Refractive Errors & Refractive Surgery 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 & Refractive Surgery 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.

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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 April 2017. The document was edited in response to the discussion and comments.

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The Refractive Errors & Refractive Surgery PPP was then sent for review to additional internal and external groups and individuals in July 2017. 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.

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FINANCIAL DISCLOSURES

In compliance with the Council of Medical Specialty Societies' Code for Interactions with Companies (available at www.cmss.org/codeforinteractions.aspx), relevant relationships with industry are listed. The Academy has Relationship with Industry Procedures to comply with the Code (available at www.aao.org/about-preferred-practice-patterns). A majority (100%) of the members of the Refractive Management/Intervention Preferred Practice Pattern Panel 2016–2017 had no financial relationship to disclose.

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The disclosures of relevant relationships to industry of other reviewers of the document from January to July 2017 are available online at www.aao.org/ppp.

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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 www.aao.org/about-preferred-practice-patterns) 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 & Refractive Surgery 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 Network[1] (SIGN) and the Grading of Recommendations Assessment, Development and Evaluation[2] (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 SIGN[1] 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 GRADE[2] 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 in 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 GRADE[2] 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 May 2016 and July 2017 in PubMed and the Cochrane Library. Complete details of the literature searches are available online at www.aao.org/ppp.

HIGHLIGHTED FINDINGS AND RECOMMENDATIONS FOR CARE

In the United States and other industrialized societies, the prevalence of myopia is increasing. 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.

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 (including the newest highly gas-permeable silicone hydrogel lenses), and that overnight wear of any contact lens is associated with a higher risk than daily wear.[4-7]

Overnight wear, regardless of contact lens type (including the newest highly gas-permeable silicone hydrogel lenses), increases the likelihood of corneal infection.[4, 8-14] 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.

Environmental risk factors and hygiene practices, such as no-rub cleaning, topping off (reuse) of solutions, contaminated lens cases, exposure to tap water, wearing contact lenses in hot tubs, and changes in water supply are risk factors for the increases in *Acanthamoeba* and fungal keratitis in association with contact lens wear in the past decade.[15-36]

Hydrogen peroxide systems may be superior to preserved disinfecting solutions in reducing pathogen binding and in cysticidal disinfection, but they require more complex care regimens.[21, 25, 28, 37-40]

Daily disposable contact lenses are a good option for reducing the likelihood of complications associated with soft contact lens wear.[5]

Presbyopia can be managed by using eyeglasses or contact lenses (soft, rigid gas-permeable, aspheric bifocal or multifocal). Surgical management of presbyopia includes keratorefractive surgery, corneal inlays, or intraocular lens implantation (multifocal, accommodative, and extended depth of focus lenses).

As data from published studies fail to demonstrate a relationship between pupil size and the quality of postoperative vision, the importance of pupillometry in the preoperative workup remains controversial.

It is recommended that keratorefractive surgery patients be provided with a record (K Card) or that the ophthalmologist maintain a record that lists information about the patient's eye condition, including preoperative keratometry readings and refraction as well as stable postoperative refraction. The K Card should be available if the patient requires cataract surgery or future eye care. (See Appendix 8.)

Excimer ablations that result in very thin residual stroma increase the risk for ectasia. For LASIK procedures, 250 μm has been suggested as a safe residual stromal bed thickness, but there is no absolute value that guarantees that ectasia will not occur. Although surgeons do not agree on a figure, they do agree that when ectasia risk is assessed, many factors should be considered. Abnormal topography is the most significant risk factor for postoperative ectasia. In the context of normal preoperative topography, percentage of tissue altered (PTA) higher or equal to 40% has been associated with higher ectasia risk.[297] Other hypothesized risk

factors include thin preoperative central corneal thickness, younger patient age, and higher attempted corrections.

Persistent diffuse lamellar keratitis (DLK) that is unresponsive to corticosteroids should prompt consideration of microbial keratitis or interlamellar fluid due to increased intraocular pressure (IOP), intraocular inflammation, or endothelial decompensation. For moderate to extensive DLK, the interface should be irrigated sooner rather than later to minimize stromal loss and changes in refractive correction.

Contraindications to corneal laser refractive surgery include:
- Unstable refraction
- Abnormalities of the cornea (e.g., keratoconus or other corneal ectasias, thinning, edema, interstitial or neurotrophic keratitis, extensive vascularization)
- Insufficient corneal thickness for the proposed ablation depth
- Visually significant cataract
- Uncontrolled glaucoma
- Uncontrolled external disease (e.g., blepharitis, dry eye syndrome, atopy/allergy)
- Uncontrolled autoimmune or other immune-mediated disease
- Unrealistic patient expectations

Adverse events related to FDA-approved products (i.e., contact lenses) and procedures should be reported to MedWatch. MedWatch (www.fda.gov/medwatch) is the Safety Information and Adverse Reporting Program for drugs and other medical products regulated by the FDA. MedWatch is the first, and most crucial, step for doctors and patients to take when reporting adverse events.

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, conversely, 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 curvature, lens tilt, and differing refractive indices within the lens.[41]

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.[42]

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.[43] 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.[44]

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
◆ 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
◆ Consider the emerging field of control of myopia progression[45, 46]
◆ Provide the patient with follow-up care and management of any side effects or complications resulting from the correction provided

BACKGROUND

PREVALENCE AND RISK FACTORS

Myopia

Over half of Americans older than 40 have ametropia of sufficient magnitude to require refractive correction.[47] Currently, an estimated 93 million Americans aged 12 years and older use some form of eyewear to correct refractive errors at distance.[48] About 41 million people in the United States used contact lenses in 2014.[49, 50] It has been estimated that over 8.5 million people in the United States have undergone keratorefractive surgery since 1995[51] and over 13 million LASIK procedures have been performed in the United States.[52]

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.[53] 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%.[54] For African American children it was 6.6% and for Hispanic children it was 3.7%.[55] 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;[56] 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.[47] 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.[47, 57-59] Individuals who develop nuclear sclerosis, however, tend to undergo a myopic shift over time.[60-62] 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.[47]

Both hereditary and environmental factors appear to play a role in the development of myopia. Studies suggest a higher concordance of myopia between monozygotic than dizygotic twins[63] and between children and parents.[64-66] Studies have identified links between several gene regions, particularly chromosome 18p, and myopia,[67-72] although other studies have either found no association[73] or more complex relationships.[74, 75] Other genetic variations associated with high myopia have been found in Asian populations.[76-82] More years of formal education have been strongly associated with a higher prevalence of myopia.[75, 83-89] Some studies have reported that a higher level of near work is associated with a higher prevalence and progression of myopia,[90-93] but subsequent studies have not, especially with respect to middle-distance activities such as those that involve video display terminals.[86, 94-97] The use of night lights for children under age 2 years has been reported as a strong risk factor for myopia;[98] however, other studies that were able to adjust for parental refractive status did not find such an association.[91, 99] Many studies in various countries have reported that myopia is associated with less time spent outdoors.[96, 100-108] Studies in Israel and England have found an association between higher prevalence of myopia and birth during the summer months.[109, 110] In a longitudinal study of myopic children, investigators found that myopia progressed more slowly during summer than during other months.[111] 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.[112] In a meta-analysis, investigators found that increasing time spent outdoors significantly decreased risk of myopic progression.[113, 114]

