CE Monograph

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Pinning Down Presbyopia

Optimizing Patient Selection and Pharmaceutical Management

Faculty

Paul **Karpecki**, OD, FAAO (Chair)

Selina **McGee**, OD, FAAO

Rishi P. **Singh**, MD, FASRS

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Activity Description and Purpose

Presbyopia causes functional limitations beyond near blur and results in decreased vision-targeted health-related quality of life. Correction of presbyopia can improve health-related quality of life. Pharmacologic options for addressing presbyopia have recently entered clinical practice with the approval of 2 miotic eye drops. This educational activity provides an update on the clinical trials supporting the new pharmacologic approaches as well as clinical insights from experts on selecting and counseling appropriate patients. The desired results of this educational activity are to improve optometrists' ability to appropriately incorporate pharmacologic drops in the management of their patients with presbyopia.

Target Audience

This educational activity is intended for optometrists.

Learning Objectives

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

- Review clinical efficacy and safety data of approved miotics to treat presbyopia
- List characteristics that would indicate a patient is an appropriate or inappropriate candidate for pharmacologic treatments for presbyopia
- Obtain retinal examinations for all patient candidates for pharmacologic treatments for presbyopia
- Apply evidence to appropriately use pharmacologic treatments for presbyopia in a variety of patients

Accreditation Statement

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Faculty

Paul Karpecki, OD, is a consultant for AbbVie Inc, AdOM Optical Technologies Ltd, AesculaTech*, AI Optics, Alcon, Aldeyra Therapeutics, Aramis Biosciences, Atlas Medical GmbH, Aurion Biotechnologies*, Azura Ophthalmics, Barti, Bausch & Lomb Incorporated, Bio-Tissue, BlephEx, Brill Pharma, Bruno Vision, Cambium Bio Limited, Derma Cautery, Dompé US, Inc, Essilor of America, Inc, Eye Cool, Eyenovia, Inc*, Grifols, Harrow, Inc, Hilco Vision, iCare USA Inc, Kala Pharmaceuticals, Lentechs, LKC Technologies, Inc, Lexitas, OASIS Medical, Oculis, OCULUS, Inc, OCuSOFT Inc, Orasis Pharmaceuticals, Rendia, Inc, RxSIGHT, Samsara Vision, Inc, ScienceBased Health, Scope, Sentiss Pharma Pvt Ltd, Sight Sciences, Sun Pharmaceutical Industries, Inc, Surface Pharmaceuticals Inc, Sydnexis Inc, Tarsus Pharmaceuticals, Inc, Théa Pharma Inc, Topcon Medical Systems, Inc, Tracey Technologies, Vial*, ViaLase, Inc, Viatris Inc*, Visus Therapeutics, Vital Tears LLC, WebMD LLC, and Zeiss; is on the speakers bureau for Mallinckrodt; has stock options that have not been exercised in Able Therapeutics, Danelli Ocular Creations LLC, Essential Biologics, Inc, Eyedaptic Inc, Eyedetec Medical, Harrow, Inc, Healthe, Hue.AI, iVeena Delivery Systems, Lubris Biopharma, Neurolens, Omega Ophthalmics, Percept, Regener-Eyes, Signal 12 Inc, Silk Technologies Ltd, SleepTite, Stuart Therapeutics, TearClear*, and TECLens, Inc; has individual stocks in Harrow, Inc; and receives other funding (royalties) from Eye Therapies*.

Selina McGee, OD, is a consultant for AbbVie Inc, Aldeyra Therapeutics, Amgen Inc, Avellino, Bruder Healthcare, Cynosure, Dompé US, Inc, Eyevance, Harrow, Inc, Kala Pharmaceuticals, Lumenis, Novartis Pharmaceuticals Corporation, Ocuphire Pharma, Optovue, Inc, Oyster Point Pharma, Inc, RVL Pharmaceuticals, Inc, ScienceBased Health, Sun Pharmaceutical Industries, Inc, Tarsus Pharmaceuticals, Inc, Théa Pharma Inc, Topcon Medical Systems, Inc, Trukera, Versant Ventures, and Zeiss; and is on the speakers bureau for AbbVie Inc, Bausch & Lomb Incorporated, Cynosure, Dompé US, Inc, Lumenis, Optovue, Inc, Oyster Point Pharma, Inc, and Tarsus Pharmaceuticals, Inc.

Rishi P. Singh, MD, is a consultant for Alcon, Apellis Pharmaceuticals, Astellas Pharma Inc, Bausch & Lomb Incorporated, EyePoint Pharmaceuticals, Genentech, Inc, Regeneron Pharmaceuticals, Inc, Regenxbio Inc, and Zeiss; and is a contracted researcher for Janssen Pharmaceuticals, Inc.

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Pinning Down Presbyopia

Optimizing Patient Selection and Pharmaceutical Management

Faculty

Paul Karpecki, OD, FAAO (Chair)
Director, Cornea and
External Disease
Kentucky Eye Institute
Lexington, Kentucky
Associate Professor
University of Pikeville
School of Optometry
Pikeville, Kentucky

Selina McGee, OD, FAAO
Visionary Founder and CEO
BeSpoke Vision
Edmond, Oklahoma
Adjunct Faculty
Northeastern State University
Oklahoma College of Optometry
Tahlequah, Oklahoma

Rishi P. Singh, MD, FASRS
Vice President and
Chief Medical Officer
Martin North and South Hospitals
Professor of Ophthalmology
Cleveland Clinic
Lerner College of Medicine
Cleveland Clinic Martin Health
Stuart, Florida

Introduction to Presbyopia

Paul Karpecki, OD, FAAO

Presbyopia is an age–related, progressive loss of accommodation, leading to an inability to focus clearly on objects at near and intermediate distances.[1] Debate continues on the mechanism for presbyopia development, but a prevailing idea posits that the condition results from increased stiffness of the lens nucleus, leaving the lens unable to change shape in response to ciliary muscle contraction.

