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PHARMACOLOGICAL PRESBYOPIA TREATMENT CONSENSUS STATEMENT: CLINICAL RECOMMENDATIONS FOR TODAY'S PRESBYOPIA PATIENT

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CONTENT SOURCE

This continuing medical education (CME/CE) activity captures content from two roundtable discussions.

ACTIVITY DESCRIPTION

This supplement, captured from a delphi panel of expert key opinion leaders, provides consensus recommendations related to defining, diagnosing, and pharmacologically treating presbyopia.

TARGET AUDIENCE

This certified CME/CE activity is designed for optometrists and ophthalmologists who care for patients with presbyopia.

LEARNING OBJECTIVES

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

- **Define** the ideal presbyopia patient for pharmacological treatment, including age ranges, refractive error levels, key demographics, and other clinical and socioeconomic parameters
- **Determine** how to diagnose the presbyopia patient
- **Compare** and contrast the advantages and disadvantages of the various pharmacological presbyopia treatments, including efficacy, safety, and functionality
- **Identify** best practices on how to identify, communicate and educate the patient

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PRETEST QUESTIONS

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

1. Please rate your confidence in your ability to compare and contrast the advantages and disadvantages of the various pharmacological presbyopia treatments (based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident).
- A. 1
- B. 2
- C. 3
- D. 4
- E. 5

2. Presbyopia occurs when the ciliary muscle contracts, causing the zonules to:
- A. Loosen
- B. Dissolve
- C. Increase in volume
- D. Tighten

3. Although presbyopia is progressive and can occur at different ages in different patients, stiffening of the natural lens most commonly begins around the age of:
- A. 20
- B. 30
- C. 40
- D. 60

4. What is the estimated number of people affected by presbyopia globally?
- A. Fewer than 500 million
- B. 500 million – 750 million
- C. 750 million – 1 billion
- D. More than 1 billion

5. Most of the participants in this panel believe a complete eye exam should be part of an initial presbyopia diagnosis. What percentage felt a questionnaire should also be used?
- A. 10%
- B. 33%
- C. 50%
- D. 75%

6. Which of the following was NOT given as a factor in presbyopia?
- A. An aging population
- B. Computer eye syndrome
- C. Increased exposure to sunlight
- D. Digital eyestrain

7. The effects of presbyopia can negatively affect a patient's quality of life, frequently making all but which of the following more difficult?
- A. Sewing
- B. Reading
- C. Walking the dog
- D. Using mobile devices

8. Increased screen time for phones and other devices can have an effect on presbyopic patients. Which of the following is NOT a possible result of this?
- A. Eyestrain
- B. Headaches
- C. Memory loss
- D. Red eyes

9. What percentage of patients with uncorrected presbyopia report difficulty in performing near-vision related tasks, as stated in the literature?
- A. Up to 60%
- B. Up to 70%
- C. Up to 80%
- D. More than 90%

10. Which method of reaching potential patients for upcoming presbyopia treatments was described as "key"?
- A. Television ads
- B. Social media and technology
- C. Word-of-mouth
- D. Ads in print publications

11. For education, brochures are sometimes useful and sometimes not. Which of these did the panelists feel is the most effective method for educating patients today?
- A. Home visits
- B. In-practice educational seminars
- C. Concise online videos
- D. Daily email

12. The main problem encountered using pilocarpine in glaucoma treatment was:
- A. Cost
- B. Lack of efficacy
- C. Availability of the drug
- D. Hard-to-tolerate side effects

13. Pharmaceutical agents being developed for presbyopia fall into one of three categories. Which of the following is NOT one of these categories?
- A. Pupil modulation
- B. Scleral tightening
- C. Lens softening
- D. Combination agents

14. The main mechanism of action being applied in the upcoming pharmacologic presbyopia treatments discussed here is:
- A. Miosis of the pupil
- B. Reduction of intraocular pressure
- C. Dilation of the pupil
- D. Relaxing the cornea

15. Patients seeking presbyopia treatment may also need treatment for other conditions. It was discussed that which of the following may be exacerbated by use of pilocarpine drops?
- A. Dry eye disease
- B. Glaucoma
- C. Keratoconus
- D. Cataracts

16. How likely do most participants feel patients will be to pay a reasonable out-of-pocket cost for these medications?
- A. Not at all likely
- B. Slightly likely
- C. Moderately likely
- D. Very or extremely likely

PHARMACOLOGICAL PRESBYOPIA TREATMENT CONSENSUS STATEMENT: CLINICAL RECOMMENDATIONS FOR TODAY'S PRESBYOPIA PATIENT

UNDERSTANDING THE ETIOLOGY OF PRESBYOPIA

Presbyopia is caused by changes that occur in the human lens with age. Richard Lindstrom, MD, said the near reflex, or accommodation, occurs when looking at a near object. The ciliary muscle contracts, causing the zonules to loosen, and the natural lens to become more powerful, especially in the anterior central 4 mm. He explained that in presbyopia, the natural lens becomes stiffer, reducing this power change during accommodation. This increasing stiffness of the natural lens begins around age 40+, continues to age 70, and is due to crosslinking of the collagen fibers, causing the natural lens to become less elastic.

"There is also a small amount of miosis that occurs with accommodation," Dr. Lindstrom said. "The pupil gets slightly smaller and actually a tiny amount of anterior movement of the natural lens also occurs during accommodation. But the primary change in near-focusing ability is due to a shape-change in the natural lens causing increased power of the entire lens. In the relaxed position, we're looking at distance and in the accommodative position, we're looking at near."

Paul M. Karpecki, OD, FAAO, said this has been known for 150 years, before there was even an ability to see zonules. He said, "It's fascinating that it turns out to be as accurate as it is, but it is still theoretical."

STRUCTURAL CHANGES CAN AFFECT FUNCTION

Patients who have had good vision all their lives will start noticing in their 40s or 50s that they have to hold reading material further away, said Sheri Rowen, MD, because they cannot focus at the closest range of what they could see when younger. "As this is happening," she said, "you can't really see tiny things anymore. You're losing your range of vision, and basically, you're losing your visual acuity or that precise vision that you were used to up close. And this impacts your daily life." She said patients will also notice they no longer see well in dim light.

From the patients' perspective, it can seem like presbyopia happens overnight, according to Edward J. Holland, MD. "Obviously it's accruing your entire life," he said, "and there seem to be three phases that presbyopes go through. The early presbyope is in the denial phase. They just think this is not happening to them. Then there's a frustration phase. This involves patients complaining to eye care professionals and wanting to have their vision fixed; at that point they are quite interested in a cure. Then, finally, older patients are in the acceptance phase when they decide to look for a solution, whether it's bifocals, trifocals, monovision lenses, or potentially, if they're a cataract patient, presbyopic-correcting IOLs."

Elizabeth Yeu, MD, added to Dr. Holland's description of presbyopic patients: "For the latent hyperopes, around the age of 38 through about 55 there is so much dynamic shift in the accommodative amplitude that we have, and that change can occur from year to year, which can feel overwhelming for patients because they're constantly needing to change their contacts and glasses. Those who are seeking freedom from those do express a lot of frustration as they go from one set of 5 years to the next. What used to work for them with a little bit of mini-monovision now has to go to multifocal with a high add, and there's a compromise in vision and some people cannot accept these changes. Something that would help during this phase would ease that transition. There's really nothing like this at this time."

"Patients who have had good vision all their lives will start noticing in their 40s or 50s that they have to hold reading material further away."

— Sheri Rowen, MD

"I think for people who haven't had glasses or contact lenses, and now they have to take care of their vision on a daily, maybe even hour-by-hour situation, it's a big deal."

— John P. Berdahl, MD

FUNCTIONAL CHANGES AFFECT VISION, AND QUALITY OF LIFE

Life tasks have changed, says Cecelia Koetting, OD, FAAO, as well as how long people are living. "That has changed significantly during the past 100 years," she said. "Even in the past 10 or 20 years, the age of retirement has changed and what people are doing, and there is much more use of the iPhone and iPad and Zoom."

John P. Berdahl, MD, said people have mentioned they see him holding his phone a little further away from his eyes to see it. "One of the things I notice is the time it takes for me to adjust to see that up-close vision, especially in the morning when I wake up and I'm fully relaxed," he said. "I think for people who haven't had glasses or contact lenses, and now they have to take care of their vision on a daily, maybe even hour-by-hour situation, it's a big deal. But it's an even bigger deal in other parts of the world where there are a lot of presbyopes who don't even have access to a pair of reading glasses for vision correction. So, it's a frustration in the United States that has a solution. Across the world, it has meaningful impact on people's quality of life and what they can do."

PRESBYOPIA IN DIFFERENT AGE GROUPS

INITIAL PRESBYOPIA SYMPTOMS

Presbyopia progresses over time. Ian Benjamin Gaddie, OD, FAAO, said he thinks presbyopia often starts before the age of 40, and that he sees patients much younger than that who have prepresbyopic or binocular vision-related symptoms.

"If you take a patient that's a +0.75 D spherical in the distance and they're 36 years old, they're probably going to have symptoms," he said. "It may not be overt symptoms of needing to put on reading glasses to read, but it may be visual fatigue over the course of the day, during a near task," Dr. Gaddie said. "I think it becomes more important when they're later presbyopes which makes you question whether a product such as the new ones coming on the market will have an impact on them."

