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Refractive Errors Preferred Practice Pattern®

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REFRACTIVE MANAGEMENT/INTERVENTION PREFERRED PRACTICE PATTERN[®] DEVELOPMENT PROCESS AND PARTICIPANTS

The **Refractive Management/Intervention Preferred Practice Pattern Panel** members wrote the Refractive Errors Preferred Practice Pattern (PPP) guidelines. The PPP Panel members discussed and reviewed successive drafts of the document, meeting in person once and conducting other review by e-mail discussion, to develop a consensus over the final version of the document.

Refractive Management/Intervention Preferred Practice Pattern Panel 2021–2022

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We thank our partners, the Cochrane Eyes and Vision US Satellite (CEV@US), for identifying reliable systematic reviews that we cite and discuss in support of the PPP recommendations.

The **Preferred Practice Patterns Committee** members reviewed and discussed the document during a meeting in June 2022. The document was edited in response to the discussion and comments.

Preferred Practice Patterns Committee 2022

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The Refractive Errors PPP was then sent for review to additional internal and external groups and individuals in July 2022. All those returning comments were required to provide disclosure of relevant relationships with industry to have their comments considered (indicated with an asterisk below). Members of the Refractive Management/Intervention Preferred Practice Pattern Panel reviewed and discussed these comments and determined revisions to the document.

Academy Reviewers	American College of Surgeons
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Council	American Glaucoma Society
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Ophthalmic Technology Assessment Committee	American Society of Cataract and Refractive Surgery
Refractive Management and Intervention Panel	American Uveitis Society*
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FINANCIAL DISCLOSURES

In compliance with the Council of Medical Specialty Societies' Code for Interactions with Companies (available at <u>https://cmss.org/code-for-interactions-with-companies/</u>), relevant relationships with industry are listed. The Academy has Relationship with Industry Procedures to comply with the Code (available at <u>www.aao.org/about-preferred-practice-patterns</u>). A majority (83%) of the members of the Refractive Management/Intervention Preferred Practice Pattern Panel 2021–2022 had no financial relationship to disclose.

Refractive Management/Intervention Preferred Practice Pattern Panel 2021–2022

Deborah S. Jacobs, MD, MSc: No financial relationships to disclose Natalie A. Afshari, MD: Consultant/Advisor—Allergan Rachel J. Bishop, MD: No financial relationships to disclose Jeremy D. Keenan, MD, MPH: No financial relationships to disclose Jimmy K. Lee, MD: No financial relationships to disclose Tueng T. Shen, MD, PhD: No financial relationships to disclose Susan Vitale, PhD, MHS: No financial relationships to disclose

Preferred Practice Patterns Committee 2022

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The disclosures of relevant relationships to industry of other reviewers of the document from January to October 2022 are available online at <u>www.aao.org/ppp</u>.

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OBJECTIVES OF PREFERRED PRACTICE PATTERN® GUIDELINES

As a service to its members and the public, the American Academy of Ophthalmology has developed a series of Preferred Practice Pattern guidelines that **identify characteristics and components of quality eye care.** Appendix 1 describes the core criteria of quality eye care.

The Preferred Practice Pattern guidelines are based on the best available scientific data as interpreted by panels of knowledgeable health professionals. In some instances, such as when results of carefully conducted clinical trials are available, the data are particularly persuasive and provide clear guidance. In other instances, the panels have to rely on their collective judgment and evaluation of available evidence.

These documents provide guidance for the pattern of practice, not for the care of a particular individual. While they should generally meet the needs of most patients, they cannot possibly best meet the needs of all patients. Adherence to these PPPs will not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results. It may be necessary to approach different patients' needs in different ways. The physician must make the ultimate judgment about the propriety of the care of a particular patient in light of all of the circumstances presented by that patient. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.

Preferred Practice Pattern guidelines are not medical standards to be adhered to in all individual situations. The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.

References to certain drugs, instruments, and other products are made for illustrative purposes only and are not intended to constitute an endorsement of such. Such material may include information on applications that are not considered community standard, that reflect indications not included in approved U.S. Food and Drug Administration (FDA) labeling, or that are approved for use only in restricted research settings. The FDA has stated that it is the responsibility of the physician to determine the FDA status of each drug or device he or she wishes to use, and to use them with appropriate patient consent in compliance with applicable law.

Innovation in medicine is essential to ensure the future health of the American public, and the Academy encourages the development of new diagnostic and therapeutic methods that will improve eye care. It is essential to recognize that true medical excellence is achieved only when the patients' needs are the foremost consideration.

All Preferred Practice Pattern guidelines are reviewed by their parent panel annually or earlier if developments warrant and updated accordingly. To ensure that all PPPs are current, each is valid for 5 years from the approved by date unless superseded by a revision. Preferred Practice Pattern guidelines are funded by the Academy without commercial support. Authors and reviewers of PPPs are volunteers and do not receive any financial compensation for their contributions to the documents. The PPPs are externally reviewed by experts and stakeholders, including consumer representatives, before publication. The PPPs are developed in compliance with the Council of Medical Specialty Societies' Code for Interactions with Companies. The Academy has Relationship with Industry Procedures (available at <u>www.aao.org/about-preferred-practice-patterns</u>) to comply with the Code.

Appendix 2 contains the International Statistical Classification of Diseases and Related Health Problems (ICD) codes for the disease entities that this PPP covers. The intended users of the Refractive Errors PPP are ophthalmologists.

METHODS AND KEY TO RATINGS

Preferred Practice Pattern® guidelines should be clinically relevant and specific enough to provide useful information to practitioners. Where evidence exists to support a recommendation for care, the recommendation should be given an explicit rating that shows the strength of evidence. To accomplish these aims, methods from the Scottish Intercollegiate Guideline Network¹ (SIGN) and the Grading of Recommendations Assessment, Development and Evaluation² (GRADE) group are used. GRADE is a systematic approach to grading the strength of the total body of evidence that is available to support recommendations on a specific clinical management issue. Organizations that have adopted GRADE include SIGN, the World Health Organization, the Agency for Healthcare Research and Quality, and the American College of Physicians.³

- All studies used to form a recommendation for care are graded for strength of evidence individually, and that grade is listed with the study citation.
- To rate individual studies, a scale based on SIGN¹ is used. The definitions and levels of evidence to rate individual studies are as follows:

I++	High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias	
I+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias	
I-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias	
II++	High-quality systematic reviews of case-control or cohort studies	
	High-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal	
II+	Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal	
II-	Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal	
III	Nonanalytic studies (e.g., case reports, case series)	

• Recommendations for care are formed based on the body of the evidence. The body of evidence quality ratings are defined by GRADE² as follows:

Good quality	Further research is very unlikely to change our confidence in the estimate of effect	
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate	
Insufficient quality	Further research is very likely to have an important impact on our confidence is the estimate of effect and is likely to change the estimate Any estimate of effect is very uncertain	

• Key recommendations for care are defined by GRADE² as follows:

Strong recommendation	Used when the desirable effects of an intervention clearly outweigh the undesirable effects or clearly do not	
Discretionary recommendation	Used when the trade-offs are less certain—either because of low-quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced	

- The Highlighted Findings and Recommendations for Care section lists points determined by the PPP Panel to be of particular importance to vision and quality of life outcomes.
- All recommendations for care in this PPP were rated using the system described above. Ratings are embedded throughout the PPP main text in italics.
- Literature searches to update the PPP were undertaken in March 2021 and May 2022 in the PubMed database. Complete details of the literature searches are available in Appendix 7.

HIGHLIGHTED FINDINGS AND RECOMMENDATIONS FOR CARE

The prevalence of myopia is increasing in the United States and other industrialized societies. Increased time spent outdoors appears to be protective against myopia in children. Increased levels of near work are less of a risk factor than previously believed.

Increased outdoor time and low-concentration atropine have been shown to reduce the likelihood of myopia onset.

Antimuscarinic eyedrops, multifocal spectacles and contact lenses, and overnight orthokeratology have been shown to be varibly effective in some populations for myopia control, that is, to reduce the progression of myopia in school age children.

Studies from around the world have confirmed that that the incidence of microbial keratitis has not been reduced with the introduction of new lens types and that overnight wear of any contact lens is associated with a higher risk of infection than daily wear.

Although there are lenses approved by the FDA for extended wear, alternatives should be presented to patients for whom this mode of contact lens wear is being considered because overnight wear, regardless of contact lens type, increases risk of microbial keratitis.

Daily disposable contact lenses (rather than planned replacement lenses) are the safest lenses with the lowest rate of complications associated with soft contact lens wear.

No-rub cleaning, topping off (reuse) of solutions, contaminated lens cases, exposure to tap water, wearing contact lenses in hot tubs and showers and while swimming, and changes in water supply are associated with *Acanthamoeba* and fungal keratitis related to contact lens wear in the recent decades.

Hydrogen peroxide systems are superior to multipurpose solutions for reducing the likelihood of infections or inflammatory complications; they are the preferred mode of nightly disinfection for patients who cannot wear daily disposable lenses, especially if they have had complications of contact lens wear in the past.

Presbyopia can be managed by using eyeglasses; contact lenses; topical agents; intraocular lenses with multifocal, accommodating, or extended depth of focus features; and monovision strategies with contact lenses or intraocular lenses.

Adverse events related to FDA-approved drugs and devices should be reported to MedWatch (<u>www.fda.gov/medwatch</u>).

INTRODUCTION

DISEASE DEFINITION

Refractive error (ametropia) is present when parallel rays of light entering the nonaccommodating eye do not focus on the retina. The visual effect is a blurred image. Myopia is a common optical aberration in which parallel light rays from a distant image are focused on a point anterior to the retina. Hyperopia is also a common aberration and one in which distant light rays converge incompletely before striking the retina. Astigmatism and other forms of optical aberrations occur when incident light rays do not converge at a single focal point. Total refractive astigmatism can be divided into corneal (or keratometric) astigmatism, lenticular astigmatism, and retinal astigmatism. Most astigmatism is corneal in origin. Lenticular astigmatism is a result of uneven lens curvature, lens tilt, and differing refractive indices within the lens.⁴

In regular corneal astigmatism, the refractive power varies successively from one meridian to the next, and each meridian has a uniform curvature. The meridians of greatest and least power, or the principal meridians, are located 90 degrees apart.⁵

In irregular corneal astigmatism, the magnitude and the axis of astigmatism vary in different points of the cornea, which can be clinically significant in conditions such as keratoconus and other corneal ectasias, corneal epithelial basement membrane and stromal dystrophies, corneal scarring, and postsurgical corneas.⁵ Coma, spherical aberration, and trefoil are examples of types of optical aberration termed higher order aberrations (HOAs). Higher order aberrations cannot be fully corrected by spherocylindrical corrective lenses. Methods for describing HOAs include Zernike and Fourier reconstruction algorithms. Zernike coefficients that most affect visual quality are coma, spherical aberration, and trefoil.

In this document, low to moderate refractive errors are defined as spherical equivalents of less than 6.00 diopters (D) of myopia, less than 3.00 D of hyperopia, and less than 3.00 D of regular astigmatism. High refractive errors are defined as 6.00 D or more of myopia, 3.00 D or more of hyperopia, and 3.00 D or more of regular astigmatism.

Natural presbyopia is a condition that develops with aging and results in insufficient accommodation for near work in a patient whose distance refractive error is fully corrected. Although not truly a refractive error, presbyopia will be considered in this document because its correction has similarities to the correction of refractive errors. The correction of presbyopia is also discussed in the Cataract in the Adult Eye PPP.⁶

PATIENT POPULATION

Individuals who have refractive errors.

CLINICAL OBJECTIVES

- Determine the patient's visual needs
- Identify and quantify any refractive errors
- Discuss with the patient the nature of the refractive error, appropriate alternatives for correction, and the risks and benefits of each approach
- Consider low-dose atropine and increased outdoor time for myopia prevention in young children at risk
- Consider antimuscarinic agents, multifocal spectacles or contact lenses, and orthokeratology for myopia control in school age children
- Inform patients, especially those with high refractive errors, about the potentially increased incidence of associated pathologic conditions
- Correct symptomatic refractive errors with eyeglasses, contact lenses, or surgery, as desired by the patient and as deemed appropriate by the physician
- Address contact lens safety in those at risk or with history of complications of contact lens wear, including elimination of extended wear (overnight wear), recommending conversion from planned

replacement to daily disposable lenses, and/or recommending switch from multipurpose solution to peroxide disinifection systems.

- Provide the patient with follow-up care and management of any side effects or complications resulting from the correction provided
- Consider the emerging field of topical agents for presbyopia

BACKGROUND

PREVALENCE AND RISK FACTORS

Over half of Americans older than 40 have ametropia of sufficient magnitude to require refractive correction.⁷ Currently, an estimated 93 million Americans aged 12 years and older use some form of eyewear to correct refractive errors at distance.⁸ About 41 million people in the United States used contact lenses in 2014.⁹ It has been estimated that over 8.5 million people in the United States have undergone keratorefractive surgery since 1995¹⁰ and over 13 million laser in situ keratomileusis (LASIK) procedures have been performed in the United States.¹¹

Myopia

The prevalence of myopia (0.75 D or more) is estimated to be 9% in children in the United States aged 5 to 17 years.¹² In children aged 6 to 72 months, the prevalence of myopia in non-Hispanic white children was 1.2% and for Asian children it was 4.0%.¹³ For African American children it was 6.6% and for Hispanic children it was 3.7%.¹⁴ A meta-analysis of population-based studies found a 25% prevalence of myopia (1.00 D or more) in persons over age 40 in the United States;¹⁵ a study based on a sample representative of the U.S. population found a prevalence of 31% in those aged 40 and older and of 36% in those aged 20 and older.⁷ A number of population-based studies have shown that the prevalence of myopia is lower in older persons than in younger persons. The prevalence is about 35% to 40% among persons in their 20s to 40s and decreases to about 15% to 20% among those in their 60s, 70s, and 80s.^{7, 16-18} Individuals who develop nuclear sclerosis, however, tend to undergo a myopic shift over time.¹⁹⁻²¹ In the United States, myopia was found to be significantly more prevalent among non-Hispanic white adults than among adults of non-Hispanic black or Mexican American race/ethnicity, in contrast to some studies in children.⁷