Studies of ethnic Chinese in Taiwan documented an increase in the prevalence and severity of myopia over two generations.[115-118] Genetics alone are unlikely to account for such a rapid change. One study has speculated that genetic factors do not preclude such a change.[119] A study of successive cohorts of enlistees in the Israeli army showed a marked increase in prevalence of myopia over a 13-year period.[120] A study in Finland showed that the prevalence of myopia doubled among teenagers and young adults over the course of the 20th century.[121] 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.[122] Several additional studies have reported that the prevalence of myopia is increasing.[88, 123, 124] In East Asia, the prevalence of myopia is rapidly increasing (now 80%–90%) in school-aged children.[125]

Hyperopia

A meta-analysis of population-based studies found the prevalence of hyperopia was 10% in the United States and increased with increasing age.[56] 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.[47] 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.[57, 58, 126] A similar pattern of higher prevalence of hyperopia in older ages was observed in a U.S. population-based study.[47] A similar prevalence and changes with age were seen among African Americans in Baltimore.[58] In contrast to myopia, hyperopia was associated with fewer years of formal education in the same populations.[57, 58]

Astigmatism

Kleinstein et al[53] 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.[127] 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.[47] 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.[47, 58] There have been conflicting data about the association of astigmatism with prematurity or low birth weight and with retinopathy of prematurity.[128-131]

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.[132] 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.[132] Fewer than 5% of infants have more than 3.00 D of hyperopia at age 1 year.[132, 133] 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.[134] Visual stimulation appears to play a role in this process.[135, 136]

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.[137-139] A study reported that progression of myopia varied by ethnicity and by age of the child.[140] For ethnic Chinese children, the rate of progression is higher.[141-146]

Astigmatism in children is commonly oriented with the steep axis vertical (with the rule). In older adults, astigmatism oriented with the steep meridian horizontally is more common (against the rule)[147, 148] and remains relatively stable in older adults,[149] although one study found that the axis of astigmatism tended to shift against the rule over a 5-year period.[150]

Individuals with high refractive errors are more likely to develop pathologic ocular changes over time.[151-155] Highly myopic patients have an increased incidence of progressive elongation of the eye with progressive retinal and choroidal thinning, peripheral retinal degeneration, retinal detachment,[156] cataract,[157] glaucoma,[158-161] and myopic choroidal neovascularization.[162] An increased risk of glaucoma and visual field defects with myopia has also been found.[163-169] An increased risk of developing primary angle-closure glaucoma among individuals with hyperopia has been reported.[170] Individuals with higher levels of myopia are more likely to have decreased foveal function as assessed by multifocal full-field electroretinogram.[171]

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.[172, 173] In patients beyond visual maturity (see Amblyopia PPP[174]), uncorrected refractive errors do not result in amblyopia. There is emerging evidence that uncorrected, peripheral hyperopic defocus may lead to worsening of axial myopia in children who might otherwise have other uncorrected refractive errors alone.[175]

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 2012 and 2017 in the English language 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 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.[176]

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.[177, 178]

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 younger patients,[179] a cycloplegic refraction can be useful.

Near vision should bemeasured 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, the most frequently used cycloplegic agents are tropicamide and cyclopentolate. 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.[180] A significant difference between manifest and cycloplegic refraction is observed frequently in children; in adults, a substantial difference between manifest and cycloplegic refraction may require a postcycloplegic refraction on a subsequent day when the 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 (BCVA) should be sought. A suddenly acquired refractive change may signal a systemic or local disease, or a drug or medication effect. Excellent visual acuity does not preclude serious eye disease; therefore, all adult patients should have a comprehensive medical eye evaluation at the recommended intervals.[176, 179]

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 and for patients who do not have risk factors for eye disease is as follows: every 5–10 years for patients under 40; 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 *(moderate quality, strong recommendation),* as specified in the Comprehensive Adult Medical Eye Evaluation PPP.[176]

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, or refractive 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).

Minimizing Progression

Treatments that aim to minimize progression of refractive errors, particularly myopia, have been reported. Evidence reported in previous randomized clinical trials and a 2011 Cochrane review were insufficient to recommend any intervention to prevent progression of refractive errors.[45, 181] (See Appendix 5.) However, there is emerging evidence that interventions should be considered for patients thought to be at risk for myopia progression.[46, 182-188] Low-concentration atropine and outdoor time have been shown to reduce the likelihood of myopia onset.[45,181, 189] (II+, *moderate quality, strong recommendation)* Orthokeratology, soft bifocal

contact lenses, and antimuscarinic agents were found to be effective for myopia control.[179-185, 190]

Eyeglasses

Eyeglasses are the simplest and safest means of correcting a refractive error; therefore, eyeglasses should be considered before contact lenses or refractive surgery. A patient's eyeglasses and refraction can be 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 6.

When hyperopia is accompanied by esotropia, eyeglasses may be required to control the strabismus or to improve fusion.[191] 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).[192] 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.[193] 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.[194] 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.[50] 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 continues to decline, but it represents 10.8% of all lens fits globally. 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.[195] 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.[196] 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

Elimination of the need for eyeglasses to correct refractive error is the most common indication for contact lens usage. Many patients who use contact lenses note better field of vision, greater comfort, and/or an 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, aniseikonia, symptomatic 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 wears.[50] The most serious risk of contact lens wear is the development of microbial keratitis, which can lead to visual loss even if properly treated.[197] Other complications with all types of contact lens wear include hypersensitivity reactions such as giant papillary conjunctivitis, problems of the ocular surface such as surface breakdown, 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.[198-205] Transient subclinical stromal edema frequently occurs, and corneal thinning of the epithelium and stroma during contact lens wear has also been reported.[203, 206-208] Endothelial changes can occur, including polymegethism, pleomorphism, and, rarely, reduction of endothelial cell density.[209-211] 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.[212-218]

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.[212, 214] Investigations into the pathogenesis of *Pseudomonas* keratitis showed that *P. aeruginosa* adhered readily to contact lens deposits.[219] 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 wear[220] 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).[13]

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.[8, 9] 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.[8, 9, 221-225] 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.[226] A recent pediatric corneal ulcer series from Taiwan found that contact lens wear was a significant risk factor, and that there was an increase in the number

of of isolated coagulase negative staphylococcus cases. The presence of a gram negative isolate was correlated with a poorer visual outcome.[227]

Although disposable contact lenses were initially introduced for extended wear, they have become popular for daily wear as well. Patients who use disposable soft contact lenses on a daily-wear basis tend to be less symptomatic in terms of lens-related complaints when compared with conventional soft daily-wear lens users.[228] Disposable soft contact lenses intended for one day of use only (daily disposables) were introduced in 1995. Their use currently represents the safest method of soft contact lens wear with regard to adverse events such as infiltrates and infections.[5, 229] There are no good studies comparing 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,[230-233] 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 wear[4, 10, 11] or with daily wear.[14] 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 than daily wear.[4-7]

These newer materials meet central and peripheral oxygen transmissibility thresholds to avoid corneal swelling during open-eye soft contact lens wear[234] have not resulted in lower infection rates. 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. 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.