Lens changes can start at an early age, Jack L. Schaeffer, OD, FAAO, pointed out. "We should not build an age-related template for categories of presbyopia," he said, "because it is a long-term progressive process that is unique to each person. You are either prepresbyopic, presbyopic, or you're not. The degree of reduced visual acuity and effect of the patient's refractive state varies in so many age groups that it makes it difficult to divide into specific age groups."

"We have to get away from this 45-year-old age thing," said Derek N. Cunningham, OD, FAAO. "Our colleagues are taught that presbyopia doesn't happen until you're 45 years old and its like clockwork, and that's just not true. I think the definition of presbyopia should be based on function. Something like the progressive loss of accommodative facility and amplitude so that it affects the patient's ability to do near tasks. Some people are crippled by presbyopia in their late 30s. Some people really look great in their late 40s."

Dr. Koetting said she also is not a fan of categorizing presbyopia patients by age. "What is it helping?" she asked. "It's not giving us further information and doesn't necessarily influence treatment. We really should just be talking more about the functionality problems that patients may be having and defining it in that aspect."

Dr. Yeu said that headaches can be one of the first signs that something is wrong, particularly at the end of the day: "Especially if someone spends a lot of time on a computer, eyestrain is an issue. Patients may simply attribute it to the stress of always needing to focus, etc., but when they look away from the computer, things in the distance become more difficult to see. So that intermittent invariable accommodative spasm can be a first sign of a patient recognizing presbyopia."

Dr. Yeu is experiencing presbyopia herself. "I used to be able to put in punctal plugs or do a probe and irrigation without looking through the microscope, and I'm nowhere near being able to do that anymore." She also said she has noticed print becoming harder to read on her phone. "It's not constant," she said, "but I'm losing the ability to focus in on microprint, and I definitely

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— Jack L. Schaeffer, OD, FAAO

"I used to be able to put in punctal plugs or do a probe and irrigation without looking through the microscope, and I'm nowhere near being able to do that anymore."

— Elizabeth Yeu, MD

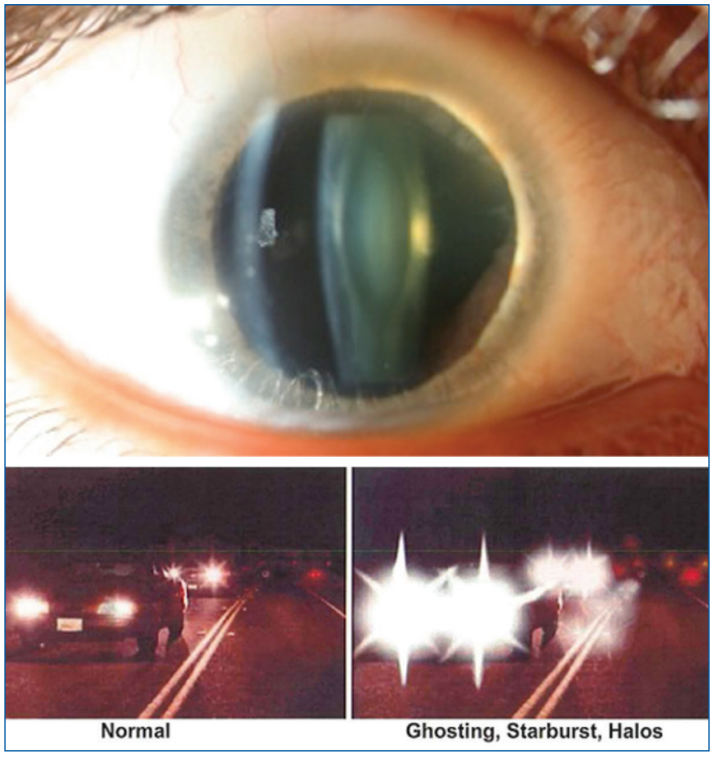


Figure. As patients age, they can have a loss of accommodation, and experience light scatter, degrading vision, and decreasing contrast and night vision.

recognize that correcting my hyperopia leads to fewer headaches and improved reading speed."

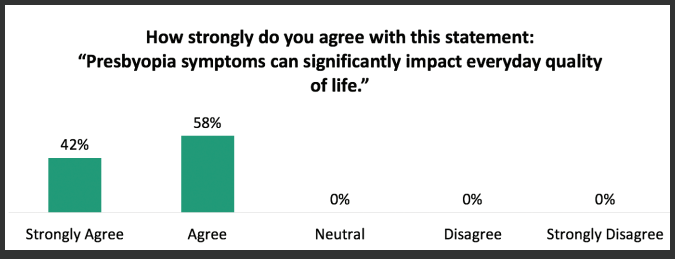
"When we look at our patients, computers are ubiquitous," said Preeya K. Gupta, MD. "Really anything—entertainment, education, it is just part of our daily functioning." She said as a result, the ways in which patients are affected by presbyopia has changed with modern society. "Because of that, patients are much less tolerant of presbyopia and feel this sort of visceral reaction where something is wrong. They think, 'It's not me. Everything else around me, something is changing.' But really, of course, it's the internal eye muscles."

PRESBYOPIA IN OLDER PATIENTS

Patients in their 50s and 60s are frustrated, Dr. Holland said, because not only can they no longer see small print, but they've also lost their ability to do any reading without assistance. "If they're a contact lens wearer," he said, "they can reduce their

CONSENSUS PANEL FINDING #1

All faculty "agree" or "strongly agree" that presbyopia symptoms significantly impact a patient's everyday quality of life.



distance correction and that benefits reading vision. This technique will carry them over for a few years until the loss of distance vision is no longer acceptable."

Dr. Rowen said she is struck by the fact that a patient can still see 20/20 or 20/25, but have abnormal light scattering and a decrease in contrast (Figure). "Eye care professionals might look at the lens and say it looks clear," she said, "but nothing is clear like it was when the patient was age 20 or 30. There are nuclear changes, opacification and yellowing, and all of these things contribute to the problem of not being able to see up close and losing that sharp, brilliant clarity our patients had when they were younger."

"Visual quality really matters," said Dr. Berdahl. "Visual acuity is a measure of the quantity of our vision. How well do we see a black letter on a white screen in a dark room? But how quickly can you zoom from distance vision to near vision, how much light do you need to appreciate that, is there scatter—is something that I think our entire profession doesn't have an easy way to quantify so we ignore it more than we should."

Dr. Schaeffer said, "We also need to be cognizant of the early adapters and new technologies. We are learning about the new category of lens aging, 'Lens Dysfunction Syndrome,' and patients' response to treatment options," he said. "These early adapters prefer to have a semi-clear lens extraction and a multifocal lens implant versus glasses, contact lenses, or any pharmacological treatment. There will be other technologies dealing with a surgical approach to early presbyopia changes so are we treating presbyopia or loss of overall visual clarity?"

PREVALENCE AND DEMOGRAPHICS OF THE PRESBYOPIA PATIENT

Two-thirds of this group of eye care professionals believe that more than 75% of 45-year-old patients have presbyopia symptoms. It is estimated that 1.8 billion people are affected by presbyopia globally.[1] The prevalence of presbyopia varied across regions and by age groups, with the highest prevalence (90%) reported in the Latin America region in adults 35 years and older.[2] There are reportedly 120 million presbyopes in the United States, approximately 86% of adults older than 45.[3]

Gina Wesley, OD, MS, FAAO, is not surprised by that degree of prevalence. "We see this in our practices every day with our patients," she said. "That frustration related to how best to help patients. The impact here is tremendous when you think about how much we are working with this. It's the No. 1 frustration in my office. Outside of any sort of physiological condition, problem, or issue, this is driving people to see us to try and come up with solutions."

AGING POPULATION AFFECTS PREVALENCE

The population is aging," said Dr. Lindstrom, "resulting in a global increase in the incidence of presbyopia. There are also increasing near-vision demands on everyone, in addition to longer life expectancy." He said computer eye syndrome and digital eyestrain can be related to these increased near-vision demands and presbyopia.

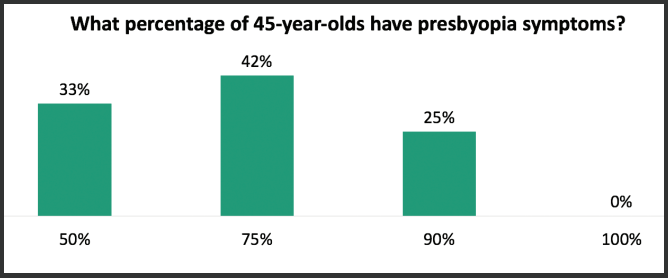
"I'm sure that magnifies the symptoms," said Dr. Yeu, "that are often shared between computer vision syndrome, the dry eye that occurs from it, plus, the actual changes that occur from presbyopia."

"One of the impressions I have," said Dr. Lindstrom, "is that along with this increasing incidence of presbyopia, there is also an increasing incidence of dry eye disease (DED) and they go together. Both are age related in incidence and prevalence. As we bring new patients into our offices to discuss the new eye drop therapies for their presbyopia, I think it's going to be incumbent on us to also look carefully for DED."

Darrell E. White, MD, agreed: "I think there's a multiplier effect that goes in both directions. The effect of the dryness is made worse by presbyopia and the effect of the presbyopia is made worse by the dryness. It's like that negative feedback loop that we have in DED. Inflammation begets dryness, which begets inflammation, which begets dryness. I think the same thing happens back and forth between the presbyopia and the dryness."