Both hereditary and environmental factors appear to play a role in the development of myopia. Birth weight/gestational age at birth have been suggested as potentially associated with refractive error; a recent meta-analysis found a modest effect of lower birth weight on risk of myopic refractive error.²² Studies suggest a higher concordance of myopia between monozygotic than dizygotic twins²³ and between children and parents.²⁴⁻²⁷ Studies have identified links between several gene regions, particularly chromosome 18p, and myopia,²⁸⁻³³ although other studies have either found no association³⁴ or more complex relationships.^{35, 36} Other genetic variations associated with high myopia have been found in Asian populations.³⁷⁻⁴³ More years of formal education have been strongly associated with a higher prevalence of myopia.^{36, 44-52} Some studies have reported that a higher level of near work is associated with a higher prevalence and progression of myopia,⁵²⁻⁵⁷ but other studies have not, especially with respect to middle-distance activities such as those that involve video display terminals.^{47, 58-61} However, a recent study from the U.K. Biobank provided further evidence that higher levels of formal education increase the risk of myopia,⁶² as has a study of the U.S. population.⁶³ The use of night lights for children under age 2 years has been reported as a strong risk factor for myopia;⁶⁴ however, other studies that were able to adjust for parental refractive status did not find such an association.^{55, 65} Many studies in various countries have reported that myopia is associated with less time spent outdoors.^{60, 65-78} Studies in Israel and England have found an association between higher prevalence of myopia and birth during the summer months.⁷⁸ In a longitudinal study of myopic children, investigators found that myopia progressed more slowly during summer than during other months.⁷⁹ A study reporting on myopic children from control groups (fitted with traditional single-vision eyeglasses) of clinical trials with 1-year follow-up

found that progression of myopia was less in summer months that in other seasons, both in terms of spherical equivalent and axial length.⁸⁰ In two meta-analyses, investigators found that increasing time spent outdoors significantly decreased risk of myopic progression.⁸¹⁻⁸³ Recent evidence suggests that violet light plays a role in prevention of myopia progression.^{84, 85} In 2021, the International myopia institute summarized that associations between more nearwork and more myopia are generally weak and inconsistent, but have been supported by meta-analysis. Associations between time outdoors and less myopia are stronger and more consistently observed, including by meta-analysis.⁸⁶

Studies of ethnic Chinese in Taiwan documented an increase in the prevalence and severity of myopia over two generations.^{53, 67, 87-90} Similar increases in prevalence have been noted in Australian middle-aged adults,⁹¹ among Indian schoolchildren,⁹² and in a study of Japanese adults.93 Genetics alone are unlikely to account for such a rapid change. One study has speculated that genetic factors do not preclude such a change.⁹⁴ A study of myopia in Japan found increasing prevalence in recent decades, suggesting environmental factors, but little change in prevalence of extreme myopia, suggesting high genetic predisposition.⁹⁵ More recent studies have demonstrated that both genetic and environmental factors are involved.⁹⁶ A study of successive cohorts of enlistees in the Israeli army showed a marked increase in prevalence of myopia over a 13-year period.⁹⁷ A study in Finland showed that the prevalence of myopia doubled among teenagers and young adults over the course of the 20th century.⁹⁸ A study comparing U.S. population-based estimates in 1971 to 1972 and 1999 to 2004 also found a marked increase in the prevalence of myopia, although the reasons for this increase could not be identified.⁹⁹ Several additional studies have reported that the prevalence of myopia is increasing.^{49, 100, 101} In East Asia, the prevalence of myopia is rapidly increasing (now 80%– 90%) in school-aged children.^{102, 103} The global prevalence of myopia and high myopia are projected to increase to nearly 5000/million and 1000/million respectively by 2050.104

Hyperopia

A meta-analysis of population-based studies found the prevalence of hyperopia was 10% in the United States and increased with increasing age.¹⁵ Another study, based on a sample representative of the U.S. population, found that the prevalence of hyperopia in those aged 40 and older was 5%, with little variation by race/ethnicity.⁷ Population-based studies of Caucasians aged 40 and older report that the prevalence of hyperopia increases from about 20% among those in their 40s to about 60% among those in their 70s and 80s.^{16, 17, 105} A similar pattern of higher prevalence of hyperopia in older ages was observed in a U.S. population-based study.⁷ A similar prevalence and changes with age were seen among African Americans in Baltimore.¹⁷ In contrast to myopia, hyperopia was associated with fewer years of formal education in the same populations.^{16, 17}

Astigmatism

Kleinstein et al¹² found that 28% of their U.S.-based study population aged 5 to 17 years had astigmatism of 1.00 D or more. In a multiethnic pediatric eye disease study, the prevalence of astigmatism in African American and Hispanic children aged 6 to 72 months was 12.7% and 16.8%, respectively.¹⁰⁶ Astigmatism of 1.00 D or more is common among older adults (31% in persons aged 40 and older), and the prevalence is higher in older age groups.⁷ In adult Americans, the prevalence of astigmatism has been reported to be 20% higher among men than women but was not associated with number of years of formal education and did not vary substantially by race/ethnicity.^{7, 17} There have been conflicting data about the association of astigmatism with prematurity or low birth weight and with retinopathy of prematurity.¹⁰⁷⁻¹¹⁰

Further discussion of the epidemiology of refractive errors is presented in Appendix 3.

NATURAL HISTORY

The distribution of refractive errors changes with age. Newborns average 3.00 D of hyperopia.¹¹¹ This may increase slightly in the first few months, but then it declines toward an average of 1.00 D of hyperopia by 1 year of age.¹¹¹ Fewer than 5% of infants have more than 3.00 D of hyperopia at age 1

year.^{111, 112} This shift toward emmetropia is a complex process that involves changes in the power of the refractive components of the eye, including thinning of the crystalline lens.¹¹³ Visual stimulation appears to play a role in this process.^{114, 115}

Myopia typically appears between 6 and 12 years of age, and the mean rate of progression is approximately 0.50 D per year, based on studies of mostly Caucasian children.¹¹⁶⁻¹¹⁸ A study reported that progression of myopia varied by ethnicity and by age of the child.¹¹⁹ For ethnic Chinese children, the rate of progression has been found to be higher.¹²⁰⁻¹²⁵

Astigmatism in children is commonly oriented with the steep axis vertical (with the rule). In older adults, astigmatism oriented with the steep axis horizontally is more common (against the rule)^{126, 127} and remains relatively stable in older adults, ¹²⁸ although one study found that the axis of astigmatism tended to shift against the rule over a 5-year period.¹²⁹

Individuals with high refractive errors are more likely to develop pathologic ocular changes over time.¹³⁰⁻¹³⁴ Highly myopic patients have an increased incidence of progressive retinal and choroidal thinning, peripheral retinal degeneration, retinal detachment,¹³⁵ cataract,¹³⁶ glaucoma,¹³⁷⁻¹⁴⁰ and myopic choroidal neovascularization.^{141, 142} An increased risk of glaucoma and visual field defects with myopia has also been found,¹⁴³⁻¹⁴⁹ although a more recent study found no evidence of genetic overlap between myopia and glaucoma.¹⁵⁰ An increased risk of developing primary angle-closure glaucoma among individuals with hyperopia has been reported.¹⁵¹ Hyperopia is associated with progressive retinopathy in patients with Type I diabetes.¹⁵² Individuals with higher levels of myopia are more likely to have decreased foveal function as assessed by multifocal full-field electroretinogram.¹⁵³ Although refractive error has little effect on development of age-related macular degeneration,¹⁵⁴ patients with "physiological myopia" in 0 to -6.00 D range are also at higher risk of ocular pathologies.¹⁵⁵

RATIONALE FOR TREATMENT

The major reasons for treating refractive errors are to improve a patient's visual acuity, visual function, and visual comfort. It may be desirable to correct a very small error in one patient, whereas another patient may function well with no ill effects when the same very small refractive error is not corrected. Patients with moderate to high refractive errors generally require correction to achieve satisfactory vision. Other reasons for treatment include enhancing binocular vision (e.g., for driver safety), controlling strabismus (e.g., accommodative esotropia), and, on a societal level, preventing economic productivity loss associated with uncorrected refractive error.¹⁵⁶⁻¹⁵⁹ In patients beyond visual maturity (see Amblyopia PPP¹⁶⁰), uncorrected refractive errors do not result in amblyopia. There is evidence that uncorrected peripheral hyperopic defocus may lead to worsening of axial myopia in children who might otherwise have other uncorrected refractive errors alone.¹⁶¹⁻¹⁶³ Globally, 10 million individuals are estimated to have visual impairment from myopic macular degeneration, and 3.3 million of them are blind.²⁷ These numbers are estimated to grow to 55.7 million people with visual impairment and 18.5 million individuals with blindness by 2050 unless new strategies to control myopia are implemented.²⁷ The importance of reducing the global burden of myopia by delaying the onset of myopia and reducing myopic progression in children warrants attention from clinicians, public health officials, agencies, and industry.¹⁶⁴

CARE PROCESS

PATIENT OUTCOME CRITERIA

Outcome criteria vary depending on the individual's needs, lifestyle, and overall medical condition. The goal is to provide vision that meets the patient's functional needs with minimal side effects. The relevant questions are to evaluate the safety and effectiveness of different nonsurgical and surgical approaches to treat refractive error in the adult patient population in terms of visual acuity, complications, and refraction. Studies selected for inclusion met the following criteria: they were published between 2017 and 2022 in the English, and they were human and clinical studies. Studies

that had fewer than 10 patients, that did not include interventions of interest, that did not adjust for bias, and in which the outcomes were not well defined were excluded.

DIAGNOSIS

The evaluation of refractive errors in children differs in technique, instrumentation, and diagnostic capacity for each child, depending on their age, developmental status, level of cooperation, and ability to interact with the examiner. (See Pediatric Eye Evaluations PPP.¹⁶⁵)

The evaluation of refractive errors in adults requires an assessment of the refractive status of the eye, the patient's current mode of correction, symptoms, and visual needs. Refraction is often performed in conjunction with a comprehensive medical eye evaluation.¹⁶⁶

History

The history should incorporate the elements of the comprehensive adult medical eye evaluation to consider the patient's visual needs and any ocular pathology. (See Appendix 4.)

Examination

Measuring Visual Acuity

Distance visual acuity is usually measured in a dimly lit room, typically at 20 feet or 6 meters, as the patient looks at a chart with lines of high-contrast characters. Distance acuity should be measured separately for each eye with current correction. Near acuity is usually measured while the patient looks at a well-lit reading card of high-contrast characters held at a specified near working distance, typically 14 inches or 36 centimeters.

Refraction

Each eye should be evaluated independently. The refraction may be performed objectively by retinoscopy, an autorefractor, or a wavefront analyzer, or it may be done subjectively. In cooperative patients, subjective refinement of refraction using a phoropter or trial lens set is preferred. Determination of vertex distance (using a vertex meter) and precise astigmatic axis is especially important in patients with high refractive errors.

The reproducibility of subjective refraction has been found to be within 0.50 D for spherical equivalent, spherical power, and cylindrical power.^{167, 168}

Distance refraction should be performed with accommodation relaxed. This may be accomplished by using manifest (noncycloplegic) refraction with fogging or other techniques to minimize accommodation with care to not provide excess minus power correction to the patient. In some cases, especially in children and many adolescents,¹⁶⁵ a cycloplegic refraction can be useful.

Near vision should be measured in each eye before cycloplegia for patients with high hyperopia, presbyopia, or complaints about near vision. If the patient is presbyopic, the near-vision add is determined at the reading or working distance preferred by the patient.

Cycloplegic refraction is especially indicated for patients in whom accommodation cannot be relaxed and for patients whose symptoms are not consistent with the manifest (noncycloplegic) refractive error. It is advised for patients when the accuracy of the refraction is in question for any reason. In adults, tropicamide and cyclopentolate are commonly used for cycloplegic refraction; tropicamide provides a more rapid onset of action and a shorter duration of effect, whereas cyclopentolate provides greater cycloplegia that may allow a more accurate refraction but a longer duration of effect.¹⁶⁹ A significant difference between manifest and cycloplegic refraction is observed frequently in children; in adults, a substantial difference between manifest and cycloplegic refraction is used to guide the final manifest prescription. The postcycloplegic refraction is performed after full accommodation has returned.

Although most normal eyes should have a corrected acuity of 20/25 or better, it may not be possible to achieve this level of acuity in patients with high refractive errors, even with optimal

refraction. For a subset of patients, this might be due to the minification produced by high myopic correction at the spectacle plane. In other cases, refractive amblyopia may be the cause. However, a pathologic basis for reduced best-corrected visual acuity should be sought. A suddenly acquired refractive change may signal a systemic or local disease, or a drug effect. Excellent visual acuity does not preclude serious eye disease; therefore, all adult patients should have comprehensive medical eye evaluations at the recommended intervals.^{165, 166}

Contact lens wearers should have a contact lens examination every 1 to 2 years to monitor for adverse effects of contact lens wear and for an update on healthy practices for contact lens wear and care.

The recommended frequency for an adult comprehensive medical eye examination for asymptomatic patients who do not have risk factors for eye disease is as follows: every 5–10 years for patients under 40 years old; every 2–4 years for patients 40 to 54 years old; every 1–3 years for patients 55 to 64 years old; and every 1–2 years for patients 65 years or older, as specified in the Comprehensive Adult Medical Eye Evaluation PPP.¹⁶⁶

MANAGEMENT

The need to correct refractive errors depends on the patient's symptoms and visual needs. Patients with low or monocular refractive errors may not require correction; small changes in refractive corrections in asymptomatic patients are generally not recommended. Correction options include eyeglasses, contact lenses, and surgery. Surgical options are discussed in the Refractive Surgery PPP.¹⁷⁰ These include refractive surgery to the cornea, such as LASIK and photorefractive keratectomy, and lens surgery, such as clear lens extraction, phakic intraocular lenses, and cataract surgery. Various occupational and recreational requirements as well as personal preferences affect the specific choices for any individual patient.

Presbyopia can be managed with eyeglasses or contact lenses (soft, rigid gas-permeable, or aspheric bifocal or multifocal). These can be used bilaterally or for monovision and modified monovision. Modified monovision is a treatment in which a bifocal or multifocal contact lens is used in one eye and a distance contact lens is used in the fellow eye. Surgical management of presbyopia includes keratorefractive surgery for monovision, intracorneal lens implants, or intraocular lens implantation (including monofocal lenses for monovision, multifocal lenses, or accommodative lenses).

Eyeglasses

Provision of appropriate spectacles is one of the simplest, most cost-effective strategies to improve vision; therefore, eyeglasses should be considered before contact lenses or refractive surgery.¹⁷¹ Additionally, patients whose primary mode of optical correction is contact lenses should have a pair of eyeglasses to decrease the risk of contact lens overwear and the use of contact lenses when the eye is red or inflamed. A patient's eyeglasses and refraction are typically evaluated whenever visual symptoms develop. Optimal eyeglass correction for higher refractive errors requires precision in fitting, especially with respect to the position of the optical center of each lens relative to the pupil. High-index lenses, which reduce the lens thickness and weight, are useful in correcting high refractive errors and providing increased comfort and better cosmetic appearance. The principles for correcting specific refractive errors with eyeglasses are outlined in Appendix 5.

When hyperopia is accompanied by esotropia, eyeglasses may be required to control the strabismus or to improve fusion.¹⁷² If minus lenses improve fusion in intermittent exotropia, eyeglass correction may be indicated even if the patient is not myopic.

