PRACTICAL MATTERS IN

Myopia Management

A SUPPLEMENT TO REVIEW of OPTOMETRY

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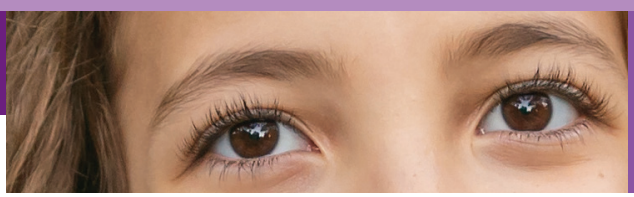

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§ Compared to a single vision 1 day lens over a 3-year period.

1. Chamberlain P et al. A 3-year Randomized Clinical Trial of MiSight® Lenses for Myopia Control. Optom Vis Sci. 2019;96(8):556-567

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CREATE AND DEFINE SUCCESS IN MYOPIA MANAGEMENT

To succeed in this new area of optometric care, consider resolving the following issues to take the next step in handling these patients.

ASHLEY WALLACE TUCKER, OD
HOUSTON

Dr. Tucker is the director of The Contact Lens Institute of Houston. She is a fellow of the American Academy of Optometry and the Scleral Lens Society. She is a consultant for CooperVision, Topcon and Bausch + Lomb.

As eyecare professionals, we have many opportunities each day to positively impact our patients' lives and eye health. Myopia management presents as certainly one of those opportunities—simple recommendations and strategic interventions can alter the entire trajectory of a patient's prescription that will ultimately decrease their risk for eye disease and improve their quality of life.

Who is a good candidate for myopia management?

When assessing a prospective candidate, bear in mind that previous myopia progression is not necessarily predictive of future progression. This statement works both ways—current prescription or axial length stability does not guarantee future stability and current progression does not predict future progression. Unfortunately, there is no reliable method to determine which category a particular child will fall in. Thus, clinicians should also consider a series of risk factors such as age of myopia onset, ethnicity, parental myopia, lifestyle, outdoor time, amount of near work and axial length.

With these thoughts in mind, deciding when to initiate myopia management can be tailored to each patient. Since myopia is progressive in the vast majority of children in which it manifests, adopting the mindset that all myopes beginning with refractions of -0.50D will benefit from myopia management is absolutely warranted. The commonly used phrase "every diopter matters" stems from the fact that slowing myopia progression by 1.00D reduces a patient's risk of developing myopic maculopathy, the most serious and sight-threatening consequence of myopia, by 40% regardless of the level of myopia.[1]

How do I discuss the benefits of myopia management with parents?

In most cases, parents are highly intrigued by the notion of controlling their child's myopia, especially if one or both parents experienced progressive myopia as a child. First off, they will likely want to know how their child became myopic or why their child's prescription is on track to surpass their own. Start the discussion with the fact that the world looks different than it did a few decades ago—kids now spend significantly less time outdoors and more time indoors on digital devices both at home and in school. This indoor/outdoor imbalance appears to be an uncontrollable variable and is contributing to a myopia epidemic worldwide.

We as a profession have adapted and shifted our focus—we no longer have to helplessly watch a child's prescription creep up; instead, we recommend myopia management. In fact, the World Council of Optometry in 2021 declared myopia management to be the standard of care. Fortunately, we now have several safe and effective options to help us accomplish the goal of myopia management, one of which is FDA approved. Secondly, be sure to clearly define success. Myopia management does not equate to preventing myopia progression or axial elongation but instead slowing it down. Conveying this distinction is imperative. The most widely accepted metric for success is slowing myopia progression by at least 50%.

To put this into perspective for parents, give them an example. Their child's prescription increased by 1.00D this past year, but had they been using some form of myopia control for that year, we would, ideally, expect only 0.50D of progression or less. Lastly, we must gently impress upon parents that myopia is not just being nearsighted,

Fig. 1. Odds ratios of increased risk of ocular pathology with increasing levels of myopia.[2]

LEVEL OF MYOPIA	CATARACTS	GLAUCOMA	RETINA DETACHMENT	MYOPIC MACULOPATHY
-1.00D TO -3.00D	2x	2x	3x	2x
-3.00D TO -6.00D	3x	3x	9x	10x
OVER -6.00D	5x	14x	22x	41x

but it is, more importantly, elongation of the eye beyond what is normal for their child's age. This axial length elongation puts their child at increased risk for pathologies like primary open-angle glaucoma, cataracts, retinal detachment and myopic maculopathy (*Figure 1*).[2] The goal of this part of the conversation is not to instill fear in the parents but to give concrete value to what we are trying to accomplish with myopia management. In addition, this reiterates that simply updating their child's glasses or contact lens prescription is not the appropriate solution. Drive home the idea that the goal for myopia control is a 50% reduction in progression. Many parents don't understand what that means.

After diving into these few points, most parents appreciate the expertise and willingness to help their child. The bottom line is that parents want what's best for their children and, at the very least, they want as much information as their eyecare provider can offer. Even if they do not sign up for a myopia management program at the first visit, by starting the conversation the practitioner has fulfilled their obligation with educating the family.

We have decided to proceed with myopia management—now what?

Prior to starting a myopia management modality of any kind, a thorough, comprehensive baseline examination should be completed. This is good clinical practice but also provides valuable baseline data that will be used to measure success. This exam includes:

Binocular vision assessment. Because myopia management strategies may impact binocular vision function and vice versa, a binocular vision assessment can provide helpful information on which treatment to choose. Specific tests recommended by the International Myopia Institute include distance and near cover test, near point of convergence, amplitude of accommodation, distance and near accommodative facility, accommodative accuracy (lead/lag), accommodative convergence/accommodation (AC/A) ratio and near fixation disparity (MEM).[3] Any binocular vision disorder, especially if symptomatic, should be managed before the commencement of myopia control efforts. Improved binocular vision function will also, ultimately, improve the patient's success in myopia management.

Cycloplegic refraction. The key to an accurate refraction in children is controlling accommodation. This is most commonly achieved with two drops of cyclopentolate 1% given five minutes apart, followed by a waiting period of 30 to 45 minutes. If the child is cooperative, cycloplegic autorefraction provides an excellent starting point for refraction. Oftentimes in younger children, a standard or handheld auto-refraction is the only measure of refractive error that can be obtained until the child is mature enough to provide reliable answers during refraction.

Anterior segment assessment. A thorough slit-lamp examination is necessary, especially for a patient who will potentially be wearing contact lenses of any kind. Give special attention to signs

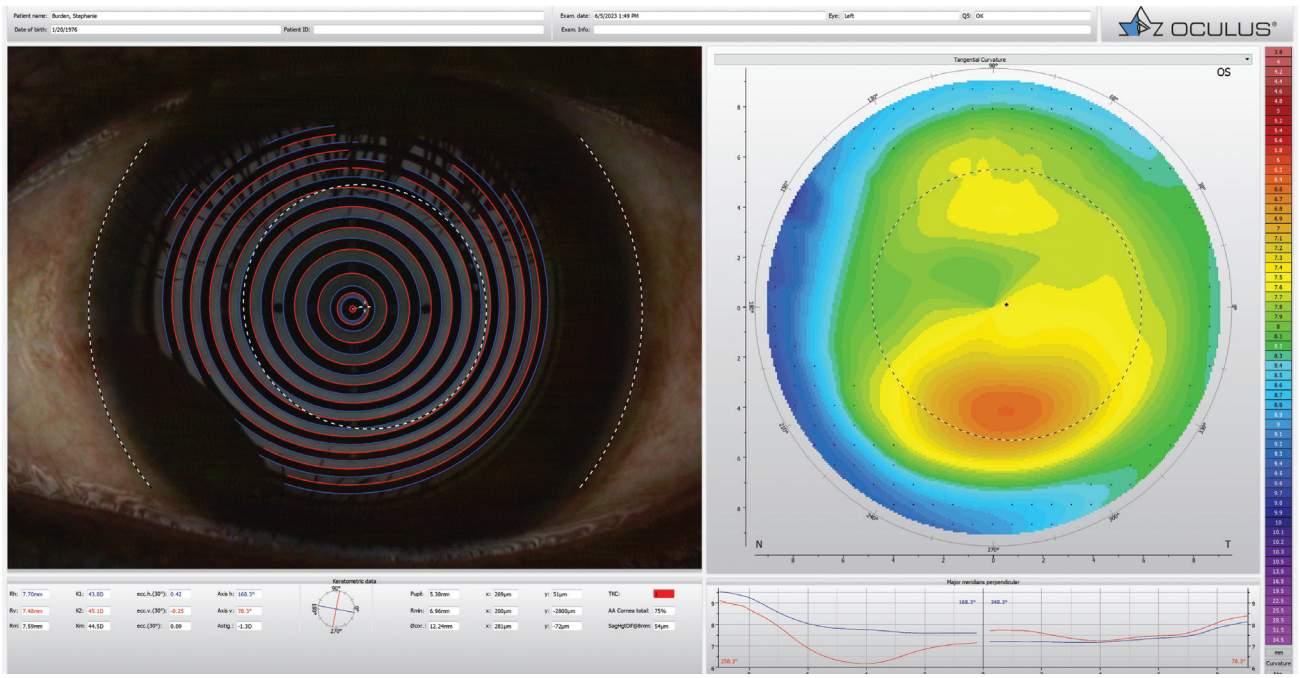

Fig. 2. Corneal topography can be a huge help in a myopia control practice.

of dry eye and/or meibomian gland dysfunction. If noted, these should be treated before a contact lens fitting.

Topography. In order to truly determine if a patient is an adequate orthokeratology (ortho-K) candidate, corneal topography is warranted (*Figure 2*). Be sure to rule out keratoconus or any other corneal irregularity that would contraindicate ortho-K.