CONSENSUS PANEL FINDING #2

Two-thirds of the panel believe more than 75% of 45-year-old patients have presbyopia symptoms.



PATIENTS HAVE INCREASED EXPECTATIONS

Dr. White also said he now receives more complaints from patients than in the past that are related to difficulties with using their bifocals as they use their computers more. "It seems to be a heavier lift for so many people with their presbyopia correction with spectacles and with multifocal contact lenses because they need that arms-length as well as the up-close vision," he said.

"Many patients we're seeing today are used to not wearing glasses," said Dr. Gupta. "Many early presbyopes have had LASIK, and they don't want to wear glasses, and haven't needed to, so it's a very jarring concept to them." She agreed that modern technology requires a range of vision and added, "it really highlights that we don't have a great solution to provide that flexibility. And certainly, our patients have the expectation because they've experienced such great vision, many of them having had refractive surgery in the past."

PATIENT DEMOGRAPHICS AND EXPERIENCE

"Obviously, we have a population that is growing," Dr. Karpecki said. "Incomes and education are rising. Life expectancy is increasing. We're working longer, and not only more hours, but we're working longer in our life expectancy. The near task becomes more important to everything that we're doing with the adoption of digital technology. Zoom calls, increased screen time

" The impact here is tremendous when you think about how much we are working with this. It's the No. 1 frustration in my office. Outside of any sort of physiological condition, problem, or issue, this is driving people to see us to try and come up with solutions."

— Gina M. Wesley, OD, MS, FAAO

on computers, tablets, and smart phones, everything done on digital displays makes better near vision a necessity. And people are picking up on it sooner. If TV time is included, the amount of time increases dramatically. Presbyopia patients suffer from additional visual stress, productivity losses, intermediate and near difficulty going in between and finding that key spot. They're left over- or under-corrected, which can affect nighttime driving distance vision."

"The diagnosis of presbyopia is such a simple diagnosis," said Dr. Schaeffer, "as you observe daily how many of our patients are using large fonts on their devices. I am surprised how many patients in their late 30s and early 40s are enlarging their fonts. Is this prepresbyopia?"

Dr. Gaddie pointed out that gamers, spending so much time on their screens, are potential candidates for a presbyopia agent as they are likely having presbyopic type challenges with the screen time.

"With the pandemic," said Dr. Wesley, "it was like taking all of our suspicions of what happens with prolonged near point work and tasks and exploding it upon us more than we've ever seen before. My conversations everyday now circulate around how patients can be more comfortable with their vision. It's not about clarity any longer. It's about comfort and being able to utilize vision to a maximum benefit on a day-to-day basis, and presbyopia is at the root of all of that."

1. Fricke TR, Tahhan N, Resnikoff S, et al. Global Prevalence of Presbyopia and Vision Impairment from Uncorrected Presbyopia: Systematic Review, Meta-analysis, and Modelling. *Ophthalmology*. 2018;125(10):1492-1499.
2. Berdahl J, Bala C, Dhariwal M, et al. Patient and Economic Burden of Presbyopia: A Systematic Literature Review. *Clin Ophthalmol*. 2020;14:3439-3450.
3. Census US. US: Estimated 2010 Prevalence of Presbyopia in Adults Aged 45 or Older; Census Figure Applied to Prevalence Number to Calculate Rate. Bonilla-Warford N; "What to Do with "New" Presbyopes." *Review of Optometry*. 2010:42.

CORRELATION BETWEEN PRESBYOPIA PROGRESSION AND QUALITY OF LIFE

Dr. Lindstrom raised the question of what brings a patient who has presbyopia into the eye care provider's office. "Let's say they didn't have any other issue, what are they worried about?" he asked.

"It's a lot of daily tasks," said Dr. Karpecki, "such as reading, writing, threading needles, mobile phones, difficulties in using navigation systems, just vision being blurred, or under-corrected so you can't read. There are a lot of things that go beyond just reading, even though these are near visual tasks." He added that people can be competitive at work, and if work slows down because of presbyopia, it can be frustrating (Figure).

"Nobody likes to pull out their readers in the middle of any social event, reading the dinner menu, being out and about," Dr. Gupta said. "And frankly, it's an inconvenience if you're not used to carrying around reading glasses. You're looking in all your pockets."

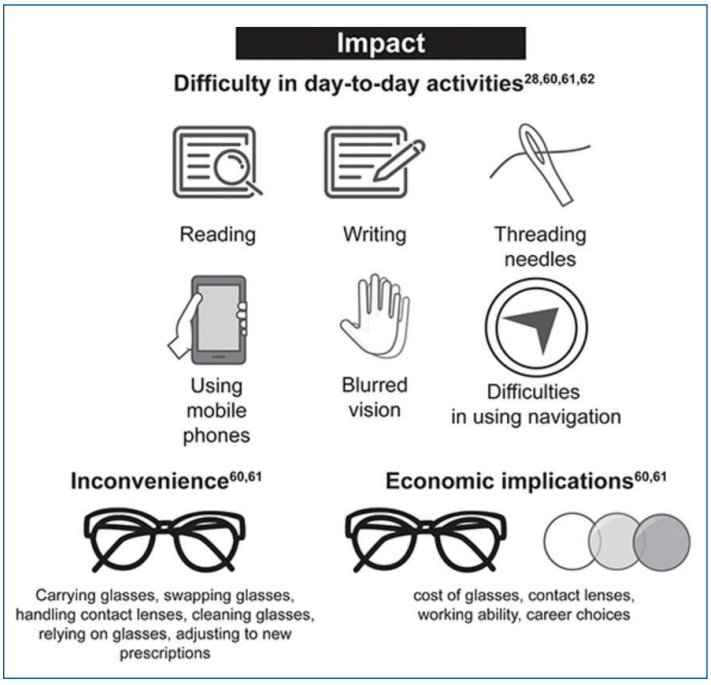


Figure. Impact of uncorrected presbyopia on daily activities.[1]

"I feel like glasses have become more of a fashionable thing in the millennial group," said Dr. Koetting, "and the eldest millennials are getting close to the presbyopic age. But overall, the patients that I have currently don't want to wear glasses. They see them as cumbersome and would prefer to stay away from them if they can."

Dr. Cunningham said that in politics there is a general unwritten rule that people are not reelected if they wear glasses. "Apparently, it's seen as a handicap or a harbinger of age," he said. "The first thing we do for these people, because typically their political analysts are telling them to do it, is either a lens exchange or a LASIK procedure."

"When the patient comes to see the eye care provider," said Dr. Lindstrom, "they often are very anxious and concerned about their loss of near vision. This is important to patients, and we are going to have more of these patients coming into our offices as the word gets out that there are new treatments, including eye drops."

PATIENT DECISION-MAKING

Dr. Karpecki said there was a time in refractive surgery, where the unwritten rule was not to mess with distance vision if you're trying to gain anything up close. Are the current presbyopia patients willing to compromise any distance vision to gain near vision?

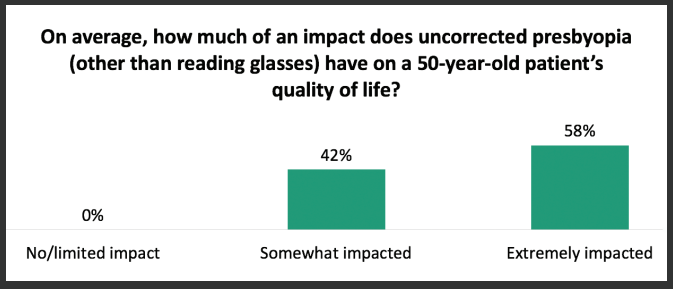
"I think people want it all," said Dr. Wesley, "and I think this is evidenced in the number of multifocal contact lens fits I have and the discussions about appropriate expectations. I usually have a conversation to determine what a patient might be willing to give

"Nobody likes to pull out their readers in the middle of any social event, reading the dinner menu, being out and about."

— Preeya K. Gupta, MD

CONSENSUS PANEL FINDING #3

Seven of 12 panel members believe uncorrected presbyopia extremely impacts a patient's quality of life.



up. Nine times out of 10, it's not distance vision. I don't think they are willing to give up on that to gain near vision."

Dr. Koetting agreed: "When I started wearing contact lenses, and having 3.00 D of astigmatism, I had to compromise because that was my only option. But now, as things have changed, I know better and there are more options. I think more people will be less likely to settle."

"I have patients coming with cataracts who have been contact lens wearers," said Dr. Holland, "and we have that difficult conversation when they want monofocal lenses and they want distance and near, and they're not fully corrected at distance with their contact lenses. I think patients are willing to give up a little distance, but not a lot."

SYMPTOMS ARE A FACTOR

Related to symptoms, patients must also decide what they will tolerate, possibly red eye, brow ache, or headache.

"I don't think this is a population that would be very accepting of red eyes," said Dr. Gupta. "Headache and brow ache, it's amazing how high the incidence of headache is in the general population, but people don't like it. Of those three, I think a little brow ache is probably acceptable. But again, the key is that it's mild because unless there's a high motivating factor, and of course, resolving presbyopia is, I think this patient population is just not used to compromising in many areas."