Overnight wear of silicone hydrogel contact lenses is associated with sterile inflammatory peripheral corneal infiltrative events (CIEs), as are smoking and lens or eyelid bioburden.[235-238] Tear stagnation may play a role in alterations of corneal epithelium associated with overnight contact lens wear.[239] 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.[240] 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.[241-245] 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 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.[4, 14] Overnight wear, regardless of contact lens type (including the newest highly gas-permeable silicone hydrogel lenses), increases the likelihood of corneal infection.[4, 8-14] 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.**[8-14]**

There have been outbreaks and reports of increases in *Acanthamoeba* and fungal keratitis in association with contact lens wear in the past several decades.[15-32, 246] This trend predates the association with the use of certain multipurpose solutions with reduced antimicrobial efficacy that are no longer on the market,[33-36] and it is associated with all lens types. The trend has continued even with the removal of ineffective antimicrobial solutions in the case of *Acanthamoeba*.[247] Environmental risk factors and hygiene practices, such as no-rub cleaning, topping off (reuse) of solutions, contaminated lens cases, exposure to tap water, and changes in water supply are emerging as possible risk factors.[6, 14, 248] 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.[249]

MedWatch (www.fda.gov/medwatch) 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 including past contact lens experience should be obtained and a comprehensive medical eye evaluation should be performed.[176, 179] 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 lid function, lid margins, meibomian glands, tear film, conjunctival surface, and the corneal surface. General principles for selecting and fitting contact lenses are described in Appendix 7.

Patient Education and Contact Lens Care

The FDA and CDC have made recommendations for contact lens wearers regarding proper lens care practices, which are incorporated into the recommendations below:[250, 251]

◆ 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 instructed by your eye doctor.
◆ Never store your contact lenses in water.
◆ Keep water away from your contact lenses. Take contact lenses out before showering, swimming, or using a hot tub.
◆ 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 yearly or as often as he or she recommends for contact lens examination.

These recommendations apply to contact lenses prescribed for refractive error and for contact lenses that alter the appearance of the eye.[252, 253] All contact lenses, even decorative and costume contact lenses are medical devices. Doctors, patients, and consumers should be aware that there is a federal statute stating that a contact lens seller cannot provide contact lenses to its customer without a valid prescription.[254] Stores or websites selling any contact lenses without requiring a prescription are engaging in business activity that is subject to federal law enforcement.

When contact lenses are initially prescribed and dispensed, patients should be trained and supervised in contact lens insertion and removal. Patients should be aware that all contact lenses, even decorative and costume contact lenses, are medical devices and require a physician's prescription and supervision. Stores or websites may sell contact lenses without requiring a prescription; these lenses are unregulated and may be counterfeit. Contact lens cleaning and disinfection should be carefully explained, because improper care may be associated with complications of contact lens wear.[9, 14, 20, 255] Hydrogen peroxide systems may be superior to preserved disinfecting solutions in reducing pathogen binding and cysticidal disinfection, but they require more complex care regimens.[6, 38-40] 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.[256] Specifically, patients should be instructed not to rinse contact lenses or lens cases with water (e.g., tap water, bottled

water).[14] 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.[14, 30, 257] Patients should be instructed to replace the solution in contact lens cases each time the lenses are disinfected.[250] 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).[50]

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.[4, 11-13, 258, 259] Even occasional overnight wear has risks[260] 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,[258] and showering with lenses seems to be part of a pattern of risk.[20] 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.[261]

For additional information about contact lens selection, fitting, and care, see Appendix 7.

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 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.[262] Patient-reported compliance does not indicate appropriate patient behavior, as a large proportion of patients remain noncompliant despite being aware of risk.[262, 263] 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.

The length of time a particular pair of 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. Conventional daily-wear soft contact lenses usually require replacement at least annually.

Conventional extended-wear soft contact lenses often require replacement more frequently than once a year. Disposable soft contact lenses and silicone hydrogel lenses for daily or extended wear should be replaced per manufacturers' guidelines, which vary from 1 day to several months. 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 1-year expirations, 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,[4, 11, 261] 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.[264] Of soft lens options, daily disposable lenses worn on a daily-wear basis remains the safest regimen.[11, 265] Extended (overnight) wear, regardless of lens type (including the newest highly gas-permeable silicone hydrogel lenses), increases the likelihood of infection,[4, 11] 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.[266, 267] Earlier attempts to predict which patients would respond to orthokeratology based on ocular biomechanical or biometric parameters were not successful,[268] and the effects of orthokeratology were unpredictable and poorly controlled.[266] 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 gas-permeable 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. Food and Drug Administration approval 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.[269-274]

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,[272, 275-277] as well as a risk similar to that of any overnight wear.[278] Microbial keratitis in association with overnight orthokeratology was first reported in 2001.[279, 280] 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.[281] 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.[281, 282] Corneal pigmentation rings have been reported, but these are reversible. In addition, patients may note a decreased quality of vision, especially under low-illumination conditions as a result of an increase in HOAs.

Although orthokeratology lenses are used internationally for myopia control in children,[185, 283, 284] they are only currently FDA approved for correction of refractive error and not for myopia control.

Refractive Surgery for Myopia, Astigmatism, and Hyperopia

Refractive surgery is a method of modifying the refractive status of the eye, and it includes various elective procedures. Procedures that involve altering the cornea are collectively referred to as keratorefractive surgery, refractive keratoplasty, or corneal refractive surgery. Other refractive surgery procedures include placing a phakic intraocular lens (IOL) implant in front of the crystalline lens or replacing the crystalline lens by means of refractive lens exchange. Refractive surgery may be considered when a patient wishes to be less dependent on eyeglasses or contact lenses, or when there are occupational or cosmetic reasons not to wear eyeglasses. Keratorefractive surgery can be applied to a broad range of refractive errors, but in some circumstances, the surgeon may consider an intraocular procedure.

Preoperative Evaluation

The operating ophthalmologist has the ultimate responsibility for the preoperative assessment and postoperative care of the patient, beginning with the determination of the need for surgery and ending with completion of the postoperative care contingent on the medical stability of the patient.[285]

The ophthalmologist who is to perform the refractive surgery has the following responsibilities:[286, 287]

◆ To examine the patient preoperatively
◆ To ensure that the record of the evaluation accurately documents the symptoms, findings, and indications for treatment
◆ To ensure that the patient provides his or her informed consent for the procedure (see Informed Consent sections)
◆ To review the results of presurgical diagnostic evaluations with the patient
◆ To formulate a surgical plan
◆ To formulate postoperative care plans and inform the patient of these arrangements (e.g., setting of care, individuals who will provide care)
◆ To give the patient the opportunity to discuss the costs associated with surgery

Although the ophthalmologist is responsible for the examination and review of the data, some or all of the data collection may be conducted by other trained individuals under the ophthalmologist's supervision and with his or her review.[286, 287]

