September/October 2025

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CONSENSUS PANEL HIGHLIGHTS:

Pharmacotherapy for Presbyopia and Considerations for the Posterior Segment

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Distributed with RT Retina Today MODERNOPTOMETRY

Release Date: September 2025
CME/COPE Expiration Date: October 31, 2026

CONSENSUS PANEL HIGHLIGHTS: Pharmacotherapy for Presbyopia and Considerations for the Posterior Segment

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Content Source

This continuing education (CE/CME) activity captures content from a closed panel discussion.

Activity Description

This supplement summarizes a panel discussion among optometrists and retina specialists who convened to discuss the expanding armamentarium of presbyopia-correcting eye drops and establish a set of best practices regarding diagnostic testing, patient candidacy, and follow-up regimens.

Target Audience

This certified CE/CME activity is designed for optometrists and retina specialists.

Learning Objectives

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

- **Explain** how presbyopia-correcting drops improve near visual acuity and affect functional vision
- **Review** clinical trial and real-world safety data for presbyopia-correcting drops, with a focus on the risk of vitreoretinal complications
- **Describe** clinical tests that may be useful to examine patients considering presbyopia-correcting drops
- **Assess** patient candidacy for presbyopia-correcting drops based on ocular anatomy, ocular history, and lifestyle
- **Collaborate** with optometry colleagues to devise follow-up regimens and provide patient education for those being treated with presbyopia-correcting drops

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Course # 99035-TD
Activity #131144

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PRETEST QUESTIONS

Please complete prior to accessing the material and submit with Posttest/Activity Evaluation/Satisfaction Measures for credit.

1. Please rate your confidence in your ability to execute collaborative strategies with the appropriate eye care provider for patients treated with presbyopia-correcting drops (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. A 48-year-old patient reports difficulty reading menus in dim lighting but prefers not to wear reading glasses. You prescribe a presbyopia-correcting eye drop. Which of the following best explains how this treatment improves her near visual acuity?

a. Increases accommodation by stimulating the ciliary muscle
b. Constricts the pupil to increase depth of field
c. Relaxes the lens to reduce refractive error
d. Shifts the focal point anteriorly to enhance convergence

3. Which of the following statements best reflects current evidence regarding the risk of retinal complications with pilocarpine-based presbyopia-correcting drops?

a. Clinical trials for 1.25% and 0.4% pilocarpine-based drops demonstrated a measurable increase in vitreoretinal traction events in phakic patients
b. Retinal adverse events were observed in real-world postmarketing data for 0.4% pilocarpine but not in clinical trials
c. No retinal adverse events were reported in phase 3 trials of 1.25% or 0.4% pilocarpine-based drops, though high-risk patients were excluded
d. The FDA Adverse Event Reporting System confirmed a 2% retinal detachment rate in the first year of 1.25% pilocarpine drop use

4. A 51-year-old with a history of LASIK presents to your clinic requesting presbyopia-correcting drops. He is currently plano with no symptoms and uncertain of his original refractive error. Which of the following tests would best inform your decision to prescribe treatment?

a. Refraction under cycloplegia
b. Corneal topography
c. Dilated fundus examination
d. Visual field testing

5. A 45-year-old man with a history of nasal squamous cell carcinoma and skin grafting presents with progressive near vision decline. He has no past ocular history and on examination you note a refraction of BCVA +0.50 sphere OU resulting in 20/15 VA OU. He cannot tolerate glasses due to significant graft-site pain and wants increased spectacle independence. Before prescribing pilocarpine-based presbyopia-correcting drops, which clinical evaluation is most important to assess his candidacy?

a. Widefield retinal photography
b. OCT of the macula
c. Dilated retinal examination
d. Referral to a retina specialist

6. Which of the following findings would most warrant caution before initiating pilocarpine-based presbyopia-correcting drops?

a. Patient aged 46 with no posterior vitreous detachment
b. Peripheral lattice degeneration on dilated fundus exam
c. History of dry eye symptoms and contact lens intolerance
d. Mild headache during previous use of glaucoma eye drops

7. Which patient is most suited to treatment with pilocarpine-based presbyopia-correcting eye drops?

a. A 52-year-old with -7.00 D myopia and bilateral peripheral lattice degeneration noted on dilated exam
b. A 55-year-old with +1.00 D hyperopia and mild dry eye controlled with artificial tears, no prior ocular procedures
c. A 50-year-old with prior LASIK and uncertain myopic history, currently plano with mild posterior vitreous detachment
d. A 48-year-old emmetrope with history of retinal detachment in the left eye, successfully repaired 3 years ago

8. A 52-year-old woman presents 4 months after starting pilocarpine 1.25% drops. She is satisfied with her near vision improvement but reports persistent burning and redness lasting 15 to 20 minutes after each instillation, with no improvement over time. She is motivated to continue treatment but wants to reduce discomfort. Which of the following is the most appropriate next step and counseling approach?

a. Discontinue the pilocarpine drops and advise that persistent irritation may indicate hypersensitivity
b. Recommend switching to pilocarpine 0.4% due to its preservative-free and lubricating formulation
c. Recommend artificial tears immediately after pilocarpine 1.25% instillation for ocular surface relief
d. Continue pilocarpine 1.25% and reassure her that irritation typically improves over time

9. Based on expert consensus and recent real-world data related to pilocarpine-based presbyopia-correcting drops, which of the following best reflects current thinking on follow-up for patients using these drops?

a. A retinal exam should be performed only if symptoms of retinal complications develop
b. Routine retinal imaging should be performed every 3 months in all patients
c. Follow-up frequency should be individualized, with at least annual retinal exams
d. Patients with no pre-existing retinal pathology do not require routine follow-up

10. A 48-year-old patient with early presbyopia presents requesting a nonsurgical option to improve near vision. She is concerned about reading difficulty in dim lighting and occasional glare while driving at night. Which of the following is the most appropriate counseling point when considering pilocarpine-based presbyopia-correcting drops?

a. They may cause temporary night vision difficulties due to pupil constriction
b. They permanently reverse the aging process of the crystalline lens
c. They provide consistent near and distance correction without side effects
d. They are best used in combination with systemic anticholinergics