Dr. Gaddie feels it's too early to know and said, "I think it depends on the side effects and what actually happens. If the side effects are temporary and they don't last past the first dose, I could see a lot of patients being willing to tolerate it. But if it's consistent and these side effects continue, it would limit its use."

"I think it may have to do not so much with the level of presbyopia, but the degree of frustration felt by the patient," said Dr. Wesley. "For patients using multifocal lenses, they're willing to deal with some side effects once they've reached a breaking point. I think it may depend on the patient level of frustration and their perception of how things are working for them in their day-to-day activities that they'd be willing to put up with some of this."

Dr. Cunningham said that in the history of using pilocarpine for glaucoma, "brow ache and headache in people who still have accommodative function is a killer for them." He also said patients would rather wear reading glasses than have red eyes. "I think any one of these on some level is a deal breaker for a lot of patients," he said. "But if there's a way around these, it's really something that could have a substantial benefit with a vast majority of our patients."

"I think men are more willing to tolerate loss of near vision than women and they want that distance because their life is sometimes based further out," noted Dr. Rowen. "Women put on makeup and they're really working with small things, and I find that more women than men tolerate loss of distance for a gain of near. I'd say women, more than men, don't want to put on glasses to read."

REPORTED QUALITY OF LIFE

Previous literature has shown that presbyopic patients report up to a 22% decrease in quality-of-life score, and up to 80% of patients with uncorrected presbyopia report difficulty in performing near-vision related tasks. About 12% of presbyopes required help in performing routine activities. These visual limitations reportedly induce distress and low self-esteem in patients with presbyopia. Presbyopia can also pose an economic burden for patients by affecting their work productivity if the job requires use of near vision.[1] Presbyopia corrected with glasses is associated with a nominal decrease in quality of life, similar to that of treated hypertension, for the average person with the condition.[2]

1. Berdahl J, Bala C, Dhariwal M, et al. Patient and Economic Burden of Presbyopia: A Systematic Literature Review. *Clin Ophthalmol.* 2020;14:3439-3450.
2. Luo BP, Brown GC, Luo SC, et al. The quality of life associated with presbyopia. *Am J Ophthalmol.* 2008;145(4):618-622.

IDENTIFYING AND DIAGNOSING PATIENTS WITH PRESBYOPIA

What are some of the best practices for finding patients as they experience the earliest symptoms of presbyopia progression? Some of these patients are already visiting eye care professionals, but there is also a significant number of patients who buy reading glasses and have never visited an optometrist or ophthalmologist.

Dr. Karpecki noted that social media can be effective because the desired patients are in their 30s, 40s, and early 50s. "If we talk about the earliest stages of presbyopia correction," he said, "we're at that cusp of millennial age group and older. How do you best target that generation?"

"Today, social media and technology are key," Dr. Schaeffer said. "A strategic social presence and the use of in-office patient communication technology allows your practice to develop an educational relationship with your patients. This technology is best utilized when your patients educate other patients about your expertise and treatment patterns that improved their vision and their lives. This takes a formal social and communication strategy and a staff person in charge of the program. A testimonial of a patient, who is now utilizing an eye drop to enhance their ability to read instead of only glasses or contact lenses, elicits others to inquire and schedule their evaluation. Of course, having your patients' emails or following your social platform of choice is the key to success. The use of professional videos and testimonials will create the branding needed to attract curiosity, and most importantly, trust."

Dr. Wesley said these marketing videos could show examples of people in situations that illustrate how, before the drop, when they were with friends or family they relied on glasses or contacts to see more clearly, but after using the drops prescribed by their doctor, they do not need glasses or contacts. "It sparks the conversation," she said.

Dr. Holland said, "This is a question about the early presbyope, and I do think social media is where you're going to reach these patients. I think that's the key for this group. Many of them probably have never had an eye examination."

"It's definitely going to be social media that's going to reach out to that generation," said Dr. Koetting. "Ads that mention having tired eyes after being on a computer or make a joke about staring at this ad too long and now you've got tired eyes. Something to reach out."

"With proper direct-to-consumer marketing and having an online presence, things can go viral very quickly," added Dr. Yeu. "It doesn't just have to be your classic social media forums like Facebook or Twitter, but utilize places like Reddit or Doximity to increase public awareness about presbyopia. 'Are you in reading glasses?' Just quick little blurbs that would require less than 1 minute of the user's time can have tremendous impact and drive patients with phone calls and queries to the optometrist's office."

Dr. White works closely with optometrists both within his practice and outside of the practice. "I think a significant percentage of these patients are already seeing an optometrist. And that likely is a primary target for anybody who is going to market into this. I think a marketing program using an iconic person in the age group of the potential patients would be highly effective," Dr. White said.

BRINGING IN NEW PATIENTS

According to the American Optometric Association, optometry delivers 85% of the primary eye health care in America[1], but Dr. Karpecki pointed out there is a large population of patients that simply buy reading glasses and have never had an eye examination. He asked about ways to drive these patients into the office, and if perhaps the larger companies developing presbyopia therapeutics will play a role.

"Something we definitely struggle with as a profession is getting our patients into the chair," said Dr. Koetting. "Even if we're not seeing them for presbyopia, they still need to be checked for general eye health." She added that while dentistry has done a good job of getting people to come in once or twice a year, similar attempts in eye care have not been successful. "I feel like we need to take that on as a profession, for the bigger picture of it, not just presbyopia. As these treatments for presbyopia become available, maybe we can utilize that to piggyback on to find a way to get patients into the office, to take care of the problem they may or may not be noticing, but also to check their general eye health."

Dr. Gaddie personally knows presbyopes who feel reading glasses are all they need and won't see a doctor despite his urging them to have the health of their eyes checked. "They don't seem to get that the health of the eyes is important," he said. "You can put it on social media, you can do all the things that you want. However, I think the companies doing direct-to-consumer marketing and the media will drive these patients to our chairs."

"It's definitely going to be social media that's going to reach out to that generation."

— Cecelia Koetting, OD, FAAO

"Overall, it is important to understand that sometime later this year, there will be awareness marketing for a medical therapy for presbyopia."

— Richard Lindstrom, MD

"With the advent of pharmaceutical treatments, patients will seek professional eye care and possibly discover undiagnosed visual and medical conditions versus buying readers at the drug store and foregoing an eye examination," said Dr. Schaeffer.

Dr. Wesley suggested showing patients how it makes their life easier, and solves their problems, to increase their interest in coming in for an examination.

DIAGNOSING AND TREATING

"Overall, it is important to understand," said Dr. Lindstrom, "that sometime later this year, there will be awareness marketing for a medical therapy for presbyopia. The phone is going to start ringing, both at the ophthalmologist's and the optometrist's office, and we're all going to have to learn how to manage this, much like many of us learned how to manage DED with some type of integrated eye care delivery model." He asked the panel what would comprise an appropriate initial workup for these patients, and said he would do refraction and a complete eye examination, but raised the question, "Do we need a questionnaire, or can we simply take the patient's history?"

"The questionnaire makes the history go so much faster," said Dr. White. "We can make the conversation so much more directed by prepping them with our questionnaire. And the more tightly the questions are targeted, the quicker the examination goes."

Dr. Holland agreed with using a questionnaire and added, "A lot of patients in that early presbyopic age group actually seek out a refractive surgeon. In the questionnaire they should be asked why they came into the office. Possibly this loss of near vision? That's not an uncommon finding we see in questionnaires. Then you have that discussion with patients that refractive surgery really can't help them when they've lost their near vision."

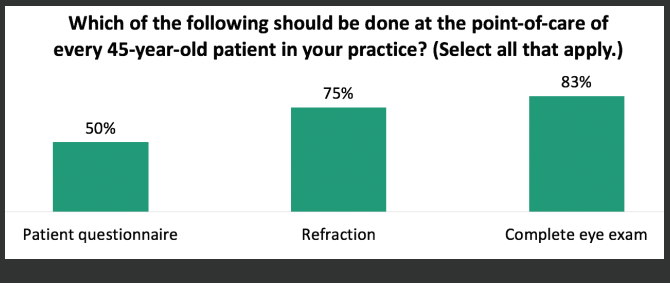
Dr. Karpecki said the initial examination needs to be comprehensive, including dilating and looking at the lens. He added, "I think patients are going to self-identify. They're going to come out and tell us they're having problems."

"It's easy for patients to self identify," said Dr. Schaeffer. "They already do. 'My arm's not long enough and I need more light to read.' I agree that a comprehensive eye examination with dilation is imperative. A complete assessment of the crystalline lens is so important with the new advances in eye care especially when considering options for visual improvement with a changing lens structure and function. This is especially important in the early 30s and 40s, so we gain more understanding of the early function changes. Whether deciding on effective pupil size and central lens changes or opacities and/or early surgical options, a comprehensive evaluation of the lens has never been more important. Prescribing a pupil size reduction on a patient with a central opacity is just going to lead to wasted time and money. There is no room for failure that can be predicted, as with new technologies we want early successes."

"We would like to develop relationships earlier with these patients," Dr. Rowen said, "and explain what their options are. If we have drops, it's a great entry into letting them see how much better they might be able to see up close without needing glasses. They might be more motivated to do surgical procedures 5 years later versus waiting 10, 15, or 20 years later with cataract, because they really want to be glasses-free. It's difficult because what are you offering them in the early phases of presbyopia? You could be offering a plano presbyope degraded distance

CONSENSUS PANEL FINDING #4

Most panel members believe patient questionnaires, refraction, and a complete eye exam should all be performed on every 45-year-old patient.