Presbyopia typically becomes functionally significant at approximately age 40 and affects approximately 80% of individuals aged 45 to 55 years.[2–4] Recent data estimate that presbyopia affects more than 1.8 billion people globally, including approximately 128 million people in the United States; the number of affected people is expected to increase coincident with growth of the aging population.[5,6]

The functional limitations of presbyopia, including difficulty with reading, engaging in hobbies, using mobile devices, and working at a computer, can negatively impact quality of life.[7–9] In 1 study, 10% of 110 patients with presbyopia indicated willingness to trade at least 5% of their remaining life years to be rid of the condition.[10]

Although there are multiple treatments for presbyopia, conventional modalities carry several limitations. Reading glasses can be inconvenient, easily misplaced, and are disliked by many people who believe these aids make them look old.[11,12] Prescription bifocal/multifocal glasses can be a significant investment and have adverse optical effects.[13] Contact lenses, either multifocal or monofocal lenses fitted for monovision, add a layer of complexity that some patients do not want to manage. These include out–of–pocket expenses, exacerbation of dry eye disease, infection risk, reduction in stereopsis (monovision), and possible tolerability issues.[12,14,15] Surgical options, including laser refractive surgery, corneal inlays, and refractive lens exchange, are invasive and expensive, have a low risk of infection, can result in visual aberrations, may not be reversible, and are not suitable for everyone with presbyopia.[12,16]

Findings of a survey of 20 individuals with presbyopia also highlight the limitations of conventional treatments.[17] Among the participants, 66% were interested in alternatives to reading glasses and approximately 75% said they would prefer a topical drop to eyeglasses, contact lenses, or surgery.

A survey of people with presbyopia found that 66% were interested in alternatives to reading glasses and approximately 75% would prefer a topical drop.

Discussion

Dr Karpecki: We see so many people today trying to do whatever they can to feel and look younger. I think the functional and cosmetic impacts of presbyopia remind people that they are not young anymore.

Are you surprised by the high proportions of patients who seem interested in alternatives to conventional treatment options for presbyopia?

Dr McGee: Each of the conventional options can work well in a particular situation, but none is a one-size-fits-all solution because each has challenges that limit success and patient satisfaction. I am a little surprised by the high level of interest in alternative solutions. Patients are very frustrated with presbyopia. They often do not realize they can use different modalities situationally to help with presbyopia. They typically have been offered eyeglasses, contact lenses, and surgery. Rarely do patients know that a topical drop exists. I am excited to see the data that patients would prefer a topical drop because they might be already comfortable using drops for another indication and consider a drop easier and safer than contact lenses or surgery.[17] The high level of patient interest in alternative treatments for presbyopia supports a need to educate clinicians on the medical options.

Dr Karpecki: I agree. I think the message to our colleagues is to mention pharmacologic treatment for presbyopia, along with conventional modalities, while setting proper expectations about their safety and effectiveness.

Mention pharmacologic treatment for presbyopia, along with conventional modalities, while setting proper expectations about safety and effectiveness.

Medical Treatment for Presbyopia: Clinical Trial Data

Paul Karpecki, OD, FAAO

Pilocarpine hydrochloride, 1.25% (Vuity), and pilocarpine hydrochloride, 0.4% (Qlosi), are available medical options for treating presbyopia in adults **(Table 1)**.[18–21] These are miotic agents that improve near vision via a pinhole effect to increase depth of focus.[12] By limiting light entering the eye to central parallel rays that converge at a focal point on the retina, they also improve image clarity.[22] Because their mechanism does not involve ciliary muscle action or change in crystalline lens shape, pilocarpine drops provide a pseudoaccommodative effect.

Table 1. Pilocarpine Products Approved for Treating Presbyopia*[18–21]

Feature	Pilocarpine, 1.25%	Pilocarpine, 0.4%
Concentration[18,19]	1.25%	0.4%
Preservative[18,19]	Yes (benzalkonium chloride)	None
pH[18,19]	Acidic	Near neutral (~6.0)
Dosing[18,19]	Once or twice daily (second dose administered 3–6 hours after the first)	Once or twice daily (second dose administered 2–3 hours after the first)
Most common adverse events in phase 3 trials[20,21]	Headache (13.5%) Hyperemia (5.1%) Blurred vision (4.5%)	Headache (6.8%) Instillation site pain (5.8%) Blurred vision (3.6%)

* Selected key differences based on comparison of product prescribing information

