Improving the cataract patient experience by managing pain and inflammation

By Eric Donnenfeld, MD

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We are at the precipice of an exciting era in ophthalmology. Two new drugs have been approved—a dexamethasone intraocular suspension and a dexamethasone intracanalicular insert. Additional promising options are in the pipeline.

In the 2018 ASCRS Clinical Survey, almost 90% of participants agreed that low to moderate intraocular inflammation after cataract surgery can significantly affect visual quality, vision recovery time, and patient comfort and satisfaction.[1]

Nearly 50% of respondents dose NSAIDs 4 weeks after surgery for most patients, whereas 18% do not prescribe them at all. Figure 1 shows NSAID practices for high-risk patients vs. standard patients.

More than 70% prescribe steroids for most standard patients for 4 weeks after surgery, and 14% dose them for 2 weeks or less. More than half continue or increase steroid use postop in high-risk patients, but 16% do not use steroids differently in high-risk patients.

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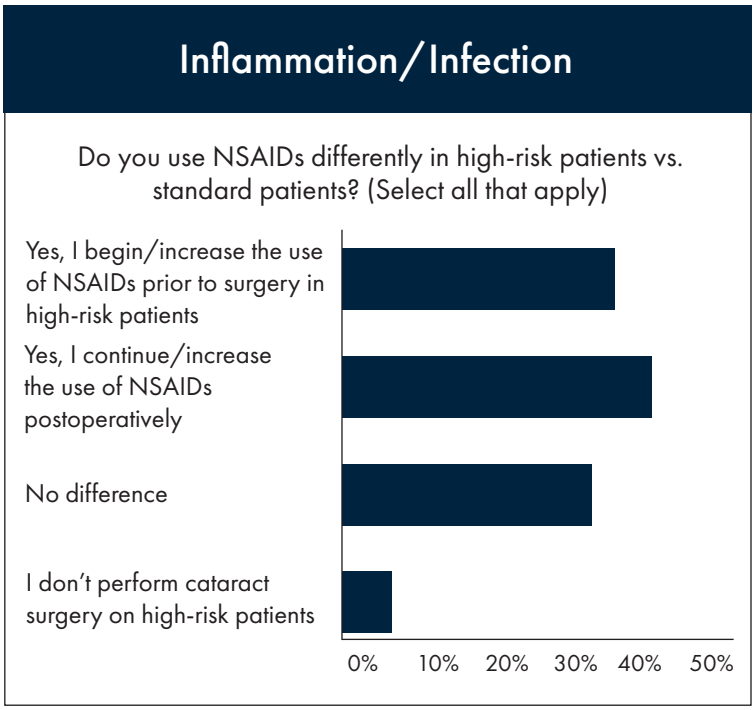

Figure 1. Responses from the 2018 ASCRS Clinical Survey showing NSAID practices for high-risk patients vs. standard patients.

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Educational Objectives
- Compare and contrast current and emerging regimens and pharmaceutical approaches for the prevention of pain and inflammation in cataract surgery, including alternative therapeutic options designed to overcome patient compliance concerns and reduce ocular toxicity:
  - Advanced topical medications
  - Intracameral medications
  - Sustained-release technologies
- Determine adjustments needed to pre-, intra-, and postoperative steroid and NSAID regimens for patients at greater risk for inflammation
- Discuss cataract patients' perceptions of intra- and postoperative pain and the impact that it has on surgical outcomes and patient satisfaction
- Describe evolving reimbursement models to expand access to new approaches to control pain and inflammation after cataract surgery

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The impact of pain and inflammation

By Edward Holland, MD

Edward Holland, MD

Pain is the most common adverse event associated with cataract surgeries. A clinical study of 306 patients measuring pain and satisfaction immediately after cataract surgery showed that 37% had mild to moderate pain and 34% required oral medications to manage it.[1,2] Postop pain was the most significant predictor of patient dissatisfaction and was associated with low surgical experience quality ratings.

The most common cause of decreased visual acuity after cataract surgery is cystoid macular edema (CME). Patients with postop inflammation have a higher risk of corneal edema. Risk factors for CME include diabetes or other autoimmune disorders, inflammatory conditions, glaucoma, intraoperative floppy iris syndrome, and retinal vascular disease. Complex cases with longer ultrasound and irrigation times and surgical complications are associated with an increased risk of inflammation.

