increase outflow via the MIGS procedure and, therefore, might have less chance for an IOP spike than routine cataract surgery alone.

From a safety perspective, I've had to reintroduce a topical steroid in only a complicated cataract case. Otherwise, for routine cataract surgeries, I've not had to use rescue drops after using those types of drug delivery systems.

Topically, I think the new formulations of loteprednol etabonate are well-tolerated. The fact that the 0.38% gel does not need to be shaken is beneficial, because patients often don't shake their medications as instructed. The BID dosing of the 1% suspension is also beneficial, as it enables us to keep the post-op regimen simplified. I just prescribe BID from the start, and then stop it when it's done after 4 to 6 weeks. It's been a lot easier not having to worry about a tapering dose of steroids. That's where I think the big benefit has come for me with these new formulations.

DR. DHALIWAL: The decreased dosage regimen from QID to BID for the newer formulation of topical steroid drops is much easier

for patients to remember. It really makes a difference. If I instruct a patient to use a medication four times a day, I think the patient is really using it two or three times. A BID dosing schedule, however, fits into people's lives, and compliance improves.

DR. ALDAVE: The loteprednol etabonate 1% suspension has changed what I do in my practice. With this more potent formulation of loteprednol etabonate available, I don't feel the need to use prednisolone acetate for all of my keratoplasty patients anymore, which is important because so many of my keratoplasty patients have glaucoma. I'm now prescribing more loteprednol etabonate.

DR. DONNENFELD: I've had extensive experience with both the dexamethasone 0.4 mg intracanalicular insert and the dexamethasone injectable suspension 9%. Patient satisfaction has been extraordinary. I believe these products represent a next generation of refractive cataract surgery, in that we can minimize medication use, which simplifies patients' lives. In addition, if a patient is receiving a sustained-release corticosteroid, I'm not as concerned about whether or not they're receiving the NSAID or the antibiotic, because, in my mind, the heart and soul of postoperative medication use a corticosteroid.

I think we'll find some significant differences between these medications that we'll be exploring. When a patient has ocular surface disease and is having cataract surgery, for instance, I think there's a real advantage to using the dexamethasone 0.4 mg intracanalicular insert, because we're killing two birds with one stone: preventing intraocular inflammation and controlling ocular surface disease. The use of an intracameral corticosteroid is advantageous for people who have an increased risk of higher amounts of inflammation postoperatively.

In my clinical experience and in the FDA trials of the dexamethasone 0.4 mg intracanalicular insert and the dexamethasone injectable suspension 9%, there were minimal pressure problems.^{14,16,17} In fact, there was no significant difference in pressure problems between the placebo and the corticosteroid. One of the advantages of both of these medications is that they are self-tapering.

How long did it take for the average patient to identify as a steroid responder?

DR. SINGH: Usually, 2 weeks out, we'll start to see a response; however, steroids such as difluprednate can cause IOP spikes even earlier than 2 weeks.

DR. DONNENFELD: Steroid responders make up about 5% of the population, and as Dr. Singh notes, we'll usually see pressure spikes at about 2 weeks. With the dexamethasone intraocular suspension 9% and the dexamethasone 0.4 mg intracanalicular insert, by that time, the medication is self-tapering. The patient receives the optimal highest amount of medication in the immediate postoperative period, and then over time, it tapers down, so that when patients need the anti-inflammatory therapy the least, they have the least amount of medication being delivered, and that prevents pressure spikes, which has been shown in the FDA trials.^{14,16,17} I think it's an ideal situation that the medication tapers on its own.

DR. SINGH: With respect to the dexamethasone 0.4 mg intracanalicular insert, let's say hypothetically you had an issue with it, you can just remove it as you would a topical drop. Having the ability to remove the insert is a beneficial aspect of that delivery system.

DR. BAUMAL: Also, the dexamethasone 0.4 mg intracanalicular insert is easy to administer, either in the office or in the OR, and the drug effect is typically completed before the timing of a steroid response effect develops.

CLOSING REMARKS

DR. ALDAVE: Inflammation can adversely affect surgical outcomes in many different fields. I think we all agree that the newer drugs and the newer modes of delivery help us achieve better control over inflammation in our patients.

DR. SINGH: The patient's experience is a significant factor in our definition of success today. Success is not just achieving 20/20 visual acuity but also making sure patients are "20/happy" throughout the entire process, from pre- to intra- to postoperatively. I do believe I have a better chance to achieve that 20/happy status with these new drug delivery platforms. Having better control of the postoperative course than I could before is a big part of it. It's an exciting time and I'm looking forward to seeing where we take it.

DR. WILSON: The drug delivery system technology is exciting. I think this is proof-of-concept, and now the experts can advance these delivery methods and change the length of delivery and the type of drugs delivered. It opens up many possibilities for the future.