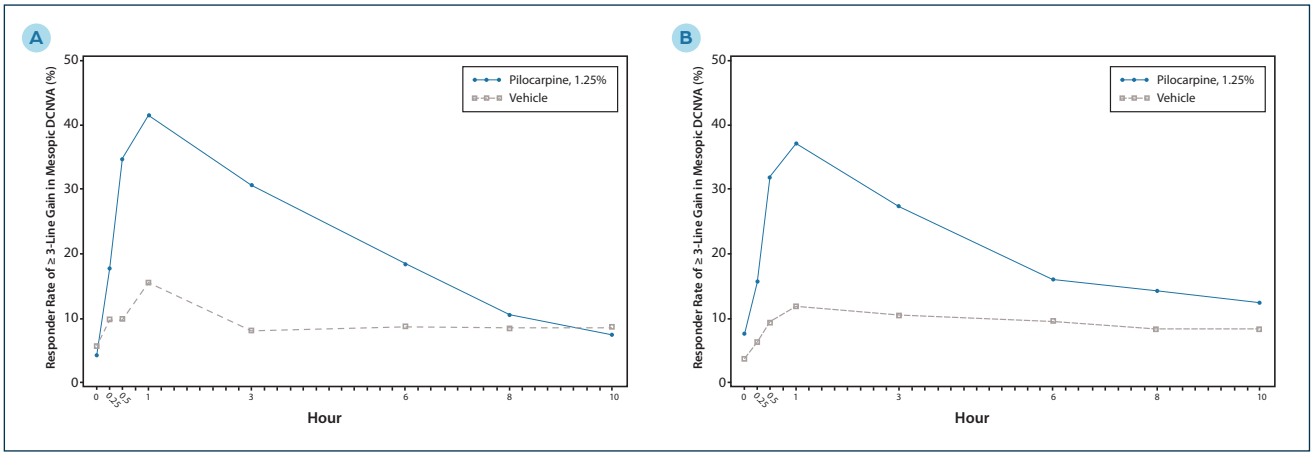

Figure 1. Proportion of participants achieving ≥ 3-line improvement in mesopic, high-contrast, binocular distance-corrected near visual acuity at day 30 in GEMINI 1 (A) and GEMINI 2 (B) (intent-to-treat population)[18]

Abbreviation: DCNVA, distance-corrected near visual acuity.

Pilocarpine, 1.25%

Pilocarpine, 1.25%, formulated in a proprietary vehicle optimized for bioavailability and tolerability, was approved in October 2021 for once-daily use administered bilaterally.[20,23] The agent was approved in March 2023 for twice-daily use with administration of a second drop in each eye 3 to 6 hours after the first dose.[24]

The phase 3 GEMINI 1 and 2 trials supporting approval of pilocarpine, 1.25%, enrolled 750 patients aged 40 to 55 years.[20] Both trials met their primary end point, showing that at day 30, a significantly higher percentage of patients using pilocarpine, 1.25%, gained ≥ 3 lines in mesopic, binocular distance-corrected near visual acuity (DCNVA) at 3 hours postdosing without losing > 1 line of mesopic corrected distance visual acuity (CDVA) than those receiving vehicle **(Figure 1)**.[18] Approval of the twice-daily dosing regimen was based on results from the phase 3 VIRGO study showing that 35.1% of 116 patients using pilocarpine, 1.25%, gained ≥ 3 lines in mesopic binocular DCNVA at day 14, 3 hours after the second dose, without losing > 1 line of mesopic CDVA vs 7.8% of 114 patients using vehicle ($P < .0001$).[20]

The safety profile of pilocarpine, 1.25%, was similar in the GEMINI and VIRGO trials.[20] The most common adverse events associated with pilocarpine were headache (13.5%), conjunctival hyperemia (5.1%), and blurring of vision (4.5%), most of which were generally mild and transient. No retinal complications occurred, but cases of retinal detachment (RD), retinal tears, and vitreoretinal traction emerged postmarketing.[25-27]

Pilocarpine, 0.4%

Pilocarpine, 0.4%, formulated in a preservative-free vehicle was approved in October 2023 for dosing up to twice daily, with a second drop instilled in each eye 2 to 3 hours after the first drop to extend the duration of effect for up to 8 hours.[19,28] The solution has a near-neutral pH of approximately 6, which increases pilocarpine bioavailability and is expected to enhance tolerability.[29] Inactive lubricant ingredients in the formulation—hypromellose (hydroxypropyl methylcellulose) and sodium hyaluronate—may contribute to comfort and tolerability.[19]

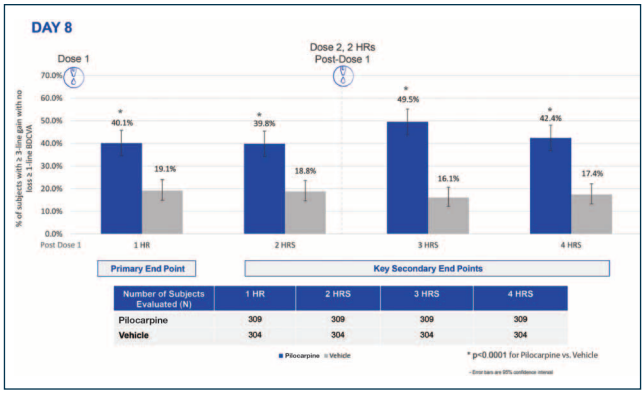

Figure 2. Percentages of patients achieving the primary end point in the NEAR-1 and NEAR-2 trials[19,21]

Abbreviation: BDCVA, binocular distance-corrected visual acuity.

Reprinted with permission from Holland E, Karpecki P, Fingeret M, et al. Efficacy and safety of CSF-1 (0.4% pilocarpine hydrochloride) in presbyopia: pooled results of the NEAR phase 3 randomized, clinical trials. *Clin Ther*. 2024;46(2):104-113. Copyright 2023 by the Authors.

The NEAR-1 and NEAR-2 phase 3 trials randomly assigned 613 patients aged 45 to 64 years to receive pilocarpine, 0.4%, or vehicle twice daily for 15 days, with the second drop administered 2 to 3 hours after the first dose.[21] The studies met their primary end point; a pooled analysis showed that on day 8 at 1 hour after the first dose, 40.1% of 309 patients receiving pilocarpine gained ≥ 3 lines of mesopic DCNVA in the study eye, with no loss of ≥ 5 letters in CDVA, compared with 19.1% of 304 patients receiving vehicle ($P < .0001$) **(Figure 2)**.[19,21] Exploratory end point analysis showed that 72.8% of patients receiving pilocarpine achieved a clinically meaningful improvement in near vision at the primary efficacy end point, defined as a DCNVA gain of ≥ 2 lines, and a similar percentage achieved ≥ 20/40 DCNVA, which is sufficient for social reading. An analysis comparing monocular and binocular near vision improvement achieved by patients receiving pilocarpine, 0.4%, bilaterally demonstrated the role of binocular summation in near vision function.[30] The analysis, which included 206 study participants whose baseline binocular DCNVA was < 20/40, found that on day 15—at all time points from 20 minutes to 8 hours post dose 1—a significantly greater proportion of patients achieved DCNVA 20/40 or better in binocular testing compared with the study eye alone ($P < .0001$) **(Figure 3)**.[30] Adverse events