Dilated fundus examination. Assess the retina for any current myopic changes and set a baseline for future comparisons. Fundus photography is an excellent adjunct to a dilated fundus exam and can be a great visual for both parents and the patient (*Figure 3*).

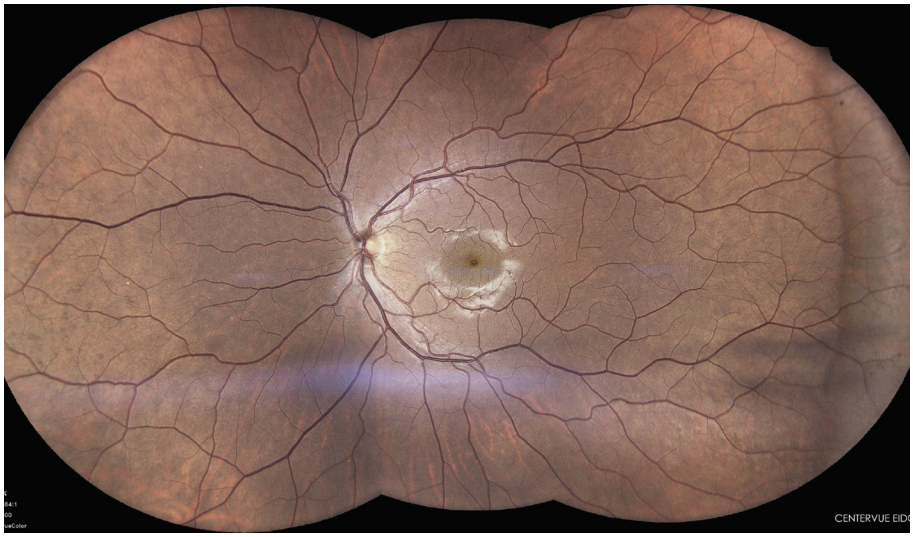

Fig. 3. Assess the retina with a dilated fundus examination for any current myopic changes and set a baseline for future comparisons.

Axial length. Although measuring axial length has yet to be widely adopted into everyday practice, its acceptance and value in myopia management is rapidly growing. Currently, there are several ultrasound devices and optical biometers on the market. Perhaps the most cost-effective options, however, are combination devices that not only measure axial length but also provide a plethora of additional information like topography, pupillometry and progression maps.

Obtaining a child's baseline axial length allows the practitioner to compare it with a normative chart and, thus, assess their risk for future progression. Consider sharing your assessment with the parents—they typically equate this information to height and weight measurement at the pediatrician. Simply knowing the value puts their child's current status into perspective. This is also another educational opportunity to reiterate that the goal of myopia management is to slow elongation of the eye which, in turn, slows myopia progression.

Pupil assessment. This responsibility is the same as in any routine exam—measure and record the size in both dim and bright illumination, check for an afferent pupillary defect and any other pupil anomaly. If any pupil abnormality is present, further investigation is warranted and use of a pharmaceutical agent for myopia control would be contraindicated.

Gathering baseline pupil measurements serves two additional purposes. If topical low-dose therapy is chosen, the practitioner can determine if there is a significant dilation effect that could be bothersome to the patient. Larger pupils may also be a contraindication for ortho-K due to the potential impact of visual disturbances like halo and glare in low-light situations.[4]

How do I choose which myopia management option is best?

Currently, the three most wildly available forms of myopia control are pharmaceutical therapy with low-dose atropine, soft multifocal or dual focus lenses, and ortho-K. Although each of these strategies could be successful for any given patient, there are special considerations for each. Atropine may be best reserved for younger patients who are not yet mature enough for contact lenses or for those who are unable or unwilling to wear contact lenses. Soft contact lenses are an excellent option for children who are current soft lens wearers and for patients mature enough to handle potential daytime nuances of soft contact lens wear (*Figure 4*). Lastly, ortho-K is the best option for any patient wishing to have freedom from daytime contact lens wear or for younger patients whose parents wish to maintain control of contact lens wear within the household.

It is important to note that there is currently only one FDA-approved option for myopia control—CooperVision's MiSight 1-day lens. Although the other options are not approved by the FDA for myopia control, many studies support their use for such purposes and validate their efficacy. For complete transparency, this information about FDA approval should be included in the discussion about which option is best suited for a child as this may impact a family's decision.

In addition, there are simple lifestyle changes that can enhance any of the above modalities, whether it be the treatment of choice for parents not ready to start a more traditional modality or a strategy to prevent myopia in pre-myopic children. Spending more time outdoors is the most common recommendation and has been recognized for years to prevent or delay myopia

onset. The current recommendation is now is to spend at least two hours per day outdoors, but the more time the better; in fact, children who spent less than 13 hours per week outdoors have a significantly higher risk of incident myopia.[5] Limiting near work to 30 continuous minutes or less and increasing the near working distance to at least 30cm are also useful recommendations.[6]

When do I follow-up?

Ongoing care for each treatment modality is slightly different and can vary depending on the needs of the patient and the clinician's comfort level. Below is a recommended follow-up schedule for each myopia management modality.

At the six-month follow-up, regardless of modality, repeat the cycloplegic refraction and axial length measurements. All additional baseline testing should be completed annually.

Atropine: One week after start, then quarterly.

At each visit, assess pupil size to ensure the dilation effect is stable from visit to visit. Also, ask the patient if they are experiencing an uncomfortable amount of photosensitivity, near blur or any other ocular or systemic side effects. If so, consider reducing the dose first before discontinuing altogether. Note, according to the Low-Dose Atropine for Myopia Progression (LAMP) trial, the recommended starting dose for atropine is 0.05%, but lower doses of 0.025% and 0.01%, although less effective, are also in use.[7] The key is to find a dosage for the patient that is tolerable and provides adequate myopia control.

Soft contact lenses: One week after start, then quarterly.

Once a patient is well-established in soft lenses, the practitioner should routinely assess the fit of the lens and the patient's ocular health. A spherical overrefraction with loose lenses provides a quick assessment of potential refractive error change. However, the most accurate assessment is the cycloplegic refraction done biannually.

Ortho-K: One day after start; one week after start; one month after, then quarterly.

Orthokeratology follow-ups can be the most variable because they depend on how well the initial lens design fits the patient. The above schedule is for the ideal lens design. More frequent follow-ups will be warranted if changes to the lens design are made at any point during the fitting process. At each visit, topography is warranted to determine proper centration and treatment of the lens. A refraction, whether cycloplegic or not, usually doesn't provide the most helpful information since the goal of ortho-K is to eliminate refractive error. For these patients, axial length is the best measure of refractive change which should be performed biannually along with the cycloplegic refraction.

Fig. 4. Consider whether patients are mature enough to be responsible with soft contact lenses.

How is success defined?

As mentioned above, most practitioners agree that a myopia management modality is considered successful if myopic progression has been slowed by at least 50%. Since no one can predict the future, it is impossible to know whether we have achieved this goal from year to year. However, the best predictor of the future is the past. Thus, if the child progressed—in refractive error and/or axial length—no more than half of what they had progressed in the year prior, then the clinician can consider their efforts successful. When assessing myopia control success in terms of axial length, the general goal is to achieve <0.2mm elongation in children under 10 years old and <0.1mm elongation in children over 10 years old per year.[8,9]

Since we have such effective myopia management options available to us now, there will be some children who hardly progress or do not progress at all. For those who do progress, be sure to put the progression into perspective and focus on the fact that had no myopia management been put into place, there would certainly be more significant progression. In addition, if the amount of progression slowing does not meet or exceeds your expectations, then switching to a different modality or combination therapy may need to be considered.

Combination therapy for myopia most commonly includes coupling low-dose atropine with soft contact lenses or ortho-K. This would also be an appropriate time to review with patients and parents the importance of outdoor time and near work habits.

Are Axial Length Measurements a part of your myopia control program ?

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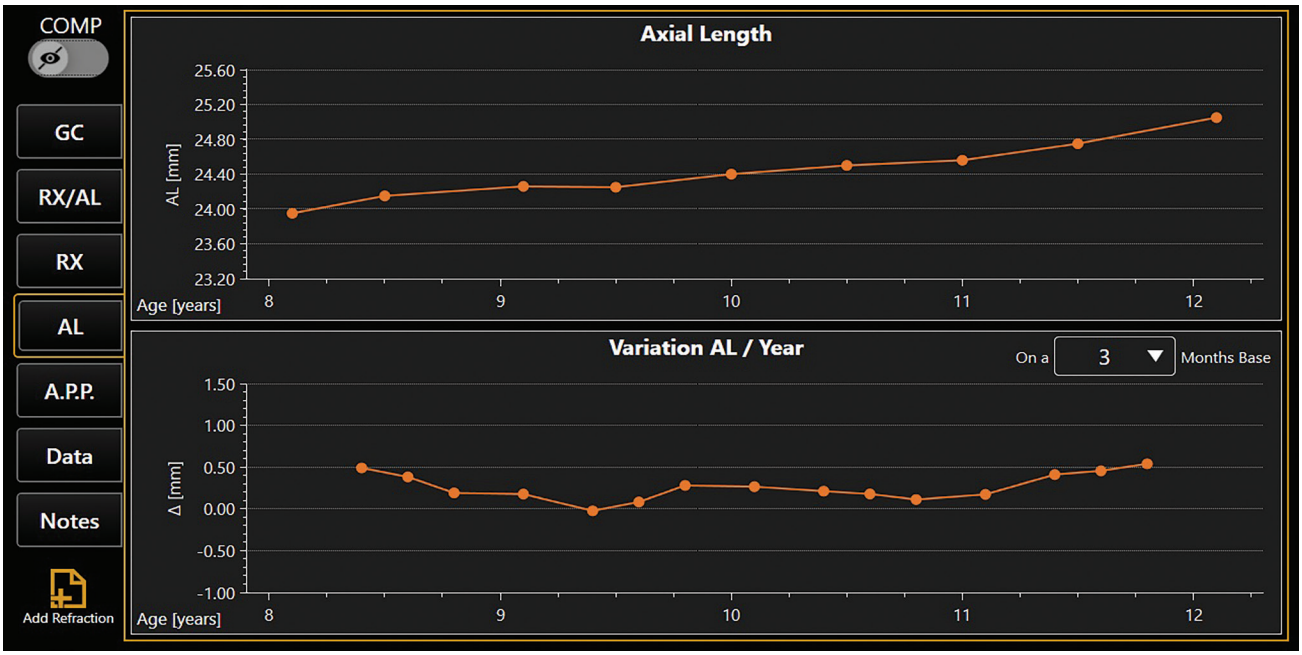

Fig. 5. Progression maps on combination devices can provide an excellent visual on the effect of myopia management for both the practitioner and parent.