11. In postmarketing surveillance of pilocarpine 1.25% ophthalmic solution, which patient characteristic has been associated with a potentially increased risk of vitreoretinal complications?

a. Age younger than 35 with no history of ocular disease
b. Myopia, especially moderate to high degrees
c. History of cataract extraction with intraocular lens implantation
d. Hyperopia with normal axial length

Consensus Panel Highlights: Pharmacotherapy for Presbyopia and Considerations for the Posterior Segment

Our patients (and let's be honest, many eye care providers) complain about loss of near vision as they age. As eye care providers, we recognize this phenomenon as presbyopia, defined as the gradual age-related loss of accommodative amplitude in the crystalline lens[1,2]; our patients merely recognize it as yet another inconvenient sign of aging. But presbyopia is not merely an inconvenience: it may cause ocular discomfort, headaches, fatigue while working, and diplopia[3]; and has serious implications for economic productivity.[4]

Some patients have embraced pharmaceutical options for presbyopia, determining that they represent a nonsurgical intervention that frees them from spectacles that are either impractical or lacking cosmetic appeal. Other patients, however, have shied away from pharmaceutical solutions to presbyopia. Some patients may be unsure if they're good candidates, while others may be underwhelmed by the safety or efficacy data their provider communicates to them. Some patients may be good candidates who believe the drug will work safely but still decline treatment for some other reason. Furthermore, there is disagreement among primary eye care providers, who are a major source of prescribing presbyopia-correcting drops, about how often (and whether at all) to refer patients to retina specialists ahead of initiating therapy, and about whether the real-world data show that such drops are safe.

All of this leads to our current reality: that presbyopia-correcting drops have not been embraced as expected,[5] and patients who could potentially benefit from therapy are left on the sidelines.

When patients are referred from primary eye care providers to retina specialists for determination on whether a patient's ocular anatomy is suitable for treatment with a presbyopia-correcting drop, a new lane of conversation is opened between primary eye care and the retina specialist. To further explore this, I chaired a consensus panel comprised of 3 leading optometrists and 2 retina specialists (including myself) to examine areas of agreement and dissent regarding presbyopia-correcting drops.

In this summary of our panel discussion, we also review the safety and efficacy clinical trials that led to the approval of 2 presbyopia-correcting drops; discuss pipeline therapies for presbyopia; summarize the mechanisms of action for various miotic drops; explore how safety may be tied to mechanisms of action; and learn how each panelist would respond to a pair of patient cases. Our discussion has been edited for clarity and brevity.

—Christina Y. Weng, MD, MBA, Program Chair

Dr. Weng: Patients often first report presbyopia to their primary eye care provider. Presbyopia is on the rise: by 2050, an estimated 1.8 billion people will have presbyopia,[6] and nearly half of those patients (866 million) will be forced to navigate vision impairment due to uncorrected presbyopia.[7] Approximately 128 million Americans are presbyopic, and most of these patients are older than 45 years.[8,9] Safe driving, comfort navigating print and handheld digital devices, and other close-vision activities are all adversely affected by presbyopia.

Mark T. Dunbar, OD, FAAO: Presbyopia is not merely a matter of inconvenience: it's a matter of economics. Among those whose presbyopia is under- or uncorrected and are younger than 50 years old or 65 years old, respectively, researchers have estimated that presbyopia is responsible for a loss of $USD 11 billion and $USD 25 billion in annual gross domestic product.[4]

Jaclyn Garlich, OD, FAAO: Spectacles can be an inexpensive and accessible means of addressing presbyopia. However, patients sometimes reject them because they are cosmetically unappealing, are inconvenient, or serve as a social marker for old age. Contact lenses may be a solution for some patients, but they can come with their own set of inconveniences and discomforts.

Patients who wish to address presbyopia without glasses or contact lenses may also reject surgical intervention due to cost or aversion to surgery. Others may simply be ineligible for surgery. Pharmacologic options to address presbyopia may be attractive to those who reject or are ineligible for spectacle and surgical solutions. Presbyopia-correcting drops also work quickly, which matters to some patients, particularly those who have embraced the modern on-demand pace of life.

Mohammad R. Rafieetary, OD, FAAO, FORS, ABO: Many patients have comorbid ocular pathologies that may render the surgical or contact lens bifocal or multifocal technologies less

effective. Presbyopia-correcting drops could be a more effective solution, as long as the patient's pathology does not make them ineligible for said drop.

As someone who practices optometry in a retina specialty clinic, I encounter patients with retinal pathology with concomitant presbyopia. They sometimes hope that all vision issues can be corrected with spectacles or contact lenses; this is especially true after patients see direct-to-consumer advertisements that say presbyopia-correcting drops can address age-related vision disorders. This signals to me that the desire for a nonsurgical solution remains top-of-mind for many patients.

CONSENSUS POINT #1: Presbyopia-correcting drops fulfill an unmet need.

Dr. Weng: **In my clinic, patients with presbyopia or refraction issues sometimes ask me if I can also address nonretina issues. I explain that eye care providers are specialized differently, and that an optometrist is best equipped to help them with refraction. Dr. Eichenbaum, as a retina specialist, do you have a similar experience?**

David A. Eichenbaum, MD: I do. When patients request that I address their presbyopia, I explain that I practice exclusively vitreoretinal specialty care in a retina-only group, and that I have never focused my practice on refraction or vision correction outside of vision improvement related to treating retinal pathology. I emphasize that the primary eye care provider who referred them is the expert to turn to on refraction and presbyopia.

Now that pharmacologic options for presbyopia exist, I have had some patients referred to me for a retinal evaluation to confirm that they are suitable candidates. These patients understand that they'll return to their primary eye care provider for refractive concerns.

PHARMACOLOGIC SOLUTIONS FOR PRESBYOPIA

Dr. Weng: Let's turn to those pharmacologic options, which include different classes of drugs. These can be categorized into parasympathomimetics, muscarinic agonists (including pilocarpine, carbachol, and aceclidine), and sympathomimetics (brimonidine).

Dr. Garlich, you articulated the unmet need. Can you tell us which ocular tissues are targeted by presbyopia-correcting drops?