"I think patients are going to self-identify. They're going to come out and tell us they're having problems."

— Paul M. Karpecki, OD, FAAO

vision by doing monovision, and although many times it works really well, sometimes they just don't like it. I think we need to let them build into the relationship so they understand these are phases of our vision life cycle. We will have options for them, many of them being surgical later after we can't use the medical, and they'll be already primed for it and understand it."

"There are many patients who are not plano and presbyopic," added Dr. Gupta. "They come in with other refractive errors. And for a refractive practice, this might be an opportunity to perform distance vision LASIK and offer an additional therapy. For patients who are wearing progressive glasses or multifocal contacts, they understand some of the limitations of glasses and contact lenses and I think there are going to be patients who could still be captured within the practice and provide value to the practice, even though they initially came for another reason."

1. American Optometric Association. 2019 year in review. aoa.uberflip.com/i/1203282-2019-year-in-review/

EFFICACY, SAFETY, AND COMFORT CONSIDERATIONS FOR PHARMACEUTICAL PRESBYOPIA TREATMENTS

Dr. Cunningham pointed out that while surgical technologies have gotten better, they all have limitations. "The idea of a pharmaceutical treatment that can rely on the natural anatomy of the eye is very appealing, even to a surgical practice like mine," he said. He also said that in patients receiving an IOL who have issues with night vision or low vision, they use a pupil-constricting drop to help alleviate the issues. "And that's probably going to work equally well with someone who has a presbyopia-correcting IOL or someone who doesn't," he said. "So we're going to have utilities for this in our patients who don't have surgical correction and we're also going to have utilities for our patients who do have surgical correction."

"The FDA will be evaluating the efficacy and safety of eye drops to enhance near vision primarily by evaluating the improvement of three lines or more of best distance corrected near vision versus control," said Dr. Lindstrom. "But I think for most of us a two-line improvement is enough to be clinically meaningful. In addition, the near vision improvement must be obtained with less than one line loss of best-corrected distance vision. The adverse events are primarily temporary burning, hyperemia, decreased distance vision if the pupil gets too small, especially in dim light, brow ache, and headache. There can of course be allergy, and then there are rare things like a cataract being enhanced, retinal detachment, angle closure, inflammation and iris cysts."

CONSENSUS PANEL FINDING #5

The top three most significant criteria for patient satisfaction with pharmaceutical presbyopia treatments are

- 75% Consistent improvement of near vision with short onset time
- 58% Limit reduction of distance and night vision
- 50% Minimize adverse events

Dr. Lindstrom also said that when treating glaucoma with pilocarpine, patients often experience headaches at first, but with regular drop application these symptoms decline. "In decades past when we treated glaucoma with pilocarpine routinely, many patients had a brow ache and headache when they first started the eye drops," he said, "but if they used them regularly, they adapted."

"I use pilocarpine fairly often with our glaucoma specialist for moderate to severe poorly-controlled glaucoma," said Dr. Koetting. "A lot of it is just giving patients a heads up that this is like a muscle that hasn't been worked in a while. It's going to be uncomfortable for the first week or two and then it will get better, but they may still have a slight brow ache continuously for the duration of use. But they usually do adapt fairly well to the side effects, and this is in the higher doses."

"Years ago, when pilocarpine was a main glaucoma treatment," said Dr. Holland, "we had patients that just wouldn't take it. They wouldn't put up with the side effects even though we had long discussions on the long-term outcomes of intraocular pressure. As soon as there was an alternative to pilocarpine, most patients switched."

"We see these patients who've been on pilocarpine in the past for chronic glaucoma use and they commonly have poor movement of the pupil even off pilocarpine due to adhesions of the

"The idea of a pharmaceutical treatment that can rely on the natural anatomy of the eye is very appealing, even to a surgical practice like mine."

— Derek N. Cunningham, OD, FAAO

"When you compare it to using pilocarpine therapeutically in glaucoma, it's going to be a huge improvement."

— Ian Benjamin Gaddie, OD, FAAO

posterior iris to the lens," Dr. Yeu said. "And I'm concerned with any level of a higher concentration of the pilocarpine. If they continually use this drug over a longer period of time, will they start to have these almost fixed miotic pupils that surgeons will have to lyse and potentially complicate lens-based surgery in the future?"

Dr. Rowen replied, "These potential side effects from glaucoma range pilocarpine that could lead to highly constricted pupils, chronic brow aches, and synechiae should not happen with the highly diluted ranges of pilocarpine. The pupil will still have plenty of movement and the dosing is not 4 times a day, it will be on a prn basis. I am not worried about the sub-glaucoma doses causing these problems."

"As a general rule," Dr. Cunningham added, "we never give this to anyone who is phakic. It's miserable and they can't tolerate it. Also, it's a much different conversation to have with a surgical patient who knows there's a limitation to the postoperative period. They're willing to put up with a lot more misery for that time. One of the things we don't know is patient sensitivity to diluted or low concentration pilocarpine. Are patients going to be almost equally reactive or is there a threshold level of pilocarpine that really triggers these brow aches?"

Dr. Gaddie said with dosing pilocarpine three or four times daily, like in glaucoma, that the pupil becomes immobile. "It's a different discussion with most of the commercially available drops that we're going to be using. My experience in glaucoma has been that patients are either going to get over those side effects within the first few weeks, or they're not. And when they're not, you have to pull them off of it. I think it will be similar here. I just don't think the side effects will be as severe."

"Lower dose and intermittent use will definitely help," said Dr. Lindstrom. "As far as comfort, the diluent matters and some of them can generate more comfort."

OCULAR SURFACE HEALTH

"What about ocular surface health?" asked Dr. Karpecki. "Does an increase in drops become inconvenient for patients? If they eliminate and minimize adverse events, and may increase comfort, would that become the better choice? Is there an issue of having to dose more than once or twice a day?"

"Drops that are preservative free," Dr. Lindstrom said, "with a pH of 6 and up, would be particularly attractive for comfort, especially with the patient that has dry eye as well."

"I don't think multidosing is an issue for people because they may actually find it advantageous," said Dr. Koetting. "They'll understand it takes three doses to last all day, but they may only want to use it for 4 hours anyway, so it doesn't create a problem."

"It's an important question," said Dr. Holland, "because these are going to be a lot of younger patients. They're going to be on drops a couple times a day for years, and if there's a component of toxicity, that's cumulative."

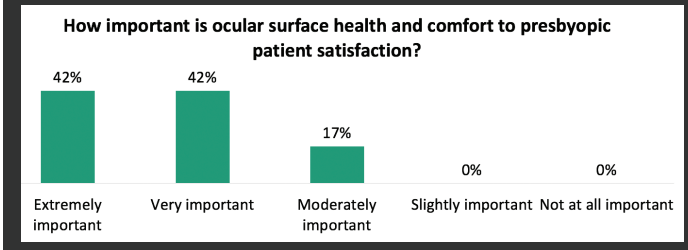
Dr. Gupta added, "I also think it's important to realize these are patients in whom we know the prevalence of dry eye increases with each decade of life. There are other factors to consider, including age-related changes. Quality of vision can be greatly impacted by DED and if there is a vehicle component, something that could provide additional protection and resolution or counteraction of that natural decline of the tear film, I think that would also be very helpful to achieve better vision quality."

"And as discussed earlier," said Dr. Yeu, "many patients never had to see an eye doctor prior to presbyopia, so there was really no ocular awareness. The eye was relatively comfortable. Then you add something that increases ocular awareness negatively, and the side-effect profile starts to not be worth the benefit for these patients. Being ocular surface-friendly and chronically comfortable would be a huge plus alongside treating this disease of presbyopia."

Dr. Gaddie added: "When you compare it to using pilocarpine therapeutically in glaucoma, it's going to be a huge improvement. When you look at the formulations that are being considered commercially, they realized there was a pH issue and those have been adjusted. It has to be something that goes in the eye, that dissipates quickly, that doesn't burn and sting, and that really has no drama with it."

CONSENSUS PANEL FINDING #6

Eighty-four percent of panel members believe that ocular surface health and comfort is "very" or "extremely" important to presbyopic patient satisfaction.



NEW AND EMERGING PHARMACEUTICAL PRESBYOPIA TREATMENTS

"There are a number of pharmaceutical agents being developed for presbyopia treatments," said Dr. Karpecki. "They can be broken into categories by treatment approaches; pupil modulation, lens softening, or combination agents that cause both pupil modulation and ciliary muscle contraction, which facilitates accommodation."

PUPIL MODULATION

Allergan (AGN-190584; 1.25% pilocarpine): Allergan completed phase 3 and announced submission of their New Drug Application (NDA) for Investigational AGN-190584 for the treatment of presbyopia on February 25, 2021.

"Allergan's 1.25% pilocarpine formulation is unique in terms of how they've made it," Dr. Karpecki said. "It's bilateral, once daily, and went for 30 days in a clinical trial. The endpoint that the FDA required was three lines or more vision improvement. They chose with mesopic light without loss of greater than five letters and it had to be that much better than the placebo. Data showed that a three-line improvement was achieved. The original formulation of this had oxymetazoline in it, but it didn't really show any extra benefits. In combination drug studies, both have to prove efficacy more than each one individually, so, the company went with just the pilocarpine."