DR. BAUMAL: In retina, the emphasis has been on longer-acting medications. There are sustained-release intraocular steroids that last 3 to 4 months and even up to 2 years, but having a steroid that lasts 1 month is also advantageous, because most patients don't need chronic long-term steroid treatment. I'm excited to use the dexamethasone 0.4 mg intracanalicular insert and the dexamethasone intraocular suspension 9% to prevent postoperative pain and inflammatory effects and relieve my patients of the burden of using topical drops.

DR. DHALIWAL: I'm definitely looking forward to taking compliance out of the equation in terms of postoperative healing.

We can perform elegant, life-changing surgeries, but then we have this list of drops for patients to administer multiple times a day. I'm excited to finally give them an option where we'll do a premium surgery, and they won't have to use any drops afterward. Hopefully, these newer technologies will be a platform for antibiotics and nonsteroidals as well, enabling us to take compliance out of the equation and optimize our postoperative results.

DR. DONNENFELD: In my estimation, the future of ophthalmic pharmaceuticals is drug delivery. Intracanalicular drug delivery and intraocular drug delivery are just the tip of the iceberg. In ophthalmology, I strongly believe that topical medications as we know them today will be changing greatly over the next several years. It's an exciting time for us as surgeons and for our patients who will benefit from these new medications.

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INSTRUCTIONS FOR CME CREDIT

To receive credit, you must complete the attached Pretest/Posttest/Activity Evaluation/Satisfaction Measures Form and mail or fax to Evolve Medical Education LLC; 353 West Lancaster Avenue, Second Floor, Wayne, PA 19087; Fax: (215) 933-3950. To answer these questions online and receive real-time results, please visit <http://evolvemeded.com/online-courses/1926-supplement>. If you are experiencing problems with the online test, please email us at info@evolvemeded.com. Certificates are issued electronically; please be certain to provide your email address below.

Please type or print clearly, or we will be unable to issue your certificate.

Full Name _____ ☐ MD/DO participant ☐ OD ☐ non-MD participant

Phone (required) _____ ☐ Email (required) _____

Address/P.O. Box _____

City _____ State/Country _____ Zip/Postal Code _____

License Number _____ OE Tracker Number _____

DEMOGRAPHIC INFORMATION

Profession	Years in Practice	Patients Seen Per Week (with the disease targeted in this activity)	Region	Setting	Models of Care
☐ MD/DO	☐ >20	☐ 0	☐ Northeast	☐ Solo Practice	☐ Fee for Service
☐ OD	☐ 11-20	☐ 1-15	☐ Northwest	☐ Community Hospital	☐ ACO
☐ NP	☐ 6-10	☐ 16-30	☐ Midwest	☐ Government or VA	☐ Patient-Centered Medical Home
☐ Nurse/APN	☐ 1-5	☐ 31-50	☐ Southeast	☐ Group Practice	☐ Capitation
☐ PA	☐ <1	☐ 51+	☐ Southwest	☐ Other	☐ Bundled Payments
☐ Other				☐ I do not actively practice	☐ Other

LEARNING OBJECTIVES

DID THE PROGRAM MEET THE FOLLOWING EDUCATIONAL OBJECTIVES?

Identify the issues surrounding patient compliance with postoperative topical medications.

AGREE **NEUTRAL** **DISAGREE**

Describe the benefits of delivery of antiinflammatory medications during cataract surgery.

Summarize the drug delivery properties of novel sustained-release medications.

State how the latest federal government regulations on reimbursement will affect practices treating Medicare-eligible patients.

POSTTEST QUESTIONS. PLEASE COMPLETE AT THE CONCLUSION OF THE PROGRAM.

1. BASED ON THIS ACTIVITY, PLEASE RATE YOUR CONFIDENCE ON YOUR ABILITY TO APPLY POSTOPERATIVE ANTIINFLMATORY TREATMENTS (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NOT AT ALL CONFIDENT AND 5 BEING EXTREMELY CONFIDENT).

- a. 1
- b. 2
- c. 3
- d. 4
- e. 5

2. BASED ON THIS ACTIVITY, PLEASE RATE HOW OFTEN YOU INTEND TO APPLY POSTOPERATIVE ANTIINFLMATORY TREATMENTS (BASED ON A SCALE OF 1 TO 4, WITH 1 BEING NEVER AND 5 BEING ALWAYS).

- a. 1
- b. 2
- c. 3
- d. 4
- e. 5

3. WHAT PERCENTAGE OF PATIENTS UNDERGOING OPHTHALMIC SURGERY INSTILL THEIR MEDICATIONS CORRECTLY?

- a. 10%
- b. 25%
- c. 50%
- d. 75%

4. WHICH OF THE FOLLOWING IS AN ADVANTAGE OF SUSTAINED DELIVERY MEDICATIONS, SUCH AS THE DEXAMETHASONE 0.4 MG INTRACANALICULAR INSERT AND THE DEXAMETHASONE INTRAOCULAR SUSPENSION 9%?