Unmet need

Traditionally, we have managed pain and inflammation with postop eye drops, increasing the dose in patients at risk for inflammation. Topical steroids were convenient and historically inexpensive. Steroids also are direct, noninvasive, and less likely to cause systemic effects. In addition, they provide good coverage, if patients use them.

However, clinical studies have shown that patients do not use 40–50% of prescribed drops.[3] Patients may believe they do not need them, find the drops uncomfortable, or have physical limitations that prevent proper instillation.

In a study evaluating eye drop administration by cataract patients who did not have experience with eye drops, 31% had trouble instilling them and 92% instilled them incorrectly.[4]

New frontier

Novel ideas and innovative solutions are emerging that will offer us new ways to prevent and manage postoperative pain and inflammation.

Approximately 2 decades ago, we had to prescribe 3 drops 4 times a day for 1 month. We have made significant strides in eliminating that regimen. Better drops are being developed with less frequent dosing, as well as combined drops, intraoperative drops and injections, and sustained-release technologies.

Sustained-release drug delivery options need to be easy to place in the eye and remove, tolerable, consistent, and cosmetically invisible but easy to identify. This will be especially important not only for cataract patients, but for patients with chronic eye disease, such as dry eye and glaucoma. ■

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Dr. Holland is director of the Cornea Service at the Cincinnati Eye Institute and professor of ophthalmology at the University of Cincinnati. He can be contacted at eholland@holprovision.com.

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Less than 30% instill anti-inflammatory agents intraoperatively as an injection or by adding it to the irrigating solution (9% always use; 18% sometimes use), and more than a third reported that they will never use these options.

Eighty-six percent are confident or very confident that combining corticosteroids and NSAIDs can reliably treat postoperative inflammation and control pain after routine cataract surgery.

We gathered insights from a panel of experts, who discussed ways to manage pain and inflammation associated with cataract surgery. They shared their experiences with intracameral dexamethasone, a dexamethasone intracanalicular insert, nanotechnology loteprednol, and other treatment options. ■

Reference

1. ASCRS Clinical Survey, 2018.

Dr. Donnenfeld practices with Ophthalmic Consultants of Long Island and Connecticut and is a clinical professor of ophthalmology at New York University and a trustee at Dartmouth Medical School. He can be contacted at ericdonnenfeld@gmail.com.

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Intracameral dexamethasone helps overcome adherence obstacles

By Eric Donnenfeld, MD

Eric Donnenfeld, MD

Patient adherence issues to drop regimens after cataract surgery decrease postop medication efficacy and can adversely impact patients' surgical outcomes.

A newly approved product—a novel, bioabsorbable, intracameral dexamethasone drug delivery suspension—can clear this stumbling block.

Delivery system

I gained experience with this new treatment option through FDA clinical trials.

In the trials and in practice, we found that when you enter at 180 degrees and pull back slowly, the dexamethasone suspension often ends up in the anterior chamber. This is common and not a problem, but it is preferable to place it behind the iris.

We developed a simple technique that is performed after the cataract procedure is completed. It's critical to hydrate the main wound so it does not leak. Wound leaks are a significant problem; when the wound leaks, it draws the dexamethasone suspension out of the eye. It is also important to remove all of the viscoelastic.

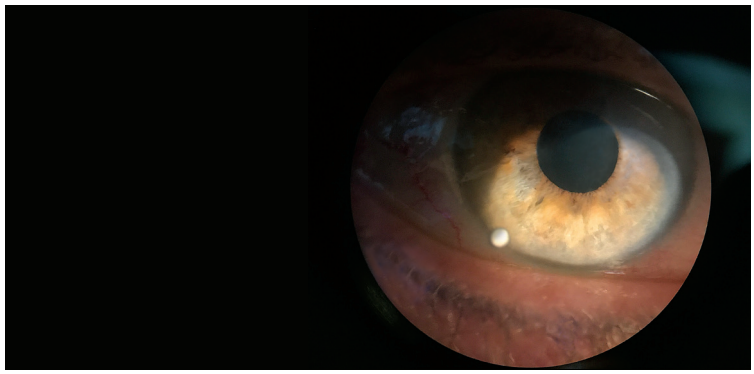
As the second-to-last step in the procedure, we inject intracameral moxifloxacin through the side port incision, filling the anterior chamber. As the final step, we use a 25-gauge cannula, taking a small volume of dexamethasone (0.005 ml), entering through the incision or paracentesis, 120 degrees across, directly behind the iris. It forms a surface tension-based sphere. We rotate it to the side, allowing the bubble of dexamethasone to scrape against the posterior iris, where it is captured and usually stays.