A nonrefractive, yet important, indication for eyeglasses is to protect the eyes from accidental injury. Safety glasses or eye protectors are strongly recommended for individuals involved in certain sports (e.g., racquetball, squash) and hazardous activities in which there is risk of flying particles (e.g., using hammers, saws, weed trimmers) or risk of UV toxicity (welders).¹⁷³ Shatterproof eyeglasses are also recommended for all individuals with good vision in only one eye. When ocular protection is the foremost consideration, polycarbonate plastic is the material

of choice because it is much more impact resistant than regular plastic or hardened glass.¹⁷⁴ Depending on the activity, frames with side protection may be important.

Contact Lenses

A contact lens can correct a wide range of refractive errors by acting as the initial refractive surface of the eye. In 2013, there were an estimated 140 million contact lens wearers globally.¹⁷⁵ Approximately 41 million individuals in the United States 18 years or older successfully used contact lenses for visual correction in 2014, and 93% of this population demographic wore soft contact lenses.⁹ Soft hydrogel contact lenses, silicone hydrogel contact lenses with greater oxygen transmissibility, or rigid gas-permeable contact lenses are used most commonly. Use of rigid gas-permeable lenses represents 10.8% of all lens fits globally, with stabilization of this declining number due to wider use of scleral and orthokeratology lenses. There is considerable variance across the 40 countries surveyed, with the highest fit rate of 37% reported in Malaysia. Ten percent of the overall reported use of rigid gas-permeable lenses is for orthokeratology.¹⁷⁶ Market research in the United States projects growth of scleral, hybrid, and orthokeratology prescriptions and sales, suggesting an increasing role of specialty lenses in clinical practice.¹⁷⁷ Polymethylmethacrylate (PMMA) contact lenses are now rarely used because the material is not permeable to oxygen. Although contact lenses are of great visual benefit, their use does carry some risk of ocular complications.

Indications

Reduced reliance on eyeglasses to correct refractive error is the most common indication for contact lens use. Many patients who use contact lenses note better field of vision, greater comfort, and/or improved quality of vision. Some patients have special occupational needs that cannot be met by eyeglasses, and others prefer their appearance without eyeglasses. Some patients achieve adequate visual function only with contact lenses. This may include patients with high refractive errors, anisometropia, or an irregular corneal surface or shape. Finally, contact lenses may be prescribed for therapeutic purposes after surgery or trauma or in the setting of ocular surface disease.

Relative Contraindications

The use of contact lenses to correct refractive errors may not be advisable when there are significant eyelid, tear film, or ocular surface abnormalities related to any of the following:

- Keratoconjunctivitis sicca
- Blepharoconjunctivitis
- Acne rosacea
- Conjunctival cicatrization
- Corneal exposure
- Neurotrophic keratitis
- Other corneal abnormalities

Other relative contraindications include the following:

- Use of topical corticosteroids
- Inflammation of the anterior segment
- Presence of a filtering bleb
- Poor personal hygiene (e.g., dirty hands and fingernails)
- Certain environmental or work settings (e.g., dust, volatile chemicals)
- History of corneal complications related to contact lenses
- Limited dexterity
- Inability to understand the risks and responsibilities involved

The risks of complications associated with contact lenses should be weighed against the protective benefit of eyeglasses for monocular or functionally monocular patients.

Complications

Centers for Disease Control and Prevention (CDC) data for 2014 reported that approximately one-third of all contact lens wearers reported previous red or painful eye conditions that required a doctor visit; at least one contact lens hygiene risk behavior was reported by almost 99% of contact lens wearers.⁹ The most serious risk of contact lens wear is the development of microbial keratitis, which can lead to visual loss even if properly treated.¹⁷⁸ Other complications with all types of contact lens wear include hypersensitivity reactions such as giant papillary conjunctivitis, problems of the ocular surface such as superficial keratitis, recurrent erosions, Salzmann nodules, subepithelial fibrosis, subepithelial opacification, and limbal stem cell deficiency, as well as corneal neovascularization, sterile infiltrates, and corneal warpage.¹⁷⁹⁻¹⁸⁶ Transient subclinical stromal edema frequently occurs, and corneal thinning of the epithelium and stroma during contact lens wear has also been reported.^{184, 187-189} Endothelial changes can occur, including polymegethism, pleomorphism, and, rarely, reduction of endothelial cell density.¹⁹⁰⁻¹⁹² The clinical significance of transient edema, thinning, and endothelial changes is uncertain.

Microbial keratitis as a complication of contact lens wear is most frequently caused by bacteria, but it can also be caused by more unusual organisms that are difficult to diagnose and treat, such as *Acanthamoeba* and fungi.¹⁹³⁻¹⁹⁹

When soft contact lenses were introduced for extended wear in the early 1980s, *Pseudomonas aeruginosa* became a frequently identified pathogen in cases of keratitis in individuals using extended-wear soft contact lenses.^{193, 195} Investigations into the pathogenesis of *Pseudomonas* keratitis showed that *P. aeruginosa* adhered readily to contact lens deposits.²⁰⁰ This was of concern because contact lenses develop more deposits as duration of use increases. Other investigations demonstrated that the relative risk of microbial keratitis was 10 to 15 times greater in patients using soft contact lenses on an extended-wear basis compared with patients using soft lenses for daily wear²⁰¹ and that extended-wear soft contact lens users had an annualized incidence five times that of daily-wear patients (21 vs. 4 per 10,000 persons).²⁰²

Disposable soft contact lenses for extended wear were introduced in the late 1980s in an attempt to improve the safety of extended wear by allowing more frequent contact lens replacement. Disposable soft contact lenses for extended wear were eventually found to have the same incidence of microbial keratitis as conventional reusable soft lenses for overnight wear.^{203, 204} It was the pattern of contact lens wear (overnight vs. daily) rather than the type of contact lens (disposable vs. nondisposable) that appeared to be the overriding risk factor for microbial keratitis.²⁰³⁻²⁰⁹ Despite the increased risk of microbial keratitis associated with overnight wear, there are contact lenses approved by the FDA for extended (including overnight) wear. Generally, *Pseudomonas* remains the most commonly isolated organism in microbial keratitis associated with contact lens use.²¹⁰ A study of pediatric microbial keratitis in Taiwan found that contact lens wear was a significant risk factor and that the number of isolated coagulase negative staphylococcus cases had increased over time. The presence of a gram negative isolate was correlated with a poorer visual outcome compared with other infectious isolates.²¹¹

Although disposable contact lenses were initially developed for extended wear use, they were introduced for daily disposable use in 1995. These lenses are intended to be worn for one day and then discarded before bedtime. These represent a popular alternative to nondisposable daily wear lenses and result in fewer lens-related user complaints when compared with conventional daily-wear soft contact lenses.²¹² Their use currently represents the safest method of soft contact lens wear with regard to adverse events such as infiltrates and infections.^{213, 214} There are no good studies comparing different contemporary modes of wear or materials with respect to impact on the corneal endothelium.

Even though investigators have shown that contact lenses of lower oxygen transmission are more likely to be associated with corneal epithelial binding of *P. aeruginosa* than are higher oxygen transmissible lenses,²¹⁵⁻²¹⁸ the introduction of soft silicone hydrogel contact lenses with extremely high gas transmission has not resulted in a reduction in the rate of microbial keratitis with extended wear²¹⁹⁻²²¹ or with daily wear.²²² Studies from around the world have confirmed that the incidence of microbial keratitis has not been reduced with the introduction of new

lens types and that overnight wear of any contact lens is associated with a higher risk than daily wear.^{213, 221, 223, 224}

These newer materials meet central and peripheral oxygen transmissibility thresholds to avoid corneal swelling during open-eye soft contact lens wear²²⁵ but have not resulted in lower infection rates as detailed above. However, they are useful options in cases where there is neovascularization suggestive of hypoxia, when thicker lenses for the correction of high refractive error are required, or when contact lenses are used therapeutically.²²⁶ Clinicians should be aware that a cosmetic iris incorporated into any contact lens is likely to reduce oxygen transmission through that lens; such a lens may not be an appropriate choice for an eye already at higher risk of complications from hypoxia. Cosmetic lens wear to change the appearance of the eye rather than to correct refractive error accounts for a substantial fraction (29.6%) of contact lens–related infection in a 2021 report from Asia. Wide internet availability, questionable quality control, and uneven regulation of the sale of these lenses present significant challenges.²²⁷

Overnight wear of silicone hydrogel contact lenses is associated with sterile inflammatory peripheral corneal infiltrative events (CIEs), as are smoking and lens or eyelid microbes (bioburden).²²⁸⁻²³¹ Tear stagnation may play a role in alterations of corneal epithelium associated with overnight contact lens wear.²³² Neither of the more recently introduced contact lens modalities, daily disposable or silicone hydrogel material, reduced the overall risk of acute nonulcerative events presenting to an emergency room.²³³ Bioburden and specific lens care products or modalities may play a role in the development of CIEs, yet there appears to be no advantage to the use of antibiotics to reduce the incidence of CIEs during extended wear of silicone hydrogel lenses.²³⁴⁻²³⁸ The exact relationship between CIEs and microbial keratitis remains unclear.

Overnight wear of a soft lens may be used on a therapeutic basis for ocular surface problems; there also are highly gas-permeable silicone hydrogel lenses that are FDA approved for extended wear on that basis. Overnight use of any contact lens is associated with a higher risk of infectious keratitis, and daily wear of a rigid gas-permeable lens is associated with the lowest rate of microbial keratitis of any lens type and wearing schedule.^{221, 222} Overnight wear, regardless of contact lens type (including the newest highly gas-permeable silicone hydrogel lenses), increases the likelihood of corneal infection.^{202-204, 219-222, 239} Although there are lenses approved by the FDA for extended wear, this and other risks, benefits, and alternatives should be presented to patients for whom this mode of contact lens wear is being considered.^{202-204, 219, 220, 222, 239, 240}

There have been outbreaks and reports of increases in *Acanthamoeba* and fungal keratitis in association with contact lens wear in the past several decades.²⁴¹⁻²⁵⁹ This trend predates the association with the use of certain multipurpose solutions with reduced antimicrobial efficacy that are no longer on the market,²⁶⁰⁻²⁶³ and it is associated with all lens types.²⁶⁴ The trend has continued even with the removal of ineffective antimicrobial solutions in the case of *Acanthamoeba*.²⁶⁵ Environmental risk factors and hygiene practices, such as no-rub cleaning, topping off (reuse) of solutions, contaminated lens cases, exposure to tap water, wearing lenses while swimming or in hot tubs, and changes in water supply are emerging as risk factors.^{222, 223, 266-269} A study of *Fusaria* isolates from the U.S. outbreaks of 2005 and 2006 found a high degree of phylogenetic diversity consistent with multiple sources of contamination.²⁷⁰

MedWatch (<u>www.fda.gov/medwatch</u>) is the Safety Information and Adverse Reporting Program for drugs and other medical products regulated by the FDA. Adverse events related to contact lens wear should be reported to MedWatch.

Selection and Fitting

Before fitting a patient for contact lenses, an ocular history that includes past contact lens experience should be obtained, and a comprehensive medical eye evaluation should be performed.^{165, 166} During this examination, particular attention should be directed at evaluating the patient's hygiene and ability to adhere to proper contact lens care as well as to ocular parameters such as eyelid function, eyelid margins, meibomian glands, tear film, conjunctival surface, and the corneal surface. General principles for selecting and fitting contact lenses are described in Appendix 6.

Patient Education and Contact Lens Care

The FDA and CDC have made recommendations for contact lens wearers regarding proper lens care practices. These are incorporated into the following recommendations:²⁷¹⁻²⁷³

- Wash hands with soap and water, and dry (lint-free method) before handling contact lenses every time.
- Do not sleep in your contact lenses unless approved by your eye doctor.
- Never store your contact lenses in water.
- Keep tap water away from your contact lenses. Remove contact lenses before showering, swimming, or using a hot tub.
- For contact lenses other than daily disposables:
 - \circ Rub and rinse contact lenses in disinfecting solution each time you remove them.
 - Rub and rinse the case with contact lens solution, dry it with a clean tissue, and store it upside down with the caps off after each use.
 - Do not top off solution. Use only fresh contact lens disinfecting solution in your case—never mix old and new solutions.
 - Wear and replace contact lenses according to the schedule prescribed by your doctor.
 - Follow the specific contact lens cleaning and storage guidelines from your doctor and the solution manufacturer.
 - Keep the contact lens case clean and replace it every 3 months.
- Remove the contact lenses and consult your doctor immediately if you experience symptoms such as redness, pain, tearing, increased light sensitivity, blurry vision, discharge, or swelling.
- See your eye doctor as often as they recommend for contact lens examination and for an update on wear and care practices.

These recommendations apply to contact lenses prescribed for refractive error as well as those used to alter the appearance of the eye.^{274, 275} All contact lenses, including decorative and costume contact lenses, are medical devices requiring a physician's prescription and supervision. Doctors, patients, and consumers should be aware that there is a federal statute prohibiting contact lens sellers from providing contact lenses to customers without a valid prescription.²⁷⁶ Stores or websites selling contact lenses without requiring a prescription are engaging in illegal business activity that is subject to federal law enforcement. Unregulated contact lens products may be counterfeit.

When contact lenses are initially prescribed and dispensed (whether for refractive or cosmetic purposes), patients should be trained and supervised in contact lens insertion and removal. Contact lens cleaning and disinfection should be carefully explained, because improper care may be associated with complications of contact lens wear.^{204, 222, 245, 277} Hydrogen peroxide systems may be superior to preserved disinfecting solutions in reducing pathogen binding and cysticidal disinfection, but they require more complex care regimens.^{223, 278-280} Patients should be instructed to use only sterile products that are commercially prepared specifically for contact lens care and to replace these at the intervals recommended by the manufacturers.²⁸¹ Specifically, patients should be instructed not to rinse contact lenses or lens cases with water (e.g., tap water, bottled water)²²² and to eliminate any water exposure as part of their wear and care regimen.²⁸² Patients should also be instructed to clean and replace contact lens cases at least every 3 months, because they can be a source of lens contamination.^{222, 255, 283} Patients should be instructed to replace the solution in contact lens cases each time the lenses are disinfected.²⁸⁴ Contact lens wearers should also use only fresh contact lens disinfecting solution in their case, and never mix old and new solutions (e.g., "topping off" solution).⁹

Patients should be made aware that using contact lenses can be associated with the development of ocular problems, including corneal infections that may threaten vision, and that overnight wear of contact lenses is associated with a fivefold relative risk of these corneal infections compared with daily wear.^{202, 220, 221, 239, 285, 286} Even occasional overnight wear has risks²⁸⁷ and is discouraged. The increased risk of corneal infections with overnight contact lens wear should

be discussed with patients who are considering this modality of vision correction. If patients choose overnight wear, they should be instructed to use only lenses specifically approved for extended wear.