A major advantage of the combination devices mentioned earlier is the built-in progression maps that some of these devices offer (*Figure 5*). They can plot both refractive error and axial length for each visit, which provides an excellent visual for both the practitioner and parents. Both stability and instability can be easily visualized, making the conversation on whether success is being achieved much easier.

How long should a patient continue myopia management?

There is no consensus amongst practitioners on exactly what age or how many years a patient should partake in myopia management, simply because every patient is different and unpredictable. We know that myopia progression is fastest in younger patients and tends to slow down during the teenage years. Thus, parents may want to discontinue myopia management once their teenager has shown consecutive years of stability. On the other hand, it is also reasonable to continue indefinitely, especially if the patient is a contact lens wearer and is happy with comfort and vision. Keep in mind that the COMET study found that at age 15, 50% of myopes were still progressing.[10] This may be useful information when parents are indecisive. Atropine as a monotherapy, however, is typically only used until the child can transition into a contact lens option, but there is no solid evidence that children cannot use atropine long term. As with use of any pharmaceutical, practitioners should routinely follow-up with the patient and adjust the treatment plan if needed.

Takeaways

Myopia management is life-changing and is truly a gift that should be offered to every child in your practice. Whether it is lifestyle recommendations, contact lenses or atropine, a child will benefit from any intervention set into place. It starts with effective communication and education that may need to occur several times before the parents say "Yes." Remember: Every single child deserves the opportunity to have better vision and quality of life; it is our job to make it happen. ■

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STEPHANIE RAMDASS, OD
TORONTO

MYOPIA MANAGEMENT: A 10-STEP PLAN FOR SUCCESS

What can seem overwhelming to start is broken down using practical advice and an outline to implement the most widespread form of control: corrective lenses.

Dr. Ramdass is in clinical practice in Toronto and Mississauga, Ontario, Canada. She graduated from the Inter American University of Puerto Rico School of Optometry and completed a cornea and contact lens residency at the Michigan College of Optometry. She's a member of the Ontario Association of Optometrists and fellow of the American Academy of Optometry and the Scleral Lens Society. Dr. Ramdass is a committee member and contributing author for the International Myopia Institute. Her practice, eyecademy.ca, is a Canadian pilot site for SightGlass Vision's Diffusion Optics Technology lenses.

Optometrists have been masters at measuring and managing refractive error for over a century, primarily by neutralizing it optically with corrective lenses rather than viewing it as a disease amenable to modification. Sentiment began to shift, however, following the 2016 publication of Brien Holden Vision Institute's prevalence estimates that alerted the world to a possible future in which half the global population would be myopic by 2050.[1] Five years after that seminal paper, the World Council of Optometry in 2021 deemed interventional treatment for myopia to be the new standard of care.[2] Whether or not you share that view, it's clear that the profession has embraced myopia management as a viable option for many children.

Newly graduating optometrists are now equipped with the proper tools to manage myopia after completing both didactic and clinical training during their time in optometric programs. A decade ago, only a handful of schools incorporated myopia management as part of the formal optometric curriculum or offered dedicated myopia management clinics to the local communities. This article will outline how myopia management can be incorporated smoothly for practitioners in their practice as well as where to start.

Step 1: Be the expert

As optometrists, we are the primary gatekeepers for managing myopia. While understanding nearsightedness as a common refractive error that is correctable with optical devices is our bread and butter, it is crucial to recognize myopia as a disease and consider it a treatable condition on par with dry eye, glaucoma and countless other ocular diseases. Our ability to classify it as such signals to young patients and their parents that we are in sync with current treatment paradigms.

To get to this point, you and your staff will need to learn more about different myopia management modalities, how they work and when they are optimal for use. Fortunately, educational resources are abundant. The International Myopia Institute (myopiainstitute.org) disseminates consensus papers from experts and many industry stakeholders provide didactic materials, too. There's also a continuously updated body of clinical peer-to-peer advice presented at *Review of Myopia Management* (www.reviewofmm.com), a sister publication to *Review of Optometry*.

Whether you are a new grad or are an eyecare provider wanting to explore myopia management for the first time, there are plenty of CE courses, both online and live, that offer great overviews of the options currently available. Local industry meetings and downloadable resources can also be helpful to summarize our current understanding of slowing the progression of myopia (*Figure 2*).

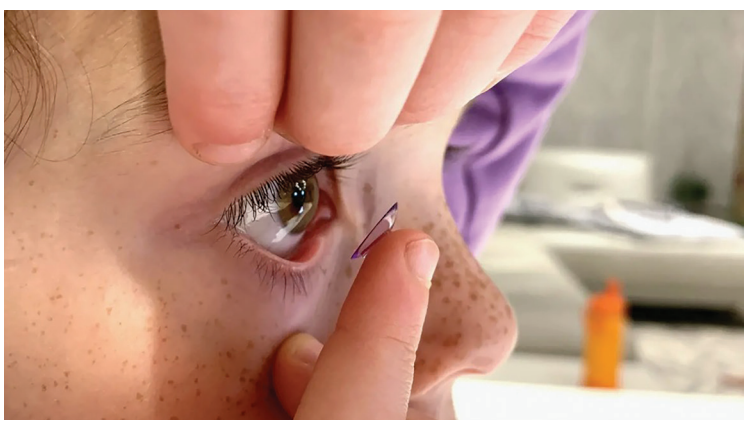

Fig. 1. Young patients can be successful in contact lenses with the proper help from parents.

Step 2: Build a patient base

I opened a cold-start practice in February 2021 with a heavy emphasis on myopia management. The biggest challenge I faced was finding patients, but if you are already in an established practice, look no further than your existing patient base. Most EHR systems have the ability to retroactively apply search criteria. This will allow you to, for example, check for myopes under the age of 10 seen in the last year. Sending these patients' parents an informative email or scheduling them for their annual visit is an excellent way to start their myopia management journey.

As a proactive approach, I used social media, conducted Zoom calls with concerned moms who questioned myopia management and had my local Business Improvement Area repost and share my

social media posts. All it really takes to get started is a handful of patients. Their parents will tell other parents, and in a short period of time you can build a local and perhaps cross-border or even international referral network. I communicated with local health professionals—the dentist next door, local family doctors, pediatricians and even pharmacists—regarding myopia management in my practice.

Step 3: Anticipate motivators and barriers to treatment

It is imperative to set the right expectations when broaching the subject of managing myopia. Parents need to understand that their child's myopia will likely progress no matter what; however, with treatment, we can significantly slow that progression. Do not promise complete cessation or even reversal of refractive error.

Once you have the parent(s) on board, determining which type of treatment to use is dependent on an interplay of factors. I often ask parents—or even the child—questions like, "Do you brush your teeth every day?" and "Do you make your bed every morning?" Adherence to common daily routines can determine if the child is ready for a contact lens option. Ultimately, it should be a group decision with parents, child and practitioner when deciding which modality to use.

Parents in and around my practice often have their children enrolled in extracurricular sports and see the use of ortho-K or myopia-slowing soft contact lenses as a way to simultaneously treat their child's myopia and provide a competitive edge over spectacle lens use. Some family doctors or pediatricians may not support myopia management, but that is typically because they are unaware of it. I simply remind parents that, although these are not new treatment options, an explosion of research in recent years supports the validity of the effort and those of us in the eyecare community are best positioned to gauge their child's viability.

The patient's ocular surface should be free of dry eye or blepharitis if choosing a contact lens option—typically not a problem with kids—and family and social situations should be considered, too. Does the child spend time at two different homes? If so, will contact lens supplies need to be provided at both? Having this type of information on your radar will ensure that parents are capable of adherence to their child's treatment protocol.

Step 4: Plant the seed during routine eye exams

I always like to reference the age-expected refractive norms for children when they receive an eye exam. The CLEERE study found that future myopia by age 13 is highly likely in children with refraction below +0.75D by the age of six to seven years.[3] These are the children who should be closely watched. Consider shorter intervals between eye examinations as well as behavioral advice on optimizing the child's visual environment (*i.e.*, the well-known recommendations of more outdoor time and less screen time).

For most new myopes, and definitely those with an esophoric posture, I will dilate them to confirm their prescription under cycloplegic conditions. Suppose the child is premyopic, meaning they are quickly on their way to losing their protective plus power. In that case, I will combine this factor with parental myopia and myopiagenic environmental factors to determine my treatment plan. Use an eye model or draw a sketch to show how cataracts and compromised retinal health can become greater risks with high myopia. Some parents will have no idea what you are talking about, while others will be on the ball and ask you if their child has progressed.