Another successful technique is to place the cannula under the iris as close to the iris root as possible. Then, pull back quickly, leaving the dexamethasone behind.

Whichever technique you choose, place the cannula parallel to the iris and don't gape the corneal wound.

Therapeutic levels are maintained for as long as 21 days with one administration.

In the first clinical trial, we examined two different doses compared with placebo.[1] Both doses showed significant improvement of inflammation. There was not a significant difference between treatment groups in anterior chamber cell and flare, corneal clarity, or endothelial cell counts.



Dexamethasone suspension in the anterior chamber

A subsequent clinical trial compared intracameral dexamethasone with topical prednisolone acetate administered 4 times per day.[2] At day 8, there was no difference in anterior chamber cell clearing between prednisolone acetate 4 times a day vs. intracameral dexamethasone used without corticosteroids.

Patient response

New drug delivery systems are meeting a major unmet need. I estimate that 20% of patients physically cannot use drops. In the intracameral dexamethasone group, 69% of patients agreed that not having eye drops was very convenient.[2]

I am pleased with the dexamethasone intraocular suspension because it guarantees compliance and gives the surgeon control. A surgeon may perform a perfect surgery, but postop complications can occur as a result of nonadherence with a topical regimen. Intracameral dexamethasone allows us to administer a precise dose, avoid systemic absorption and topical toxicity, and overcome obstacles to adherence. ■

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Dr. Donnenfeld practices with Ophthalmic Consultants of Long Island and Connecticut and is a clinical professor of ophthalmology at New York University and a trustee at Dartmouth Medical School. He can be contacted at ericdonnenfeld@gmail.com.

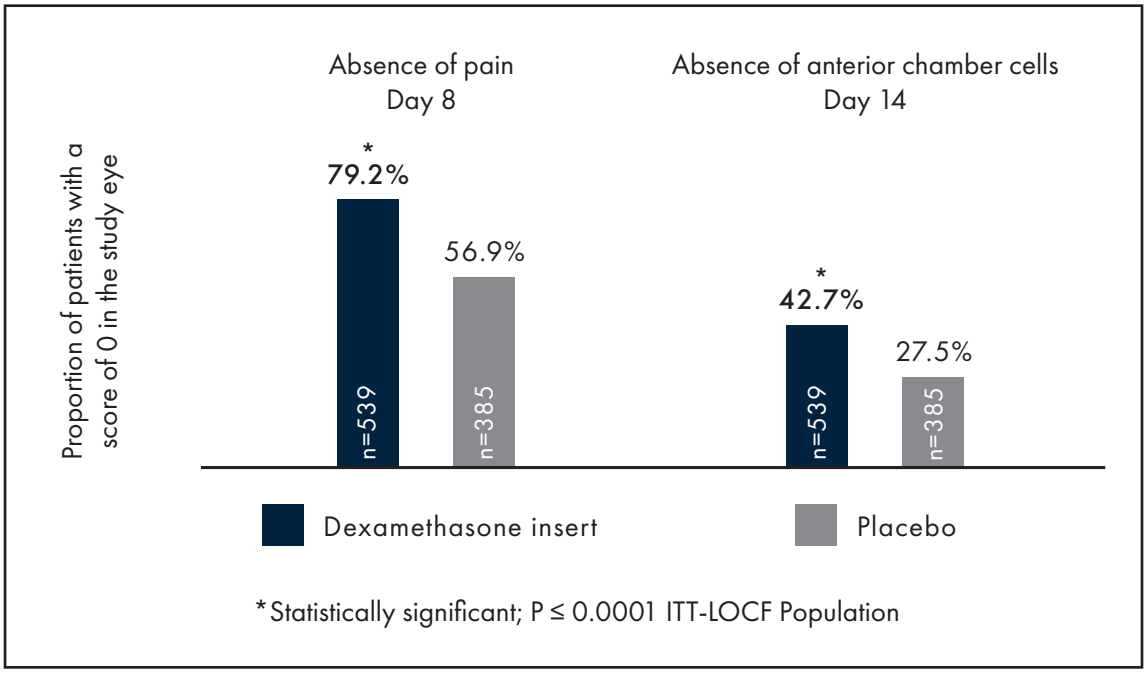
Bridging the gap: Dexamethasone punctal insert