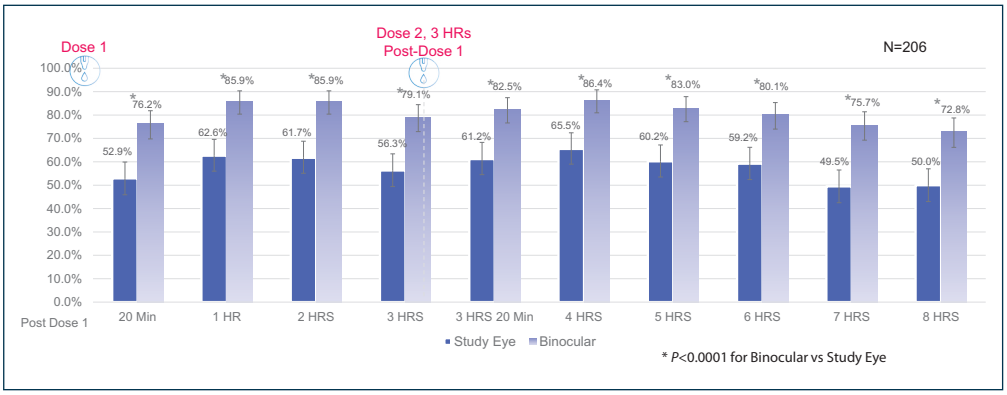

Figure 3. Pooled results for participants in the NEAR-1 and NEAR-2 trials showing proportion of patients achieving distance-corrected near visual acuity ≥ 20/40 in binocular testing vs study eye alone[30]

in the pilocarpine groups in the NEAR-1 and NEAR-2 studies were generally mild and transient, with headache (6.8%), instillation site pain (5.8%), and blurred vision (3.6%) being the most common.[21] Tolerability scores were similar in the pilocarpine and vehicle groups. There were no retinal complications.

Additional analyses showed that a mean pupil reduction of approximately 30% correlated with > 3 lines of near visual acuity (VA) improvement, suggesting that optimal functional pupil size for improving near vision without compromising distance vision often falls within the 2- to 3-mm range.[31,32] There was also evidence of neuroadaptation because near VA improved between day 1 and day 15, and low luminance testing showed preservation of distance VA, suggesting minimal compromise of night vision.[21,32]

Discussion

Dr Karpecki: Pilocarpine, 1.25%, was the first pharmacologic treatment available for presbyopia. I had patients who achieved great results with this drop. Some of the issues with treatment were improperly set expectations and adverse effects, such as dimming of vision, which we were unaware should be mentioned to patients prior to treatment.

Dr McGee, what has been your patients' experience with pilocarpine, 1.25%?

Dr McGee: I have patients who are very happy using it. It is important to choose patients who are good candidates, especially those who are motivated and will likely benefit from treatment **(Table 2)**.

Table 2. Considerations for Safe and Successful Treatment With Miotic Drops for Presbyopia

Patient Motivation • Patients should have specific vision goals and are likely to use the medication for an adequate trial that allows for neuroadaptation and early adverse effects to diminish
Pupil Size • The photopic pupil should be neither too big nor too small to allow for benefit from the miotic effect
Refraction • Patients with emmetropia and those with mild myopia or hyperopia may be the best candidates o With best correction for distance vision in place, low levels of refractive error matter less
Uncorrected Near Visual Acuity • Patients with early to moderate presbyopia and some residual accommodation are most likely to benefit
Retinal Status and Other Safety Concerns • Patients with risk factors for retinal detachment (eg, high myopia, vitreomacular traction, evolving posterior vitreous detachment, history of retinal tear or detachment, lattice degeneration, and retinal holes), uveitis, posterior synechiae, or narrow angles should be excluded

Initially, I was estimating the required added magnifying power according to patient age, but I have found that many people have different levels of accommodation, not necessarily directly correlated with age. Now I check uncorrected near VA (UNVA), which takes just a few seconds after the distance refraction. We know from the NEAR-1 and NEAR-2 studies that > 70% of patients gained ≥ 2 lines of DCNVA and the same percentage achieved 20/40.[21] Therefore, I can expect that most patients who see 20/50 uncorrected at near distance will be able to read 20/30 when using pilocarpine and therefore will be highly functional.

At the same time, I think it is important to consider patient motivation, or what is known as the "X factor". I have been amazed by the level of near vision that is functional for highly motivated patients.

Pupil size is also important to consider in determining if patients are candidates for miotic drops. Someone who already has a small pupil is unlikely to benefit. I am fortunate that the instrument we use for autorefraction measures mesopic and photopic pupil size, but I do not think there is a need for special equipment. I think that optometrists can visually judge if a patient's pupils are already so small that they are unlikely to benefit from a miotic drop.

Dr Karpecki: Although the 2 pilocarpine products approved for presbyopia have not been compared in head-to-head studies, we have safety data from the 2 relatively large premarketing trials that suggest using a lower concentration of pilocarpine reduced the incidence of many adverse effects, including headaches.[20,21]

Dr McGee, are there any other notable differences between the 2 pilocarpine products?