Step 5: Dedicate time to communicate

For parents who have not heard of myopia management—and barely understand myopia itself—it is vital to take your time to relay the critical information. There will be skeptics, but the more data you can provide, the higher the likelihood they will at least consider the value of starting myopia treatment. Educational tools such as normative growth curves and refractive error

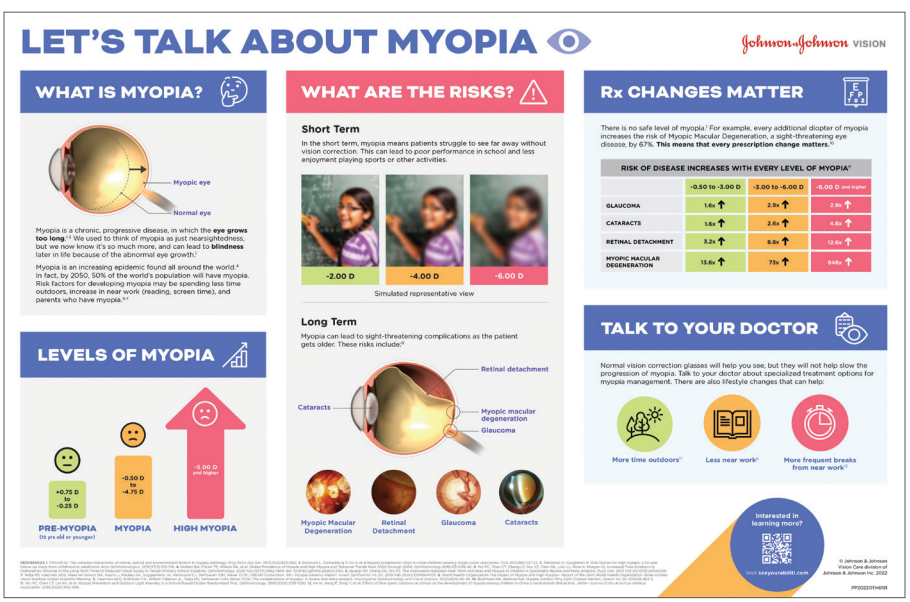

Fig. 2. This infographic aimed at parents succinctly conveys the risks of childhood myopia progression and why management should be considered. It's available for download to use in your practice.

prediction algorithms can be useful, especially if incorporated into instrumentation that can track patient data over time. The Myopia Calculator from the Brien Holden Vision Institute allows you to enter a patient's age, ethnicity, refractive error and prospective myopia management treatment. The calculator will estimate the level of expected myopia with or without treatment.[3]

In my patient scheduling, I use a dedicated myopia management consultation time-slot of 15 to 30 minutes to confirm the prescription, take axial length measurements and discuss risks, which is also where the calculator might come in handy to present both treated and untreated courses of action. With the focused consultation, there is time for all questions to be answered, and I also will follow up with an email to summarize the visit. This can be directly from you or a staff member who is dedicated to dealing with myopia management questions in your office. If the patient is referred in, completing reports back to the referring doctor reinforces referral loop closures and possibly secures future referrals.

Step 6: Present all options

Managing myopia is great in its versatility; many options are possible. It is important to communicate all options, whether they be optical, pharmaceutical, environmental or behavioral lifestyle modifications. I love displaying the flowchart in *Figure 3* on a screen and reviewing it with parents.

Regarding corrective lens modalities, contact lenses and spectacles lenses (available in Canada but not yet approved in the US) are the main first-line treatment options. Either off-label multifocal, approved dual-focus or orthokeratology (ortho-K) lenses can work effectively, as countless studies demonstrate. Optometrists in the US can use CooperVision's MiSight contact lenses on-label or VTI's NaturalVue lenses off-label. In Canada, we also have access to a dual-focus lens from Johnson & Johnson Vision called Acuvue Abiliti 1-Day, which uses a unique, ring-focused optical design. Also marketed in Canada but not yet the US are three spectacle lens options: Hoya's MiyoSmart, Essilor's Stellest and, most recently, Zeiss's MyoCare.

Forthcoming in the pipeline is CooperVision's SightGlass Vision MiSight spectacles. These lenses will use a different optical principle than traditional contact or spectacle lenses for myopia, which induce peripheral blur to blunt the signal that stimulates axial elongation.[4] Instead, SightGlass MiSight spectacle lenses will use a concept the manufacturer calls "diffusion optics technology" (DOT). The DOT concept differs by decreasing contrast sensitivity instead of inducing peripheral blur.[5] Since high contrast has been shown to cause myopia progression, this decrease may potentially slow down its course.[6]

Although dual-focus contacts and spectacles are different physical forms of vision correction, the two modalities offer comparable efficacy, hovering around 50% slowing of myopia.[7,8] The three spectacle options available in Canada also achieve nearly the same efficacy. Rather than competing, both contact lens and spectacle lens interventions offer a greater level of customized care that can be tailored to each patient's needs. Despite the deep penetration of myopia management seen with contact lenses because of their established availability in recent years, spectacle use so far has taken over a significant portion of pediatric contact lens wearers in my practice, achieving about a 50/50 split between modalities in use by my patients.

Potentially contributing to this trend, parents of my youngest patients seem most amenable to spectacle lens use; they are also easy for clinicians to prescribe. However, with these benefits also come drawbacks. Eyeglasses for myopia control are expensive; the single-vision lenses that parents may have bought before for $200 or less can reach prices of $800+ (CAD), which can be hard for parents to accept.

Moreover, while prescribing spectacles is straightforward, follow-through and management of the disease process of myopia can prove more challenging with glasses than contacts. When prescribing spectacles lenses, you want to determine the patient's baseline axial length and will want to keep continuous measurements on a three- or six-month basis to confirm if it is changing. If axial elongation is occurring along with refractive error changes, additional questions must be brought to the forefront: Is the patient

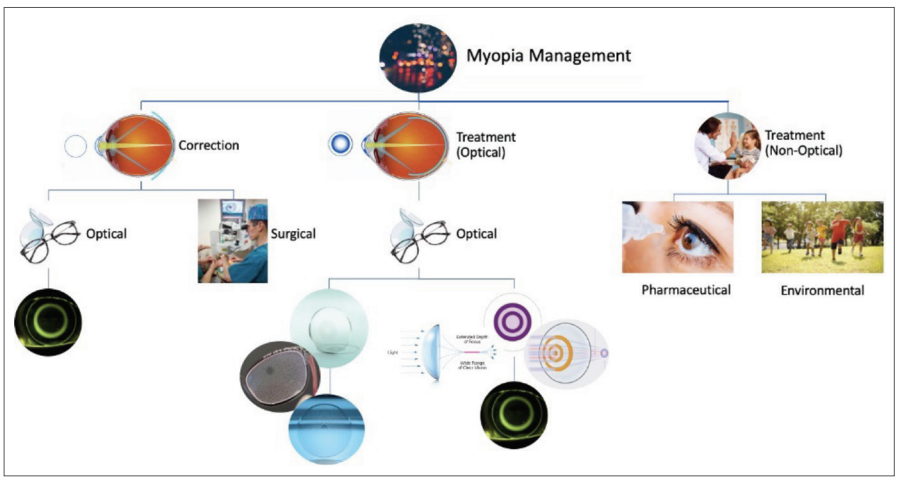

Fig. 3. This flowchart of possibilities for myopia management can help parents appreciate what options are available for each route.

being managed properly? Does adjunctive therapy need to be added? What would adjunctive therapy be? What would follow-up look like when initiating this? In this respect, contact lenses may be the easier modality to recommend if you anticipate the patient's prescription to change frequently.

The spectacle lens company policy usually has a 12-month warranty window for families who accept the spectacle lens option. For example, if the patient's Rx changes by a half-diopter or more within 12 months, one company will remake the lenses at no extra cost. After 12 months, lens use can be continued if there is no change in prescription, but if so, parents would again have to pay for another set of lenses (with the 12-month warranty window starting over for that set).

When considering contact lens options, I am more inclined to recommend hybrid multifocal and monthly toric multifocal lenses in patients with astigmatism, but it depends on their Rx. If it lies outside a specific range, I would lean toward a daily option over ortho-K or do partial ortho-K treatment. I also do not recommend single-use lenses for patients with considerable astigmatism unless going for a daily option with single vision glasses over top—that way, astigmatism is corrected.

Atropine can be first-line therapy for young children when contacts or glasses aren't options, say if the child is four to five years old or if parents are hesitant to try another modality. As the patient ages and their parents become more comfortable with you as their provider, adding spectacles or contact lenses may become more feasible. I will use 0.05% atropine as an adjunct to boost the efficacy of spectacle or contact lens corrective options if there has been additional progression or if there is high risk of increasing myopia. While I almost never use atropine at first, in rare cases I will administer it at three-month follow-ups with fast progressors. Most of the time, I add it in at six months if the patient's prescription has changed beyond what I expected, or if they jump a quarter or half step in a six-month period. More importantly, I will add atropine if axial length is also increasing with no explanation for a jump in length, which can happen normally with growth spurts.

I like to follow a stepwise approach to aid in my decision of which modality to start. It is by no means a hard and fast rule, but breaking down the various factors to consider when choosing can be quite helpful. These include the age of the child, their prescription, any history of myopia progression and whether axial length has already passed a certain point. There are additional social factors that are just as important, like the child's comfort level at putting lenses in their eyes, how confident the parents are with the child taking on this responsibility and the parent(s) ability to coax or help the child with lens insertion, removal and care, especially while taking care of other kids. If the child participates in extracurriculars, will one lens modality give them a competitive edge or help them perform better in sports? Questions such as these should also be given weight.