By Alice Epitropoulos, MD

Alice Epitropoulos, MD

In the last several years, we have had multiple advancements in cataract surgery technology. However, until recently, we have had an unmet need for delivering medications to the eye postoperatively.

New drug delivery systems are a major step forward.



Pooled efficacy results from three Phase 3 clinical trials for postop pain and inflammation

Source: Data from Tyson et al.[4]

Overcoming challenges

Patient adherence to topical regimens is poor, but the new dexamethasone intracanalicular insert is an innovative route of administration and one of the surgeon-controlled solutions we can offer our patients. The insert is a corticosteroid indicated to treat postop pain and inflammation after ocular surgery, reducing patient error and nonadherence.

It delivers a tapered dose of dexamethasone over a period up to 30 days; investigators rated it as easy to insert; and it resorbs following treatment.[1–3] Furthermore, it is conjugated with fluorescein to assist in visualization.

This drug delivery system is preservative-free and the punctal occlusion provided by the insert may also benefit patients with dry eye.

Three Phase 3 prospective, randomized, double-masked, vehicle-controlled trials evaluated the safety and efficacy of the dexamethasone insert in 926 patients having cataract surgery.[3,4]

In each Phase 3 study, more patients treated with the insert were pain-free at day 8 and had absent anterior chamber cells at day 14 vs. placebo. In one trial, the difference of absent anterior chamber cells at day 14 vs. placebo was not statistically significant.

The dexamethasone insert received FDA approval in November 2018 for the treatment of ocular pain following ophthalmic surgery. In June 2019, the FDA approved a supplemental New Drug Application with the addition of treatment of ocular inflammation to its indication.

All three trials showed the device was safe and well tolerated, with a low incidence of increased intraocular pressure.

Patients reported highly favorable outcomes in comfort, convenience, and satisfaction.[5]

Conclusion

Innovative drug delivery systems will improve patient compliance and reduce ocular toxicity. Manufacturers are working on additional technologies to eliminate nonadherence and treat other conditions. ■

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Targeted drug delivery: Nanotechnology loteprednol

By Edward Holland, MD

Edward Holland, MD

	Inflammation		Pain	
	Loteprednol (%)	Vehicle (%)	Loteprednol (%)	Vehicle (%)
Day 4			43	25
Day 8	24	13	56	36
Day 15	50	27	69	48

Percentage of patients with complete resolution of anterior chamber cells and pain

The development of better eye drops that can be administered less frequently may help reduce therapy adherence challenges. Not only could this help our postop patients but also those with chronic ophthalmic conditions.

One strategy has been the formulation of mucus-penetrating particle nanotechnology, which was applied to loteprednol.

Twice-daily dosing

Nanotechnology loteprednol etabonate suspension 1%, which was approved by the FDA in 2018, is the first twice-daily corticosteroid for postop pain and inflammation. It was developed based on the concept that smaller particles penetrate more effectively and can potentially reduce the drug concentration.

Traditional suspension eye drops become trapped in the mucus layer, the defense system of the ocular surface, which prevents penetration of the drug. However, mucus-penetrating particles pass through the mucus layer without disrupting it, resulting in better penetration and higher drug concentrations.

In two multicenter, randomized clinical trials for FDA approval, at days 8 and 15, nanotechnology loteprednol significantly resolved pain and inflammation compared with the vehicle.[1]

Resolution of pain to grade 0 was 43% on day 4, 56% on day 8, and 69% on day 15. Most cataract surgeons add a nonsteroidal anti-inflammatory, which is quite effective.

We also need to know whether increasing the drug penetration will worsen side effects. However, loteprednol is a very good molecule and the only available ester steroid. Ester steroids usually do not increase IOP like ketone steroids do. This clinical trial showed that there was no significant difference in side effects compared with the control.