Dr McGee: One difference between the 2 products, other than the obvious difference in concentration, is that pilocarpine, 1.25%, contains benzalkonium chloride,[18] which we know can be damaging to the ocular surface and corneal nerves. Therefore, I think it is an important distinction that pilocarpine, 0.4%, is preservative free.[19]

Dr Karpecki: I agree, especially considering that dry eye disease is common in the target population for miotic drops.[33]

Pilocarpine Drops and the Risk of Retinal Complications

Rishi P. Singh, MD, FASRS

Topical pilocarpine has a long history of use in ophthalmology, and, along with other miotic drugs, has been suspected to increase the risk of RD.[25] The proposed mechanism involves increased traction on the retina secondary to induction of ciliary muscle contraction that causes anterior movement of the lens and vitreous.[34] Certain preexisting conditions, including high myopia, lattice degeneration, and history of RD, are considered risk factors for RD with use of pilocarpine.[25]

There were no reports of retinal tears or detachments in the identically designed, 30-day, phase 3 GEMINI 1 and 2 studies investigating pilocarpine, 1.25%, for treating presbyopia.[20] Because of the protocol's eligibility criteria and required screening retinal examination, however, the enrolled patients represented a select group without significant risk factors for retinal complications. Reports of retinal complications in patients using pilocarpine, 1.25%, began to emerge postmarketing.[25,26,35–37] The reports led to labeling revisions noting these events and advising both retina examination prior to treatment initiation and providing patient education on the symptoms of RD and the need to seek immediate medical care if they occur **(Table 3)**.[18]

Table 3. Updates to the Pilocarpine, 1.25%, Package Insert That Were Prompted by Reports of Retinal Complications[18]

WARNINGS AND PRECAUTIONS
Risk of Retinal Detachment
Rare cases of retinal detachment and retinal tear have been reported with miotics, including pilocarpine hydrochloride ophthalmic solution, 1.25%. Individuals with preexisting retinal disease are at increased risk. Therefore, examination of the retina is advised in all patients prior to the initiation of therapy. Patients should be advised to seek immediate medical care with sudden onset of flashing lights, floaters, or vision loss.
POSTMARKETING EXPERIENCE
The following adverse reactions have been identified during postapproval use of pilocarpine hydrochloride ophthalmic solution, 1.25%.
Eye disorders: Vitreous detachment, vitreomacular traction, retinal tear, retinal detachment.
PATIENT COUNSELING INFORMATION
When to Seek Physician Advice
Advise patients with sudden onset of flashing lights, floaters, or vision loss to seek immediate medical care.

Between January and December 2022, the US Food and Drug Administration (FDA) received approximately 30 reports of RDs in patients using pilocarpine, 1.25%, which translates into an incidence of approximately 0.02%.[36,37] Fewer cases were reported to the FDA over the next 2 years, indicating that incidence of RD associated with pilocarpine, 1.25%, decreased after the package insert update and introduction of educational efforts directed at consumers and prescribing clinicians. Furthermore, the observed rate of RD in postmarketing experience with pilocarpine, 1.25%, is within or below the natural history rate of RD that has been reported in the literature.[38–40] The rate of RD associated with pilocarpine, 1.25%, is also within or below the rate associated with laser-assisted in situ refractive keratomileusis, refractive lens exchange, and cataract surgery.[41–43]

Dr Singh: Early reports of retinal complications after the launch of pilocarpine, 1.25%, were rare, but were somewhat surprising. What transpired from these events was recognition of the importance of conducting proper patient screening, education, and monitoring.

As a screening consideration, I would like to raise awareness that the finding of a slight hyperopic shift during the refractive examination can be due to central serous chorioretinal detachment and should not be assumed to be a natural consequence of aging. Therefore, it is critical to conduct a dilated examination to look for retinal pathology before prescribing pilocarpine for presbyopia.

It is critical to conduct a dilated examination for retinal pathology before prescribing pilocarpine for presbyopia.

How do you screen patients for risk of retinal complications before prescribing miotic drops for presbyopia?

Dr Karpecki: I perform a dilated fundus examination (DFE), optical coherence tomography (OCT) scan of the macula to look for vitreomacular traction, and high-resolution ultra-widefield (UWF) imaging to pick up findings that might be missed on the DFE. I also look at the patient's history and refractive error to assist in decision making for potential miotic drops. Some postrefractive surgery patients are very interested in these drops and may not recall the level of myopia they had before receiving laser-assisted in situ keratomileusis. A good examination of the peripheral retina looking for holes, tears, or lattice is essential.

Dr McGee: I saw a patient who developed an RD after using pilocarpine prescribed for his wife. My examination showed that he had –6.0 D myopia with lattice degeneration. I never would have given him a prescription for pilocarpine.

I think that DFE is sufficient for screening if UWF imaging is unavailable, and that UWF imaging could be done by itself without a full DFE if the image is broad and of high quality. In terms of risk factors, I think it is important to look at axial length in patients with a history of laser refractive surgery if full historical refractive data are unavailable. I will not prescribe pilocarpine for presbyopia to anyone with more than –6.0 D myopia or whose axial length is > 26 mm.

I also include macula OCT when screening patients interested in a miotic drop for presbyopia because it allows me to see vitreomacular traction. If there is complete posterior vitreous detachment, I know that the drops will not cause retinal traction, and the patient could be a candidate.

Dr Singh: What findings should trigger a patient's referral to a retina specialist before prescribing a miotic drop?

Dr Karpecki: I expect that depends on how comfortable optometrists are with their retina examination skills. If I see a retinal tear, especially in a superior location, I am more likely to send the patient for expert evaluation. I might choose to monitor a patient more frequently and

provide even more intensive education on warning signs for RD and the need to seek attention should they occur if a patient has a few isolated small peripheral holes or lattice degeneration. In such cases, I would not prescribe a presbyopia-correcting drop. My decision for patients with vitreomacular traction would vary, taking their history into account and looking closely at OCT images.
In general, I refer all patients to a retina specialist when I have any doubts about the retinal findings and advise my colleagues to do the same.