- a. For many patients, there is no cost because of pass-through legislation.
- b. The preservative-free medications are better for the ocular surface.
- c. These medications remove the issue of compliance.
- d. All of the above

5. WHICH OF THE FOLLOWING IS TRUE WITH REGARD TO CATARACT SURGERY IN YOUNG CHILDREN?

- a. There is an enhanced inflammatory response after surgery.
- b. Parents often struggle to place postoperative drops.
- c. Physician-applied medications could improve surgical outcomes.
- d. All of the above

6. THE DEXAMETHASONE OPHTHALMIC INSERT 0.4 MG IS (SELECT ALL THAT APPLY):

- a. An intracanalicular insert containing dexamethasone
- b. Preservative free
- c. Delivers steroid for up to 30 days
- d. Delivers steroid for only 7 days

7. WHICH TREATMENT FOR POSTOPERATIVE INFLAMMATION PROVIDES THE OPTION OF BEING USED EITHER PREOPERATIVELY OR IN THE OPERATING ROOM?

- a. Dexamethasone 0.4 mg intracanalicular insert
- b. Dexamethasone intraocular suspension 9%
- c. Both formulations of dexamethasone
- d. Neither formulation dexamethasone

8. WHICH FORMULATION OF LOTE Prednol ETABONATE HAS TWICE-DAILY DOSING?

- a. Loteprednol etabonate 0.5% gel
- b. Loteprednol etabonate 0.38% gel
- c. Loteprednol etabonate 1% suspension
- d. All of the above

9. WHICH OF THE FOLLOWING IS THE APPROVED DOSING REGIMEN FOR LOTE Prednol ETABONATE OPHTHALMIC SUSPENSION 1%?

- a. One to two drops into the affected eye four times daily beginning the day after surgery and continuing throughout the first 2 weeks of the postoperative period.
- b. One to two drops into the affected eye four times daily beginning two days before surgery and continuing throughout the first week of the postoperative period.
- c. One to two drops into the affected eye twice daily beginning the day after surgery and continuing throughout the first 2 weeks of the postoperative period.
- d. One to two drops into the affected eye twice daily beginning 2 days before surgery and continuing throughout the first 2 weeks of the postoperative period.

10. WHICH OF THE FOLLOWING IS NOT A CORRECT STATEMENT REGARDING THE DEXAMETHASONE 0.4 MG INTRACANALICULAR INSERT?

- a. It is indicated for the treatment of ocular inflammation and pain following ophthalmic surgery.
- b. It is preservative free, resorbable, and does not require removal.
- c. Dexamethasone is released for up to 30 days following insertion.
- d. It is contraindicated in patients with active corneal, conjunctival or canalicular infections or glaucoma.

ACTIVITY EVALUATION/SATISFACTION MEASURES

Your responses to the questions below will help us evaluate this continuing medical education (CME) activity. They will provide us with evidence that improvements were made in patient care as a result of this activity as required by the Accreditation Council for Continuing Medical Education (ACCME).

Rate your knowledge/skill level prior to participating in this course: 5 = High, 1 = Low _____

Rate your knowledge/skill level after participating in this course: 5 = High, 1 = Low _____

This activity improved my competence in managing patients with this disease/condition/symptom ____ Yes ____ No

I plan to make changes to my practice based on this activity? ____ Yes ____ No

Please identify any barriers to change (check all that apply):

☐ Cost	☐ Lack of experience	☐ Lack of resources (equipment)
☐ Lack of consensus or professional guidelines	☐ Lack of time to assess/counsel patients	☐ Patient compliance issues
☐ Lack of administrative support	☐ Lack of opportunity (patients)	☐ No barriers
	☐ Reimbursement/insurance issues	☐ Other. Please specify: _____

The design of the program was effective for the content conveyed.	☐ Yes ☐ No	The content was relative to your practice.	☐ Yes ☐ No
The content supported the identified learning objectives.	☐ Yes ☐ No	The faculty was effective.	☐ Yes ☐ No
The content was free of commercial bias.	☐ Yes ☐ No	You were satisfied overall with the activity.	☐ Yes ☐ No
		Would you recommend this program to your colleagues?	☐ Yes ☐ No

Please check the Core Competencies (as defined by the Accreditation Council for Graduate Medical Education) that were enhanced through your participation in this activity:

☐ Patient Care	☐ Medical Knowledge
☐ Practice-Based Learning and Improvement	☐ Interpersonal and Communication Skills
☐ Professionalism	☐ System-Based Practice

Additional comments:

☐ I certify that I have participated in this entire activity.

This information will help evaluate this CME activity; may we contact you by email in 3 months to see if you have made this change? If so, please provide your email address below.