Conclusion

I believe better formulations, muco-adhesive technology, muco-penetrating particles, smaller drug particle size, and sustained-release technology will play an important role in managing pain postop with fewer drops. This strategy also would be beneficial in treating chronic diseases such as dry eye and glaucoma. ■

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Dr. Holland is director of the Cornea Service at the Cincinnati Eye Institute and professor of Ophthalmology at the University of Cincinnati. He can be contacted at eholland@holprovision.com.

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Dr. Epitropoulos is clinical assistant professor at The Ohio State University Wexner Medical Center, co-founder of the Eye Center of Columbus, and partner at Ophthalmic Surgeons & Consultants of Ohio. She can be contacted at aepitrop@columbus.rr.com.

Intracameral ketorolac/phenylephrine improves surgical experience

By Denise Visco, MD, MBA

Denise Visco, MD, MBA

To minimize postop topical eye drops, I take a number of approaches, but intracameral phenylephrine 1.0%/ketorolac 0.3% has had significant benefits for my patients. I actually do not use topical or injected steroids.

Clinical evidence

Intracameral phenylephrine/ketorolac, which is added to the irrigating solution during cataract surgery, maintains iris tone during cataract surgery, prevents intraoperative floppy iris syndrome, maintains pupil dilation better than epinephrine, and decreases surgical complications.[1,2] An additional indication is that it reduces pain.

In research by Hovanesian et al., 7% of patients in whom this formulation was used vs. 14% of patients receiving placebo reported moderate or severe pain.[3] It also significantly decreased the use of narcotics at the time of cataract surgery.

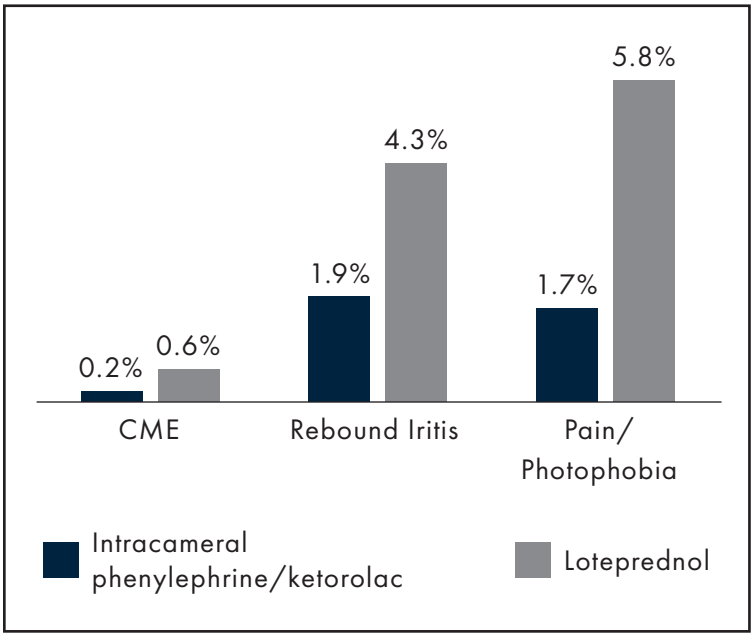
Most intraoperative approaches for mydriasis and pain use off-label applications or compounded medications. I prefer not to use compounded medications because of potential risks.

Retrospective investigation

Taking a look at patients' surgical experience, we retrospectively reviewed pain and inflammation in 2,277 eyes in our practice that had cataract surgery. A topical nonsteroidal anti-inflammatory was used 2 days before surgery and 10 weeks postop in all patients. Group 1 received intracameral phenylephrine/ketorolac, whereas Group 2 received a 4-week tapered dose of loteprednol.

Patients in Group 1 had less pain and photophobia, half the incidence of rebound iritis, and one-third the incidence of cystoid macular edema (CME) compared with Group 2. I did not expect to see such a significant difference. In fact, when we began using intracameral phenylephrine/ketorolac instead of the topical steroid with our regimen, I expected I could have more problems, not less.

In addition, by switching to intracameral phenylephrine/ketorolac, we eliminated 196 drops per eye.



Patient experience with intracameral phenylephrine/ketorolac vs. topical loteprednol for 4 weeks

Conclusion

In my practice, intracameral phenylephrine/ketorolac has resulted in a better patient experience, with less pain, and it has reduced the need for analgesics. In addition, patients have better vision on postop day 1 and we use fewer drops after surgery.