Orasis (CSF-1; low dose pilocarpine): Orasis began enrollment in their phase 3 identical clinical trials, NEAR-1 and NEAR-2, in October 2020 with 600 subjects (300 subjects per study). Promising results from their well-powered phase 2b study pave a favorable path for advancement of their product candidate.

Dr. Karpecki said he thinks CSF-1, from Orasis, will be the next product out, following Allergan's launch. He explained that it has a preservative-free, low-dose pilocarpine and a multifaceted proprietary vehicle. The Orasis drop was designed to find the optimal balance of efficacy, safety, and comfort. "In clinical trials this was given twice a day for two weeks. They looked at improvement in distance corrected near visual acuity of two lines or three or greater. They wanted to look at both. The number of patients with greater than or equal to three lines improvement was 47% with the drug versus 16% with the vehicle. Patients achieving greater than 2 lines of improvement was 80%, which for many, will provide enough of an improvement. In this study there were only mild and temporary adverse events, and the drug had high levels of comfort and no redness, especially compared to the vehicle."

Dr. Lindstrom said, "The Orasis drug is preservative free in a lubricious vehicle while the Allergan drop is in a multi-dosed container and is preserved. Orasis completed their phase 2b study and they're currently enrolling in their phase 3 clinical trials. In phase 2, the Orasis low-dose pilocarpine showed ~8% headaches while Allergan showed ~20% plus which is due to Allergan's pilocarpine being over 3 times the concentration of Orasis. However, the higher concentration did demonstrate a higher peak effect on pupil size and slightly longer duration."

"There's this odd benefit," said Dr. Yeu, "of having a shorter duration of action with a lower potency pilocarpine, because it allows the pupil to move a little more. A shorter acting drop would also mitigate concerns under mesopic conditions, like nighttime driving. Once you start going above 1%, and if you are at a once-daily and a stronger miotic, I do have concerns that without the pupil moving intermittently, it can create some of those problems that we've seen in the past with stronger concentrations of pilocarpine."

Presbyopia Therapies (PRX-100; aceclidine): PRX-100 causes miosis without stimulating accommodation. The company completed a small-scale phase 2b study in mid-2018 and has not yet reported enrolling patients in phase 3.

Eyenovia (MicroLine; 1% or 2% pilocarpine): Eyenovia announced enrollment in the first of its phase 3 VISION trials on December 16, 2020, and expects to complete enrollment and have topline data in 2021.

"Eyenovia's Optejet dispenser delivers about 8 microliters," said Dr. Karpecki, "instead of a typical drop, which is between 30 and 50 microliters. So even though this is a 1% or 2% formulation, Eyenovia's hope is that with the small amount, there will be fewer adverse events, with a duration of about three to four hours. This is in phase 3 trials."

COMBINATION DRUGS

Ocuphire (0.75% Nyxol + 0.4% pilocarpine): Ocuphire announced on February 18, 2021, that it has enrolled the first patients in a phase 2 proof of concept trial, titled VEGA-1, to evaluate a combination kit of Nyxol and low-dose pilocarpine in presbyopia.

"Ocuphire has a combination drug that uses low-dose pilocarpine and Nyxol, two different mechanisms," said Dr. Karpecki.

"We're talking about the importance of ocular surface health, and I think we all understand that even a little bit of preservative can be sometimes just enough to tip the balance in a negative direction for these patients."

— Darrell E. White, MD

"I think what will happen is that patients will decide based on the efficacy and the side effect profile."

— Edward J. Holland, MD

"The company is finding that the Nyxol can last a significant period of time to offset the shorter duration for the pilocarpine.

But any time you do double agents, you have to be able to show that the end results are better than each one individually, so the clinical trials are a little more involved.

A phase 2 study of Nyxol alone showed it reduced pupil diameter resulting in better contrast. They're now in a phase 2 study of the combination drug."

Visus (Brimochol; brimonidine + carbachol): Visus announced the commencement of its phase 2 clinical trial of Brimochol topical ophthalmic solution under investigation for the treatment of presbyopia on March 25, 2021.

Dr. Karpecki continued, saying, "Visus has Brimochol, a combination of brimonidine and carbachol 3%, which is a miotic. An early study showed statistically significant improvement in visual acuity, a duration of eight to twelve hours, and was well tolerated, there were no reports of headaches or brow aches. The company is starting their phase 2 trials this year."

"This Visus drug makes the pupil the smallest of any other drug, but most of us that have used 3% carbachol in the past are a little bit concerned that such a strong miotic will cause a meaningful headache, especially if used intermittently. The company claims no headaches or brow aches because of the combination with brimonidine. I think we just have to follow that data," said Dr. Lindstrom.

LENS SOFTENING

Novartis (EV-06): Novartis' EV-06 eye drop is a lipoic acid-based, topically instilled prodrug that penetrates the cornea. Enzymes metabolized by the crystalline lens help reduce disulfide bonds between proteins and restore elasticity.

Dr. Lindstrom noted, "Novartis is using alpha-lipoic acid choline ester to reduce the disulfide bonds. They have shown near vision improvement in a phase 2a and phase 2b controlled randomized masked clinical trial."

"The sulfhydryl bonds that we are born with are very flexible when a person is young," said Dr. Karpecki, "and a cytosol muscle contracting agent is able to weave between them. As we age, we develop disulfide bonds through oxidation, which become very rigid. Novartis believes this is a big reason why the lens shows such rigidity. This agent is really an antioxidant, so it has significant benefits in terms of almost reversing, to an extent, what is occurring, and they've been able to take these disulfide bonds and convert them to sulfhydryl bonds, very similar to what we would have had at a younger age. In early studies, at day 91, they have shown significant improvement in distance corrected near vision compared to placebo. That was just looking at the difference from placebo though; if the FDA requires three lines, that could be difficult for this drug. However, because it's a different mechanism, it may apply in other areas."

"The thing that I would note," Dr. White said, "is the fact that not all of these are nonpreserved. We're talking about the importance of ocular surface health, and I think we all understand that even a little bit of preservative can be sometimes just enough to tip the balance in a negative direction for these patients. And these are people who are coming in to see doctors for one specific problem and all of a sudden they have a new problem to be solved because of drop side effects. I think that there's going to be an important emphasis placed on not giving them a new problem."

Dr. Holland added, "The other thing is that we will have a variety of different miotics that have a different duration of action. Some you take one drop that will last many hours and other medications don't last as long. That gives the patient the option of using it once a day or twice a day depending on how much near vision they want, how many hours a day. We have a variety of concentrations and we'll see a variety of side effects, and I think what will happen is that patients will decide based on the efficacy and the side effect profile."

THE PATIENT JOURNEY

INTERACTING AND COUNSELING WITH THE EYE CARE PROFESSIONAL

Dr. Karpecki said he's aware that some doctors increase their success in interacting with patients through subtle things such as sitting a little bit to their side when talking with them, instead of directly facing them, to help the patient feel more like it's a partnership.

"When I talk to patients," Dr. Cunningham said, "I really let them know there are several options available, and my goal is to give them the best vision possible. That's basically how I talk about it. I don't talk about lens technologies. I don't talk about specifics. I talk about vision and how they're going to see. And it's very much a face-to-face engagement. I'm not typing on the computer. I'm not writing anything down. I'm listening to their issues."

EDUCATING PATIENTS

Dr. Lindstrom said a recent study showed only 50% of presbyopes who saw an eye care provider in the last 12 months received the information they needed, and only 15% received printed information.[1]

"Imagine a professional video, produced and performed by you, the doctor, that educates the patient on presbyopia, describes the treatment options, and has a patient testimonial explaining the benefits."

— Jack Schaeffer, OD, FAAO

"Is there a need for more educational materials," asked Dr. Karpecki, "or is that just inundated today because of social media and the way we communicate? There are doctors that say brochures get thrown into the trash or they get stuck in a drawer, and others that have patients who love being able to take something home. Other doctors say that it saves them time and they don't have to go through it to such a great extent."

"If I've got something to offer that's totally new," Dr. White said, "if I have a brochure, I'm going to give them a brochure. As soon as I have a video, through one of the online platforms such as Rendia, MDbackline, and CheckedUp, I'm going to send a video home to them because it's easy and quick and simple. And I'll link to whichever celebrity the companies do. Video has a much greater impact."

Dr. Cunningham said what would be valuable for his practice would be a concise video that explained the different options to a presbyope. "Every single person who schedules an appointment at my clinic automatically would be sent the video so they could watch it before they came to the practice. We could resend it afterwards. The video would easily provide detailed information and would also allow them to share it with family members."

"This is where social media and new communication technologies will allow a practice to introduce and maximize new technologies," said Dr. Schaeffer. "Imagine a professional video, produced and performed by you, the doctor, that educates the patient on presbyopia, describes the treatment options, and has a patient testimonial explaining the benefits. This would be sent to your entire database of patients older than 40. A second targeted video would be sent to all patients old than 40 who are scheduled for an eye examination. They can request a brochure that is custom designed for your practice and is specific for the treatment modality they desire. The work is already done by technology and technicians before that patient ever sees the doctor. Technology, when used effectively, is beautiful."

Dr. Wesley said she has been running drip campaigns. "It is an email regarding a specific topic or interest," she explained, "that a patient may get over a period of one month to three months, and it's spaced out by a week to several weeks, depending on the topic. We send Bitly links to patients with PDFs they can enlarge on their screens. I think we need to market to and educate our patients more like they're being marketed to and educated in other industries."