Dr. Garlich: There are two FDA-approved presbyopia options with different concentrations of pilocarpine: pilocarpine hydrochloride 1.25% and pilocarpine hydrochloride 0.4% (this panel discussion took place before the FDA approval of aceclidine ophthalmic solution 1.44%). They both act on the iris sphincter and modulate the pupil size to initiate miosis. Pilocarpine 0.4% is less than one-third the strength of pilocarpine 1.25%. There is reason to believe that a link exists between lower concentration and increased safety without diminished efficacy. By reducing concentration, the thought is that potentially the effect on the ciliary muscles might be lessened.

The approval of pilocarpine 1.25% was based on the placebo-controlled phase 3 GEMINI 1 and GEMINI 2 clinical trials, which evaluated pilocarpine 1.25% in 750 patients aged 40 to 55 years with presbyopia.[10,11] Drops were administered once daily. Both trials met their primary efficacy endpoints by showing that a significantly greater proportion of patients dosed with pilocarpine 1.25% gained at least 3 lines in mesopic, high-contrast, binocular distance-corrected near visual acuity (DCNVA) at day 30, hour 3, and hour 6 compared with placebo. Notably, patients experienced no loss in mean distance vision. No serious adverse events (SAEs) were reported among treatment patients, and the most common treatment-emergent non-SAEs occurring in the treatment group was headache at 14.9% and conjunctival hyperemia at 5.1%.[12]

In VIRGO, researchers assessed the efficacy of pilocarpine 1.25% dosed twice daily, with the second drop dosed 6 hours after the first, in 230 patients. The study found that significantly more patients in the dosing group demonstrated mesopic DCNVA improvement by at least 3 lines without losing more than 1 line of CDVA at hour 9 (ie, 3 hours after the second dose was administered).[11]

Pilocarpine 0.4% was approved by the FDA for the treatment of presbyopia in October 2023 and has been commercially available since April 2025.[13] Pilocarpine 0.4% leverages a few advantages of its engineering: it uses a preservative-free formulation of a proprietary multifaceted vehicle with a pH of ~6 (which ensures dispensation of an effective dose of pilocarpine)[14] and minimizes the typical side effects related to miotics while maintaining efficacy.[15] FDA approval was based on the NEAR 1 and NEAR 2 studies, which evaluated the safety and efficacy of pilocarpine 0.4% in 613 patients with presbyopia aged 45 to 64 years. Pilocarpine 0.4% was dosed twice daily at an interval of 2 to 3 hours during a 15-day period.[16]

NEAR 1 and NEAR 2 met their primary endpoints, with a significantly higher proportion of pilocarpine 0.4%-treated patients gaining at least 3 lines in mesopic DCNVA without losing 1 or more lines of vision at all time points on day 8. The studies' results also showed significant improvement in mesopic DCNVA up to 8 hours compared with the vehicle group on day 15. Safety data overall were positive. The most common AE was headache at 6.8%, and instillation site pain at 5.8%. No treatment-related SAEs were observed. This means that, even with the lower concentration, pilocarpine 0.4% demonstrated efficacy and a lower side effect profile. The lower headache rate may also be linked to the concentration difference mentioned earlier.

Dr. Eichenbaum: Given that it comprises a lower concentration of pilocarpine, should eye care providers expect a lower

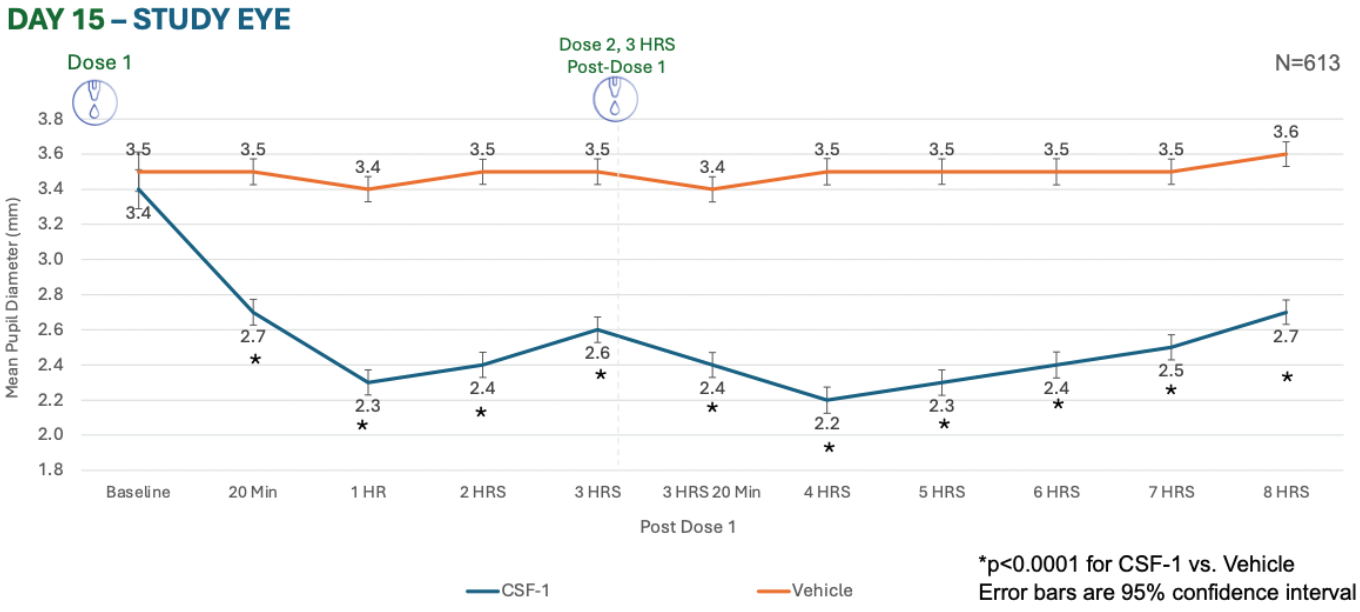


Figure. Pupil size in the NEAR studies dropped from mean 3.4 mm to mean 2.7 mm at 20 minutes postadministration, and pupil size stayed at or below 2.7 for 8 hours thereafter. Eyes dosed with vehicle, meanwhile, remained within 1 mm of baseline, ranging from 3.4 mm to 3.6 mm out to 8 hours.[28]

rate of minor side effects such as headache when using pilocarpine 0.4%?