All of these benefits indicate that intracameral phenylephrine/ketorolac is good for the surgeon and good for the patient. ■

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Dr. Visco is medical director and founder of Eyes of York Cataract & Laser Center in York, Pennsylvania. She can be contacted at dvisco@eyesofyork.com.

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Compounded combination therapies streamline topical drop regimens

By William Wiley, MD

William Wiley, MD

Prescription eye drops are a significant source of frustration for cataract surgery patients. Using multiple medications on different dosing schedules can be confusing, and they must cope with the expense and trips to the pharmacy.

To streamline the process, we began using a compounded formulation. As a result, our patients usually need to instill only 1 drop per day.

Searching for better options

When we began looking for simpler alternatives to traditional eye drop regimens, we injected a compounded formulation of triamcinolone and moxifloxacin into the vitreous. It worked well but lasted only 2 weeks and originally did not contain an NSAID. We were not sure how long the antibiotic lasted, but it did prevent endophthalmitis. Inflammation occurred postop in some patients, who needed to return to using drops. There was also a 2% risk of cystoid macular edema (CME).

To prevent postop inflammation, we placed the steroid sub-tenons, where it lasted 4 to 6 weeks. It did not cause floaters, and postop inflammation or rebound did not occur.

Bromfenac virtually eliminates CME, so we added it to our regimen, along with prednisolone and gatifloxacin to address potential abrasions, limbal relaxing incisions, or other conditions that could arise.[1]

We worked with a compounding pharmacy to create this formulation of prednisolone acetate 1%, gatifloxacin 0.5%, and bromfenac 0.075%. We can prescribe compounded medications from a compounding pharmacy following strict requirements under section 503B by the FDA and the Federal Food, Drug and Cosmetic Act. We bulk order the drops and provide them so patients do not need to visit the pharmacy.

It can be tapered or used with a bolus of steroid elsewhere. If we use dexamethasone intraocular suspension plus this drop, the dexamethasone ophthalmic insert in the lower punctum with this drop, or sub-tenons triamcinolone/moxifloxacin, patients need to instill only one drop of this compound per day.

The compounded drop has had a favorable safety record. We have used this technique in 4,000 eyes, virtually eliminating endophthalmitis, reducing postop inflammation, and significantly reducing CME. ■

Conclusion

The triple combination drop allows once-daily dosing, if used in combination with a steroid and virtually eliminates CME and endophthalmitis.

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Dr. Wiley is medical director of the Cleveland Eye Clinic. He can be contacted at drwiley@clevelandeyeclinic.com.

Previous dosing schedule		Fewer drops		Fewer drops plus sub-tenons	
Steroid	4 times a day, taper down to once a day over 30 days	1 bottle of triple drop	Week 1: 4 drops per day. Week 2: 3 drops per day. Week 3: 2 drops per day. Week 4: 1 drop per day	1 bottle of triple drop	Week 1–4 1 drop per day
Antibiotic	4 times a day for 10 days				
NSAID	1 time a day for 30 days				

IMPROVING THE CATARACT PATIENT EXPERIENCE:

Minimizing pain and inflammation while reducing the need for topical drops

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CME questions (circle the correct answer)

1. Which of the following are risk factors of cystoid macular edema?
a. Diabetes
b. Glaucoma
c. Intraoperative floppy iris syndrome
d. All of the above

2. What is the preferred location for dexamethasone suspension?
a. In the anterior chamber
b. Behind the iris
c. In the posterior chamber
d. In front of the iris

3. Which of the following is true of dexamethasone intracanalicular inserts?
a. It delivers a tapered dose over 30 days.
b. It resorbs following treatment.
c. It is conjugated with fluorescein.
d. All of the above

4. Which of the following is an advantage of mucus-penetrating particle (MPP) technology?
a. The smaller particles penetrate the mucus layer more effectively.
b. MPP technology may result in higher drug concentrations.
c. MPP technology may help reduce patient adherence challenges.
d. All of the above

5. Which of the following is true of intracameral phenylephrine/ketorolac?
a. It results in a worse patient experience.
b. It results in more pain.
c. It reduces the need for analgesics.
d. It results in more drops after surgery.

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