Swimming with contact lenses has been associated with the development of *Acanthamoeba* keratitis,²⁸⁵ and showering with lenses seems to be part of a pattern of risk.²⁴⁵ Patients should be instructed to minimize water contact when wearing contact lenses and informed of the risks of wearing contact lenses while swimming, sitting in a hot tub, showering, bathing, and washing hair.

Patients should be advised to have regularly scheduled examinations to monitor the fit of the contact lens; to monitor ocular health, including pannus, scarring, inflammation and ectasia; and to reinforce proper lens care and hygiene.²⁸⁸

For additional information about contact lens selection, fitting, and care, see Appendix 6.

Follow-up Examination and Contact Lens Replacement

The initial contact lens fitting process should include follow-up examinations to assess visual acuity, comfort, contact lens fit, and the effect of the contact lens on the health of the ocular surface. First-time daily-wear or extended-wear contact lens users should be checked soon after the contact lenses are initially dispensed. Experienced contact lens wearers should generally be examined every 1 to 2 years to monitor for adverse effects of contact lens wear and for an update on healthy practices in contact lens wear and care. Patients should be questioned about problems such as irritation, redness, itching, discharge, decreased vision, or eyeglass blur upon contact lens removal. The patient's wear schedule and contact lens care regimen should be reviewed, and any deviations from recommended practice should be addressed. Of note, patient noncompliance with recommended hygienic practices in contact lens wear is often considered a significant risk factor for microbial keratitis and adverse contact-lens-related events. One study found that 86% of patients believed that they were compliant with hygienic practices; however, an interview about their lens care practices revealed that only 34% of those who reported themselves as compliant exhibited good lens care practices.²⁸⁹ Patient-reported compliance does not indicate appropriate patient behavior, as a large proportion of patients remain noncompliant despite being aware of risk.^{289, 290} Visual acuity with the contact lenses should be checked and the cause of any changes should be determined. The contact lenses themselves should be examined to make certain that they fit and wet well and are free of deposits or defects.

The external eye and cornea should also be evaluated in the follow-up examination. Findings of conjunctival injection, corneal edema, staining, infiltrates, changes at the superior limbus, or tarsal papillary conjunctivitis all indicate possible problems with contact lens wear. The practitioner should examine patients for signs of corneal hypoxia, evidence of infiltrative events, corneal neovascularization, and corneal warpage. If findings of corneal hypoxia are recognized, the contact lens fit, material, or wearing time should be adjusted to allow for better oxygenation of the cornea. Keratometry or corneal topography/tomography as well as refraction without the contact lenses should be compared with initial readings for patients suspected of having corneal warpage.

As far as replacement, the length of time a particular pair of rigid gas-permeable contact lenses can be used will vary among individual patients. Rigid gas-permeable contact lenses are generally useful for 18 to 24 months, although the surface quality of these lenses may deteriorate more rapidly for some individuals. Other individuals can use the same lenses for several years with little deterioration in optical or surface qualities. Replacement schedules are determined by the eye care practitioner based on clinical evaluation.

Traditional daily-wear soft contact lenses typically require replacement at least annually. Traditional extended-wear soft contact lenses often require replacement more frequently than once a year. Disposable lenses, which includes frequent/planned replacement and daily disposable hydrogel and silicone hydrogel lenses, for daily wear (less than 24 hours while awake) or extended wear (greater than 24 hours, including while asleep) should be replaced per manufacturers' guidelines, which vary from 1 day to several months. These guidelines are included in the lens package insert that can be found in the box of lenses and online. The frequency of contact lens replacement should also be adjusted based on patient symptoms and findings at eye examinations. If a contact lens shows excessive deterioration or deposits, it should be replaced regardless of the length of wear. Typically, contact lens prescriptions are written with a 1-year expiration, although there are some situations where the expiration is shortened.

Rigid gas-permeable corneal lenses continue to have the lowest rate of adverse events of any lens type,^{220, 221, 288} but initial patient discomfort and resources required for fitting and supplying these lenses compared with soft lenses have resulted in a continued decline in their use.²⁹¹ Of soft lens options, daily disposable lenses worn on a daily-wear basis remains the safest regimen.^{220, 292} Extended (overnight) wear, regardless of lens type (including the newest highly gas-permeable silicone hydrogel lenses), increases the likelihood of infection,^{220, 221} and discussion of this increased risk should be undertaken with patients who continue with this modality of vision correction. Patients should be instructed that contact lens hygiene, including case lens replacement, is important for any lens that is to be reworn. Finally, hydrogen peroxide disinfection has the lowest rate of adverse events compared with any other disinfection system regardless of lens type.

Orthokeratology

Rigid gas-permeable contact lenses can be prescribed as a nonsurgical and reversible method of refractive error reduction for the treatment of mild to moderate myopia with less than 1.50 D of corneal astigmatism. The technique of corneal reshaping is known as orthokeratology.

Orthokeratology, as originally described, utilized the application of sequentially flatter PMMA hard contact lenses to flatten the cornea and thereby reduce the myopic refractive error. When patients stop wearing contact lenses after undergoing orthokeratology, their corneas tend to revert to their original shape.^{293, 294} Earlier attempts to predict which patients would respond to orthokeratology based on ocular biomechanical or biometric parameters were not successful,²⁹⁵ and the effects of orthokeratology were unpredictable and poorly controlled.²⁹³ In the 1990s, there was a resurgence using highly gas-permeable rigid contact lenses for temporary corneal reshaping. In this technique, patients with myopia are fitted with reverse-geometry rigid gaspermeable contact lenses that are used only during sleep. The center of the contact lens is deliberately fitted flatter than the central corneal curvature to transiently induce central corneal flattening by a thinning or molding of the epithelium, which will reverse myopia during the day when the lens is not worn. The contact lens must be used every one to two nights in order to maintain the effect. Approval by the FDA has been granted for the use of this technique, often referred to as overnight orthokeratology, for temporary reduction of up to 6.00 D of myopia (in eyes with up to 1.75 D of astigmatism). Average uncorrected visual acuity (UCVA) ranges from 20/19 to 20/24, with a refractive error ranging from +0.27 to -0.41 D after 1 to 6 months of wearing reverse-geometry contact lenses.²⁹⁶⁻³⁰¹

The complications of overnight orthokeratology overlap those of rigid contact lens wear. As with any overnight contact lens modality, orthokeratology is associated with an increased risk of microbial keratitis,^{299, 302-304} which is a risk similar to that of any overnight wear.³⁰⁵ Microbial keratitis in association with overnight orthokeratology was first reported in 2001.^{306, 307} Most of these cases originated in Asia, particularly in China and Taiwan, and were reported during a relatively short period when regulation of orthokeratology was limited.³⁰⁸ A high incidence of cases of Acanthamoeba keratitis reported with this modality demonstrates the importance of eliminating the use of tap water in care regimens for overnight orthokeratology. ^{308, 309} A report of Acanthamoeba keratitis in minors from a single center in the United States collected over a decade as solutions came on and off the market and as lens care standards have evolved found increased risk among orthokeratology users.²⁶⁴ Recent meta-analysis suggests that risk of microbial keratitis with orthokeratology is similar to that of other types of overnight wear of contact lenses³¹⁰ even though reports of safety in small cohorts have been reported globally.^{311,} ³¹² Orthokeratology patients may note a decreased quality of vision, especially under lowillumination conditions, as a result of induction of irregular astigmatism and an increase in HOAs that sometimes occurs with orthokeratology.

In addition to a transient reduction in refractive error, orthokeratology has been shown to slow myopic progression in children and adolescents (myopia control).^{311, 313, 314} (*II*++, *moderate*, *discretionary*)

Myopia Control

A global increase in the prevalence of myopia is the subject of increased attention.¹⁶⁴ Treatments that aim to minimize progression of refractive errors, particularly myopia, have been reported. Low-concentration atropine and increased outdoor time have been shown to reduce the likelihood of myopia onset.³¹⁵⁻³¹⁷ There is evidence that interventions should be considered for patients thought to be at risk for myopia progression.³¹⁸⁻³²⁵ (*I*++, good, strong) Effective interventions for slowing the progression of myopia include topical antimuscarinic agents, which are most effective, as well as multifocal contact lenses and spectacles, and orthokeratology.^{165, 169, 319, 322, 326, 327} (*II*+, moderate, discretionary)

Most myopic refractive errors develop and progress during childhood and adolescence.¹¹⁸ Slowing progression of myopia has a considerable public health impact, and thus the field of myopia control has emerged. A Cochrane review assessed the effects of several types of interventions (eve drops; undercorrection of nearsightedness; multifocal eveglasses; and contact lenses, including multifocal contact lenses and orthokeratology) on the progression of nearsightedness in myopic children. It compared these interventions with each other and to eyeglasses, placebo, or no treatment. The largest positive effects for slowing myopia progression were exhibited by antimuscarinic medications. Antimuscarinic eyedrops have undesirable side effects at commercially available concentrations and are not available commercially in the United States at low concentrations except through compounding pharmacies. Multifocal spectacles and contact lenses and orthokeratology are also effective in slowing progression, but to a lesser degree.³¹⁷ Reduction of peripheral hyperopic defocus may be the mechanism by which these interventions are effective. Despite the belief that excessive near work (e.g., reading, screen time) is a causative factor in the myopia epidemic, recent evidence suggests that it is time outdoors that is the controlling factor.^{81, 328} Recently, there have been a number of studies investigating this factor. A meta-analysis indicated that outdoor time as an intervention was correlated with a reduced myopia shift over a 3-year follow-up period.³²⁹ In a study of 693 first grade schoolchildren in 16 schools, children with longer outdoor time while at school (more than 200 minutes) showed significantly less myopic shift.³³⁰ In a cohort of high school students, more than 1 hour of outdoor activity was protective from cumulative spherical-equivalent refractive decrease.³³¹ Other studies have similarly found outdoor time to be a factor in reducing myopia progression.332,333

A multifocal soft lens was found to slow myopia progression in Hong Kong Chinese schoolchildren.³²⁷ The BLINK randomized clinical trial in the United States found that treatment with high add power multifocal contact lenses significantly reduced the rate of myopia over 3 years.³³⁴ In 2019, the FDA approved the first multifocal soft contact lens to slow the progression of myopia in children ages 8 to 12 years at initiation of treatment.³³⁵

Spectacle Correction of Myopia with Myopia Control Features

Optical correction in the form of bifocal eyeglasses, multifocal eyeglasses, or removal of distance eyeglasses when performing close work has been recommended in an attempt to reduce accommodation, since accommodation has been implicated in the progression of myopia. Studies examining distance eyeglasses alone have failed to demonstrate any overall effects on the progression of human myopia.³³⁶ Furthermore, undercorrection of human myopia is myopigenic.³³⁷

A study of 75 esophoric children, approximately half of whom used +1.50 D add bifocals, did show a slight reduction in the progression of myopia compared with controls. Among the children completing the 30 months of follow-up, mean myopia progression was statistically significantly lower for bifocals than for single-vision eyeglasses (1.00 to 1.24 D).³³⁸ Progressive addition lenses have been shown to have similar effect.³³⁹ Another study of 469 children ages 6 to 11 years reported that progressive addition lenses compared with single-vision lenses slowed the

progression of myopia by a small, statistically significant amount only during the first year.³⁴⁰ A meta-analysis of nine clinical trials comparing the effects of multifocal and single-vision lenses in school aged children found that multifocal lenses with powers ranging from +1.50 to +2.00 D were associated with a significant decrease in myopia progression compared with single-vision lenses.³⁴¹ One randomized trial found that bifocal eyeglasses slowed myopia progression over 3 years in children who previously had an annual progression rate of at least 0.50 D.³⁴² Meta-analysis suggests that early treatment effects may not be maintained.³⁴³ There are novel spectacle lens designs for myopia control that are in the early stages of study and regulatory oversight.³⁴⁴

Atropine (Antimuscarinic Agents)

Administration of atropine eyedrops has long been proposed as a treatment to prevent progression of myopia. Atropine inhibits accommodation, which may exert forces on the eye that result in axial elongation. In animal studies, atropine also appears to inhibit growth factors acting to elongate the eye independent of accommodation.³⁴⁵⁻³⁴⁷

There are clinical trials from around the world demonstrating the effect of low-dose atropine in slowing the progression of myopia.

The results of randomized, controlled clinical trials conducted in Taiwan and Singapore (three of which were masked) provide reasonable evidence that administration of atropine eyedrops retards the progression of myopia in school children.^{123, 124, 348, 349} In one study, a range of atropine concentrations was utilized: 0.1%, 0.25%, and 0.5%. All reduced progression of myopia compared with the control group. Furthermore, atropine 0.01% has been found to have efficacy in controlling myopia progression compared with atropine 0.1% and 0.5% with minimal side effects.^{320, 321} A more significant myopic rebound was noted after 0.5% atropine treatment cessation compared with 0.01%.³²⁴

Another published study (LAMP), a randomized, double-masked clinical trial from the Chinese University of Hong Kong, looked at the efficacy and safety of 0.05%, 0.025%, and 0.01% from atropine eye drops over 2 years. The efficacy of topical 0.05% atropine was double that of 0.01% atropine, and it remained the optimal concentration among the studied atropine concentrations in slowing myopia progression.³⁵⁰ There is a continued benefit in year 3 compared with stopping treatment.³⁵¹

It has also been shown that atropine eyedrops are effective in populations in the United States, where children generally have less rapid rates of progression of myopia than in Taiwan and Singapore.^{321, 352-354} Different concentrations of atropine have been studied. Atropine 0.01% eye drops are more effective in slowing myopia progression with fewer visual side effects compared with atropine 0.1% or 0.5% evedrops over a 5-year period.³²¹ A recent meta-analysis of atropine concentrations for myopia control has shown that the ranking probability of efficacy was not proportional to the dose.³⁵⁵ Once the use of atropine is discontinued, the beneficial effects remain.³⁵⁴ Potential risks of long-term atropine use are uncertain and include the risk of light toxicity to ocular structures, the potential for local allergic and systemic reactions, and reduced accommodative amplitudes following discontinuation of atropine. However, it has been reported that daily atropine usage over 2 years for the treatment of myopia has no significant effect on retinal function, as demonstrated by multifocal electroretinograms in children.³⁵⁶ Other potential disadvantages include the inconvenience of using daily eyedrops and the possible need for bifocal or multifocal eyeglasses for near work (depending on the concentration of atropine administered), photosensitivity and glare, and rebound upon cessation of use. Use of lower concentrations of atropine reduce or eliminate these potential disadvanges.325

Cyclopentolate 1% administered nightly was evaluated in one study in school children in Taiwan and was found to slow the rate of progression of myopia compared with controls, but not as much as atropine did.³⁴⁸ One study of tropicamide 1% found no significant difference in the progression of myopia compared with controls.³⁵⁷