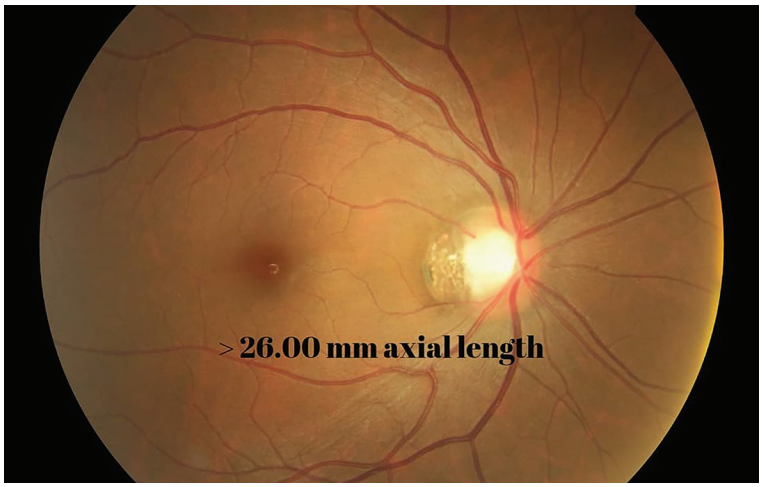

Fig. 4. Axial length of 26.00mm or greater in children greatly increases their risk of eye disease in adulthood.

Step 7: Outline a follow-up schedule

I have listed this as a separate step to emphasize—to readers, and ultimately to parents—the value of the service you're providing. Without describing specific fees, I'll note that it is vital to remember the added chair time myopia management entails so that you are compensated accordingly. Discussing costs with parents upfront is vital, too, so they can anticipate and plan for what is coming next. I like the global fee model, which is similar to the orthodontic world that some parents may have familiarity with. Once a decision has been made to proceed with treatment, I use the consultation fee and apply it to whatever the balance would be for treatment.

I outline for patients the sequence of follow-ups over the next year once a myopia management plan has been adopted. Presenting an annual package to the patient and their parents, with a schedule of visits, helps convey the value of your services and avoids any surprises for parents. Also be sure to provide take-home and follow-up material; if parents know what's coming next, they will be more motivated and prepared for compliant behavior and care. A comprehensive package also adds reassurance; parents leave knowing that time was taken to outline important material for them. They may even show your program to friends when talking with other parents, spreading the word about your available services.

Exact follow-up schedules will depend on the modality used. For spectacles lenses, follow-up should occur every three months. Ortho-K involves

Fig. 5. Here is a door decal that was up at my office to raise awareness about childhood myopia and its risks.

a bit more of an intense schedule, including follow-ups at one day after dispensing, one week, one month, three months, six months and 12 months. Daily disposable contact lens use will need a one-to-two-week follow-up, as well as three-month, six-month and 12-month visits. These are all designated visits included in my package with fees outlined. Still, if a patient is having trouble outside of a scheduled visit, an additional fee for chair time may be necessary.

Depending on the modality, I will offer contracts that provide a one-month warranty; if the patient wants to change modality within the first month, the parents will get back a percentage of the fitting fee. What the practice retains from that can be used to apply to the change. This gives parents and patients the time to decide what they do or don't want.

How much can be saved with an annual supply of daily disposables or what is the cost of a backup pair of ortho-K lenses? If you are specific in your treatment plan, it distinguishes the specialized care you are providing from routine care. Also make sure to have a plan for what year two fees will be. If ortho-K treatment is going well and only a replacement pair is needed, a refitting fee is unnecessary.

Step 8: Exude patience with your patients

Regardless of how buttoned-up you are with knowledge of myopia management and how transparent your fee package is, some parents will not be ready to proceed. This is where I am receptive to cues in the office. I will proactively suggest we recheck their child's prescription in three to six months or will follow-up with email content for them to review once they have gone home. No one should feel forced or guilted into pursuing myopia management, but be clear with parents that there is a finite window of viability for treatment that will eventually close.

Step 9: Keep parents in the know

Whether parents seem receptive to moving forward with treatment or not, I will send an email after the initial consultation visit to reiterate what was discussed: the child's prescription, what might happen if their myopia is left uncorrected and the steps we discussed. It is both a financial and time investment that needs to be articulated from the beginning for parents to understand the commitment involved.

After they are enrolled, I will send parents periodic newsletter emails from my office about news regarding different myopia management modalities and what new research is saying. It not only shows that you are on top of your game, but differentiates your practice from others that may just give the child the treatment with no up-to-date information on current research. Also, make sure that at least one staff member is designed as a parental liaison who is available to field calls and provide educational materials. Parents appreciate having a "go-to" person's name and emergency number and/or email address.

Step 10: Don't try to be a hero right from the start

I find that practitioners who are newcomers to myopia management struggle most with the perceived need to become an overnight expert before even entertaining the idea of offering the service. While additional expertise is obviously beneficial to the practice's ability to provide this type of service, it *is* possible to begin slowly.

If encountering a -3.00D child at age seven, it is acceptable to tell the parents that the standard of care is no longer just to prescribe a single-vision pair of glasses. Starting a patient's myopia management journey can be as simple as starting daily disposables. Single-vision soft contact lenses are an easy first step to start in kids with no or low amounts of astigmatism. Once there's comfort among patient and parent(s) alike, suggest switching to dual-focus contact lenses designed to mitigate myopia and see where it takes you.

Think about your patients in the last two weeks and consider: Would any benefit from being in a non–single-vision pair of spectacles or contacts? I suspect plenty would. ■

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LIFESTYLE CHANGES AND CHALLENGES IN MYOPIA MANAGEMENT

How to counsel patients on adopting good habits to survive growing up in the digital age, using evidence-based recommendations.

Dr. Psarakis is a senior research optometrist at the Brien Holden Vision Institute. His research areas have included myopia management and contact lenses. He has 20 years of experience in clinical practice and a passion for delivering eyecare services in lower-income settings within Australia and internationally.

While the proliferation of myopia management options has grabbed our attention in recent years, public awareness surrounding basic lifestyle factors must remain front and center regarding the role optometrists play in mitigating the increasing presence of myopia in our young populations. After all, the weight of scientific evidence over the last few decades suggests that environmental factors are driving the rise in the prevalence of myopia.[1] As primary eyecare providers, we have a duty of care to accurately advise our patients on which worthwhile lifestyle modifications and habits can be adopted to minimize the risk of myopia development and/or progression.

The challenge before us is twofold: First, we need to identify which lifestyle factors have been scientifically shown to be associated with myopia, and secondly, we must determine which recommendations are realistically achievable for a child in the modern age. I aim to address both points in this article by reviewing what the science currently tells us about the effect of various lifestyle factors and habits on myopia control and providing specific tips on how to advise your patients.

Fig. 1. Research suggests that children should aim for two hours of outdoor time per day to reduce myopia risk.

Outdoor Time and Natural Light

Of all the lifestyle factors that have been studied, time spent outdoors in natural light is perhaps the most widely supported by the literature as being protective against myopia onset.[2–8] Many population-based studies, including randomized clinical trials, have shown the protective benefits of increased outdoor time in preventing myopia.[3–7,9–12]

Various theories suggest that the positive effects of outdoor time could be attributed to factors such as increased exposure to bright light and dopamine release, short-wavelength/ultraviolet light, the stimulation of vitamin D synthesis and the relatively even dioptric landscape of a typical outdoor scene, among others.[7,14-17] It is worth noting that the protective benefit against myopia has been attributed to time outdoors, not the physical activity itself.[13,14]

When it comes to slowing down myopia progression in children who are already myopic, the results are less clear. In 2017, a systematic review of 25 studies found no association between the dosage of outdoor time and myopia progression in existing myopic eyes. On the other hand, a study from 2019 showed an association between increased outdoor time and myopic progression. In this prospective study involving children who were already myopic, spherical equivalent refraction increased over 18 months by -1.13 ± 0.6D in children whose daily outdoor time was low (0.51 ± 0.2 hours/day), -0.72 ± 0.6D for moderate (1.37 ± 0.3 hours/day) and -0.66 ± 0.5D for high (2.5 ± 0.5 hours/day).[11]

While there is still some debate as to the effect that outdoor time has on myopia progression, it is now clear, at the very least, that it plays a significant role in protecting against myopia onset.

Expert agreement on how much outdoor time we should recommend to our patients is still

evolving, but the literature can provide some clues. A meta-analysis compiling data from multiple studies found that every additional hour of outdoor time per week equated to a reduction in myopia risk by 2%.[15] Other analyses claim a one-third reduction in the risk of myopia onset by increasing outdoor time from zero to five hours/week to 14 hours/week or more.[16,17]

In 2021, The European Society of Ophthalmology and the International Myopia Institute (IMI) published an update plus guidance on the management of myopia and recommended a minimum of eight to 15 hours of outdoor time per week for school-aged children to gain "clinically meaningful protection from myopiagenic stimuli."[18] The most recent Facts and Findings infographic published by IMI in 2023 now recommends a minimum of two hours per day of outdoor time for the prevention of myopia onset.[19]

When reflecting on all the current evidence, it's safe to say that children and their parents should be aiming for a goal of at least two hours outside or more per day for myopia prevention.

Indoor Lighting Conditions

There is credible evidence that indoor lighting levels can significantly impact myopia onset and progression. A recent multivariate logistic analysis found that time under lighting levels greater than 3000 lux produced a protective factor for myopia in Chinese students.[20] Also in China, a study from 2015 showed that even a modest increase in light levels in classrooms (from 100 lux to 500 lux) provided a significant reduction in myopia onset and the rate of axial length elongation among students.[21] Interestingly, this study found that before intervention, the average lux levels at the student desk across 13 randomly selected classrooms was between 74 lux (intervention group) and 98 lux (control group), falling significantly short of the recommended 300 lux in China, the US and Europe.[21-23]

Moreover, the type of artificial illumination used has been called into question in recent years, particularly with the rise in popularity of light-emitting diode (LED) bulbs. One study based in China examined the prevalence of myopia among young teenagers and which types of lamps they used for homework tasks. It was found that students who used LED lamps had larger myopic refractive errors and longer axial lengths when compared to students who used incandescent or fluorescent lamps.[24]

Myopia risk aside, the French Agency for Food, Environment and Occupational Health and Safety warns against the use of LED lights in areas frequented by children to avoid potential photochemical damages and photoreceptor loss.[25] At odds with the argument against use of LED lighting is the reality of their rapid uptake in recent years, with the US Energy Information Administration reporting an increase in houses using them for all or most of their lighting from 4% in 2015 to 47% in 2020.[26]

Fig. 2. Near tasks, such as digital device use, have been linked to faster myopia progression.