Dr McGee: I, too, advise sending patients with any suspicious findings needing medical intervention to a retina specialist.

Case 1

From the Files of Selina McGee, OD, FAAO

A 52-year-old male patient presented with a chief concern of constant blurry uncorrected near vision for the past year. He said that his over-the-counter reading glasses "feel too strong" and that he developed mild headaches after prolonged computer use while wearing computer glasses. Uncorrected distance VA was 20/20 OU and 20/15 binocular. Binocular UNVA was 20/70. Anterior segment examination results and DFE, UWF imaging, and macula OCT images were unremarkable.

The patient was very interested in an option that would make him as spectacle independent as possible. On the basis of his examination, he was considered a good candidate for a miotic drop and was prescribed pilocarpine ophthalmic solution, 1.25%, with instructions to use it once daily for 2 weeks and then twice daily as needed. He was asked to return in 6 months. At follow-up, he stated he loved his pilocarpine drops and was using them every day.

Dr McGee: The reason I instruct patients to use the medication once daily every day for the first 2 weeks is because there is evidence from both the GEMINI and NEAR studies of a neuroadaptation response after starting pilocarpine drops.[21,44] I think that routine use enables faster neuroadaptation compared with as-needed use. I explain that the drop clarifies—not magnifies—images and that although the brain is quite plastic and able to interpret new images, it needs time to adapt. I also inform patients that the length of the adaptation period can vary and tends to be higher in younger vs older patients with presbyopia. Making patients aware of this information minimizes the likelihood that they think I prescribed an ineffective medication if they do not immediately benefit from improved, comfortable vision.

When prescribing pilocarpine for presbyopia, I think it is important to not only discuss RD symptoms with patients, but also to document the discussion in the patient's record, along with discussion of all risks, benefits, and alternatives.

I ask patients to return for a first follow-up in 6 months so that I can assess the retina. Dr Karpecki, what is your practice?

Dr Karpecki: I generally do a yearly examination in anyone who has any risk factors for RD. If there are no concerning changes, I reinforce education on RD symptoms and the need to seek immediate attention, and extend the follow-up interval to every 2 years. Because I try to be very selective about who receives pilocarpine, I am not compelled to check the retina after just 6 months.

Dr Singh: I think an annual retinal examination is reasonable when patients are using the pilocarpine drops chronically, but the timing also depends on the individual's age and other factors, such as if there is partial or complete posterior vitreous detachment and the status of the fellow eye.

Case 2

From the Files of Paul Karpecki, OD, FAAO

A 54-year-old male patient had concerns about using reading glasses. He said he was always searching for them and did not like wearing eyeglasses because of his work as a geologist in mines and because of his hobbies, which were playing racquetball and pickleball. He also had blurry vision, occasional eye dryness, and foreign body sensation, which he said was worse in the left eye and described as an occasional feeling that something was in his eyes.

*Findings on examination were VA of 20/20-1 OD and 20/25+1 OS, and refraction of +0.25-0.25 × 167 OD and +0.25 - 0.75 × 024 OS. Distance vision, however, did not improve much with correction (20/20-1 OD and 20/25+2 OS). Uncorrected near VA was J9 (20/80-) OU. Other findings were tear osmolarity of 303 mOsm/L OD and 301 mOsm/L OS; intraocular pressure of 14 mm Hg OU; mild/moderate epithelial basement membrane dystrophy appearing as maps, dots, and fingerprint patterns; no corneal or conjunctival staining; with inverse staining over areas of epithelial basement membrane dystrophy (OS > OD) **(Figure 4)**; and normal meibomian gland expression and tear meniscus height. There were no remarkable findings on DFE, OCT scan of the macula, or high-resolution widefield imaging.*

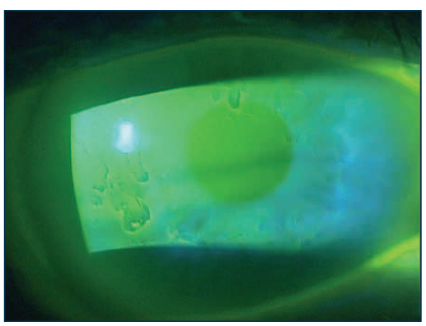

Figure 4. Fluorescein staining of the patient in Case 2 reveals epithelial basement membrane dystrophy
Image courtesy of Paul Karpecki, OD, FAAO

The patient was started on pilocarpine, 0.4%, twice daily, with instructions to instill the second drop into each eye 2 to 3 hours after the first drop. He returned for a follow-up visit after 2 weeks and had instilled the first drop of pilocarpine in both eyes approximately 1 hour before being examined. Distance best-corrected VA was 20/20-1 OD and 20/20-1 OS; UNVA was J5; and pupil diameter was 2.5 mm OU.

The patient stated that he was thrilled with his vision and asked for another prescription. He said he was using the pilocarpine drops to improve his vision at work and had set an alarm on his watch to remind him when to use the second dose. He said he felt like he saw at both distance and near as well as he did when he was younger. He mentioned that he could see the rotation of the ball in racquetball again, and was amazed by the improvement in his reading vision and distance vision. He had not experienced headaches or burning upon instillation. He did note, however, some mild dimming of his vision.

Dr Karpecki: I typically have patients return 2 to 4 weeks after starting pilocarpine, which is long enough for neuroadaptation to occur. The follow-up visit gives me the opportunity to see how patients are using the drops and what they are experiencing with respect to efficacy and safety. I also remind patients about warning signs of RD even though the risk is very low.