Pirenzepine hydrochloride has been evaluated in two multicenter, double-masked, placebocontrolled parallel studies to slow the progression of myopia in school aged children.^{358, 359} Both studies found 2% pirenzepine ophthalmic gel effective and relatively safe in slowing myopia progression over a 1-year treatment period. Further investigation of this selective muscarinic antagonist was abandoned by industry. A network meta-analysis based on 30 randomized controlled trials involving 5422 eyes compared the efficacy of 16 interventions for myopia control in children. It concluded that muscarinic antagonists, such as atropine and pirenzepine, were the most effective in reducing myopia progression, followed by specially designed contact lenses.³¹⁸ (*I*++, good, strong) In a Cochrane analysis of the effect of several interventions on myopia progression, antimuscarinic agents were shown to have the largest positive impact on slowing myopia.³¹⁷

In another meta-analysis looking at 10 randomized controlled trials, myopia progression slowed down the most with atropine treatment compared with controls.³⁶⁰ A smaller meta-analysis showed that myopia from axial elongation was lower in the group that received a combination of atropine and orthokeratology compared with orthokeratology alone.³⁶¹

Contact Lenses for Myopia Control

It has long been postulated that rigid contact lens wear could slow the progression of myopia in children.^{362, 363} Previous published studies were limited by methodological difficulties.³⁶⁴⁻³⁶⁹ A 2-year randomized clinical trial evaluating the effect of rigid contact lenses on myopia progression in school children was conducted in Singapore,³⁷⁰ and another study was conducted concurrently in the United States.³⁷¹ Together they indicated that rigid gas-permeable contact lenses should not be prescribed primarily for myopia control.³⁷¹

A randomized clinical trial in the United States evaluated soft contact lens wear compared with spectacle correction on the course of myopia.³⁷² No statistically significant difference in the rate of myopia progression could be demonstrated between the contact lens group and the group using single-vision eyeglasses. Soft contact lenses with a positive spherical aberration were compared with the spherical design and were found to slow axial growth in children after 1 to 2 years of treatment. However, spherical equivalent cycloplegic autorefraction was not significantly affected in concordance.³²³

Bifocal or multifocal contact soft lenses have been studied as a method of slowing progression of myopia, with the presumed mechanism being a reduction of peripheral hyperopic defocus. As of this writing, there is one multifocal daily disposable soft contact lens, MiSight (CooperVision, San Ramon, CA) that is approved by the FDA for myopia control. This mode of wear was not associated with complications during monitoring over 6 years in children ages 8 to 12 years.³⁷³

There is emerging evidence from Hong Kong, Australia, and Spain that there is a role for orthokeratology in the control of myopia,^{322, 374-376} with reduction of peripheral hyperopic defocus as the likely mechanism.³⁷⁷ Whether these results will apply to broader populations remains to be proven. The risk of microbial keratitis with this approach must be considered.³¹³

The safest way to incorporate contact lens into clinical practice for reduction of axial elongation in young children remains to be determined.

Other Approaches

Pressure-Lowering Eyedrops

Lowering IOP has been suggested as a pharmacologic intervention that might reduce progression of myopia, presumably by reducing internal pressure on the ocular wall. One prospective clinical trial comparing the administration of 0.25% timolol maleate with the use of single-vision eyeglasses failed to show any retardation of progression of myopia.^{378, 379} Therefore, this treatment is not recommended.

Visual Training

Visual training purported to reduce myopia includes exercises such as near-far focusing change activities.³⁸⁰⁻³⁸² There are no scientifically acceptable studies that document that these treatments are clinically effective, and, therefore, this therapy is not recommended.^{380, 383, 384}

Acupuncture, and Nutrition

In a Cochrane review, acupuncture was studied for slowing the progression of myopia in children, but no conclusions could be drawn.³⁸⁵ Information about the effects of nutritional changes on the progression of myopia is largely anecdotal and no scientifically valid studies are available.

Medical Management of Presbyopia

The management of presbyopia can be divided to nonsurgical and surgical approaches.

Nonsurgical management of presbyopia includes eyeglasses (reading glasses, bifocal, trifocal, or progressive lenses) and contact lenses (soft or rigid gas-permeable with aspheric bifocal or multifocal optics). Monovision strategies can also be used. A modified monovision involves using a bifocal or multifocal contact lens in one eye and a distance contact lens in the fellow eye.

Recently, there have been a number of clinical trials studying the effect of topical therapies to manage presbyopia, and the results have been promising. In 2021, 1.25% pilocarpine ophthalmic solution (Vuity, Allergan) was approved by the FDA for daily use to treat presbyopia. Retinal detachement and retinal tear have been reported with miotics, including 1.25% topical pilocarpine.³⁸⁶ Individuals with pre-existing retinal disease are at increased risk. Dilated fundus examination is advised in all patients prior to initiation of therapy to look for holes, tears, or breaks in the retina. Numerous trials of other agents are ongoing globally.

Refractive surgery for presbyopia is covered in the Refractive Surgery PPP.¹⁷⁰ The use of intraocular lenses for presbyopia is covered in the Cataract PPP.⁶

PROVIDER AND SETTING

Patients with refractive errors should be examined and evaluated for treatment by an ophthalmologist or an optometrist.

SOCIOECONOMIC CONSIDERATIONS

Global Burden of Uncorrected Refractive Error

The Global Burden of Disease study estimates that 123 million people have vision worse than 20/60 due to uncorrected refractive error, with the burden of disease greatest in developing countries.³⁸⁷ Globally, uncorrected refractive error is the leading cause of moderate to severe visual impairment (52% of cases)³⁸⁷ and the third-leading cause of blindness after cataract and glaucoma.³⁸⁸ A 2016 report estimates that within the United States, up to 8.2 million people have a vision impairment due to uncorrected refractive error.³⁸⁹ The global burden of refractive error increases when presbyopia is taken into account. An estimated 1.8 billion people are estimated to have presbyopia, over half of whom do not have adequate presbyopic correction.³⁹⁰

Quality of Life

Numerous patient-reported outcomes instruments have been developed to estimate quality of life specifically in the context of refractive error.³⁹¹ Studies have demonstrated that refractive error reduces vision-related quality of life. In a British study, persons with myopia of 10.00 D or more had significantly worse vision-related quality of life compared with persons with less severe myopia.³⁹² An Australian study found that individuals with myopia of 0.50 D or more reported worse vision-related quality of life measures compared with emmetropes.³⁹³ In a European study, more than half of pseudophakic patients who wore eyeglasses after cataract surgery would be willing to pay more than €0.50 per day to be free from wearing eyeglasses.³⁹⁴

Eye-related quality of life and functional vision were reduced in children wearing glasses for refractive error and not other eye conditions and in their parents, compared to controls.³⁹⁵ Overall, systematic review of long-term contact lens wear reveals that contact lens use improves quality of life in children and adults.³⁹⁶

Cost-Effectiveness

A 2013 report estimated that the cost of eye disorders and vision loss in the United States was approximately \$139 billion per year. Refractive error was the most expensive eye condition in this report, accounting for \$16 billion per year.³⁹⁷ Worldwide, the burden of uncorrected refractive error has substantial economic repercussions. The global productivity loss of \$244 billion has been estimated for uncorrected myopia alone—a far greater cost than the estimated \$20 billion that would be required to correct the world's refractive error. ^{158, 398}

APPENDIX 1. QUALITY OF OPHTHALMIC CARE CORE CRITERIA

Providing quality care is the physician's foremost ethical obligation, and is the basis of public trust in physicians. AMA Board of Trustees, 1986

Quality ophthalmic care is provided in a manner and with the skill that is consistent with the best interests of the patient. The discussion that follows characterizes the core elements of such care.

The ophthalmologist is first and foremost a physician. As such, the ophthalmologist demonstrates compassion and concern for the individual, and utilizes the science and art of medicine to help alleviate patient fear and suffering. The ophthalmologist strives to develop and maintain clinical skills at the highest feasible level, consistent with the needs of patients, through training and continuing education. The ophthalmologist evaluates those skills and medical knowledge in relation to the needs of the patient and responds accordingly. The ophthalmologist also ensures that needy patients receive necessary care directly or through referral to appropriate persons and facilities that will provide such care, and he or she supports activities that promote health and prevent disease and disability.

The ophthalmologist recognizes that disease places patients in a disadvantaged, dependent state. The ophthalmologist respects the dignity and integrity of his or her patients and does not exploit their vulnerability.

Quality ophthalmic care has the following optimal attributes, among others.

- The essence of quality care is a meaningful partnership relationship between patient and physician. The ophthalmologist strives to communicate effectively with his or her patients, listening carefully to their needs and concerns. In turn, the ophthalmologist educates his or her patients about the nature and prognosis of their condition and about proper and appropriate therapeutic modalities. This is to ensure their meaningful participation (appropriate to their unique physical, intellectual, and emotional state) in decisions affecting their management and care, to improve their motivation and compliance with the agreed plan of treatment, and to help alleviate their fears and concerns.
- The ophthalmologist uses his or her best judgment in choosing and timing appropriate diagnostic and therapeutic modalities as well as the frequency of evaluation and follow-up, with due regard to the urgency and nature of the patient's condition and unique needs and desires.
- The ophthalmologist carries out only those procedures for which he or she is adequately trained, experienced, and competent, or, when necessary, is assisted by someone who is, depending on the urgency of the problem and availability and accessibility of alternative providers.
- Patients are assured access to, and continuity of, needed and appropriate ophthalmic care, which can be described as follows.
 - The ophthalmologist treats patients with due regard to timeliness, appropriateness, and his or her own ability to provide such care.
 - The operating ophthalmologist makes adequate provision for appropriate pre- and postoperative patient care.
 - When the ophthalmologist is unavailable for his or her patient, he or she provides appropriate alternative ophthalmic care, with adequate mechanisms for informing patients of the existence of such care and procedures for obtaining it.
 - The ophthalmologist refers patients to other ophthalmologists and eye care providers based on the timeliness and appropriateness of such referral, the patient's needs, the competence and qualifications of the person to whom the referral is made, and access and availability.
 - The ophthalmologist seeks appropriate consultation with due regard to the nature of the ocular or other medical or surgical problem. Consultants are suggested for their skill, competence, and accessibility. They receive as complete and accurate an accounting of the problem as necessary to provide efficient and effective advice or intervention, and in turn they respond in an adequate and timely manner.
 - The ophthalmologist maintains complete and accurate medical records.
 - On appropriate request, the ophthalmologist provides a full and accurate rendering of the patient's records in his or her possession.

- The ophthalmologist reviews the results of consultations and laboratory tests in a timely and effective manner and takes appropriate actions.
- The ophthalmologist and those who assist in providing care identify themselves and their profession.
- For patients whose conditions fail to respond to treatment and for whom further treatment is unavailable, the ophthalmologist provides proper professional support, counseling, rehabilitative and social services, and referral as appropriate and accessible.
- Prior to therapeutic or invasive diagnostic procedures, the ophthalmologist becomes appropriately conversant with the patient's condition by collecting pertinent historical information and performing relevant preoperative examinations. Additionally, he or she enables the patient to reach a fully informed decision by providing an accurate and truthful explanation of the diagnosis; the nature, purpose, risks, benefits, and probability of success of the proposed treatment and of alternative treatment; and the risks and benefits of no treatment.
- The ophthalmologist adopts new technology (e.g., drugs, devices, surgical techniques) in judicious fashion, appropriate to the cost and potential benefit relative to existing alternatives and to its demonstrated safety and efficacy.
- The ophthalmologist enhances the quality of care he or she provides by periodically reviewing and assessing his or her personal performance in relation to established standards, and by revising or altering his or her practices and techniques appropriately.
- The ophthalmologist improves ophthalmic care by communicating to colleagues, through appropriate professional channels, knowledge gained through clinical research and practice. This includes alerting colleagues of instances of unusual or unexpected rates of complications and problems related to new drugs, devices, or procedures.
- The ophthalmologist provides care in suitably staffed and equipped facilities adequate to deal with potential ocular and systemic complications requiring immediate attention.
- The ophthalmologist also provides ophthalmic care in a manner that is cost-effective without unacceptably compromising accepted standards of quality.

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APPENDIX 2. INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES AND RELATED HEALTH PROBLEMS (ICD) CODES

Refractive errors, which includes entities with the following ICD-10 classifications:

	ICD-10 CM
Aniseikonia	H52.32
Anisometropia	H52.31
Hyperopia	Н52.0-
Myopia (axial) (congenital)	H52.1–
Astigmatism, regular	H52.22-
Astigmatism, irregular	H52.21-
Astigmatism, postkeratoplasty	T86.848-
Astigmatism, postoperative, surgically induced	T88.8
Presbyopia	Н52.4
Specified NEC	Н52.6

CM = Clinical Modification used in the United States; NEC = Not elsewhere classified; (-) = 0, unspecified eye; 1, right eye; 2, left eye; 3, bilateral

Additional Information:

- Certain categories have applicable 7th characters. The applicable 7th character is required for all codes within the category, or as the notes in the Tabular List instruct. The 7th character must always be the 7th character in the data field. If a code that requires a 7th character is not 6 characters, a placeholder X must be used to fill in the empty characters.
- For bilateral sites, the final character of the codes indicates laterality. An unspecified side code is also provided should the side not be identified in the medical record. If no bilateral code is provided and the condition is bilateral, assign separate codes for both the left and right side.
- When the diagnosis code specifies laterality, regardless of which digit it is found in (i.e., 4th digit, 5th digit, or 6th digit):
 - Right is always 1
 - Left is always 2
 - Bilateral is always 3

APPENDIX 3. GLOBAL EPIDEMIOLOGY OF REFRACTIVE ERRORS

Over half of Americans over the age of 40 have ametropia of sufficient magnitude to require refractive correction.⁷ It has been estimated that 93 million Americans aged 12 years and older use some form of eyewear to correct refractive errors in distance.⁸ About 41 million people in the United States used contact lenses in 2005.³⁹⁹ It has been estimated that over 8.5 million people in the United States have undergone refractive surgery since 1995¹⁰ and it is estimated that over 13 million LASIK procedures have been performed in the United States.¹¹

The prevalence of myopia in the U.S. population was estimated in the early 1970s to be 25% in persons aged 12 to 54 years.⁴⁰⁰ A meta-analysis of population-based studies found a prevalence of 25% in persons over age 40.¹⁵ A study based on a sample representative of the U.S. population found a prevalence of 31% in those 40 and older and of 36% in those 20 and older.⁷ A number of population-based studies have shown that the prevalence of myopia is lower in older persons than in younger ones, ranging from about 35% to 40% among persons in their 20s to 40s to about 15% to 20% among persons in their 60s, 70s, and 80s.¹⁶⁻¹⁸ Individuals who develop nuclear sclerosis, however, tend to undergo a myopic shift over time.¹⁹⁻²¹