A comprehensive medical eye evaluation should be performed before any refractive surgery procedure.[286] Visual acuity determination and refraction require particular attention. In addition to the elements listed in the comprehensive adult medical eye evaluation[176] (see Appendix 4), the refractive surgery examination should include the following elements:

◆ Distance and near visual acuity with and without correction
◆ Manifest and, when appropriate, cycloplegic refraction
◆ Computerized corneal topography/tomography
◆ Central corneal thickness measurement
◆ Evaluation of tear film and ocular surface
◆ Evaluation of ocular motility and alignment

The data from published studies fail to demonstrate a relationship between pupil size and the quality of postoperative vision. Most studies of conventional and wavefront-guided laser in situ keratomileusis (LASIK) have not shown a relationship between the diameter of the low-light pupil and disturbing visual symptoms postoperatively.[288-293] Thus, the importance of pupillometry in the preoperative workup remains controversial.[293] A benefit of more complex aspheric ablations relative to conventional ablations may be found under low-light conditions when the pupil is dilated, because this is when a reduction, or less induction, of HOAs, particularly spherical aberration, should be most apparent. Some studies comparing conventional and wavefront-guided LASIK have reported fewer postoperative complaints of glare or halo under mesopic conditions with wavefront-guided procedures.[294, 295] Irrespective of pupil size, it is important for potential patients to understand that there is a risk for night-vision problems after surgery.

Because of the possibility of contact-lens-induced corneal warpage and corneal edema, patients who use contact lenses should discontinue their use before the preoperative examination and procedure.[296] As a general guideline, spherical soft contact lenses should be discontinued for at least 3 days to 2 weeks.[296, 297] Toric soft contact lenses and rigid contact lenses should be discontinued for a longer period because they are associated with a greater potential for corneal warpage and refractive instability, which takes longer to resolve upon contact lens discontinuation. Particular attention should be paid to establishing refractive stability for these patients, which may require multiple visits.

When astigmatism determined by subjective refraction or optical biometry differs significantly from astigmatism found by corneal topography/tomography, lenticular astigmatism may be a possible cause. Keratorefractive surgery is intended to correct total astigmatism identified on refraction. Caution should be taken to identify early cataract formation in the presence of significant lenticular astigmatism. In this situation, lenticular refractive surgery may be a better option for the patient than keratorefractive surgery.

The patient should be evaluated using corneal topography/tomography to look for evidence of irregular astigmatism, corneal warpage, or signs of keratoconus or other corneal ectasias, because these may be associated with unpredictable outcomes of keratorefractive surgery and a decrease in best spectacle-corrected visual acuity (BSCVA). Caution should be taken to ensure that any irregular astigmatism, typically identified on corneal topography/tomography, is not a sign of keratoconus or another corneal ectatic condition before proceeding with any keratorefractive surgery.[298-301]

Corneal topography/tomography is also important when considering intraocular refractive surgery to assess any contour abnormalities as well as to measure keratometry.

Measurement of the central corneal thickness should be obtained during the preoperative evaluation to identify unusually thin corneas and estimate residual stromal bed thickness. Corneal tomographic imaging systems measure the shape of the anterior and posterior surface of the cornea, allowing for assessment of abnormal pachymetric distribution across the entire cornea. Pachymetric maps demonstrating abnormal pachymetric distribution may be helpful in identifying the presence of keratoconus.[302]

Excimer ablations that result in very thin residual stroma increase the risk for ectasia. In the case of LASIK procedures, 250 μm has been suggested as a safe residual stromal bed thickness,[303] but there is no absolute value that guarantees that ectasia will not occur. Although surgeons do not agree on a particular figure, they do agree that when ectasia risk is assessed, many factors should be considered. Abnormal topography is the most significant risk factor for postoperative ectasia. In the context of normal preoperative topography, percentage of tissue altered (PTA) higher or equal to 40% has been associated with higher ectasia risk.[304] Percentage of tissue altered is derived from [PTA=(FT+AD)/CCT], where FT = flap thickness, AD = ablation depth, and CCT = preoperative central corneal thickness. Other hypothesized risk factors include thin preoperative central corneal thickness, younger patient age, thin postoperative stromal bed thickness, and higher attempted corrections.[298-300]

Patients' preoperative expectations and psychological characteristics have been shown to affect satisfaction with LASIK.[305] Depressive symptoms have been associated with decreased patient satisfaction with visual quality after LASIK.[306] This study is consistent with studies from the cosmetic surgery literature, which identified the presence of a personality disorder or a history of depression or anxiety as predictors for poor psychological or psychosocial outcome following surgery.[307]

Keratorefractive Surgery

The most frequently performed procedures for low to moderate myopia utilize the excimer laser, which was first approved for this purpose by the FDA in 1995. A surface ablation technique, photorefractive keratectomy (PRK), was the first procedure performed; subsequently, LASIK has become the most commonly performed keratorefractive surgery. Other keratorefractive procedures to correct low to moderate myopia include variations of PRK called laser epithelial keratomileusis (LASEK) and epi-LASIK, femtosecond intrastromal lenticular extraction,[308] insertion of intrastromal corneal ring segments,[309] and radial keratotomy

(RK).[310] It should be noted that the FDA approved the small-incision lenticule extraction (SMILE) technology in 2016.

An advantage of surface ablation techniques over LASIK is that more residual posterior stromal tissue is preserved and there are no flap-related complications. Disadvantages of surface ablation techniques when compared with LASIK include more discomfort and slower recovery of vision due to the longer re-epithelialization time and potential development of subepithelial haze.[311-313] A Cochrane review in 2016 found no difference in efficacy between LASEK and PRK in correcting myopia.[314] Similarly, a 2017 Cochrane review found no comparable difference between LASEK and LASIK in correcting myopia, and earlier Cochrane reviews found no comparable difference between LASIK and PRK.[311, 313, 315] Based on these systematic reviews, LASEK, PRK, and LASIK may be equally effective in correcting myopia. (I-, *moderate quality, strong recommendation*) [311, 313-316] Therefore, selection of a surgery can be dependent on individual patient characteristics or surgeon preferences.

Excimer laser-based procedures can have less predictable results when used for correcting high myopia than when used for low to moderate myopia.[317] Because of the greater functional impairment experienced by highly myopic patients, however, the potential limitations of keratorefractive surgery may be more acceptable. Alternative procedures to correct high myopia include SMILE, refractive lens exchange, and phakic IOL implantation.

Surgery to correct hyperopia is performed less commonly than surgery to correct myopia and high quality randomized controlled trials are needed for evidence.[318] A hyperopic ablation profile is a peripheral annular ablation around the central optical zone, which results in steepening of the central cornea relative to the periphery. The FDA first approved use of the excimer laser to correct hyperopia in 1998.

Photorefractive keratectomy was the first refractive laser procedure to address astigmatism.[319, 320] With the excimer laser, a spheroelliptical ablation is made in the corneal stroma to correct both the spherical and astigmatic refractive error. The laser ablation either flattens the steep meridian, steepens the flat meridian, or both (bitoric or cross-cylinder ablation), depending on the laser and its algorithm for the specific refractive error. In general, cross-cylinder and bitoric ablations remove less tissue and change the spherical equivalent less than ablations that only steepen the flat meridian or only flatten the steep meridian.[321] Different laser platforms use different proprietary ablative patterns, which may affect the outcomes of long-term stability of the refractive procedures.