Near Work

The association between increased near work and increased rates of myopia has long been asserted, with solid evidence to support this. Several studies have shown excessive near work can increase myopia onset and progression.[27–29] A three-year follow-up study in Finland found that increased time on near tasks was associated with faster progression of myopia.[30] In this study, "fast" progressors spent an average of 3.5 ± 0.9 hours/day on near tasks, while "slow" progressors spent an average of 2.9 ± 0.8 hours/day. The Consortium for Refractive Error and Myopia studies have observed that educational level significantly affects the overall risk of myopia, with time spent on near work and years of education posing a greater risk than genetic factors alone.[31–33] Similarly, European studies have shown that greater near work activity is a risk factor for myopia and that a higher level of education is linked to higher myopic refraction.[35,34]

Quantifying the exact impact of near work on risk is not straightforward, but a systematic review from 2015 found that more time spent on near tasks was associated with higher odds of

Fig. 3. A diet consisting of mostly whole foods could help minimize myopia risk.

becoming myopic.[35] The review concluded that the odds of myopia increased by 2% for each additional "diopter hour" (a more comprehensive weighted metric based on use of visual task questionnaires that consider time and viewing distances) spent on near work per week.[35]

"NOTING SEASONAL VARIATIONS AND DIURNAL PATTERNS OF AXIAL LENGTH AND REFRACTIVE ERROR, SOME HAVE RAISED THE POSSIBILITY OF CIRCADIAN RHYTHMS PLAYING A ROLE IN MYOPIA ONSET AND PROGRESSION."

Other studies have examined more specific characteristics of near work and found that a close working distance (20cm to 25cm), a head tilt when reading, continuous reading for more than 45 minutes at a time and gripping the pen closer to the pen tip (associated with a greater probability of a head tilt) were all associated with greater odds of myopia progression.[20,27,36,37]

Digital Devices

Perhaps the most common concern parents may have these days when it comes to their children's vision is the excessive time spent on screens or digital devices. These devices constitute a significant form of near work, which we acknowledge is a risk factor for myopia. Recent studies have found significant associations between myopia and digital screen time.[38,39]

However, the exact contribution to risk attributed to digital screen use itself has yet to be determined, and two recent systematic reviews challenge the true independence of digital devices as a stand-alone risk factor.[40,41] Such device use favors an indoor lifestyle and constitutes near work, which are two established risk factors for myopia. Both reviews concluded that digital device use may be an independent risk factor but point out that there remains a need for research with objective measures of screen time and myopia-related outcomes that investigates smart device exposure as an independent risk factor.

Regardless, there is no doubt that digital devices have become ubiquitous among children for educational purposes and entertainment. Their usage is even rampant among children of a much younger age, such as those who aren't yet attending school. Until proven otherwise, we must proceed with caution and be wary that digital device use may contribute to the onset and progression of myopia. With this approach, the Erasmus Myopia Research Group in the Netherlands recommends complete absence of close-up screen use for children up to the age of two, a maximum of one hour per day for children up to age five and a maximum of two hours per day for children aged five to 12 years.[42,43] The American Optometric Association promotes the World Health Organization's recommendation that screen time be limited to one hour per day for children under five and no time at all for children less than one year of age.[44]

Fig. 4. Circadian rhythms might play a role in myopia onset and progression, studies show.

Sleep Habits

The importance of sleep for children's health has long been acknowledged, but evidence for its role in childhood myopia is relatively new. Noting the seasonal variations and diurnal patterns of axial length and refractive error, some authors have raised the possibility of circadian rhythms playing a role in myopia onset and progression.[46-47]

Recent studies have produced mixed results in linking poor sleep patterns with myopia risk. A systematic review from 2023 identified 17 studies covering four main aspects of sleep—duration, quality, timing and efficiency—and their associations with myopia in children.[46] Although findings were inconsistent and a causal relationship between poor sleep and myopia cannot be established from current evidence, there are implications for an association of poor sleep with childhood myopia. Specifically, insufficient sleep hours (in seven of 15 studies), poor sleep quality (in three of four studies) and late bedtime (in three of six studies) were reported to be associated with a greater degree, progression and incidence of myopia.[46]

Nutrition

Much like good sleep patterns, nutritional habits may be connected to better general health outcomes. Therefore, it stands to reason that parents may want to know whether nutritional changes might improve their child's eye health or even reduce their myopia risk.

Very little research has investigated the role that nutrition and diet may play in the development and progression of myopia in children to this point. A study from 2010 found higher saturated fat and cholesterol intake was associated with longer axial length in otherwise healthy Singapore Chinese schoolchildren.[47] More recently, a review of the National Health and Nutrition Examination Survey examined data from almost 7,000 ethnically diverse Americans and found that the nutritional factors of serum vitamin D, glucose levels and caffeine intake were unrelated to refractive error or myopia. However, it found that increased insulin levels were associated with greater odds of myopia.[48] It is worth noting that the age range examined in this review was 12 to 25 years, thus excluding a large proportion of the younger pediatric population where myopia often first manifests.

Nonetheless, others have made the link between higher insulin levels and myopia, with evidence that the state of hyperinsulinemia can lead to continued growth of the sclera.[49,50]

Given that we know that a diet rich in highly refined carbohydrates can lead to worsening glycemic control and potentially insulin resistance, it is a worthy lifestyle consideration when it comes to myopia risk minimization.

Challenges of Modern-Day Life

It's clear that the sharp rise in myopia goes beyond genetics and that our environment is playing a driving role in its ever-increasing prevalence. Some lifestyle factors that appear to be contributors have been identified with varying degrees of scientific certainty. More time spent outdoors and less time spent indoors on near tasks have gained solid status as protective factors for reducing the risk of myopia development. Other factors such as digital device exposure, sleep patterns and nutrition all require further investigation. Still, at the very least, they currently present compelling implications for playing a part in the myopia story.

As optometrists on the front line, the question we need to ask ourselves is this: Armed with the evidence we do have, how do we realistically advise on lifestyle changes and habits that patients and their parents should adopt?

The answer must take into consideration the ways in which children today are educated, how they are entertained and even how they socialize. Most children use tablets or laptops at school, do homework on screens at home, play games or watch videos on handheld devices and even spend countless hours on social media. The convergence of so many aspects of a young person's life plays out on their digital devices, so how realistic is it of us to advise against using them? Similarly, we don't want to encourage our children to be less diligent with reading, writing or participating in near activities at school or with their homework.

TABLE 1. TAKE-HOME STRATEGIES FOR MYOPIA CONTROL

Based on the current evidence and challenges presented in this article, here is a compiled list of take-home strategies that may guide your next conversation with your young patients and their parents:

GOOD COMMUNICATION

- Living and breathing myopia on a daily basis does not mean that our patients necessarily do the same. Patients, and more importantly their parents, may not even be aware that lifestyle factors play a role in the myopia story.
- Having a well-rehearsed spiel and even a take-home information sheet may be worthwhile.
- Involving the child in the conversation and encouraging questions will impart a sense of ownership.
- Listen to the concerns and challenges the patient and their family may have.

MAXIMIZE OUTDOOR TIME

- Advise your patients that some of the strongest evidence for risk minimization relates to spending more time outdoors, especially for children who are not yet myopic.
- It's the outdoor time that is crucial, not the activity, so get creative. For example, "Why don't you play that game on your tablet outside?!"
- Aim for two hours per day.

OPTIMIZING INDOOR LIGHTING

- Maximize brightness for all indoor activities.
- Avoid LED lighting and replace with incandescent globes where possible.

NEAR WORK

- Encourage regular breaks (at least every 45 minutes)- set a timer!
- Appropriate reading distances (greater than 25cm).
- Avoid head tilting.
- Encourage regular near-to-distance fixation changes.

DIGITAL DEVICES

- Apply the same guidance as you would for near work.
- Encourage desktop use over hand-held devices for longer working distances.
- Where possible, set agreed-on daily use limits.

SLEEP HABITS AND NUTRITION

- Remember that these factors may increase the risk of myopia, so pick your battles!
- Encourage healthy, regular sleep patterns.
- Avoid foods high in refined sugars and fat.

The risk of undermining academic success or social inclusion cannot be overlooked. Of course, the reality of more near work is that it likely results in less time spent outdoors and more time spent indoors, adding two additional scenarios that encourage myopic development and even progression. For specific guidance on how to communicate lifestyle recommendations to your myopic patients and their patients while balancing these concerns, see *Table 1*.

The challenges of myopia prevention and control are complex and intertwined, but with good communication, creative solutions and targeted advice, we can strive for some type of balanced compromise and help minimize the risks that modifiable lifestyle factors may present. ■

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ERIN S. TOMIYAMA, OD, PhD
FULLERTON, CA

THE LOWDOWN ON LOW-DOSE ATROPINE

It's been proven effective, but the optimal concentration remains a matter of debate and sourcing from compounding pharmacies comes with concerns over quality and efficacy.

Dr. Tomiyama is an assistant professor of optometry at Marshall B. Ketchum University, where she offers a contact lens curriculum and serves as a clinical attending in the Stein Family Cornea & Contact Lens Center. She recently established the Myopia Management Service at the university. She receives consulting fees from Vyluma and conducts research with CooperVision.

All optometrists have familiarity with atropine as a diagnostic mainstay in routine dilation, as well as its therapeutic uses in managing iritis and other pupillary concerns. Somewhat newer, however, is the drug's role in myopia management. Various low dosages of this topical nonselective muscarinic antagonist have been studied, and are routinely used, to curtail axial elongation through a presumed dopaminergic mechanism. This application of atropine is currently an off-label use in the United States.