MYOPIA

Studies of ethnic Chinese in Taiwan documented an increase in the prevalence and severity of myopia over two generations.^{53, 67, 87-90} Similar increases in prevalence have been noted in Australian middle-aged adults,⁹¹ among Indian schoolchildren,⁹² and in a study of Japanese adults.⁹³ Genetics alone are unlikely to account for such a rapid change. One study has speculated that genetic factors do not preclude such a change.⁹⁴ A study of successive cohorts of enlistees in the Israeli army showed a marked increase in prevalence of myopia over a 13-year period.⁹⁷ A study in Finland showed that the prevalence of myopia doubled among teenagers and young adults over the course of the 20th century.⁹⁸ A study comparing U.S. population-based estimates in 1971 to 1972 and 1999 to 2004 also found a marked increase in the prevalence of myopia, although the reasons for this increase could not be identified.⁹⁹ Several additional studies have reported that the prevalence of myopia is increasing.⁴⁹, ^{53, 67, 91-93, 100, 101} In one report from East Asia, the prevalence of myopia was found to be rapidly increasing (now 80%–90%) in school aged children.¹⁰³

In the United States, myopia was found to be significantly more prevalent among non-Hispanic white persons than among persons of non-Hispanic black or Mexican American race/ethnicity.⁷ Two population-based studies in the United States have reported that the prevalence of myopia in Latino persons aged 40 and older was 17% to 18%.^{15, 401} A similar pattern was reported in Australia^{105, 402} and in populations of African descent in Baltimore and Barbados.^{17,403} The prevalence of myopia in Chinese Americans aged 50 years and older has been estimated at 35.1% (at least 0.50 D of myopia), and high myopia (at least 5 D of myopia) was found in 7.4%.⁴⁰⁴ There have been a number of population-based studies in different East Asian countries that indicate that the prevalence of myopia varies considerably. In elderly Taiwanese persons, the prevalence was 19% (65 years and older);⁴⁰⁵ in Indonesia, the prevalence was 26%;⁴⁰⁶ in Beijing, the prevalence was 23% (40 years and older).⁴⁰⁷ In Chinese people aged 30 years and older, the prevalence was 26.7%, 408 and the prevalence was 9.5% in persons living in southern China aged 50 years and older.⁴⁰⁹ A study of Japanese persons aged 40 years and older found a prevalence of myopia (0.50 D or more) of 41.8%;⁴¹⁰ more recent studies have found prevalence estimates increasing from 38% to 46% from 2005 to 2017, with a concurrent increase in the prevalence of myopic maculopathy,⁹³ and a prevalence of 50% in a different Japanese population, with much higher prevalence in those aged 34 to 59 than in older indivduals.⁹⁵ Other studies of young adult East Asian populations indicate that the prevalence of myopia is much higher than in their U.S. counterparts, ranging from 56% in 15- to 19-year-old Singaporean students⁴¹¹ to 85% in 19- to 23-year-old medical students in Singapore,⁴¹² to 30.7% in persons of Malay ethnicity aged 40 to 80 years.⁴¹³ A more recent study in Korea found myopia prevalence in ages 19 to 49 to be very high, nearly 71%.⁵² Studies in South Asian countries found prevalences of 13% for persons aged 30 or older living in rural India,⁴¹⁴ 37% for persons living in Andhra Pradesh state (India),⁴¹⁵ and 36% for persons aged 30 and older in Pakistan.⁴¹⁶ A survey in Nigeria found that the prevalence of myopia in persons aged 40 years or older was 16.2%.⁴¹⁷ Finally, a study of the prevalence of myopia in

Australian adults aged 49 to 70 years found it ranging from 29% (in the 2010s) to 16% (in the early 1990s).⁹¹

The prevalence of myopia in American children aged 12 to 17 was estimated to be approximately 25% in the early 1970s.⁴⁰⁰ In one study, myopia (0.75 D or more) was found in 9% of children aged 5 to 17 years.¹² In children aged 6 to 72 months, the prevalence of myopia in non-Hispanic white children was 1.2% and for Asian children it was 3.98%.¹³ For African American children it was 6.6% and for Hispanic children it was 3.7%.¹⁴ Data from the Orinda, California, Longitudinal Study found that the prevalence of 0.50 D or more of myopia was about 3% among 5- to 7-year-olds, 8% among 8to 10-year-olds, and 14% among 11- to 12-year-olds.¹¹³ In a U.S. study based on Kaiser Permanente data in California, prevalence of myopia was greater in Asian/Pacific Islander participants than in white or Black participants.⁴¹⁸ Data suggest that ethnic Chinese children have much higher rates of myopia at all ages. A national survey in Taiwan found the prevalence was 12% among 6-year-old children and 84% among those 16 to 18 years old.⁸⁷ More recent studies in Taiwan (2017) found that the prevalence of myopia increased to 25% in 7-year-olds and to 77% in 12-year-olds⁵³ and the prevalence of myopia in 5- and 6-year-olds dropped from 15% in 2014 to 8% in 2016. This decrease was attributed to a policy intervention promoting outdoor activities.⁶⁷ In a series of studies using similar methodology and definitions for myopia (0.50 D or more of myopia) in children aged 7 to 15 years, prevalences of myopia varied widely by country and ethnicity: 4% in India,⁴¹⁹ 10% to 34% in Malaysia,⁴²⁰ 5% to 17% in southern China,⁴²¹ 7% in New Delhi,⁴²² and 9% to 40% in Malaysia and Singapore.⁴²³ A study of individuals aged 6 to 21 years in Inner Mongolia found a prevalence of myopia of 77% without cycloplegia and 54% after cycloplegia, highlighting an important methodological consideration in population prevalence estimates of refractive error, particularly myopia.⁴²⁴ A recent meta-analysis of prevalence of myopia (-0.50 D or more) in schoolchildren in India found that the prevalence was 7.5% over the past 44 decades for ages 5 to 15.⁹² Similar rates have been found in Singapore (12% among 6- to 7-year-olds to 79% among 18-year-old males), and in Japan (44% among 12-year-olds to 66% among 17-year-olds).^{44, 88, 425, 426} A study in the Netherlands found a prevalence of myopia of 2.4% in 6-year-olds;⁶⁸ a study of Israeli military candidates (ages 17 to 18) found a high prevalence of myopia that varied by intensity of religious educational programs (range, 30% to 50% to 82%).⁵¹ The Ireland Eye Study⁴²⁷ found that myopia prevalence in 6- to 7-year-olds was 3.3%, and in 12- to 13-year-olds it was nearly 20%. A study of disadvantaged Australian schoolchildren aged 6 to 15 found that prevalence of myopia was between 3.5% and 4.4% over a 4-year period, lower than prevalence estimates among schoolchildren from areas with higher socioeconomic status.⁴²⁸ In young Australian men enlisting in the military, prevalence of myopia increased from 14% to 24% over a 35-year period.⁴²⁹ A survey in Bhutanese schoolchildren found a prevalence of myopia of 6.6% in those aged 10 to 15 years.⁴³⁰ In a metaanalysis of available data from Middle Eastern countries, the prevalence of myopia in those 15 years and younger was 4%; for individuals over 15 years old, the prevalence was 30%.⁴³¹

A meta-analysis of prevalence studies from the WHO-defined world regions found the prevalence of myopia in children was 11.7%, ranging from 4.9% in South-East Asia to 18.2% in the Western Pacific region. In adults, the prevalence of myopia was 26.5%, ranging from 16.2% in the Americas to 32.9% in South-East Asia. This study also found that the prevalence of myopia increased from 1993 (10.4%) to 2016 (34.2%), although this difference did not reach statistical significiance.⁴³²

HYPEROPIA

Less is known about the epidemiology of hyperopia and astigmatism than about myopia. Populationbased studies of Caucasians aged 40 and older report that the prevalence of hyperopia increases from about 20% among those in their 40s to about 60% among those in their 70s and 80s.^{16, 17, 105} A metaanalysis of population-based studies found the prevalence of hyperopia was 10% in the United States and increased with increasing age.¹⁵ Another study, based on a sample representative of the U.S. population, found that the prevalence of hyperopia in those aged 40 and older was 5%, with little variation by race/ethnicity.⁷ A similar pattern of higher prevalence of hyperopia in older ages was observed in a U.S. population-based study.⁷ In a population of rural Chinese persons aged 50 and older, the prevalence of hyperopia was 8.9%,⁴⁰⁹ and in another rural Chinese population aged 30 and older, the prevalence was 15.9%.⁴⁰⁸ A similar prevalence and association with age were seen among African Americans in Baltimore.¹⁷ In Australian children aged 6 years and 12 years, the prevalence of hyperopia was 13.2% and 5.0%, respectively.⁴³³ In a multiethnic pediatric eye disease study, the

prevalence of hyperopia was found to be significantly higher in African American and Hispanic children aged 6 to 72 months than in non-Hispanic white children.⁴³⁴ Data from a 5-year follow-up of residents of Beaver Dam, Wisconsin, documented a hyperopic shift in individuals under age 70 but a myopic shift in individuals who were developing nuclear sclerosis even if under age 70.¹⁹ A study in Salisbury, Maryland, also found that nuclear sclerosis was associated with myopia,⁴³⁵ consistent with a report from a Latino population.²¹ In contrast to myopia, hyperopia was associated with fewer years of formal education in the same populations.^{16, 17} African American men in Baltimore, Maryland, had half the prevalence of hyperopia that women had¹⁷ and female Mexican American participants in the Provecto Ver study were more likely than their male counterparts to have hyperopia.¹⁵ but this gender difference was not observed among individuals of European descent.¹⁵⁻¹⁷ A study of persons aged 30 or older in rural India found a prevalence of hyperopia (0.50 D or more) of 18% ⁴¹⁴ and a study of persons of similar age in Pakistan found a prevalence of 27%.⁴¹⁶ A study of persons of Malay ethnicity in Singapore, aged 40 to 80, found a prevalence of hyperopia of 27%.⁴¹³ In Japanese persons aged 40 and older, the prevalence of hyperopia was 28%.⁴¹⁰ The prevalence of hyperopia in Asian children in the United States aged 6 to 72 months was 13.5%; in non-Hispanic white children it was 25.6%.¹³ In Chinese kindergartners, the prevalence of hyperopia greater than 2.00 D was 14.3%.⁴³⁶ In adult populations, the prevalence of hyperopia greater than 0.50 D ranged from 31.5% in Singapore⁴³⁷ to 31.8% in Germany,⁴³⁸ and 41.8% in Korea.⁴³⁹ In a meta-analysis of available data from Middle Eastern countries, the prevalence of hyperopia in those 15 years and younger was 8%; for individuals over 15 years, the prevalence was 21%.⁴³¹ For hyperopia of 1.00 D or less, prevalence was reported as 25.2% in Europeans aged 25 to 90 years⁴⁴⁰ and 22.1% in Latinos 40 years and older in the United States.⁴⁴¹ More recently, the Ireland Eye Study⁴²⁷ found that hyperopia (2.00 D or more) prevalence in 6- to 7-year-olds was 25% and in 12- to 13-year-olds it was nearly 9%. A survey in Bhutanese schoolchildren found a prevalence of hyperopia (2.00 D or more) of 2.2% in those aged 10 to 15 years.⁴³⁰ In young Australian men enlisting in the military, the prevalence of hyperopia (0.50 D or more) was less than 5% over a 35-year period.⁴²⁹

A meta-analysis of population studies combining information from world-wide regions found the prevalence of hyperopia in children to be 4.6%, ranging from 2.2% in South-East Asia to 14.3% in the Americas. In adults, the prevalence of hyperopia was 30.9%, ranging from 23.1% in Europe to 38.6% in Africa and 37.2% in the Americas.⁴³²

ASTIGMATISM

Population-based data document the prevalence of astigmatism in children or young adults. In a multiethnic pediatric eye disease study, the prevalence of astigmatism in African American and Hispanic children aged 6 to 72 months was 12.7% and 16.8%, respectively.¹⁰⁶ Kleinstein et al¹² found that 28% of their U.S.-based study population aged 5 to 17 years had at least 1.00 D of astigmatism. A study of Australian 6-year-olds found a prevalence of astigmatism of nearly 5%.442 A series of studies carried out in children aged 7 to 15 from different countries but using similar methodology found a wide range of prevalences of astigmatism, varying from approximately 3% in Andhra Pradesh, India,⁴¹⁹ to 7% in New Delhi,⁴²² to 6% in Chinese children.¹²⁵ The prevalence of high astigmatism in Native American children was reported as 23% to 29% in those aged 2 to 7 years.⁴⁴³ In Taiwanese preschoolers, the prevalence of astigmatism was 13.3%.⁴⁴⁴ One or more diopters of astigmatism is common among older adults (31% in persons aged 40 years and older) and the prevalence is higher in older-age groups.^{7, 17} This increase with age was also seen among African Americans, although the prevalence was about 30% lower than among Caucasians at every age.¹⁷ In adult Americans, the prevalence of astigmatism has been reported to be 20% higher among men than women but was not associated with number of years of formal education.^{7, 17} Astigmatism was found in 7.6% of Chinese subjects aged 50 and older⁴⁰⁹ and in 24.5% of subjects aged 30 and older.⁴⁰⁸ A study of persons of Malay ethnicity aged 40 to 80 living in Singapore reported a prevalence of astigmatism of 33%.⁴¹³ In Japanese persons aged 40 and older the prevalence of astigmatism was 54%.⁴¹⁰ A study of persons aged 30 and older in Pakistan found a prevalence of astigmatism of 37%.⁴¹⁶ In a meta-analysis of available data from Middle Eastern countries, the prevalence of astigmatism in those age 15 years and younger was 15%; for individuals over 15 years, the prevalence was 24%.⁴³¹ A survey in Bhutanese schoolchildren found prevalence of astigmatism (0.75 D or more) of 9.8% in those aged 10 to 15 years.⁴³⁰ More recently, the Ireland Eye Study⁴²⁷ found that astigmatism (1.00 D or more) prevalence in 6- to 7-year-olds was 19% and in 12- to 13-year-olds it was 16%. There have been conflicting data about the association of astigmatism with prematurity or low birth weight or with retinopathy of prematurity.107-110

These studies cannot be directly compared because the definitions of myopia, hyperopia, and astigmatism vary greatly from study to study, as do the populations under study.

In the abovementioned meta-analysis of WHO regions, the prevalence of astigmatism in children was estimated to be 14.9%, ranging from 9.8% in South-East Asia to 27.2% in the Americas. In adults, the prevalence of astigmatism was 40.4%, ranging from 11.4% in Africa to 45.6% in the Americas, 51% in Mexico, and 44.8% in South-East Asia.^{432, 445}

APPENDIX 4. ELEMENTS OF THE COMPREHENSIVE ADULT MEDICAL EYE EVALUATION PPP EXCERPT¹⁶⁶

A comprehensive medical eye evaluation includes a history, examination, diagnosis, and initiation of management.¹⁶⁶ The examination includes a careful and thorough detection and diagnosis of ophthalmic disorders, implementation of appropriate therapy for refractive error and for both ocular and systemic disease. The items listed are basic areas of evaluation or investigation and are not meant to exclude additional elements when appropriate. For example, because history-taking is an interactive process, the patient's responses may guide the clinician to pursue additional questions and evaluation.