Dr. Garlich: It's hard to say. I expect both final pupil size and constriction percentage to play a role in a patient's side effect profile. In patients with baseline large pupil, for example, I would expect higher rates of headache than in those with typical pupil size. That said, I do in general expect a lower concentration to be linked with a lower incidence of side effects, but we must acknowledge that there are other factors at play.

Dr. Weng: I think the overarching goal of these trials is to find the minimum concentration of drug that will work effectively and minimize some of those safety issues.

Dr. Dunbar: While the focus of this conversation remains on FDA-approved drugs, we shouldn't forget that pipeline candidates designed to address presbyopia are under investigation. Three such candidates—brimochol (carbachol 2.75%/brimonidine tartrate 0.1%), aceclidine 1.75%, and phentolamine 0.75% have undergone phase 3 studies.[17-20]

Carbachol is a cholinergic agent that, at a 2.75% concentration, is mixed with the alpha-2 adrenergic agonist brimonidine tartrate 0.1% to formulate the combined carbachol 2.75%/brimonidine tartrate 0.1% drop. Carbachol's AEs are balanced by brimonidine, which blocks pupillary dilation via inhibition of alpha-2 adrenergic receptors on the ciliary body.[21] Aceclidine is a parasympathomimetic muscarinic agonist that targets all muscarinic subtypes (compared with pilocarpine, which exhibits selectivity for the M1 and M3 receptor subtypes).[22] Phentolamine 0.75% is a nonselective alpha-adrenergic antagonist drop that inhibits contraction of the iris dilator muscles, without affecting the ciliary muscle. This drug was approved by the FDA in 2023 for the reversal of pharmacologically-induced mydriasis.[23,24] These drugs could be used to create a pinhole effect that leads to improved depth of focus.

Dr. Weng: With all this talk of miosis, it might be useful to circle back to the pinhole effect. Can you educate us on how the pinhole effect results in improved near vision for presbyopic patients?

Dr. Rafieetary: I explain to patients that their eye is like a camera, and that when we make the diaphragm smaller, you

CONSENSUS POINT #2
Not all miotics behave the same way.

CONSENSUS POINT #3
Patient selection is key.

CONSENSUS POINT #4
Patient selection can mitigate risk of retinal complications.

experience better depth of focus.[25] Following instillation of a presbyopia-correcting drop, contraction of the iris leads to pupillary constriction, which in turn increases depth of focus.[26] This may mean that patients trade off depth of focus for decreased field of view, which is something each provider can discuss with their patient ahead of treatment initiation.

Dr. Dunbar: The key for the population seeking presbyopia correction, which is typically between 45 and 60 years old, is finding a pupil size that allows excellent reading vision without limiting distance vision. Research shows that this pupil size is between 2 and 3 mm.[27] The main issue is that there comes a point where, if the pupil is too small, patients experience dimming of vision or reduced visual field.

Clinical trial data from the NEAR studies found that on day 15 of the trial, the average predosing pupil size was 3.4 mm. At 20 minutes after instilling a single drop of pilocarpine 0.4%, mean pupil size decreased to 2.7 mm and consistently stayed between 2.1 and 2.7 mm for up to 8 hours. Note that a second dose was administered 3 hours after the first dose.[28] Among the vehicle arm, mean pupil size was 3.5 mm at baseline and stayed within 0.1 mm of that size for the 8 hours (Figure).

Similarly, in the VIRGO trial (day 14), the vehicle arm showed negligible change in mesopic pupil diameter in the nondominant eye over 9 hours (mean ~4.3 mm), whereas pilocarpine 1.25% significantly reduced pupil diameter at all time points, peaking 1 hour after each drop (~2.2 mm at hour 1 and 7).[11]

PATIENT SELECTION

Dr. Weng: What qualities make a patient a good candidate for presbyopia-correcting drops?

Dr. Garlich: For my patients in my practice, I consider ideal candidates to be motivated patients who want to avoid spectacle and contact lens correction and are aged 42 to 55 years. Additionally, ideal candidates also have no significant ocular histories other than mild refractive error and, obviously, presbyopia.

Dr. Rafieetary: Selecting ideal candidates is as much about selecting patients that fit the symptom and demographic profile as it is about selecting patients who find the value proposition worthwhile.

Dr. Dunbar: Patients with posterior segment conditions such as lattice degeneration, patients with high myopia, and patients with a history of retinal detachment may be at risk for ocular complications when using miotics.

The concentration of pilocarpine is 0.4% is much lower than concentrations used in the past for glaucoma treatment and theoretically should reduce the risk profile.

I want to clarify that pilocarpine 1.25% is within the range of pilocarpine concentrations previously used to treat glaucoma. Still, I would proceed with caution when prescribing presbyopia-correcting drops to a patient with a history of lattice degeneration, high myopia, or retinal detachment. This is why retinal examination is recommended prior to prescribing a miotic for presbyopia.

RETINAL EXAMINATION PRIOR TO INITIATION OF PRESBYOPIA-CORRECTING DROPS

Dr. Weng: We all agree that a retinal examination should be done prior to writing a prescription for an FDA-approved drop to address presbyopia.

Dr. Eichenbaum: The labels for pilocarpine 1.25% and pilocarpine 0.4% contain identical language: "examination of the retina is advised in all patients prior to initiation of therapy."[29,30]

Dr. Weng: The label language about needing a retinal examination is likely linked to parasympathomimetic muscarinic agonists as a class rather than to the specific drugs themselves. I would expect any future FDA options in this class to contain the same language. But who should execute that exam? And to what extent?

Dr. Eichenbaum: In my estimation, primary eye care providers are more than equipped to conduct a sufficient retinal examination to determine if a patient is at increased risk of a retinal complication following initiation of treatment. If an examination in a primary eye care setting shows clear peripheral pathology like, for example, lattice degeneration or a retinal tear, then referral to a retina specialist would probably result in confirmation that the patient is not a good candidate. Other issues that would decrease the likelihood that a patient is a good candidate—including perhaps, reports of recent flashes and floaters associated with a recent posterior vitreous detachment (PVD) or a family or personal history with retinal detachment—can be captured and assessed in a primary care setting.