Excimer Laser Systems

Conventional

By varying the ablation pattern, the excimer laser can alter the anterior corneal curvature to modify a particular refractive error described by sphere and cylinder. The laser delivery methods currently being utilized to achieve the ablation pattern are broad-beam, scanning-slit, or flying-spot systems. Eye-tracking technology is integrated into all the current commercially available excimer laser systems and permits the ablation to remain centered on the pupil in the presence of small ocular movements.

Advanced

Wavefront-guided and wavefront optimized patterns are available. Wavefront analysis makes use of a detailed map of the optical system of the eye, measured across an entrance pupil aperture. This map is unique to the measured individual eye and can be described by varying degrees of standard optical aberration terms. Lower order aberrations consist of regular astigmatism and defocus. Higher order aberrations consist of an infinite series of increasingly complex optical imperfections that characterize what was previously known as irregular astigmatism (i.e., astigmatism not correctable with spherocylindrical lenses). Wavefront-guided and wavefront optimized techniques attempt to maintain a more prolate corneal shape, thus reducing induced spherical aberration. Compared with conventional LASIK, both wavefront-guided and wavefront optimized ablations may lead to improved quality of vision under dim lighting conditions.[322] Wavefront-guided or wavefront

optimized techniques generally remove a greater volume of tissue than conventional procedures.[323-330]

An excimer ablation, using the wavefront aberrometry information, is able to limit the induction of HOAs and, in some instances, reduce pre-existing HOAs.[331, 332] Eyes that are otherwise healthy and have not had previous refractive surgery typically have very low levels of irregular astigmatism that do not significantly affect visual function. Some evidence exists that even healthy eyes, with relatively low levels of existing HOAs, may benefit from wavefront-guided excimer ablation because of the ability of the technology to reduce the induction of HOAs, particularly spherical aberration.[333]

Procedures used to treat regular astigmatism include PRK and its variants (collectively termed surface ablation), LASEK, LASIK, SMILE, and astigmatic keratotomy (AK). Customized treatments may be used to reduce irregular astigmatism in eyes with high degrees of aberration.[334] Surface ablation using wavefront-guided technology is considered an off-label use of an FDA-approved device.

Indications

Table 1 and Table 2 list some of the excimer lasers for LASIK and PRK, respectively, that have been approved by the FDA for the correction of myopia, hyperopia, astigmatism, and combinations thereof, and are commercially available. For the most up-to-date list of approved lasers visit:
www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm168641.htm.

MedWatch (www.fda.gov/medwatch) is the Safety Information and Adverse Reporting Program for drugs and other medical products regulated by the FDA. Adverse experiences of refractive surgery should be reported to MedWatch.

Contraindications

◆ Unstable refraction
◆ Abnormalities of the cornea (e.g., keratoconus or other corneal ectasias, thinning, edema, interstitial or neurotrophic keratitis, extensive vascularization)
◆ Insufficient corneal thickness for the proposed ablation depth
◆ Visually significant cataract
◆ Uncontrolled glaucoma
◆ Uncontrolled external disease (e.g., blepharitis, dry eye syndrome, atopy/allergy)
◆ Uncontrolled autoimmune or other immune-mediated disease
◆ Unrealistic patient expectations

Relative Contraindications

◆ Functional monocularity
◆ Ocular conditions that limit visual function
◆ Excessively steep or flat corneas (e.g., increased risk of microkeratome complications)
◆ Abnormal corneal topography/tomography indicating forme fruste keratoconus
◆ Significant irregular astigmatism
◆ Visually significant corneal stromal or endothelial dystrophies
◆ History of herpes simplex virus (HSV) or varicella zoster virus keratitis
◆ Inadequately controlled dry eye
◆ Glaucoma[335]
◆ History of uveitis[336]
◆ Diabetes mellitus[337]
◆ Pregnancy or lactation[338]
◆ Autoimmune or other immune-mediated diseases[339]
◆ Certain systemic medications (e.g., isotretinoin, amiodarone, sumatriptan, levonorgestrel implants, colchicine)
◆ Age under 21 years (FDA labeling should be consulted for each laser platform)

TABLE 1   FDA-APPROVED INDICATIONS FOR EXCIMER LASERS FOR LASIK

Company (Model)	LASIK for Myopia and Astigmatism	LASIK for Hyperopia and Astigmatism	Mixed Astigmatism
Abbott Medical Optics (VISX Star S2)	Myopia less than –14.00 D with or without astigmatism between –0.50 and –5.00 D (P990010; 11/19/99)		
Abbott Medical Optics (VISX Star S2/S3)		Hyperopia between +0.50 and +5.00 D with or without astigmatism up to +3.00 D (P930016/S12; 4/27/01)	Mixed astigmatism up to 6.00 D; cylinder is greater than sphere and of opposite sign (P930016/S14; 11/16/01)
Abbott Medical Optics (VISX Star S3, EyeTracker)	Myopia less than –14.00 D with or without astigmatism between 0.50 and –5.00 D with eye tracker (P990010/S1; 4/20/00)		
Alcon (Apex Plus)	Myopia less than –14.00 D with or without astigmatism from 0.50 to 5.00 D (P930034/S13; 10/21/99)		
Alcon (LADARVision)	Myopia less than –9.00 D with or without astigmatism from –0.50 to –3.00 D (P970043/S5; 5/9/00)	Hyperopia less than 6.00 D with or without astigmatism less than –6.00 D (P970043/S7; 9/22/00)	Mixed astigmatism less than +6.00 D sphere with less than –6.00 D cylinder (P970043/S7; 9/22/00)
Alcon (LADARVision) wavefront-guided	Myopia up to –7.00 D with or without astigmatism less than 0.50 D (P970043/S10; 10/18/02) Myopic astigmatism up to –8.00 D sphere with –0.50 to –4.00 D cylinder and up to –8.00 D SE at the spectacle plane (P970043/S15; 6/29/04)	Hyperopia less than +5.00 D with or without astigmatism less than –3.00 D (P970043/S20; 5/1/06)	Mixed astigmatism from 1.00 to 5.00 D; cylinder is greater than sphere and of opposite sign (P970043/S22; 5/2/06)
Alcon (WaveLight ALLEGRETTO WAVE)	Myopia up to –12.00 D with or without astigmatism up to –6.00 D (P020050; 10/07/03)	Hyperopia up to +6.00 D with or without astigmatism up to +5.00 D (P030008; 10/10/03)	Mixed astigmatism up to 6.00 D at the spectacle plane (P030008/S4; 4/19/06)
Alcon (WaveLight ALLEGRETTO WAVE) wavefront-guided	Myopia up to –7.00 D with up to –7.00 D of spherical component and up to 3.00 D astigmatic component (P020050/S4; 7/26/06)		
Carl Zeiss Meditec (MEL 80)	Myopia less than or equal to –7.00 D with or without astigmatism less than or equal to –3.00 D (P060004; 8/11/06)	Hyperopia less than or equal to +5.00 D with or without astigmatism of more than +0.50 and less than or equal to +3.00 D, with maximum MRSE of +5.00 D (P06004/S1; 3/28/11)	
Nidek EC-5000	Myopia from –1.00 to –14.00 D with or without astigmatism less than or equal to –4.00 D (P970053/S9; 10/11/06)	Hyperopia between +0.50 and +5.00 D with or without astigmatism from +0.50 to +2.00 D (P970053/S9; 10/11/06)	
Technolas Perfect Vision GmbH* (Technolas 217a)	Myopia from less than –11.00 D with or without astigmatism less than –3.00 D (P99027; 2/23/00)	Hyperopia between 1.00 and 4.00 D with or without astigmatism up to 2.00 D (P99027/S4; 2/25/03)	