HISTORY

In general, a thorough history may include the following items:

- Demographic data (e.g., name, date of birth, gender, and ethnicity or race)
- Patient's other pertinent health care providers
- Chief complaint and history of present illness
- Present status of visual function (e.g., patient's self-assessment of visual status, visual needs, any recent or current visual symptoms, and use of eyeglasses or contact lenses)
- Ocular symptoms (e.g., eyelid swelling, diplopia, redness, photophobia)
- Ocular history (e.g., prior eye diseases, injuries, surgery, including cosmetic eyelid and refractive surgery, or other treatments and medications)
- Systemic history: medical conditions and previous surgery
- Medications: ophthalmic and systemic medications currently used, including nutritional supplements and other over-the-counter products
- Allergies or adverse reactions to medications
- Family history: pertinent familial ocular (e.g., glaucoma, age-related macular degeneration) and systemic disease
- Social history (e.g., occupation; tobacco, alcohol, illicit drug use; family and living situation as appropriate)
- Sexual history
- Directed review of systems

OCULAR EXAMINATION

The comprehensive eye examination consists of an evaluation of the physiologic function and the anatomical status of the eye, visual system, and its related structures. This usually includes the following elements:

- Visual acuity with current correction (the power of the present correction recorded) at distance and, when appropriate, at near
- Refraction when indicated
- Visual fields by confrontation
- External examination (e.g., eyelid position and character, lashes, lacrimal apparatus and tear function; globe position; and pertinent facial features)
- Pupillary function (e.g., size and response to light, relative afferent pupillary defect)
- Ocular alignment and motility (e.g., cover/uncover test, alternate cover test, ductions and versions)
- Slit-lamp biomicroscopic examination: eyelid margins and lashes; tear film; conjunctiva; sclera; cornea; anterior chamber; and assessment of central and peripheral anterior chamber depth, iris, lens, and anterior vitreous
- Intraocular pressure measurement, preferably with a contact applanation method (typically a Goldmann tonometer). Contact tonometry may be deferred in the setting of suspected ocular infection or corneal trauma.
- Fundus examination: mid and posterior vitreous, retina (including posterior pole and periphery), vasculature, and optic nerve
- Assessment of relevant aspects of patient's mental and physical status

Examination of anterior segment structures routinely involves gross and biomicroscopic evaluation prior to and after dilation. Evaluation of structures situated posterior to the iris is best performed through a dilated pupil. Optimal examination of optic nerve, macula, and the peripheral retina requires the use of the indirect ophthalmoscope or slit-lamp fundus biomicroscopy with appropriate accessory diagnostic lenses.

Based on the patient's history and findings, additional tests or evaluations might be indicated to evaluate further a particular structure or function. These are not routinely part of the comprehensive medical eye clinical evaluation. Specialized clinical evaluation may include the following:

- Monocular near-vision testing
- Potential acuity testing
- Glare testing
- Contrast sensitivity testing
- Color-vision testing
- Testing of stereoacuity and fusion
- Testing of accommodation and convergence amplitudes
- Central visual field testing (Amsler grid)
- Expanded evaluation of ocular motility and alignment in multiple fields of gaze at distance and near
- Exophthalmometry (e.g., Hertel)
- Tear breakup time
- Ocular surface vital dye staining
- Corneal sensation
- Gonioscopy
- Functional evaluation of the nasolacrimal system
- Indirect ophthalmoscopy with scleral indentation
- Contact lens stereoscopic biomicroscopy (e.g., Goldmann three-mirror lens)

Additional diagnostic testing may include the following:

- Keratometry (e.g., to assess surface quality and power)
- Corneal topography/tomography, including analysis
- Measurement of corneal thickness (optical and ultrasonic pachymetry)
- Corneal endothelial cell analysis
- Meibomography
- Tear osmolarity
- External, slit-lamp, or fundus photography
- Anterior and posterior segment optical coherence tomography
- Confocoal microscopy
- Wavefront analysis
- Visual fields by automated and/or manual perimetry
- Biometry
- Stereophotography or computer-based image analysis of the optic disc and retinal nerve fiber layer or macula
- Ophthalmic ultrasonography (A-scan, B-scan, ultrasound biomicroscopy)
- Fluorescein, indocyanine green, and optical coherence tomography angiography
- Electrophysiological testing
- Microbiology and cytology of ocular or periocular specimens
- In-office point-of-care testing (e.g., immunochromatography)
- Radiologic imaging
- Laboratory tests for systemic disease

APPENDIX 5. Eyeglasses

Guidelines for correcting specific refractive errors with eyeglasses are outlined below.

MYOPIA

Individuals with low myopia may not need eyeglass correction except for distance activities such as driving or school work. Overcorrecting myopic patients will cause excessive accommodation, which may create symptoms. Some patients may become symptomatic from an increased degree of myopia that occurs at low levels of illumination (night myopia), and they may require increased minus correction for clearer vision at night.

Because of the progressive nature of myopia in childhood and adolescence, screening examinations that include visual acuity are recommended every 1 to 2 years (see Pediatric Eye Evaluations PPP¹⁶⁵).

HYPEROPIA

Slight undercorrection may be desirable in young and middle-aged individuals with hyperopia because there is some physiologic accommodative tone. As the patient ages, full correction may be necessary to provide optimal distance vision and to minimize difficulties with near vision.

ASTIGMATISM

Full correction may not be needed for individuals with regular astigmatism. Adults with astigmatism may not accept full cylindrical correction in their first pair of eyeglasses or in subsequent eyeglasses if their astigmatism has been only partially corrected. In general, substantial changes in axis or power are not well tolerated.

PRESBYOPIA

Patients with presbyopia have several options for eyeglass correction: bifocals; trifocals; progressive addition lenses; or separate eyeglasses for distance, intermediate, and reading. Individuals with myopia must exert more accommodative effort when using contact lenses, or after refractive surgery, than when using eyeglasses. Individuals with hyperopia must exert more accommodative effort when using eyeglasses than contact lenses.

Bifocals

Bifocals come as flat-top, round-top, and executive styles. Flat top is the most popular but can induce a base-up prism effect, whereas round top can create a base-down prism effect. The height of the segment is more critical than its width. The top of the segment is generally set about 3 to 5 mm below the optical center of the distance lens and is usually positioned to align with the level of the lower limbus, but it may need to be higher or lower for certain occupations or depending on individual preference. Individuals who use computers may find a modified bifocal helpful; the upper segment is selected for the computer monitor distance and the lower segment is selected for reading.

Trifocals

Trifocals should be considered for patients with specific intermediate-vision needs, and they may also be very helpful for individuals who use computers. Identifying the specific working distances allows the trifocal powers to be prescribed most accurately.

Progressive Addition Lenses

Progressive addition lenses can be useful to increase the range of vision, and they are cosmetically well accepted. A good candidate for this type of lens is an individual with early presbyopia who has not worn bifocals before and who does not require an especially wide field of vision at near. The disadvantages of progressive lenses are peripheral distortion inherent in

the lens design, the smaller size of the reading zone compared with bifocals, higher cost, and the difficulty in properly fitting the lenses. The positioning of the optical centers and progressive add corridors are critical if the visual advantages of these lenses are to be appreciated. Problems with reading zone size and peripheral distortion increase with stronger addition lenses.

ANISOMETROPIA

The majority of adults can tolerate up to 3.00 D of difference in eyeglass refractive correction between the two eyes.⁴⁴⁶ Occasionally, individuals may tolerate more than 3.00 D of difference. Reduction of symptomatic aniseikonia may be accomplished either by undercorrecting at the expense of acuity or modifying the lens base curve or lens thickness to alter relative image size.⁴⁴⁷

Vertical prism-induced diplopia can be a problem in presbyopic patients who wear bifocals. Small amounts of induced prism can be corrected by either slabbing-off or slabbing-on the bifocal segment.⁴⁴⁷ Dissimilar segment types can also be used. A separate pair of reading eyeglasses, although less convenient, will avoid the problem of vertical anisophoria.

DIFFICULTIES AND COMPLICATIONS OF EYEGLASS WEAR

A variety of factors related to lenses and frames may cause difficulties in wearing eyeglasses. These include the following:

- Incorrect prescription
- Base curve and location of the cylinder on the front or back surface
- Bifocal power and segment position (height and size)
- ♦ Tint
- Anisometropia (if large)
- Prisms or prism effects
- Pantoscopic tilt
- Centration of lenses with respect to the pupil
- Vertex distance
- Size of frame and fit
- Contact sensitivity to frame material
- Change in lens material

In addition, the lenses in the eyeglasses can cause spherical and chromatic aberrations as well as lens distortions, including magnification (hyperopic lenses) and minification (myopic lenses). Eyeglasses are protective, however, which is especially important for monocular patients.

APPENDIX 6. CONTACT LENSES

CONTACT LENS FITTING

Careful attention should be directed towards optimizing contact lens fit, including size, centration, and movement in order to minimize contact lens interference with normal ocular function.

Keratometry or corneal topography/tomography is usually performed to assist in the fitting process. The refractive error can also be compared with keratometry or corneal topography/tomography readings to assess the relative contributions of the cornea and the natural lens to astigmatism and to help determine what type of contact lens will provide the best vision and fit. These readings also provide baseline information for future comparison.

Once a contact lens that provides good vision has been selected, the contact lens should be evaluated to ensure good movement on the eye.

CONTACT LENS SELECTION

The type of contact lens selected (soft hydrogel, rigid gas-permeable, silicone hydrogel, or hybrid) and the method of wear (daily or overnight) depend on the needs of an informed patient. Additionally, contact lenses can be replaced at various intervals ranging from every day for daily disposable soft lenses to every 1 to 2 years for certain rigid gas-permeable lenses.

Type of Contact Lens

Spherical refractive errors can be corrected with soft hydrogel, rigid gas-permeable, or silicone hydrogel contact lenses.⁴⁴⁸ Low to moderate astigmatism can be corrected with soft toric contact lenses or with rigid gas-permeable contact lenses. Rigid gas-permeable, soft hydrogel, and silicone hydrogel contact lenses with varying abilities to transmit oxygen are available for patients with different corneal metabolic demands, and some are approved for extended wear. A recent study showed that neither hydrogel nor silicone hydrogel showed superiority in comfort. Adverse event rates were low with each material type, suggesting that choice of material is a patient and practitioner preference; however, for patients ar risk of hypoxia related complications, SiHy material should be considered.²²⁶

Daily disposable lenses as a type of lens and mode of wear have emerged as the type of soft lens, regardless of material, that is least likely to be associated with infectious or inflammatory complications. Daily disposable wear of contact lenses causes less damage to the ocular surface and less increase in proinflammatory cytokine levels compared with the use of reusable lenses.^{449, 450} Finally, reusable daily wear lenses require adherence to disinfection protocols and use of solutions, and noncompliance increases the likelihood of complications.⁴⁵¹

High astigmatic errors can be corrected effectively with rigid gas-permeable and hybrid contact lenses. In cases of greater amounts of corneal astigmatism, it may be preferable to use a bitoric or back-surface toric contact lens–design in order to minimize corneal bearing and improve centration. Custom-designed soft toric contact lenses provide another means to correct high astigmatic refractive errors. These contact lenses offer good centration when properly fitted, a flexible wear schedule, and improved comfort in some patients. The piggyback modality, in which a rigid gas-permeable lens is worn on top of a soft lens, may have utility in some of these circumstances. Aspheric and reverse geometry designs may also be useful for high astigmatism or postoperative refractive error. Regardless of the design chosen, adequate contact lens movement is essential for comfortable wear and maintenance of corneal integrity.

Rigid gas-permeable scleral lenses (diameter more than 17 mm) are an option for the correction of high and/or irregular astigmatism, particularly if combined with anisometropia. These lenses do not contact the cornea and are not designed to rely on movement for physiologic tolerance.

Contact lenses used to correct high refractive errors place increased physiologic demands on the cornea and anterior segment. The thickness and weight of some of these contact lenses may adversely affect delivery of oxygen to the cornea, leading to hypoxia, pannus, neovascularization, and opacification.

Soft hydrogel and rigid gas-permeable bifocal or multifocal contact lenses can be used to address presbyopia. Another option for the management of presbyopia with contact lenses is monovision. Generally, the dominant eye is corrected for distance and the nondominant eye for near. Patients wearing monofocal contact lenses may benefit from eyeglasses worn over the contact lenses while driving, especially at night, or for critical visual needs to correct the near eye for distance and thereby improve depth perception. Modified monovision is the use of a bifocal or multifocal contact lens in one eye and a distance contact lens in the fellow eye.

Polymethylmethacrylate hard contact lenses are now rarely fitted to correct refractive errors because they have a very limited ability to transmit oxygen to the corneal surface.

Method/Modality of Wear

Disposable soft contact lenses, rigid gas-permeable contact lenses, and silicone hydrogel contact lenses are available for either daily or extended wear. Daily wearis defined as less than 24 hours of continuous wear. Extended wear is defined as under closed eyelids, but to the lay person it means overnight wear.

Several FDA-mandated clinical studies carried out into the late 1990s have confirmed that overnight wear of contact lenses is the most important risk factor for microbial keratitis. Fifty to seventy-five percent of the risk of microbial keratitis can be attributed to overnight wear. Generally speaking, the longer the duration of continuous wear, the greater the chance of developing microbial keratitis. The risk for those who used daily wear contact lenses and sometimes wore them overnight was estimated to be approximately 12 times the risk of those who used daily wear lenses and did not wear them overnight. Extended-wear users who wear their contact lens overnight have a 10- to 15-fold risk over conventional daily wear lens users who do not sleep in their contact lens.²⁰³ Reports from the United Kingdom,²²⁰ Australia²²¹ and France in 2020⁴⁵² confirmed substantial increased risk of microbial keratitis with overnight wear regardless of lens type.

The increased risk of corneal infections with overnight contact lens wear should be discussed with patients who are considering this modality of vision correction. If patients choose overnight wear, they should be instructed to use only lenses specifically approved for extended wear.

CONTACT LENS CARE

Proper contact lens care involves a combination of cleaning, disinfecting, rinsing, and wetting solutions.²⁸⁴ Surfactant cleaning solutions act like detergents to solubilize debris that is not chemically bonded to the contact lens. Rubbing the contact lens enhances the cleaning performance of the solution, likely by removing loosely bound deposits.^{253, 258, 453} Enzymatic cleaners remove deposits that are chemically bonded to the surface. Disinfecting solutions reduce the number of microorganisms carried on the contact lens. Wetting solutions make a water-repellant lens surface hydrophilic. Many manufacturers combine these agents into multipurpose solutions.