Dr. Koetting said that speaks more to those who are emerging presbyopes. "I know my older patients will ask for pamphlets and things like that," she said, "but I just don't know if that's a longer-term solution, especially as we're talking about the future. I think we need to start moving toward other modalities."

"It might be valuable to upgrade our websites to let people learn about these new presbyopia eye drop treatments," said Dr. Lindstrom. "Any other thoughts on what you might do as far as patient education adjuncts?"

Figure. Dr. Gina Wesley consults with a patient.

Image courtesy of Gina Wesley, OD, FAAO

"A great option is to involve your staff members," said Dr. Gupta, "and diversify what they're doing, whether it's the people who are working up patients from the start of your practice or even being advocates. When a pharmacological therapy is introduced into the market, offices will likely be flooded with phone calls. Even at that point of contact, have the person answering the telephone be able to answer questions. It's going to be a group effort in trying to educate."

"I think it's important for us to have roundtable discussions with our community ODs," said Dr. Yeu, "to better understand how we can work with them. This is an area that generates revenue for them as well."

"It's also an opportunity to improve your relationship with your referring optometrist, give them back new patients," said Dr. Holland. "If a presbyopic patient comes to see me, I'll talk to them about the options available with these new drops. But I'm not going to be the person who will evaluate whether they like a certain one or potentially try a different one. I want my referring ODs to take over this patient and then refer them back to me when the patient has a cataract."

"I will want to be integrated with the community optometrist, and with the optometrists in my own practice, in this regard," said Dr. Lindstrom, "because they will likely be the primary caregivers for presbyopia treatment. Patients will want to be educated about spectacles, contact lenses and surgical options as well as eye drops. The patient can also be educated about the natural history of presbyopia, that they will progress through all the stages of the so-called dysfunctional lens syndrome and eventually develop a cataract with decreased quality of vision. Along that journey, natural lens removal and replacement will become an increasingly attractive option. I believe it will be attractive to capture these patients in any eye care practice and create a long-term relationship."

"Communication between the MDs and ODs, and providing education routinely for ODs, is so important," Dr. Yeu said, "and it creates greater opportunity. We know how debilitating the

"I think patients are starting to realize that not only do they go to the dentist every year, they also will come to the eye care doctor every year."

— Sheri Rowen, MD

traditional monovision of a -2.00 or a 2.00 D separation is for stereopsis. If you were to even create and prolong mini-monovision and add the drop into the near eye, you are now providing a greater benefit for the patient in preserving stereopsis. There is opportunity to enhance patient care by utilizing this as an adjunct in their presbyopia journey."

"I was just thinking that same thing," said Dr. Rowen, "because it's a perfect adjunct for a lot of things that we do. We don't have to necessarily make them a -1.50 or a -1.75 D. We could possibly leave them a -1.00 D and enhance that with the drops. It might even serve some of our pseudophakic patients to be able to allow them to get some increased depth of field. This is a vision life cycle paradigm. This is patient awareness. I think patients are starting to realize that not only do they go to the dentist every year, they also will come to the eye care doctor every year. And we can help integrate that. We will manage with our optometrists, and we will be partners with them to manage patients from this stage all the way through their cataract surgery and following their vision for life."

PATIENT MANAGEMENT

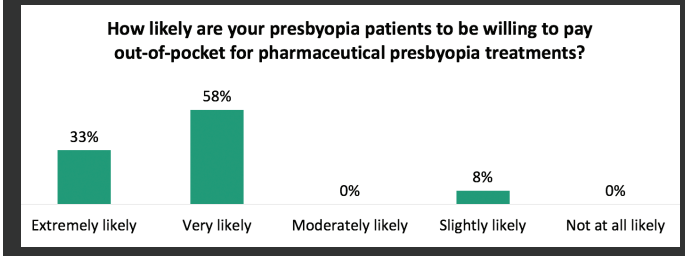
Dr. Karpecki asked if a certain model of practice (MD only, MD/OD hybrid, or OD referral) might be best suited for taking care of these patients. "Do you think an integrated OD/MD practice might have more difficulty because there are other incentives like surgical procedures?" he asked.

"I think it's pretty irrelevant," said Dr. Cunningham, who works in an MD/OD practice. "I'm not sure how independent optometry is going to do with this. Obviously, early adopters are early adopters and they're going to pick it up right away. I don't think it's going to affect our surgeries at all; in fact, I think it's going to increase them. We saw a similar thing recently with oxymetazoline. We thought it was going to decrease the number of blepharoplasties we were doing, and it significantly increased the amount because it brought a lot more awareness to it. And it brought patients into our clinic who had never had an eye examination because they were simply coming in for the cosmetic side of things, and we were identifying a lot of dry eye and other conditions. From our standpoint, I see this as doing nothing but increasing our business model and helping every aspect of our practice."

Dr. Koetting agreed: "I don't think it's going to take away from the surgeries. We had similar experiences with oxymetazoline. It brings up the conversation about the problem they're having. And even moving outside of the surgical realm, in the offices of doctors, it's adding to our armamentarium of what we have to actually treat these patients with and offer them. And it brings in those patients who probably were never wearing glasses anyway and just getting everything over the counter. They're going to want to be free of glasses because they always have been. I think it's just going to bring in a new group of patients."

CONSENSUS PANEL FINDING #7

Eleven of 12 panel members believe their presbyopia patients will be "very likely" or "extremely likely" to pay out-of-pocket for pharmaceutical presbyopia treatments.



Dr. Gaddie believes this will bring more patients into primary care optometry.

Dr. Cunningham said: "I think this is going to be a drug that people use as needed in combination with different types of vision correction. There are people who use-over the-counter drops and readers who don't see an eye doctor. They're going to want this drug so they can use it occasionally. Contact lens and cataract patients will use this. I really can't think of a single patient over the age of 35 who is not going to use this in some capacity."

Dr. Lindstrom said that for a small refractive error, something less than you'd need to wear glasses for, (i.e. -0.25 or +0.25 D, or 0.50 D of cylinder), or for someone with meaningful higher order aberrations, small aperture optics also work very well. "In a bright-light environment," he said, "small aperture optics induced by a miotic eye drop enhances your vision at all distances; far, intermediate and near. We are going to see a number of patients that we're going to be able to help with their overall quality of vision using miotic eye drops. For example, I have used miotic eye drops to help post radial keratotomy patients for decades. We will also have some patients where we will prescribe drops so they see better at golf, tennis, or hunting, for example. Golfers will see the ball more clearly, and not only that, if they are presbyopic, they will see their scorecard better. These drops will enhance many patients' lifestyles and quality of life. They will help people see better for several purposes and in many environments."

"And for night vision issues," said Dr. Rowen, "it will help the dysphotopsia problems that patients have, or that we've created with other surgeries."

FOLLOWING UP

"When do you see these patients back?" asked Dr. Karpecki. "Again, these are active lifestyle people. You put them on a drop and we don't expect a lot of adverse events, though there might be some in the beginning. We're going to communicate with them. But do you schedule follow-up visits like you might do for other conditions like dry eye disease?"

"The key to success with any new treatment is patient communication and effective follow-up procedure," said Dr. Schaeffer. "Success means, first and foremost, ocular health and patient satisfaction. Success also starts with the pre-evaluation, which includes ocular health evaluation, effect of the treatment on the ocular status and complications, and patient expectations. I know this will be a controversial topic, but I believe if we are going to prescribe a drug that may affect IOP, a complete optic nerve evaluation, pachymetry, and of course an IOP is important (even a possible screening visual field if any of the findings warrant). With patient expectations, possible adverse reactions should be covered. The first follow-up can be a virtual office visit to cover patient success, concerns, and any adverse reactions. There should be a 2- to 3-month follow-up with IOP evaluation and patient usage for our records. Over time we will learn how are patients are utilizing pharmaceutical treatments and we will better understand how to prescribe."

"I think we're going to probably see these patients more often as these therapies are starting to roll out, just because we aren't familiar with them," Dr. Koetting said. "So, probably at three or six months. Eventually we might feel more comfortable adjusting to six months or a year, depending on what we find we want to be doing with these patients."

Dr. Gaddie said he'll likely do follow-up at 2 weeks. "If they're going to have a problem," he said, "it's going to be in those first two weeks. And if they're doing well after that, I'm going to hopefully see them once a year for a comprehensive eye examination."

OUT OF POCKET PAYMENT

Given the parameter that the price will be "reasonable, but not inexpensive", most of the panelists felt patients will be very and extremely likely to use these treatments on an out-of-pocket basis. ■

1. Presbyopia: A Natural Part of Aging, Or A Frustrating Daily Challenge? *Ophthalmology Times,* April 13, 2021. ophthalmologytimes.com/view/presbyopia-a-natural-part-of-aging-or-a-frustrating-daily-challenge-

PILOCARPINE'S PATH TO THE PRESENT

By John Berdahl, MD; Murray Fingeret, OD, FAAO; and Ian Benjamin Gaddie, OD, FAAO

Pilocarpine has been used in glaucoma treatment for more than 120 years. It is predominantly used in open angle glaucoma but has a role in angle closure as well, pulling the iris away from the angle. It was the initial medication used for open angle glaucoma until the introduction of timolol in 1978.