TABLE 1   FDA-APPROVED INDICATIONS FOR EXCIMER LASERS FOR LASIK (CONTINUED)

Company (Model)	LASIK for Myopia and Astigmatism	LASIK for Hyperopia and Astigmatism	Mixed Astigmatism
Technolas Perfect Vision GmbH (Technolas 217z) wavefront-guided	Myopia up to –7.00 D with or without astigmatism up to –3.00 D (P99027/S6; 10/10/03)		
VISX, Inc. (VISX Star S4 & WaveScan WaveFront System) wavefront-guided	Myopia up to –11.00 D with or without astigmatism up to –5.00 D (P930016/S16; 5/23/03) Myopia from –6.00 to –11.00 D with or without astigmatism up to –3.00 D (P930016/S21; 8/30/05) Monovision treatment for myopia up to –6.00 D with or without astigmatism up to –3.00 D allowing for retention of myopia from –1.25 to –2.00 D (P930016/S25;7/11/07)	Hyperopia up to +3.00 D with or without astigmatism up to +2.00 D (P930016/S17; 12/14/04)	Mixed astigmatism from 1.00 to 5.00 D (P930016/S20; 3/17/05)

SOURCE: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm168641.htm, accessed March 15, 2017.

D = diopter; LASIK = laser in situ keratomileusis; FDA = Food and Drug Administration; MRSE = manifest refraction spherical equivalent; SE = spherical equivalent

* Technolas Perfect Vision GmbH is a joint venture of Bausch & Lomb and 20/10 Perfect Vision AG.

NOTE: For a comprehensive list of approved lasers, visit:

www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm192109.htm, accessed March 15, 2017.

TABLE 2   FDA-APPROVED INDICATIONS FOR EXCIMER LASERS FOR PHOTOREFRACTIVE KERATECTOMY

Company (Model)	PRK for Myopia and Astigmatism	PRK for Hyperopia and Astigmatism	Mixed Astigmatism
Abbott Medical Optics (VISX Model B & C [Star & Star S2])	Myopia from –1.00 to –6.00 D (P930016; 3/27/96) Myopia from 0 to –6.00 D with or without astigmatism from –0.75 to –4.00 D (P930016/S3; 4/24/97) Myopia from 0 to –12.00 D with or without astigmatism from 0 to –4.00 D (P930016/S5; 1/29/98)		
Abbott Medical Optics (VISX Star S2)		Hyperopia from +1.00 to +6.00 D (P930016/S7; 11/2/98)	
Abbott Medical Optics (VISX Star S2/S3)		Hyperopia from +0.50 to +5.00 D with or without astigmatism +0.50 to +4.00 D (P930016/S10; 10/18/00)	
Abbott Medical Optics (VISX Star S4 & WaveScan WaveFront System) wavefront-guided			Mixed astigmatism from 1.00 to 5.00 D (P930016/S20; 3/17/05)

TABLE 2   FDA-APPROVED INDICATIONS FOR EXCIMER LASERS FOR PHOTOREFRACTIVE KERATECTOMY (CONTINUED)

Company (Model)	PRK for Myopia and Astigmatism	PRK for Hyperopia and Astigmatism	Mixed Astigmatism
Alcon (SVS Apex & Apex Plus)	Myopia from –1.50 to –7.00 D (P930034; 10/25/95)		
Alcon (SVS Apex Plus Workstation)	Myopia from –1.00 to –6.00 D with or without astigmatism from –1.00 to –4.00 D (P930034/S9; 3/11/98)	Hyperopia from +1.50 to +4.00 D with or without astigmatism less than –1.00 D (P930034/S12; 10/21/99)	
Alcon (LADARVision)	Myopia from –1.00 to –10.00 D with or without astigmatism less than –4.00 D (P970043; 11/2/98)		Mixed astigmatism less than +6.00 D sphere with less than –6.00 D cylinder (P970043/S7; 9/22/00)
Alcon (LADARVision) wavefront-guided			Mixed astigmatism from 1.00 to 5.00 D; cylinder is greater than sphere and of opposite sign (P970043/S22; 5/2/06)
Alcon (WaveLight ALLEGRETTO WAVE)			Mixed astigmatism up to 6.00 D at the spectacle plane (P030008/S4; 4/19/06)
Bausch & Lomb Surgical (KERACOR 116)	Myopia from –1.50 to –7.00 D with or without astigmatism less than –4.50 D (P970056; 9/28/99)		
Nidek EC-5000	Myopia from –0.75 to –13.00 D with astigmatism less than or equal to –0.75 D and myopia –1.00 to –8.00 D with astigmatism –0.50 to –4.00 D (P970053/S9; 10/11/06)		

SOURCE: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm168641.htm, accessed March 15, 2017.

D = diopter; MRSE = manifest refraction spherical equivalent; FDA = Food and Drug Administration; PRK = photorefractive keratectomy; SE = spherical equivalent

* Technolas Perfect Vision GmbH is a joint venture of Bausch & Lomb and 20/10 Perfect Vision AG.

NOTE: For a comprehensive list of approved lasers, visit:

www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm192110.htm, accessed March 15, 2017.

Informed Consent

Although there is a high probability of successful outcomes for keratorefractive surgery, care should be taken to emphasize potential adverse events or complications that may occur and explain which may be transient and which may be permanent. The patient should be informed of the potential risks, benefits, and alternatives to and among the different refractive procedures before surgery. The informed consent process should be documented, and the patient should be given an opportunity to have all questions answered before surgery. The surgeon is responsible for ensuring that the patient provides his or her informed consent.[286, 287] Elements of the discussion may include the following:

◆ Range of expected refractive outcomes
◆ Residual refractive error
◆ Reading and/or distance correction postoperatively
◆ The limitations of keratorefractive surgery with respect to presbyopia and the potential loss of uncorrected near visual function that accompanies myopia correction
◆ Monovision advantages and disadvantages (for patients of presbyopic age)

◆ Loss of BCVA

◆ Side effects and complications (e.g., microbial keratitis, sterile keratitis, keratectasia)

◆ Changes in visual function not necessarily measured by visual acuity testing, including glare and function under low-light conditions

◆ Night-vision symptoms (e.g., glare, haloes) developing or worsening. Careful consideration should be given to this issue for patients with high degrees of ametropia or for individuals who require a high level of visual function in low-light conditions. *(good quality, strong recommendation)*

◆ Effect on ocular alignment

◆ Development or exacerbation of dry eye symptoms

◆ Recurrent erosion syndrome

◆ Advantages and disadvantages of same-day bilateral keratorefractive surgery versus sequential surgery. Because vision might be poor for some time after bilateral same-day PRK, the patient should be informed that activities such as driving might not be possible for weeks.