Patients should also be instructed to clean and replace contact lens cases every 3 months because they can be a source of lens contamination,^{222, 255, 283, 454} and damaged or cracked cases should be discarded. Patients should be instructed to eliminate all water exposure in their wear-and-care regimens to reduce risk of *Acanthamoeba* keratitis.²⁸²

The American Academy of Ophthalmology (<u>www.aao.org/store</u>) and the Contact Lens Association of Ophthalmologists (<u>(www.clao.org/publications</u>) have patient information brochures for contact lens care. Also, the FDA and CDC have issued recommendations.^{284, 454}

Daily Wear Soft Contact Lenses

Daily disposable soft contact lenses should not be worn longer than manufacturers' recommendations, nor should they be reused. Standard daily wear soft contact lenses (non-daily disposable) should be cleaned with a contact lens cleaner or multipurpose solution daily at time of removal from the eye to remove biofilm and deposits from the lens surface. Rubbing the contact lenses during cleaning and rinsing with contact lens solution is necessary for removal of deposits.^{246, 253, 453} Contact lenses should be disinfected using either a chemical or peroxide

system. Contact lens cases should be rinsed with disinfecting solution and air dried. The frequency of adverse events varies with silicone hydrogel contact lens and lens-solution combinations; nonpreserved (hydrogen peroxide) systems have the lowest incidence of corneal infiltrates.⁴⁵⁵ Hydrogen peroxide systems may be superior to preserved disinfecting solutions in reducing pathogen binding and cysticidal disinfection, but they require more complex care regimens.²⁷⁸ Hydroben peroxide systems may have advantages over multipurpose solution for symptomatic contact lens wearers.⁴⁵⁶

Periodic enzymatic cleaning may be useful for some patients. Manufacturers' recommendations for contact lens care and replacement should be followed. As mentioned above, daily disposable lens wear has the advantages of less risk of complication as a result of poor compliance with disinfection, storage, and replacement recommendations.⁴⁵¹

Extended-Wear Soft Hydrogel Contact Lenses and Silicone Hydrogel Contact Lenses

The FDA recommends that overnight-wear soft hydrogel contact lenses be removed at least once a week for overnight cleaning and disinfection.^{224, 457} Disposable contact lenses for extended wear should also be discarded on a regular basis consistent with manufacturers' recommendations or the specific instructions of eye care professionals. Silicone hydrogel contact lenses are now FDA approved for up to 30 days of continuous wear. Extended-wear soft hydrogel and silicone hydrogel contact lenses worn on a daily basis are cared for in the same way as daily wear soft lenses.

Rigid Gas-Permeable Contact Lenses

After rigid gas-permeable contact lenses are removed, they should be surface cleaned and rinsed. As with soft contact lenses, nonsterile water such as tap or bottled water should not be used. The lenses should be stored overnight in a disinfecting solution. Tap water should be eliminated from the care regimen, as its use is associated with the prevalence of *Acanthamoeba* keratitis, particularly in cases associated with overnight orthokeratology, as is topping off of solutions.^{266, 308} Cases for lenses should be rinsed with disinfection solution and air dried after insertion of the lenses. Rigid gas-permeable contact lenses may also require periodic enzymatic cleaning. Rigid gas-permeable contact lenses that are approved for overnight wear should be cared for according to the above guidelines for daily wear rigid gas-permeable contact lenses.⁴⁵⁸

Specialized Uses of Contact Lenses

Contact lenses are also used for therapeutic purposes in corneal and ocular surface diseases.

Decorative Contact Lenses

Physicians should advise patients and consumers that there are risks of using unprescribed costume contact lenses. The risks include adverse events, such as corneal abrasions and corneal ulcers and infections, including blinding infections. Contact lenses, including colored contact lenses, theatrical designs, Halloween-inspired designs, and other holiday designs, require a prescription and supervision by an eye care professional. They should never be shared, just like regular contact lenses.⁴⁵⁹

APPENDIX 7. LITERATURE SEARCHES FOR THIS PPP

Literature searches of the PubMed database were conducted on July 2021. The search strategies were as follows. Specific limited update searches were conducted after May 2022. The searches had added filters for randomized controlled trials and systematic reviews and date limiters to capture literature published since 2017. The panel analyzed 5360 studies of which 79 were included in the PPP.

Refractive Errors - Epidemiology & Risk Factors:

(("refractive errors/epidemiology"[MAJR:noexp]) OR ("refractive errors/ethnology"[MAJR:noexp]) OR (hyperopia/epidemiology[MAJR:noexp]) OR (hyperopia/ethnology[MAJR:noexp]) OR (myopia/epidemiology[MAJR:noexp]) OR (astigmatism/epidemiology[MAJR:noexp]) OR (astigmatism/ethnology[MAJR:noexp]) OR (presbyopia/epidemiology[MAJR:noexp]) OR (presbyopia/ethnology[MAJR:noexp]))

((Refractive Errors[MAJR:noexp]) OR (Hyperopia[MAJR:noexp]) OR (Myopia[MAJR:noexp]) OR (Astigmatism[MAJR:noexp]) OR (Presbyopia[MAJR:noexp])) AND (Prevalence[MeSH Terms)

((Refractive Errors[MAJR:noexp]) OR (Hyperopia[MAJR:noexp]) OR (Myopia[MAJR:noexp]) OR (Astigmatism[MAJR:noexp]) OR (Presbyopia[MAJR:noexp])) AND (Risk Factors[MeSH Terms])

(("myopia/epidemiology"[MeSH Terms]) OR (("myopia"[MeSH Terms]) AND ("risk factors"[MeSH Terms])))) AND ((reading[tiab]) OR (near work[tiab]) OR (nearwork[tiab]) OR (cylinder power[tiab]) OR (optical power[tiab]) OR (accommodation[tiab]))

(refractive error*[tiab] OR hyperopia[tiab] OR myopia[tiab] OR astigmatism[tiab] OR presbyopia[tiab]) AND (epidemiolog*[tiab] OR ethnolog*[tiab] OR prevalen*[tiab] OR risk factor*[tiab])

(myopia[tiab]) AND (reading[tiab] OR nearwork[tiab] OR near work[tiab])

Diagnosis – Reproducibility of Results:

("refractive errors/diagnosis"[MAJR]) AND ("reproducibility of results"[MeSH Terms]) OR (refractive error*[tiab] OR hyperopia[tiab] OR myopia[tiab] OR astigmatism[tiab] OR presbyopia[tiab]) AND (diagnos*[tiab] OR reproducib*[tiab]) OR (refractive error*[tiab] OR hyperopia[tiab] OR myopia[tiab] OR astigmatism[tiab] OR presbyopia[tiab]) AND (accur*[tiab] OR detect*[tiab])

Refractive Errors – Prevention & Control:

((hyperopia[MAJR:noexp]) OR (myopia[MAJR:noexp]) OR (astigmatism[MAJR:noexp]) OR (presbyopia[MAJR:noexp])) AND (disease progression[MeSH Terms])

(("refractive errors/prevention and control"[MAJR:noexp]) OR ("hyperopia/prevention and control"[MAJR:noexp]) OR ("myopia/prevention and control"[MAJR:noexp]) OR ("astigmatism/prevention and control"[MAJR:noexp])) OR ("presbyopia/prevention and control"[MAJR:noexp]))

("myopia"[MeSH Terms]) AND (("atropine"[MeSH Terms]) OR ("cyclopentolate"[MeSH Terms]) OR ("tropicamide"[MeSH Terms]) OR ("pirenzepine"[MeSH Terms]))

(refractive error*[tiab] OR hyperopia[tiab] OR myopia[tiab] OR astigmatism[tiab] OR presbyopia[tiab]) AND (progress*[tiab] OR prevent*[tiab] OR atropine[tiab] OR cyclopentolate[tiab] OR tropicamide[tiab] OR prevent*[tiab])

Aniseikonia: "aniseikonia" [MeSH Terms] OR aniseikonia [tiab]

Contact Lenses: ("contact lenses"[MAJR]) AND ("keratitis"[MeSH Terms]) OR "contact lenses/adverse effects"[MAJR] OR (contact lens*[tiab]) AND (keratitis[tiab] OR ulcer*[tiab]) OR (contact lens*[tiab]) AND (dry eye*[tiab] OR meibomian[tiab] OR cornea*[tiab] OR inflamm*[tiab] OR ptosis[tiab] OR adverse[tiab])

Orthokeratology: (orthokeratology[tw])

Keratorefractive Surgery:

(("keratomileusis, laser in situ"[MeSH Terms]) OR ("photorefractive keratectomy"[MeSH Terms]) OR ("keratectomy, subepithelial, laser assisted"[MeSH Terms]) OR (epi-LASIK[tw]) OR (epi-laser in situ keratomileusis[tw]) OR (epipolis-laser in situ keratomileusis[tw]) OR (epi-LASEK[tw]) OR (epi-Laser-Assisted Sub-Epithelial Keratectomy[tw]) OR (epi-Laser-Assisted Subepithelial Keratectomy[tw]) OR (epi-

Laser Epithelial Keratomileusis[tw])) AND ((Quality of Life[MeSH Terms]) OR (Patient Satisfaction[MeSH Terms]))

(("pregnancy"[MeSH Terms]) OR ("lactation"[MeSH Terms])) AND (("keratectomy, subepithelial, laser assisted"[MeSH Terms]) OR ("photorefractive keratectomy"[MeSH Terms]) OR ("keratomileusis, laser in situ"[MeSH Terms]) OR (Lasers, Excimer[MeSH Terms]))

((Norplant[tw]) OR (levonorgestrel[tw])) AND (("keratectomy, subepithelial, laser assisted"[MeSH Terms]) OR ("photorefractive keratectomy"[MeSH Terms]) OR ("keratomileusis, laser in situ"[MeSH Terms]) OR (Lasers, Excimer[MeSH Terms]))

("wound healing"[MeSH Terms]) AND (("colchicine"[MeSH Terms]) OR ("levonorgestrel"[MeSH Terms]) OR ("sumatriptan"[MeSH Terms]) OR (norplant[tw])) AND ((Retina[MeSH Terms]) OR (Cornea[MeSH Terms]))

(("keratectomy, subepithelial, laser assisted"[MeSH Terms]) OR ("photorefractive keratectomy"[MeSH Terms]) OR ("keratomileusis, laser in situ"[MeSH Terms]) OR (Lasers, Excimer[MeSH Terms])) AND (("colchicine"[MeSH Terms]) OR ("levonorgestrel"[MeSH Terms]) OR ("sumatriptan"[MeSH Terms]) OR (norplant[tw]))

(lasik[tiab] OR prk[tiab] OR lasek[tiab] OR epi-lasik[tiab] OR epi-lasek[tiab] OR laser in situ keratomileusis[tiab] OR photorefractive keratectomy[tiab] OR subepithelial laser-assisted keratectomy[tiab] OR surface ablation*[tiab]) AND (quality of life[tw] OR patient satisfaction[tw] OR pregnan*[tw] OR lactat*[tw] OR norplant[tw] OR levonorgestrel[tw] OR sumatriptan[tw] OR colchicine[tw])

Wavefront Aberrometry: (wavefront[tw]) AND (aberromet*[tw])

PRK: ("photorefractive keratectomy/adverse effects"[MeSH Terms]) OR (photorefractive keratectomy[MeSH Terms]) AND (Treatment Outcome[MeSH Terms]) OR (photorefractive keratectomy[MeSH Terms]) AND (Time Factors[MeSH Terms]) OR (photorefractive keratectomy[MeSH Terms]) OR (photorefractive keratectomy[tiab] OR PRK[tiab])

LASEK: (keratectomy, subepithelial, laser assisted[MeSH Terms]) OR (LASEK[tiab]) OR (laser-assisted subepithelial keratectomy[tiab]) OR (lasek[tiab] OR laser assisted subepithelial keratectomy[tiab]) AND

Epi-LASIK: (epi-LASIK[tw]) OR (epi-laser in situ keratomileusis[tw]) OR (epipolis-laser in situ keratomileusis[tw])

Epi-LASEK: (epi-LASEK[tw]) OR (epi-Laser-Assisted Sub-Epithelial Keratectomy[tw]) OR (epi-Laser-Assisted Subepithelial Keratectomy[tw]) OR (epi-Laser Epithelial Keratomileusis[tw])

LASIK:

(keratomileusis, laser in situ/adverse effects[MAJR])

(keratomileusis, laser in situ[MAJR]) AND (Treatment Outcome[MeSH Terms])

(keratomileusis, laser in situ[MAJR]) AND (Time Factors[MeSH Terms])

(keratomileusis, laser in situ[MAJR])

(lasik[tiab] OR laser in situ keratomileusis[tiab]) AND (outcome*[tiab] OR adverse[tiab] OR long-term[tiab] OR effect*[tiab] OR complication*[tiab] OR safety[tiab] OR trial[tiab] OR random*[tiab] OR review[tiab] OR comparative[tiab]) NOT (rabbit*[tiab] OR mouse[tiab] OR mice[tiab] OR animal*[tw])

Intrastromal Corneal Ring Segments: (intrastromal corneal ring*[tw]) OR (intacs[tw]) OR ((intracorneal[tw]) AND ((implant*[tw]) OR (ring*[tw])) OR (inlay*[tw])) OR ((ICRS[tw]) AND (cornea*[tw]))

Radial Keratotomy: Keratotomy, Radial[MAJR] OR (radial keratotomy[tiab])

Thermal Keratoplasty: (thermal keratoplasty[tw]) OR (conductive keratoplasty[tw])

Incisional Astigmatic (Transverse or Arcuate) Keratotomy: (keratotomy[tiab]) AND ((astigmatic[tiab]) OR (arcuate[tiab]) OR (transverse[tw]))

Automated Lamellar Keratoplasty: (Automated Lamellar Keratoplasty[tw])

Epikeratoplasty: (Epikeratoplasty[tw]) OR (Epikeratophakia[tw])

Intracorneal Alloplastic Inlays: (intracorneal inlay*[tiab]) OR (intracorneal lens*[tiab]) OR (intracorneal implant*[tiab])

Intraocular Refractive Surgery: "phakic intraocular lenses"[MeSH Terms] OR (phakic intraocular lens*[tiab]) OR (refractive lens exchange[tw]) OR (clear lens extraction[tw])

Refractive Surgery for Presbyopia:

"presbyopia/surgery"[MeSH Terms] OR ((photoablation[tw]) OR (ablation[tw])) AND (presbyop*[tw]) OR (anterior ciliary sclerotomy[tw]) OR ((Sclerostomy[MeSH Terms]) AND (Ciliary Body[MeSH Terms])) OR (scleral expansion[tw]) OR (presbyop*[tiab]) AND (surg*[tiab]) OR (sclerostomy[tiab]) AND (ciliary[tiab]) OR scleral expan*[tiab])

Surface Ablation: (Surface ablation*[tiab])

Socioeconomic: "refractive errors" [MeSH Terms] AND "refractive surgical procedures" [MeSH Terms] AND "economics" [MeSH Terms] OR "refractive errors" [MeSH Terms] AND "refractive surgical procedures" [MeSH Terms] AND "quality of life" [MeSH Terms]

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