I think requiring a retina specialist to examine a patient prior to prescribing a presbyopia-correcting drop is a significant barrier to entry for most patients. Most importantly, it would not

CONSENSUS POINT #5
Routine referral to a retina specialist is not required for all patients.

CONSENSUS POINT #6
Patient education is essential.

necessarily improve safety outcomes as long as the primary eye care provider understands the drugs, their risks and benefits, and their labels.

Dr. Weng: I believe it's important, at least right now, that all patients receive a dilated retinal examination or ultra-widefield fundus photographs before commencing therapy to identify potential risk factors. A gradient exists, which is to say that certain patients with risk factors, such as lattice degeneration or atrophic hole, should not receive a parasympathomimetic drug. I think there needs to be patient involvement and risk counseling, but it's also important to remember that, across the board, these trials excluded patients with significant retinal pathology that was noted beforehand.

Dr. Dunbar: There is a perception that presbyopia-correcting drops may lead to retinal complications. This reputation has come, in part, from usage by some patients who either did not undergo a thorough retinal examination, or didn't realize the risks and then experienced retinal detachments (RDs) and other complications.

Prescriptions from providers outside of eye care (eg, aesthetics specialists) could be responsible for poor screening.[5] The large commercial launch of pilocarpine 1.25% was followed by reports of RD and vitreomacular traction (VMT)[31-33]; the label now includes a warning against use in patients with preexisting retinal pathology, as it may lead to RD, and also cautions against using the drug in patients with iritis.[29]

Dr. Weng: What do the real-world safety data tell us?

Dr. Dunbar: Per the FDA Adverse Events Reporting System, 30 cases of RD have been reported through the end of 2022.[34] When you consider that through December 2, 2022, approximately 150,000 prescriptions of pilocarpine 1.25% were filled, this puts the real-world risk of RD at approximately 0.02%.[35] These reports have also shown the cases of floaters (50 cases) and PVD (39 cases) following pilocarpine 1.25% prescription.[34]

Dr. Garlich: PVD in and of itself is not an AE: two-thirds of adults aged 66 to 86 experience PVD. Most PVD events are asymptomatic,[36] but others may include flashes, floaters, and blurred vision. We must closely monitor patients reporting PVD-like symptoms after starting pilocarpine-based presbyopia-correcting drops, as VMT macular pucker, macular hole, vitreopapillary traction, and neovascularization of the optic disc and retina are all possible following PVD.[36]

Importantly, we should note that the presence or absence of a PVD itself does not necessarily preclude a patient from starting therapy with a presbyopia-correcting drop.

Dr. Weng: Do you feel patients need regular monitoring of the retina following initiation of therapy with a presbyopia-correcting drop?

Dr. Rafieetary: This depends on who you ask. To me, if a patient has a history of retinal conditions, no matter how slight, then I believe they require regular monitoring. If they're a new patient on a presbyopia-correcting drop without a history of retinal complications, then I believe monitoring is prudent, but we don't have to be as vigilant because this population is less at risk for events like RD and VMT.

Providers may wish to adjust their monitoring strategies as real-world datasets grow more robust. Paying specific attention to patients with the risk factors outlined is advised and may inform patient selection. A recent real-world study showed that patients who used pilocarpine 1.25% were significantly more likely to experience rhegmatogenous RD at 3, 6, and 12 months compared with patients who did not use pilocarpine 1.25%.[37] Specifically, use of pilocarpine 1.25% was associated with a 3.14-fold increased risk of rhegmatogenous RD, and risk factors included male sex, myopia, vitreous degeneration, lattice degeneration, and pseudophakia.

Regardless, this is an opportunity for optometry to step up to the plate to provide continued care to patients and educate them about the risks and benefits of engaging a new therapy, which is something we already do in contexts outside of presbyopia.

Dr. Dunbar: This brings us to the nuances of the word "monitoring." To some providers, monitoring means conducting a thorough retinal exam during an annual primary eye care visit; to others, monitoring could mean following up several weeks or months after initiation of treatment and then setting a regular schedule that does or does not align with annual ocular examinations.

"I was not practicing when laser-vision correction first arrived on the scene, but I imagine the conversation around the risks and rewards of intervention resembled the conversation we're having today."

– Jaclyn Garlich, OD, FAAO

Dr. Garlich: As much consensus as we have on several topics in this roundtable, I don't expect to find consensus on the definition of monitoring. Eye care providers all have different thresholds for risk tolerance. I, for one, would not prescribe a presbyopia-correcting drop to a patient with any level of retinal pathology, and I would consider annual monitoring aligned with the timing a regular eye care examination to be sufficient among the patients I deem at low risk for complication and, therefore, eligible for therapy.

That doesn't mean someone practicing differently is incorrect. This merely reflects my comfort with the drugs and the data at this time. It also says something about the packed nature of my clinic: I simply cannot afford to schedule more patients for frequent postprescription monitoring visits without adversely affecting the workflow of my clinic.

Dr. Dunbar: We can arm our patients with education and instruct them to follow up with our clinics if they experience flashes, floaters, or any changes in vision, which could be a sign of posterior segment complications. Of course, these symptoms could also be secondary to a PVD and may resolve without significant disruption to vision. But erring on the side of caution is wise, and patients reporting such symptoms to the clinic for examination is a best practice.

Dr. Rafieetary: In addition to educating patients about safety, primary eye care providers should set expectations about side effects and about duration of therapy. Patients who know that the duration of treatment lasts several hours and that instillation of the drop may potentially be associated with headache and instillation site discomfort will feel prepared.

Dr. Eichenbaum: Patients are often as concerned about safety as we are. If a primary eye care provider is on the fence about deeming a patient qualified or disqualified for a presbyopia-correcting drop based on an abnormality detected in the assessment of the posterior segment, refer that patient to your friendly neighborhood retina specialist. We'll be happy to characterize the patient's anatomy and communicate our findings back to the primary eye care provider. A retina specialist can reinforce the value of symptom monitoring to the patient, too, which may drive the message home in certain patient scenarios.