◆ Possibility that it may influence predictive accuracy of IOL calculations for subsequent cataract surgery

◆ Postoperative care plans (setting of care, providers of care)

◆ Loss of uncorrected near vision in myopic presbyopes

Surface Ablation Techniques

Photorefractive Keratectomy

In PRK, the central corneal epithelium is removed and the excimer laser is used to ablate the Bowman membrane and superficial corneal stroma centered over the entrance pupil.

All instrumentation must be checked and calibrated before the procedure.[340] The surgeon should confirm the identity of the patient, the operative eye, and that the parameters are correctly entered into the laser's computer.[340] In the setting of significant astigmatism or a wavefront-guided treatment, the surgeon should take appropriate steps to ensure torsional alignment. Axis alignment is crucial in the treatment of astigmatic errors because there can be a large reduction in effect if the astigmatic ablation is not aligned with the true axis of astigmatism. Because there can be ocular cyclotorsion when the patient changes from the seated to supine position, it may be useful to place reference marks on the operative eye before the laser procedure while the patient is seated upright.[341] These marks are then aligned intraoperatively with the laser reticle, thus compensating for ocular cyclotorsion. The use of a tracker or, in some cases, a fixation ring, may help to stabilize the eye and increase the accuracy of the placement of the astigmatic ablation.

The nonoperative eye should be occluded. Sterile instruments must be used for each patient. The operative eye is anesthetized topically, the surrounding skin and eyelashes are cleansed and/or isolated, and a lid speculum is placed to optimize corneal exposure.

The epithelium can be removed mechanically (by brush, blade, or epikeratome), chemically (most often with approximately 20% alcohol), or by laser.[342-347] Expeditious removal minimizes nonuniform drying of the stroma. Enough epithelium should be removed to permit placement of the full, planned laser optical zone diameter onto the stroma. The excimer laser ablation is performed. Care should be taken to maintain a proper head position so that the facial/corneal planes are parallel to the floor and orthogonal to the laser beam. In an off-label application, mitomycin-C is sometimes used to reduce the chance of corneal subepithelial haze developing, particularly in the setting of a high correction (i.e., deep ablation) or in eyes that have undergone prior corneal surgery such as RK, LASIK, or penetrating keratoplasty.[348-350] Long-term studies of the effect of mitomycin-C on corneal physiology are not yet available. Most studies show no significant effect on endothelial cell counts when mitomycin-C is used at a concentration of 0.02% (0.2 mg/ml) for a brief period (e.g., 15 seconds).[351, 352]

A bandage contact lens is usually applied, and the lid speculum is removed. Postoperative regimens of topically applied antibiotics, corticosteroids, NSAIDs, and oral analgesic

agents vary among practitioners.[353] Therefore, it is the decision of the operating surgeon to use any or all of these products singly or in combination. Judicious short-term use of dilute topical anesthetics can help to control postoperative pain.

Laser Epithelial Keratomileusis and Epi-LASIK

Laser epithelial keratomileusis is a modification of PRK that attempts to preserve the epithelium. After dilute ethanol alcohol is applied to the corneal epithelium, an epithelial trephine and spatula are used sequentially to score, loosen, and roll up the epithelium, which remains attached at a nasal or superior hinge. Photoablation is then performed, and the epithelium is unrolled back over the central corneal stroma.[354] A bandage contact lens is used for several days until the surface re-epithelializes.

An alternative surface ablation procedure to LASEK is epi-LASIK. Instead of using alcohol to loosen the epithelium, an epikeratome is used to dissect an epithelial sheet from the Bowman membrane. The epikeratome is similar in design to a mechanical microkeratome used for LASIK. Instead of using an oscillating sharp blade to incise the corneal stroma beneath the Bowman membrane, the epikeratome uses a blunt oscillating separator that moves across the cornea held under high pressure with a suction ring. This separator lifts a sheet of epithelium from the Bowman membrane. The laser ablation is then performed and the epithelial sheet is either replaced or discarded. It is unclear whether patient discomfort and subepithelial haze formation is reduced with LASEK or epi-LASIK when compared with PRK.[314] Visual recovery and discomfort with LASEK and epi-LASIK are similar to PRK and are prolonged relative to LASIK. Similarly, a 2017 Cochrane review found no comparable difference between LASEK and LASIK for treating myopia.[315] (I-, *moderate quality, strong recommendation)* Epi-LASIK should be used only in eyes in which the Bowman membrane is intact. Breaks in the Bowman membrane (e.g., from previous PRK, LASIK, or even some corneal scars) increase the risk of the epi-LASIK blade separating stromal tissue and not just epithelium.[355] Because LASEK and epi-LASIK are modifications of PRK, the potential for corneal haze to develop remains a concern.[350-353] In an off-label application, mitomycin-C is sometimes used to reduce the chance of corneal subepithelial haze developing, particularly in the setting of a high correction (e.g., deep ablation) or in eyes that have undergone prior corneal surgery such as RK, LASIK, or penetrating keratoplasty.[356-358]

Results

Photorefractive keratectomy reduces myopia, is most predictable for low to moderate myopia, and is less predictable for high myopia.[317] A systematic review of data from over 2000 eyes with 1.00 to 14.00 D of myopia reported that 70% and 92% of participants had a UCVA of 20/20 and 20/40, respectively, at 12 or more months following PRK.[317] After 12 or more months of follow-up, 86% of eyes treated for myopia and myopic astigmatism were within 1.00 D of the expected correction.[317] Loss of BCVA of two lines or more after PRK for low to moderate myopia varies between 0% and 1% at 1 year following surgery.[317] Following PRK for high myopia, 6% of eyes lost two or more lines of BCVA.[317]

In a study of wavefront-guided PRK for myopia and myopic astigmatism, 81% of patients achieved a UCVA of 20/20 or better.[359] In a contralateral eye study comparing wavefront-guided PRK with wavefront-guided LASIK, visual recovery was faster with LASIK than with PRK (88% vs. 48% were 20/20 or better at 1 month). At 6 months, however, visual acuities were similarly excellent in both groups (LASIK: 92% 20/20 or better; PRK: 94% 20/20 or better).[360] Using wavefront-guided PRK, 1% of eyes lost one line of BCVA at 1 year (relative to pre-LASIK BCVA).[359]

Regression of the surgical effect was more common in patients with higher degrees of preoperative myopia.[317] Long-term studies examining 10- to 12-year results demonstrated excellent safety and efficacy of PRK for the treatment of myopia.[361-364] Two studies published together looked at 10-year follow-up of PRK in eyes with less than −6.00 D of myopia (lower myopic group) and more than −6.00 D of myopia (higher myopic group). While the long-term results were excellent, there was more regression of effect in the higher

myopic group (−1.33 D over 10 years) compared with the lower myopic group (−0.10 D over 10 years).[363, 364]