Higher concentrations of atropine, ranging from 0.5% to 1%, have been used for years, but more recently, lower concentrations have demonstrated approximately 50% slowing of myopia progression.[1-5]

The ease of use as a once-nightly eye drop has made it a common treatment option for eye care practitioners to prescribe. A 2018 survey showed 70% of pediatric ophthalmologists are prescribing eye drops to decrease myopia progression, although only 8% of myopia control treatments prescribed by optometrists worldwide include pharmaceuticals.[6,26] Despite its widespread use, there are still several unknowns when prescribing and obtaining low-dose atropine.

Which Concentration is Appropriate?

The story of atropine use for slowing myopia progression begins with the Atropine Treatment Of Myopia (ATOM) studies. In 2006, ATOM1 demonstrated that nightly monocular treatment with 1% atropine was effective in slowing axial elongation and myopia progression over two years compared to placebo (0.38mm, 1.20D vs. 0.02mm, 0.28D).[1] Children aged six to 12 were able to tolerate the treatment and achieved myopia control effects. However, the researchers acknowledged the unwanted side effects of glare, photophobia and blurred near vision from cycloplegia. These were more tolerable in this study since the treatment was administered monocularly, but with binocular treatment these effects would become more deleterious.

To mitigate the unwanted side effects, ATOM2 explored the nightly binocular treatment of lower concentrations of atropine (0.5%, 0.1%, or 0.01%) for two years.[5] Historical data from ATOM1 was used as the control since it was considered unethical to withhold treatment after showing its efficacy. After two years, the researchers found that axial elongation and myopia progression were greater with lower concentrations (0.27mm, 0.30D with 0.5%; 0.28mm, 0.38D with 0.1%; and 0.41mm, 0.49D with 0.01%).

After two years, the medication was stopped for one year, then any children demonstrating myopia progression of 0.50D or more in at least one eye were restarted on 0.01% atropine.[7] During the one year of cessation, there was a rebound effect, with an inverse dose-related increase in myopia with higher concentrations. After three years, more children in the higher concentration groups had to restart treatment due to 0.50D or more of progression (24% on 0.01%, 59% on 0.1% and 68% on 0.5%). The researchers concluded that, over five years, the 0.01% atropine was effective in slowing myopia progression with limited side effects and rebound. However, it was later pointed out that while atropine 0.01% was effective in slowing myopia progression, it had a limited effect on slowing axial elongation.[8]

With the recognition that perhaps lower concentrations are more tolerable while still maintaining efficacy, the Low-Concentration Atropine for Myopia Progression (LAMP) study was initiated in Hong Kong.[9] The first phase of the study evaluated atropine 0.05%, 0.025%, 0.01% and placebo over one year in myopic Chinese children aged four to 12 years. As expected, the use of higher concentrations resulted in less axial elongation and myopia progression (0.20mm, 0.27D on 0.05%; 0.29mm, 0.46D on 0.025%; 0.36mm, 0.59D on 0.01%; and 0.41mm, 0.81D on placebo). In the second phase of the study, the children in the placebo group were switched to 0.05% atropine and the others continued with the same therapy.[4] Those that switched demonstrated the efficacy of initiating treatment even after a year of placebo. In the final phase of the study, children in each group were randomized to either continue treatment or washout.[10] Those that washed out showed

a rebound effect, greater with higher concentrations, and those that continued treatment showed continued efficacy of the assigned therapy. The LAMP study results advocated using atropine 0.05% as the optimal concentration to achieve myopia control efficacy with limited side effects.

Based on the ATOM1, ATOM2 and LAMP studies, the primary concentration of first choice has been atropine 0.05% for many practitioners.

The ideal atropine concentration is effective in slowing both myopia progression and axial elongation while also mitigating the side effects of the drug. Systemic side effects can occur with higher concentrations, but with low-dose atropine the most common side effects are ocular. Glare, photophobia and rarely blurred near vision are the most common side effects. The LAMP study demonstrated that atropine 0.05% is similar in efficacy to optical treatments such as orthokeratology and soft multifocal contact lenses.[11] However, the debate on the optimal concentration of atropine is still undecided and may differ by patient.

The complexity of the concentration debate increased as two additional clinical studies were published in 2023. The Child Atropine for Myopia Progression (CHAMP) study compared preservative-free low-dose atropine in two concentrations, 0.01% and 0.02%, and was the first placebo-controlled study in the US and Europe to compare the safety and efficacy of low-dose atropine use in children as a treatment for myopia.[12] Participants from ages three to 17 were included, with varying levels of myopia (-0.50 to -6.00 D). The 0.01% concentration slowed axial elongation and myopia progression more than the 0.02% concentration (least squares mean difference: 0.13mm, 0.24D vs. 0.08mm, 0.10D). These results raised questions about clinical significance vs. statistical efficacy over three years of treatment, and whether 0.13mm axial length and 0.24D Rx reductions (vs. placebo) justify a decision to treat.

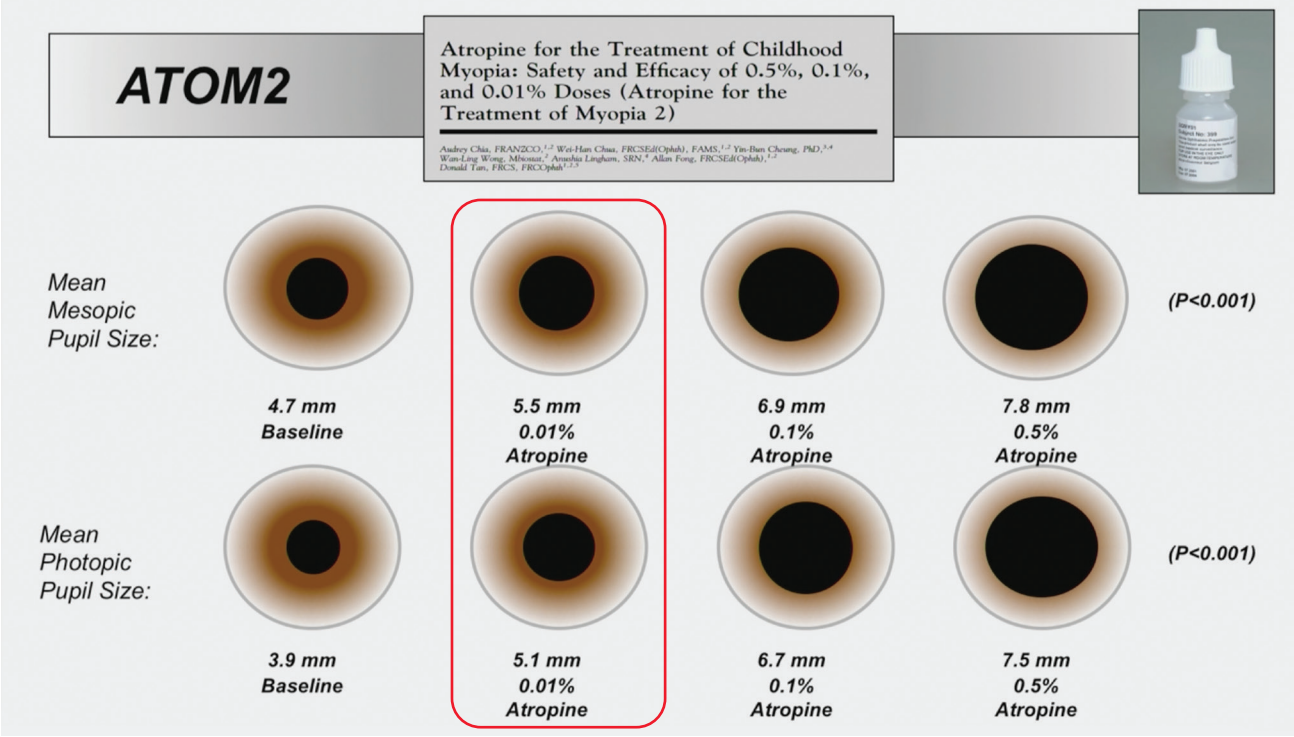
The FDA also required the study to add responder analysis as an endpoint, or how many children progressed -0.50D or less over the three-year study. Thirty percent of those using 0.01% atropine met this endpoint, which was statistically significant. The study also demonstrated the safety of the medication over the three years, with no reported serious ocular or systemic adverse events.

In contrast, the Pediatric Eye Disease Investigator Group (PEDIG) completed a 30-month study in US children aged five to 12 years that compared atropine 0.01% to placebo.[13] After two years of nightly bilateral instillation, there was no difference between the atropine 0.01% group and the placebo group in terms of axial length or spherical equivalent refractive error change from baseline (0.44mm, -0.82D vs. 0.45mm, -0.80D).

The lack of treatment effect is not likely due to compliance or participant retention, but the results conflict with previous studies showing the efficacy of atropine 0.01% against placebo.

Fig. 1. The 0.01% dose in the ATOM2 study showed the least amount of pupillary dilation, an important safety issue to consider.

Photo: Donald Tan, MD



The authors point out that most of these studies demonstrating a treatment effect were done in East Asian and South Asian populations, whereas this study was performed in the US with almost half of the sample being Caucasian children. Walline and Berntsen point out that the discrepancy in findings between Asian and Caucasian children may be a consequence of differences in iris pigmentation, study length, age and rate of myopia progression.[14] Interestingly, they note that darker irises, more common amongst Asian children, contain more melanin, which atropine binds to and may continue to release for a longer period.

Regardless, the CHAMP study results offer hope that there may be an FDA-approved low-dose atropine compound available in the future. An approved marketed product would resolve many issues that arise with the use of compounded products—including stability, sterility and efficacy. There would be greater assurance that the inconsistencies between the product and its storage or use would affect the delivery of the medication. Practitioners could feel more confident in prescribing a medication that is true to the intended concentration, and parents may be less apprehensive about sterility issues that could pose safety concerns.