As we all agree, patient selection is key to success with pilocarpine 1.25% or pilocarpine 0.4% or whatever options may come. The risk of retinal complications is lowered, although not eliminated, when patients are carefully selected and, if needed because of anatomy, changes, or other patient-specific issues, regularly monitored.

Dr. Garlich: I was not practicing when laser-vision correction first arrived on the scene, but I imagine the conversation around the risks and rewards of intervention resembled the conversation we're having today. So, we can say that while patients and providers may be especially careful in the earliest stages of commercial availability, we may gain greater comfort with prescribing presbyopia-correcting drops as we learn more about real-world data and patient responses to complication monitoring and self-reporting.

Dr. Weng: That's an astute observation. As retina specialists, we too must take a long view of the role presbyopia-correcting drops will play in retina practice. Right now, our antennae may be up because of the occurrences of RD or other posterior segment events occurring in the real world, but we also must recognize that we know very little about the patients who reported those complications. Did they have an ocular history that put them at increased risk for complication already? Was there something else missed on screening? As we learn more about patients who experience complications, we'll know more about what limiting factors may or may not exist.

CASE 1
STARTING A SUITABLE CANDIDATE ON PRESBYOPIA-CORRECTING DROPS—WHAT DO YOU LOOK FOR?

Dr. Garlich: A 44-year-old woman who dislikes wearing glasses or contact lenses presents to the clinic curious about how she can improve her near vision. She underwent LASIK 10 years ago to correct mild myopia and has had no complications since then.

She works full time in public relations, which means she spends a lot of time in front of a computer screen. She spends half of her week working from home, and the other half working from the office. She is embarrassed that she needs to enlarge fonts on her computer when working from the office and is irritated by the need to constantly take off and put on glasses.

Dilated fundus examination and slit-lamp examination show normal anatomy, and a minimal refractive error for distance vision that she is unbothered by. At this point, she is prescribed pilocarpine 1.25%. She reports satisfaction with its durability: it lasts about 7 hours for her, which is a little shorter than her 8-hour workday. She applies drops immediately upon arriving at work and, by the time she needs to use near vision on her computer, she feels confident. If she feels the need to reapply drops after a few hours, she does so.

She also reports using the drops in social situations. For example, she'll instill them prior to going to dinner with friends so that she can avoid glasses and read the menu at the table without pulling out her phone's flashlight. She reported initial headache following use of the drops but that side effect has since subsided.

Dr. Weng: This patient fits the description of an ideal patient Dr. Garlich discussed earlier. The fact that the duration of action aligns with her needs at work probably means that this patient is overall quite satisfied with her decision to start a presbyopia-correcting drop.

Dr. Garlich: Presbyopia-correcting drops are not covered by insurance plans, so if a patient is willing to absorb out-of-pocket

> *" … I don't believe an asymptomatic or chronic PVD itself is a reason to not prescribe a presbyopia-correcting drop."*
>
> – David A. Eichenbaum, MD

costs, that may be a sign that they're very motivated. And yes, this patient is happy with her results.

Dr. Weng: What if this patient had a -4.00 D preoperative refractive error and a history of LASIK? Would you feel any differently about prescribing either of the pilocarpine-based drops approved by the FDA?

Dr. Garlich: This is where the art of patient conversation comes in. In the case of a patient such as the one you described, I would have a conversation with her about potential side effects and risks of using a pilocarpine-based drop. I would also seek to understand her motivation for using the drop. But overall, I would be comfortable prescribing this patient a presbyopia-correcting drop.

Dr. Dunbar: A retinal examination could prove useful for a patient on the younger end of the spectrum, as it could tell us whether a PVD exists. I'd be interested to hear from the retina specialists about whether such information is valuable or merely satisfies our clinical curiosity.

Dr. Eichenbaum: Retinal imaging may be useful when evaluating some patients, but overall, I'd say that unless concerning pathology shows up during the primary eye care provider's dilated retinal examination, most patients without tractional symptoms like flashes and floaters don't need to undergo fundus photography or optical coherence tomography (OCT) imaging in a retina specialist's office. OCT may show you if the patient has experienced a PVD, but even then, I don't believe an asymptomatic or chronic PVD itself is a reason to not prescribe a presbyopia-correcting drop.

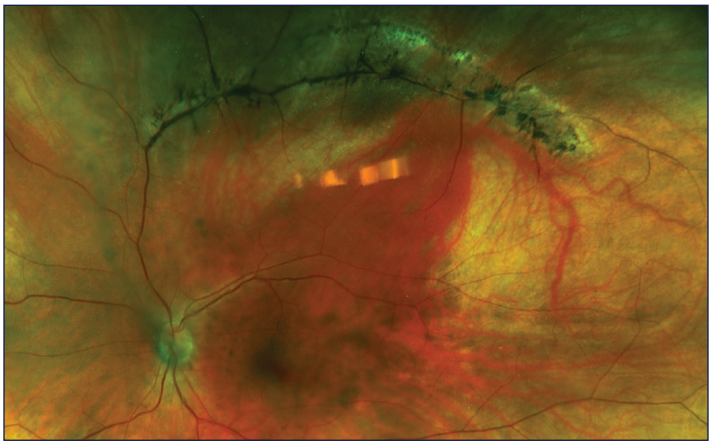
Still, let's remember that patients at a potentially higher risk of developing complications because of diagnoses made during the dilated exam, or patients especially anxious about the risk of retinal detachment, are worthy of a retina specialist examination. In those instances, OCT and other imaging could be informative or educational.

CASE 2
A 42-YEAR-OLD PATIENT WITH A HISTORY OF REFRACTIVE AND RETINAL SURGERY—WHAT DIRECTION WOULD YOU TAKE?