This case illustrates that pilocarpine's miotic effect has potential benefits aside from increasing depth of focus to improve near vision. Decreasing pupil size decreases light scatter caused by higher-order aberrations or peripheral corneal irregularity that might be present in patients such as this who have eyes with epithelial membrane dystrophy or in those with Salzmann nodular degeneration or keratoconus. Although the patient in this case did not mention initially that he had night vision problems, he did note improvement that I think was an assessment of quality of vision.

Dr McGee: Improvement in night driving glare is another recognized effect of miosis and is the rationale for the off-label use of brimonidine.[45] A phase 3b placebo-controlled study, however, showed that pilocarpine, 1.25%, reduced night driving performance.[46]

This case also demonstrates that patients using pilocarpine for presbyopia can experience dimming of vision. With that in mind, I caution patients about using the drop before driving at night and recommend that their first use should be when they are planning to stay home so they can see if it causes dimming or blurred vision.

Dr Karpecki: When I first started prescribing pilocarpine, 1.25%, I counseled patients about the potential for headache, brow ache, and redness, but I only started to talk about dimming after some patients told me their vision seemed a little dark at times.

Strategies for Patient Counseling

Selina McGee, OD, FAAO

Managing expectations is essential for achieving patient satisfaction with miotic drops for presbyopia—it is best to underpromise and overdeliver. First, however, it is important that patients understand how the drops work to improve near vision. For that piece of education, patients should be asked if they have noticed less need for reading glasses in bright lighting conditions, such as when they are inside by a window or outdoors during the day. Bright light causes their pupils to get smaller, and the miotic drops mimic that situation. The miotic drops also provide image clarification, which differentiates their action from the magnification effect of reading glasses. In addition, the drops do not restore natural accommodation. Therefore, depending on a patient's current age and residual accommodative ability, he/she may see the benefit of the drops decrease with age.

In discussing the expected visual outcome, it should be emphasized that the treatment is intended to provide functional improvement, meaning it will allow individuals to read menus or their phones without aids, but their near vision will also depend on existing lighting and they may still need to wear eyeglasses for prolonged near vision tasks or reading fine print.

Directions for use should also be reviewed when counseling the patient, including instructions on instillation if he/she wears contact lenses and information on onset and duration of effect. Patients should also be counseled on common adverse effects (eg, headache, blurred vision, dimming, hyperemia, local instillation reactions).[20,21] A discussion on the risk of retinal complications, their warning signs, and the urgent need for evaluation should they occur is crucial. The risk may be contextualized so that patients understand it is low, but real, and why a retinal examination is necessary.

Finally, patients should understand that insurance likely does not cover the drops or a presbyopia examination. Any available patient assistance programs should be mentioned.

Practice Implications

Selina McGee, OD, FAAO

Clinicians may struggle with initiating a discussion about miotic drops for presbyopia because they are a new category. No single approach is applicable to all situations. The topic may be introduced to existing patients during a comprehensive examination. It is important to be intentional when doing this, such as asking, "Would you be interested in a drop to help you see better at near?"

"Presbyopia consultation" visits may also be implemented for people who are not existing patients. These are cash-pay visits that include the full retinal examination and necessary counseling, which can be leveraged as an opportunity to grow a practice.

There is a need to establish a flow-through process, but chair time is minimal and follow-up can also be simple. Checking in with patients after 2 and 4 weeks via text message is reasonable. Patients can be asked how they are doing with the drops or if they have any questions. When first prescribing pilocarpine, collecting information on the patients' experience, such as asking them to complete a structured questionnaire after they have used the medication for 2 weeks, may help set proper future expectations.

Offering medical treatment for presbyopia is a growth opportunity that can bring in new patients. Patients can be attracted through marketing efforts, and they can call the office because they heard about a new medication that can help them see better at near distance. Attracting patients wanting treatment for presbyopia provides other opportunities for growth, considering that many people in this age group have other conditions and vision needs.

Concern about retinal complications should not deter optometrists from offering miotic drops. If they perform a proper examination and counsel patients appropriately, they should feel comfortable about identifying appropriate patients and mitigating risk. Concerns that offering medical treatment for presbyopia threatens revenue from contact lens fitting or an optical department should also be dispelled. In fact, prescribing the drops has allowed fitting patients with contact lenses who would otherwise not be wearing them, such as those with astigmatism who may have stopped wearing their toric lenses because they could not adapt to a multifocal toric lens. With the presbyopia drops, they can return to contact lens wear.

Closing Thoughts

Dr Karpecki: Optometrists should not be concerned that offering presbyopia medications will upend their practice. People with presbyopia represent a large segment of our patient population. Many of these individuals would like to know about the drops in addition to their use of spectacles, contact lenses, or even cataract or refractive surgery. A patient may tell other family members or friends with presbyopia about these drops. Considering that many patients with presbyopia are emmetropic and do not see an optometrist routinely, miotic drops may attract a new population of patients to the clinic. Offering miotic drops for presbyopia introduces another focus into practice and represents a growth opportunity, but it does not dramatically change what we are doing as optometrists.

Dr McGee: Patients with presbyopia are interested in alternatives to conventional solutions. It is up to clinicians to uncover that interest.

Dr Singh: Education affects patient satisfaction with care and therapeutic outcomes. It takes just a few minutes to describe the medical options for presbyopia management to patients and make sure they understand the information. A good retinal examination is essential before starting a patient on pilocarpine. Optometrists should never hesitate to refer patients to a retina specialist if they have any doubt about the findings.