TABLE 1. VARIABILITY IN COMPOUNDED ATROPINE DROPS[21]
From a recent survey of 26 suppliers on product characteristics.

BOTTLE SIZE	
<3mL	12%
3ml TO 3.5mL	23%
5ml	35%
10ml	23%
15ml	8%
REFRIGERATION RECOMMENDED	
YES	38%
NO	62%
BEYOND-USE DATE (DAYS)	
≤14	15%
28 OR 30	12%
45	12%
60 OR 70	15%
90	19%
180	27%
COST PER 10mL	
$45 TO $75	19%
$76 TO $100	42%
$101 TO $150	19%
$151 TO $229	19%

Treatment Initiation, Duration and Cessation

Though the mechanism of atropine in slowing myopia progression is still unknown, it is clear that it can be an effective therapy for children. As with all myopia control therapies, it is best to initiate treatment as soon as possible. The benefit of atropine is the ease of use, specifically in younger children who may not be ready for contact lens wear. Low-dose atropine has been shown to be effective in children as young as three years old.[12]

During low-dose atropine use, it is important to monitor for side effects, specifically photophobia and near blur. While children are very adaptable and tolerant, these potential side effects could affect their visual performance, academic achievement and quality of life. If these side effects are deemed intolerable, practitioners can consider prescribing light-adaptive bifocal spectacle lenses, altering the time of administration or decreasing the atropine concentration.

With its ease of use, low-dose atropine is also easily added to monotherapy of orthokeratology or soft multifocal contact lens use. With different mechanisms of action, it is assumed that combining atropine and contact lenses would further slow myopia progression. Several randomized control trials have shown that there is an additive effect of atropine 0.01% with orthokeratology lens wear than orthokeratology alone.[15,16] Most recently, one retrospective study found that this additive effect was only significant for the first 1.5 years.[17] Over the course of the two-year study, there was a significantly smaller change in axial length with combination therapy compared to orthokeratology alone for the first three six-month periods, but there was no difference in axial elongation between the two groups during the last six-month period (0.05mm, 0.04mm, 0.05mm vs. 0.03mm). Additionally, the study analyzed age at baseline and found that the difference in combination therapy vs. orthokeratology alone in children 10 years or younger could achieve a greater effect of slowing axial elongation (0.24mm vs. 0.07mm in children over 10 years).

A recent study comparing soft multifocal contact lenses and 0.01% atropine to soft multifocal contact lenses alone did not find a statistically significant slowing of eye growth, although the difference between the combination and monotherapies was similar in magnitude to the differences using 0.01% atropine and orthokeratology.[18] The combination therapy group showed

similar slowing of axial elongation and myopia progression as the soft multifocal lens group alone (0.31mm, 0.52D vs. 0.39mm, 0.55D) over a three-year period.

Parents are always concerned with how long their child must be on these therapies, perhaps even more so when medication is involved. The World Health Organization recommends only two years of use; however, several studies have shown efficacy over longer periods of time.[19] There are also no reported long-term side effects of low-dose atropine use.[20] With such low concentrations of atropine, the safety profile is likely greater than that of commercially available 1% atropine, often used for penalization in amblyopia therapy. In all studies observing the potential for a rebound effect, the medication was discontinued and not gradually decreased in frequency or concentration. Ultimately, low-dose atropine can be a safe and effective treatment for slowing myopia progression in young children as a monotherapy or combination therapy.

Inconsistencies in Compounding

Presently, low-dose atropine must be obtained directly from a compounding pharmacy. These outlets are not held to the same strict guidelines by the FDA as commercial drug manufacturers. Rather, they operate under the jurisdiction of their state boards of pharmacy and are not required to undergo the same rigorous product testing. This discrepancy between manufacturing facilities may affect the safety and efficacy of these low-dose atropine products.

A recent survey of 26 different compounding pharmacies across 19 states was conducted to find out more about the compounding and manufacturing of low-dose atropine.[21] The pharmacies were asked specific questions about their products, including storage instructions, bottle size, beyond-use dates and compounding ingredients (*Table 1*). These factors may affect the quality, stability and sterility of compounded low-dose atropine products.

The average reported bottle size was a 5mL bottle, which should contain about 100 drops and last about 50 days with nightly bilateral use. The median beyond-use date was 65 days (range: 45-158); however, some pharmacies specified a shorter time frame once the bottle was opened (*e.g.*, 28 or 30 days). Some pharmacies prepare their formulations in batches, so the beyond-use date may not be from the date of receipt or opening. Many of the smaller pharmacies prepared the medication to order. The beyond-use dates indicate how long the product can maintain its stability and potency against degradation after it is made.

Photo: Getty Images

Fig. 2. One of atropine's chief advantages is ease of use in younger children, especially those who may struggle with contact lens wear. It can also be additive to successful lens wear.

The active ingredient may be sourced from US Pharmacopeia (USP) powdered atropine or commercially available 1% atropine ophthalmic solution. Inactive ingredients are added to dilute the concentration or increase sterility, tolerability and efficacy. Half of the pharmacies reported using commercially available 1% atropine solution as the active ingredient, whereas 38% used USP powdered atropine. Commercially available artificial tears were mostly commonly used for dilution (42%), followed by saline (23%). The remainder used more than one inactive ingredient, including preservatives like benzalkonium chloride (BAK) for sterility or boric acid to lower the pH. BAK is found in commercially available 1% atropine solution, so if this is used as the base for low-dose concentrations, these preservatives are likely diluted by other inactive ingredients, resulting in a low level of preservatives that may be ineffective in maintaining a product's sterility.

Most smaller compounding pharmacies do not have the capability to do analytical testing of their products routinely. Some may use analytical methods on batches of drugs being compounded, but it is unlikely that testing of stability over time is completed. Conversely, FDA-approved marketed products must undergo extensive testing for sterility, efficacy and stability until the expiration date. Atropine in solution is intrinsically unstable and breaks down into tropic acid and tropine.[22] Both pH and storage temperatures will affect the stability of these low-dose products and their potency over time. The limited testing may also pose a public health risk as the contamination of products and subsequent widespread use can occur. Several outbreaks with ocular medications have resulted in permanent vision loss from contaminated compounded drugs.[23,24]

It is imperative that any prescribed drug, including low-dose atropine, is a quality product that will remain sterile and stable for the duration of its use. With compounded medications, variable formulations and a lack of consistent analytical testing, it becomes more challenging to ensure repeatability between products for patients.

"IT IS IMPERATIVE THAT ANY PRESCRIBED DRUG, INCLUDING LOW-DOSE ATROPINE, IS A QUALITY PRODUCT THAT WILL REMAIN STERILE AND STABLE FOR THE DURATION OF ITS USE."

To explore potential product inconsistencies, the same researchers obtained 24 samples of 0.01% atropine from nine different compounding pharmacies.[25] They sent the samples to be analyzed 30 days after receipt and found a wide variety of formulations. The median pH of the samples was 6.9, close to that of the ocular surface. Atropine is stable at lower pH levels (2-4), but most ophthalmic solutions are closer to neutral (6.6-7.8). At higher pH levels, atropine degrades faster to tropic acid, which has no antimuscarinic properties. Samples from two pharmacies had tropic acid concentrations greater than the USP limit, indicating the breakdown of atropine. Though lower pH levels may cause stinging or discomfort for the patient upon instillation, the lower pH increases the drug stability.

Thirty days after receipt, the median percent concentration of atropine was 7% less than the target (*i.e.*, 93%), with six samples having less than 90% of the target. The concentration should be within 10% of the prescribed or labeled concentration. Given that 0.01% is the lowest concentration of atropine used clinically, this poses concerns for efficacy. Research is still developing regarding the tolerable or most effective concentration, but perhaps results can be skewed if the concentration eye care providers are prescribing is not truly what the patient is receiving.

Greater Certainty Needed

The aforementioned issues with the stability of low-dose atropine can lead to inconsistent treatment results for patients. Variable quality of products can be a public health risk. Furthermore, the ongoing uncertainty over which dose is optimal for specific patient populations adds a level of guesswork that clinicians would clearly prefer to do away with. With increased prescribing of low-dose atropine for myopia management, there is a need for a commercial product that can be held to higher standards of regulation. With the CHAMP study results, it is clear that an FDA-approved product may be available in the near future.[12] The debate about which concentration of low-dose atropine is most effective will continue as new research emerges. ■

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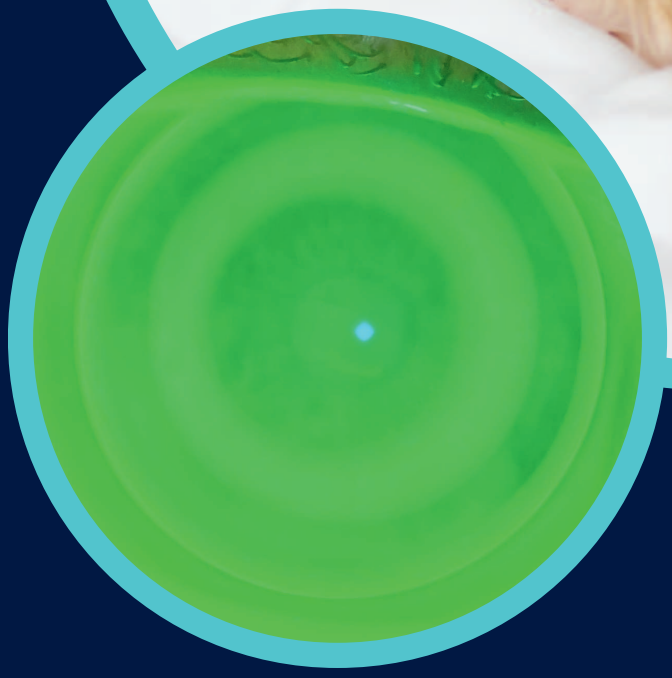

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