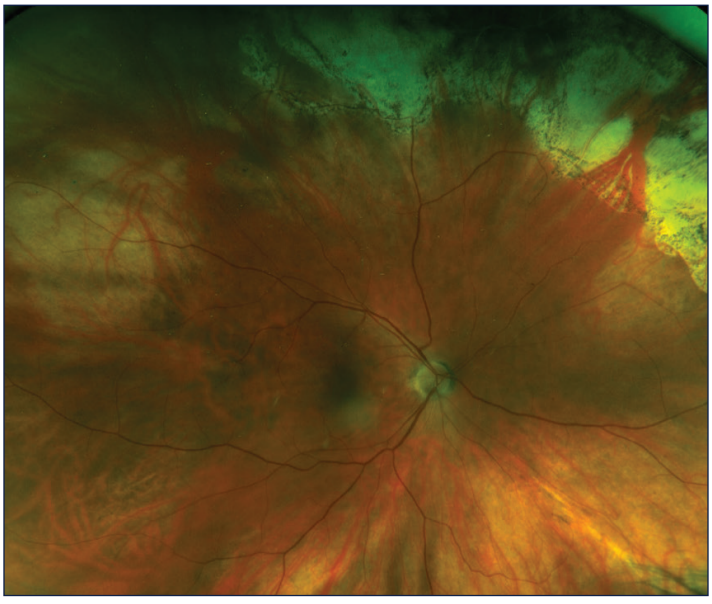
Dr. Rafieetary: A 42-year-old woman presents to a clinic with no significant medical history. She's curious about the eye drops that she heard will improve her reading vision, as she doesn't want to wear glasses. Her ocular history includes LASIK surgery 20 years ago, RD 5 years ago in her left eye (which was successfully repaired), and uneventful cataract surgery 3 years ago.

She does not recall her pre-LASIK refraction, only remembers use of gas bubble after RD surgery, and has nothing to say about her cataract surgery. She reports that she failed to schedule follow-up appointments following some of her surgeries, which she says is due to her busy life.

Color fundus photography and a slit-lamp examination revealed a normal disc and macula in both eyes (Figures 1 and 2). Her left eye showed evidence of laser photocoagulation, presumably used during surgery to correct her RD. Her right eye showed prevascular lattice along the superior and temporal vessels.



CASE 2: Figure 1. The patient's left eye shows a normal disc and macula. Prevascular lattice is noted along the superior temporal vessels.



CASE 2: Figure 2. In the right eye, the patient has a normal disc and macula, evidence of laser is noted superiorly indicating previous surgical intervention.

How would you begin to have a conversation with this patient about the possibility of starting therapy on a presbyopia-correcting drop?

Dr. Eichenbaum: This patient already has a history of unilateral RD. It's great that it was repaired—but I would be worried that a pilocarpine-based drop, even one with a low concentration of pilocarpine, could contribute to an RD in the other eye, especially if the patient has not yet had a PVD in her unoperated eye. I would start talking to the patient about spectacle correction.

Dr. Garlich: Generally, patients who have had an RD do not find this to be an enjoyable experience and are, therefore, averse to anything that might create a retinal risk. I would educate this patient about the risk of recurrent RD with or without using a presbyopia-correcting drop given her history with RD.

CONCLUSION

Dr. Weng: This panel discussion and consensus points are insightful, and they may evolve over time. If patients adopt presbyopia-correcting drops after undergoing an appropriately thorough retinal examination, then there's good reason to believe that patients will reap the benefits of this technology with predictable side effects and an overall safe experience.

As more patients in real-world settings adopt pilocarpine-based drops to address presbyopia, we will have greater insights into how patients of various anatomies respond to drop therapy. And of course, the more conversations there are between retina and primary care, the better we can collaborate for the sake of our patients. ■

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POSTTEST QUESTIONS

Please complete at the conclusion of the program.

1. Based on this activity, please rate your confidence in your ability to execute collaborative strategies with the appropriate eye care provider for patients treated with presbyopia-correcting drops (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. A 48-year-old patient reports difficulty reading menus in dim lighting but prefers not to wear reading glasses. You prescribe a presbyopia-correcting eye drop. Which of the following best explains how this treatment improves her near visual acuity?

a. Increases accommodation by stimulating the ciliary muscle
b. Constricts the pupil to increase depth of field
c. Relaxes the lens to reduce refractive error
d. Shifts the focal point anteriorly to enhance convergence

3. Which of the following statements best reflects current evidence regarding the risk of retinal complications with pilocarpine-based presbyopia-correcting drops?

a. Clinical trials for 1.25% and 0.4% pilocarpine-based drops demonstrated a measurable increase in vitreoretinal traction events in phakic patients
b. Retinal adverse events were observed in real-world postmarketing data for 0.4% pilocarpine but not in clinical trials
c. No retinal adverse events were reported in phase 3 trials of 1.25% or 0.4% pilocarpine-based drops, though high-risk patients were excluded
d. The FDA Adverse Event Reporting System confirmed a 2% retinal detachment rate in the first year of 1.25% pilocarpine drop use

4. A 51-year-old with a history of LASIK presents to your clinic requesting presbyopia-correcting drops. He is currently plano with no symptoms and uncertain of his original refractive error. Which of the following tests would best inform your decision to prescribe treatment?

a. Refraction under cycloplegia
b. Corneal topography
c. Dilated fundus examination
d. Visual field testing

5. A 45-year-old man with a history of nasal squamous cell carcinoma and skin grafting presents with progressive near vision decline. He has no past ocular history and on examination you note a refraction of BCVA +0.50 sphere OU resulting in 20/15 VA OU. He cannot tolerate glasses due to significant graft-site pain and wants increased spectacle independence. Before prescribing pilocarpine-based presbyopia-correcting drops, which clinical evaluation is most important to assess his candidacy?

a. Widefield retinal photography
b. OCT of the macula
c. Dilated retinal examination
d. Referral to a retina specialist

6. Which of the following findings would most warrant caution before initiating pilocarpine-based presbyopia-correcting drops?

a. Patient aged 46 with no posterior vitreous detachment
b. Peripheral lattice degeneration on dilated fundus exam
c. History of dry eye symptoms and contact lens intolerance
d. Mild headache during previous use of glaucoma eye drops

7. Which patient is most suited to treatment with pilocarpine-based presbyopia-correcting eye drops?

a. A 52-year-old with -7.00 D myopia and bilateral peripheral lattice degeneration noted on dilated exam
b. A 55-year-old with +1.00 D hyperopia and mild dry eye controlled with artificial tears, no prior ocular procedures
c. A 50-year-old with prior LASIK and uncertain myopic history, currently plano with mild posterior vitreous detachment
d. A 48-year-old emmetrope with history of retinal detachment in the left eye, successfully repaired 3 years ago