Take-Home Messages

- **Pharmacologic miotics offer a valuable new pillar for presbyopia management**
- **Two pilocarpine products are FDA approved for treating presbyopia in adults on the basis of clinical trial data showing acceptable tolerability, safety, and superiority for improving mesopic binocular DCNVA vs vehicle**
- **Pilocarpine drops provide pseudoaccommodation via a pinhole effect**
  - Set expectations accordingly; pilocarpine drops provide clarification, not magnification
  - Careful patient selection is paramount for safety and success; consider refraction, DCNVA, pupil size, retinal health, and vision goals
- **A proper baseline evaluation of the peripheral retina is MANDATORY to mitigate RD risk**
- **Comprehensive counseling on benefits, limitations, adverse effects, and critical RD symptoms, with documentation, is essential for patient safety and satisfaction**
- **Consider follow-up after 2 to 4 weeks to check for efficacy and safety, then after 1 year for repeat retinal examination**
- **Integrating pilocarpine drops requires workflow adjustments but offers practice growth potential**

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CE Posttest Questions

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1. What is the recommended dosing regimen for pilocarpine, 0.4% and 1.25%?
   a. Once daily in the nondominant eye
   b. Once or twice daily in the nondominant eye
   c. Once or twice daily in the dominant eye
   d. Once or twice daily in both eyes

2. The primary end point in the phase 3 studies investigating the pilocarpine drops for presbyopia assessed the percentage of patients achieving:
   a. 20/20 mesopic DCNVA without > 1–line loss of mesopic CDVA
   b. 20/40 mesopic DCNVA without > 1–line loss of mesopic CDVA
   c. ≥ 2–line improvement in mesopic DCNVA without > 1–line loss of mesopic CDVA
   d. ≥ 3–line improvement in mesopic DCNVA without > 1–line loss of mesopic CDVA

3. What was the most common adverse event associated with pilocarpine, 1.25%, in the GEMINI 1 and 2 trials?
   a. Headache
   b. Hyperemia
   c. Ocular burning
   d. Retinal detachment

4. What was the most common adverse event associated with pilocarpine, 0.4%, in the NEAR–1 and NEAR–2 trials?
   a. Blurred vision
   b. Dysgeusia
   c. Headache
   d. Instillation site pain

5. Labeling changes for pilocarpine, 1.25%, on the basis of the emergence of reports of retinal complications postmarketing included updates to all the following sections, EXCEPT:
   a. Contraindications
   b. Patient Counseling Information
   c. Postmarketing Experience
   d. Warnings and Precautions

6. Risk factors for RD with topical pilocarpine use include all the following, EXCEPT:
   a. Glaucoma
   b. High myopia
   c. History of RD
   d. Lattice degeneration

7. A screening examination for patients being considered for pilocarpine drops for presbyopia must include:
   a. Anterior segment OCT
   b. Proper evaluation of the peripheral retina to ensure no pathology
   c. Macular OCT
   d. Optic nerve OCT

8. Which factor should be considered when choosing a candidate for a miotic drop for presbyopia?
   a. Baseline uncorrected near vision
   b. Findings of DFE
   c. Refraction
   d. All the above

9. Which characteristic indicates a patient may be a good candidate for a miotic drop for presbyopia?
   a. Mild myopia
   b. Moderate myopia
   c. No history of RD
   d. All the above

10. Which situation warrants referring patients to a retina specialist before prescribing pilocarpine for presbyopia?
    a. All patients should be examined by a retina specialist prior to starting pilocarpine
    b. DFE reveals possible concerning findings
    c. The practice does not have macula OCT
    d. The practice does not have UWF imaging

11. Which of the following statements should be included when counseling patients on miotic drops for presbyopia?
    a. The drops may cause dimming of vision, so be cautious about using the drops before driving at night
    b. By reducing pupil size, the drops act to magnify images at near distances
    c. The drops are the only treatment for presbyopia that restores the natural focusing ability of the eye
    d. Seek immediate medical attention if you experience headache after using the drops

12. Which of the following patients is a good candidate for a pilocarpine drop to treat presbyopia?
    a. 45–year–old patient with a history of laser–assisted in situ refractive keratomileusis for –7.0 D myopia who is having difficulty reading his mobile phone
    b. 50–year–old patient with emmetropia who wants to avoid wearing reading glasses in social situations
    c. 50–year–old patient with emmetropia who drives a truck at night and wants to be able to see the dashboard clearly without eyeglasses
    d. 70–year–old patient with pseudophakia, residual astigmatism, and 2–mm mesopic pupil who wants to be spectacle independent

13. A 55–year–old male wants to reduce his dependence on readers for social situations. He has a history of mild dry eye, prefers a preservative–free drop, and has a slightly reduced mesopic pupil size (~3.0 mm). Retina examination results are normal. Which treatment would best suit his needs?
    a. Pilocarpine, 0.4%
    b. Pilocarpine, 1.25%
    c. Multifocal contact lenses
    d. Laser–assisted in situ refractive keratomileusis

14. A 68–year–old male needs bilateral cataract surgery. He has low myopia with minimal astigmatism and a history of retinal tear OD and an epiretinal membrane OS. He enjoys reading a book for several hours in the afternoon, and is hoping he will not need to keep searching for his reading glasses. Which treatment would you recommend to this patient?
    a. Multifocal intraocular lens
    b. Prescription progressive eyeglasses
    c. Pilocarpine, 0.4%
    d. Pilocarpine, 1.25%

15. A 48–year–old female presents with difficulty reading her phone. She has no significant past ocular history and normal retinal examination results. Her baseline photopic pupil size is 4.0 mm and her UNVA is 20/70. She expresses a strong desire for spectacle independence. Which is the most appropriate treatment option for this patient?
    a. Progressive addition spectacles
    b. Pilocarpine, 0.4% or 1.25%
    c. Reading glasses
    d. Refractive lens exchange