The medication is in the parasympathomimetic family and has an effective pharmacology of stretching the spaces in the trabecular meshwork, opening the outflow system. Pilocarpine contracts the ciliary muscle, causing increased tension on the scleral spur and opening of the trabecular meshwork spaces to facilitate outflow of aqueous humor. Outflow resistance is reduced, lowering intraocular pressure. However, pilocarpine also stimulates the iris sphincter muscle, which leads to the pupil becoming smaller.

Pilocarpine is effective in most patients, but side effects are a problem, especially in younger patients. In glaucoma use the drops were applied every 4 to 6 hours, and the side effects—including headache, brow ache, blurry or fluctuating vision, tearing, and mild irritation—could became apparent as the drop was put in. There was also an unexpected impact on night and distance vision.

The medication has been prescribed in different concentrations, 1, 2, and 4%. The higher concentrations create more pressure lowering effect but may also cause less-tolerable side effects and can contribute to noncompliance.

Pilocarpine was quickly replaced by timolol when it became available, and then by prostaglandins like latanoprost, and by combination products and lasers. Pilocarpine is rarely used in glaucoma treatment now, but most glaucoma specialists still have a few patients on it due to age and other factors.

PILOCARPINE'S MIOTIC EFFECT

Pilocarpine is a miotic; it constricts the pupil. It causes contraction of the ciliary muscle and iris sphincter contraction. Combined, the sphincter contraction causes the diameter of the pupil to lessen, and the ciliary muscle contraction keeps it from opening back up, by preventing the iris sphincter from returning. The duration of effect varies based on dose and concentration. When the pupil gets smaller, at a certain size a pinhole effect is created, which can improve near vision.

IRIS COLOR MATTERS

When a medication is instilled into the eye and absorbed, some of the medication is bound by pigment. A darker colored eye, that has more pigment than a lighter colored eye, will bind up more of the drug, and patients with lighter colored irises will be more sensitive to medication.

USING A VISCOSITY AGENT

Pilocarpine can burn and sting on instillation. An agent with more viscosity should be more comfortable to the patient. Viscosity agents also raise the pH of pilocarpine, which increases the residence time on the cornea, creating a better chance of having an effect in the anterior chamber.

FOR FUTURE CONSIDERATION

Eye care professionals considering the use of pilocarpine on younger presbyopia patients should remember that these patients will accept no compromise for unwanted side effects or impact on distance or night vision. Additionally, the drop must be comfortable upon administration for use as a quality-of-life choice. At a lower dose, the miotic side effect profile may no longer be seen, but it will be important to remain receptive to any initial impressions of brow ache, blurred vision, or irritation.

PHARMACOLOGICAL PRESBYOPIA TREATMENT CONSENSUS STATEMENT: CLINICAL RECOMMENDATIONS FOR TODAY'S PRESBYOPIA PATIENT

CME Release Date: June 2021
COPE Release Date: June 18, 2021
COPE Expiration Date: June 18, 2023

INSTRUCTIONS FOR CREDIT

To receive credit, you must complete the attached Pretest/Posttest/Activity Evaluation/Satisfaction Measures Form and mail or fax to Evolve Medical Education LLC; 353 West Lancaster Avenue, Second Floor, Wayne, PA 19087; Fax: (215) 933-3950. To answer these questions online and receive real-time results, please go to https://evolvemeded.com/course/2111-Supplement. If you experience problems with the online test, please email us at info@evolvemeded.com. Certificates are issued electronically, therefore, please provide your email address below.

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

Full Name_____ ❑ MD/DO participant ❑ OD ❑ non-MD participant

Phone (required) _____ ❑ Email (required) _____

Address/P.O. Box _____

City _____ State/Country____ Zip/Postal Code _____

License Number _____ OE Tracker Number _____

DEMOGRAPHIC INFORMATION

Profession
___ MD/DO
___ OD
___ NP
___ Nurse/APN
___ PA
___ Other

Years in Practice
___ >20
___ 11-20
___ 6-10
___ 1-5
___ <1

Patients Seen Per Week (with the disease targeted in this activity)
___ 0
___ 1-15
___ 16-30
___ 31-50
___ 50+

Region
___ Northeast
___ Northwest
___ Midwest
___ Southeast
___ Southwest

Setting
___ Solo Practice
___ Community Hospital
___ Government or VA
___ Group Practice
___ Other
___ I do not actively practice

Models of Care
___ Fee for Service
___ ACO
___ Patient-Centered Medical Home
___ Capitation
___ Bundled Payments
___ Other

LEARNING OBJECTIVES

Did the program meet the following educational objectives?	Agree	Neutral	Disagree
Define the ideal presbyopia patient for pharmacological treatment, including age ranges, refractive error levels, key demographics, and other clinical and socioeconomic parameters	_____	_____	_____
Determine how to diagnose the presbyopia patient	_____	_____	_____
Compare and contrast the advantages and disadvantages of the various pharmacological presbyopia treatments, including efficacy, safety, and functionality	_____	_____	_____
Identify best practices on how to identify, communicate and educate the patient	_____	_____	_____

PLEASE COMPLETE AT THE CONCLUSION OF THE PROGRAM.

POSTTEST QUESTIONS

1. Based on this activity, please rate your confidence in your ability to compare and contrast the advantages and disadvantages of the various pharmacological presbyopia treatments (based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident).
A. 1
B. 2
C. 3
D. 4
E. 5

2. Presbyopia occurs when the ciliary muscle contracts, causing the zonules to:
A. Loosen
B. Dissolve
C. Increase in volume
D. Tighten

3. Although presbyopia is progressive and can occur at different ages in different patients, stiffening of the natural lens most commonly begins around the age of:
A. 20
B. 30
C. 40
D. 60

4. What is the estimated number of people affected by presbyopia globally?
A. Fewer than 500 million
B. 500 million – 750 million
C. 750 million – 1 billion
D. More than 1 billion

5. Most of the participants in this panel believe a complete eye exam should be part of an initial presbyopia diagnosis. What percentage felt a questionnaire should also be used?
A. 10%
B. 33%
C. 50%
D. 75%

6. Which of the following was NOT given as a factor in presbyopia?
A. An aging population
B. Computer eye syndrome
C. Increased exposure to sunlight
D. Digital eyestrain

7. The effects of presbyopia can negatively affect a patient's quality of life, frequently making all but which of the following more difficult?
A. Sewing
B. Reading
C. Walking the dog
D. Using mobile devices

8. Increased screen time for phones and other devices can have an effect on presbyopic patients. Which of the following is NOT a possible result of this?
A. Eyestrain
B. Headaches
C. Memory loss
D. Red eyes

9. What percentage of patients with uncorrected presbyopia report difficulty in performing near-vision related tasks, as stated in the literature?
A. Up to 60%
B. Up to 70%
C. Up to 80%
D. More than 90%

10. Which method of reaching potential patients for upcoming presbyopia treatments was described as "key"?
A. Television ads
B. Social media and technology
C. Word-of-mouth
D. Ads in print publications

11. For education, brochures are sometimes useful and sometimes not. Which of these did the panelists feel is the most effective method for educating patients today?
A. Home visits
B. In-practice educational seminars
C. Concise online videos
D. Daily email

12. The main problem encountered using pilocarpine in glaucoma treatment was:
A. Cost
B. Lack of efficacy
C. Availability of the drug
D. Hard-to-tolerate side effects

13. Pharmaceutical agents being developed for presbyopia fall into one of three categories. Which of the following is NOT one of these categories?
A. Pupil modulation
B. Scleral tightening
C. Lens softening
D. Combination agents

14. The main mechanism of action being applied in the upcoming pharmacologic presbyopia treatments discussed here is:
A. Miosis of the pupil
B. Reduction of intraocular pressure
C. Dilation of the pupil
D. Relaxing the cornea

15. Patients seeking presbyopia treatment may also need treatment for other conditions. It was discussed that which of the following may be exacerbated by use of pilocarpine drops?
A. Dry eye disease
B. Glaucoma
C. Keratoconus
D. Cataracts

16. How likely do most participants feel patients will be to pay a reasonable out-of-pocket cost for these medications?
A. Not at all likely
B. Slightly likely
C. Moderately likely
D. Very or extremely likely

ACTIVITY EVALUATION/SATISFACTION MEASURES

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

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

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

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

Probability of changing practice behavior based on this activity: _____ Yes _____ No _____No change needed

If you plan to change your practice behavior, what type of changes do you plan to implement? (check all that apply)

_____ Change in pharmaceutical therapy
_____ Change in diagnostic testing
_____ Change in current practice for referral
_____ My practice has been reinforced
_____ Change in nonpharmaceutical therapy
_____ Choice of treatment/management approach
_____ Change in differential diagnosis
_____ I do not plan to implement any new changes in practice

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

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

The design of the program was effective for the content conveyed. ___ Yes ___ No

The content supported the identified learning objectives. ___ Yes ___ No

The content was free of commercial bias. ___ Yes ___ No

The content was relative to your practice. ___ Yes ___ No

The faculty was effective. ___ Yes ___ No

You were satisfied overall with the activity. ___ Yes ___ No

Would you recommend this program to your colleagues? ___ Yes ___ No

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

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

Additional comments:
_____

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

This information will help evaluate this CME/CE activity; may we contact you by email in 3 months to see if you have made changes to your practice based on this activity? If so, please provide your email address _____

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