8. A 52-year-old woman presents 4 months after starting pilocarpine 1.25% drops. She is satisfied with her near vision improvement but reports persistent burning and redness lasting 15 to 20 minutes after each instillation, with no improvement over time. She is motivated to continue treatment but wants to reduce discomfort. Which of the following is the most appropriate next step and counseling approach?

a. Discontinue the pilocarpine drops and advise that persistent irritation may indicate hypersensitivity
b. Recommend switching to pilocarpine 0.4% due to its preservative-free and lubricating formulation
c. Recommend artificial tears immediately after pilocarpine 1.25% instillation for ocular surface relief
d. Continue pilocarpine 1.25% and reassure her that irritation typically improves over time

9. Based on expert consensus and recent real-world data related to pilocarpine-based presbyopia-correcting drops, which of the following best reflects current thinking on follow-up for patients using these drops?

a. A retinal exam should be performed only if symptoms of retinal complications develop
b. Routine retinal imaging should be performed every 3 months in all patients
c. Follow-up frequency should be individualized, with at least annual retinal exams
d. Patients with no pre-existing retinal pathology do not require routine follow-up

10. A 48-year-old patient with early presbyopia presents requesting a nonsurgical option to improve near vision. She is concerned about reading difficulty in dim lighting and occasional glare while driving at night. Which of the following is the most appropriate counseling point when considering pilocarpine-based presbyopia-correcting drops?

a. They may cause temporary night vision difficulties due to pupil constriction
b. They permanently reverse the aging process of the crystalline lens
c. They provide consistent near and distance correction without side effects
d. They are best used in combination with systemic anticholinergics

11. In postmarketing surveillance of pilocarpine 1.25% ophthalmic solution, which patient characteristic has been associated with a potentially increased risk of vitreoretinal complications?

a. Age younger than 35 with no history of ocular disease
b. Myopia, especially moderate to high degrees
c. History of cataract extraction with intraocular lens implantation
d. Hyperopia with normal axial length

Consensus Panel Highlights: Pharmacotherapy for Presbyopia and Considerations for the Posterior Segment

Release Date: September 2025
CME/COPE Expiration Date: October 31, 2026

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Your responses to the questions below will help us evaluate this activity. They will provide us with evidence that improvements were made in patient care as a result of this activity.

1. Years in practice:
☐ <1 ☐ 1–5 ☐ 6–10 ☐ 11–15 ☐ >15

2. Primary practice setting:
☐ Academic hospital ☐ Community hospital ☐ Private practice ☐ Outpatient facility ☐ Government ☐ Other:

3. How confident are you in applying the information from this activity to clinical decision-making/practice? 5 = High, 1 = low
☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1

4. How much of this content is new to you?
☐ <25%
☐ 25%–50%
☐ 51%–75%
☐ 76%–100%

5. How do you rate your knowledge/skills before and after participating in the program?

	High Low
Rate your knowledge/skill level before participating in this course.	5 4 3 2 1
Rate your knowledge/skill level after participating in this course.	5 4 3 2 1
What is the probability of making a change in your practice as a result of this activity?	5 4 3 2 1

6. I'm applying some or all of the knowledge and skills gained from this activity in my practice.
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7. Please select the extent to which you agree/disagree with the following:	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
I am satisfied overall with the activity (ie, design/content)	5	4	3	2	1
I would recommend this program to my colleagues	5	4	3	2	1

8. Please indicate the extent to which you agree that the activity/faculty supported the achievement of the learning objectives:					
Explain how presbyopia-correcting drops improve near visual acuity and affect functional vision)	5	4	3	2	1
Review clinical trial and real-world safety data for presbyopia-correcting drops, with a focus on the risk of vitreoretinal complications	5	4	3	2	1
Describe clinical tests that may be useful to examine patients considering presbyopia-correcting drops	5	4	3	2	1
Assess patient candidacy for presbyopia-correcting drops based on ocular anatomy, ocular history, and lifestyle	5	4	3	2	1
Collaborate with optometry colleagues to devise follow-up regimens and provide patient education for those being treated with presbyopia-correcting drops	5	4	3	2	1

9. As a result of participating in this activity, I anticipate my practice will be improved in the following areas (select all that apply):
   - ☐ Assessment
   - ☐ Differential diagnosis/diagnostic testing
   - ☐ Treatment
   - ☐ Patient education
   - ☐ Shared decision-making
   - ☐ Team-based care
   - ☐ Interpersonal communication
   - ☐ Adoption of new therapy
   - ☐ Adoption of updated or new guidelines
   - ☐ Enrollment of patients in clinical trials

10. What barriers might prevent you from implementing changes? (Select all that apply):
    - ☐ Time constraints
    - ☐ Insurance/financial issues
    - ☐ Formulary restrictions
    - ☐ Lack of support from the care team
    - ☐ Lack of patient-assistance programs
    - ☐ Patient compliance issues
    - ☐ Lack of guidelines or consensus
    - ☐ I don't anticipate any barriers to implementing changes

11. What changes did you make in your clinical practice due to this activity? (select all that apply):
    - ☐ Modify diagnostic approach
    - ☐ Initiate new treatment options
    - ☐ Improve patient communication/care
    - ☐ Improve team communication/practice improvement
    - ☐ Address treatment adherence
    - ☐ Other_____

12. How many patients' lives do you think you will impact over the next 30 days based on the knowledge you acquired or that was reinforced by this program?
    - ☐ 0
    - ☐ 1-15
    - ☐ 16-30
    - ☐ 31-50
    - ☐ 51-100
    - ☐ >100

13. The activity demonstrated fair balance.
    - ☐ Yes
    - ☐ No

ACTIVITY EVALUATION

Your responses to the questions below will help us evaluate this activity. They will provide us with evidence that improvements were made in patient care as a result of this activity.

14. Was there any specific patient interaction or clinical moment where this education influenced your approach?_____

15. Can you tell us what other programs/content you would like to see?_____

16. Your feedback is so important and has a direct impact on future education. May we contact you by email with 3 follow-up questions to inquire about the changes you made to your practice as a result of this activity? If yes, please list your email:_____

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