One study of the incidence of retreatments following wavefront optimized PRK and LASIK found no difference in the retreatment rates between the two procedures (6.3%).[365] Another study identified older preoperative age, higher degrees of astigmatism, hyperopia, colder operating room temperature, and lack of surgical experience as factors increasing the risk for retreatment after refractive surgery.[366] The efficacy and predictability of PRK retreatment are less than for primary procedures.[367-371]

Photorefractive keratectomy for hyperopia (H-PRK) reduces hyperopic refractive errors. Lower degrees of hyperopia (0 to +3.50 D) can be corrected with better predictability than higher hyperopic errors.[317] A systematic review with data from more than 300 eyes treated with H-PRK reported that 79% of eyes achieved within 1.00 D of their intended refractive correction at 12 months after surgery.[317] In one study, 85% of eyes with a mean preoperative correction of 2.88 D of hyperopia achieved corrections of ±1.00 D of the attempted correction.[372] In eyes with more than 3.50 D of hyperopia, 79% were within 1.00 D of the intended correction.[373] In another study 79% of eyes with a mean preoperative refraction of 3.03 D of hyperopia achieved ±0.50 D of emmetropia at 12 months.[374] Following H-PRK, 5% of patients with less than 3.50 D of hyperopia and 20% of those with 3.50 D or more hyperopia lost two or more lines of BCVA relative to the preoperative BCVA, respectively.[317] In a study of wavefront-guided PRK for hyperopia (mean preoperative refraction +2.90 ± 0.80 D), 100% of eyes achieved within 1.00 D of the intended correction and 12% of patients lost two or more lines of BCVA at 6 months of follow-up, primarily due to increases in HOAs.[375] Ninety percent of eyes were 20/40 or better 6 months following surgery.

Although overall corneal haze was generally mild, there were more-significant haze problems in the midperipheral ring, usually sparing the entrance pupil.[376] Achievement of best postoperative vision is slower with H-PRK than with myopic PRK. Centration of the ablation is more critical in hyperopic treatments because of the smaller effective optical zone. The use of excimer lasers with eye trackers may reduce decentrations.

In a study comparing hyperopic PRK and LASIK outcomes at 2 years, refractive outcomes were less stable with PRK, as evidenced by a statistically significant regression at 2 years in the PRK group compared with no significant regression in the LASIK group.[377] Higher regression in the PRK group was present even though the amount of hyperopic spherical equivalent in the LASIK group (4.49 D vs. 2.85 D) was greater.

In three studies of PRK to correct astigmatism with 6 months of follow-up, less than 2% of patients lost two or more lines of BCVA. In these reports, 63% to 86% of patients were within 1.00 D of their intended correction and 82% to 94% had a UCVA of 20/40 or better.[378-380]

A systematic review of LASEK studies reported that loss of two or more lines of BCVA ranged from 0% to 8%; loss of two or more lines was more frequent in studies of high myopia and astigmatism.[317] Outcomes for accuracy and UCVA were similar to those for PRK. A study comparing outcomes of LASEK and LASIK for low to moderate myopia reported clinically insignificant differences in the results obtained.[381]

Postoperative Care

Postoperative management is integral to the outcome of any surgical procedure and is the responsibility of the operating surgeon.[287] Topical antibiotics are usually administered. Topical corticosteroids are generally started immediately after surgery and tapered over a period of days to weeks, and in some cases, months. Mild transient elevations of intraocular pressure (IOP) can most likely be managed with topical therapy, but close monitoring is essential because IOP control can easily be lost with prolonged corticosteroid use.[382, 383]

Although postoperative pain can be reduced by using a bandage contact lens and NSAID drops, some patients may benefit from dilute topical anesthetics and/or oral analgesics. Because NSAID drops may delay corneal epithelialization, they should be prescribed

judiciously.[384-388] Sterile corneal infiltrates associated with the use of NSAID drops without the concomitant use of topical corticosteroids have been described.[389] Microbial keratitis, however, must be considered whenever a corneal infiltrate is seen.

Postoperative examination, including slit-lamp biomicroscopy of the cornea, is advisable on the day following surgery and every 2 to 3 days thereafter until the epithelium is healed. Epithelialization usually is complete within 5 days after surgery. If a bandage contact lens is used, it usually can be discontinued once significant re-epithelialization has occurred. Stable vision and refraction might not be achieved for many months. Periodic examinations are necessary to monitor ocular status and to check for corticosteroid-related side effects such as elevated IOP.

It is recommended that patients be provided with a record (for example, the K Card) or that the ophthalmologist maintain a record that lists information about the patient's eye condition, including preoperative keratometry readings and refraction, as well as stable postoperative refraction, so that it will be available if the patient requires cataract surgery or additional eye care. (See Appendix 8.)

Retreatments

Retreatments should generally not be performed until refraction, corneal haze, and corneal topography/tomography have stabilized, which usually requires at least 6 months after primary PRK surgery. Retreatment in the presence of any but mild corneal haze should be carefully considered.[369] The off-label application of mitomycin-C at the time of retreatment has been reported to reduce the recurrence of haze.[390, 391]

Side Effects and Complications

Surface ablation procedures are associated with side effects and complications that are uncommon, sometimes permanent and rarely debilitating. These side effects and complications include the following:

◆ Symptomatic undercorrection or overcorrection[392-395]
◆ Partial regression of effect[396]
◆ Loss of BCVA[392-395, 397-403]
◆ Visual aberrations, including transient or permanent glare or starburst/halo effect, especially at night[396, 404]
◆ Decreased contrast sensitivity[405-407]
◆ Induced regular or irregular astigmatism[392, 395]
◆ Induced anisometropia[392-395]
◆ Need for reading correction[392-395]
◆ Corneal haze or scarring (early or delayed onset)[408]
◆ Corneal infiltrates, ulceration, melting, or perforation (sterile or microbial)[389, 402, 409]
◆ Corneal ectasia (progressive corneal steepening)[410]
◆ Development or exacerbation of dry eye symptoms
◆ Decreased corneal sensitivity[411]
◆ Recurrent corneal erosion[412]
◆ Reactivation of HSV keratitis[413]
◆ Corticosteroid-induced complications (e.g., ocular hypertension, glaucoma, cataract)[395]
◆ Adverse effect on ocular alignment[414]
◆ Ptosis[395]
◆ Artifactual reduction of measured IOP (due to corneal thinning)
◆ Complications related to mitomycin-C (e.g., endothelial cell decrease)[415]

Although there are case reports of retinal abnormalities that have been recognized following PRK, it is unclear if the incidence is any different in a comparable myopic population.[416, 417]

Patient Satisfaction

Patient satisfaction depends on both patient expectations and surgical outcome. Patients have generally been satisfied with the results of PRK.[418-420] Some individuals who achieve the intended correction, however, may be unhappy because of visual aberrations.

The most frequent complaints of patients dissatisfied with refractive surgery are blurred distance or near vision, glare, dry eyes, and night-vision problems. In many cases, dissatisfied patients had relatively good UCVA.[421, 422]

Questionnaires have been developed to assess the functional and psychological impact of refractive error and its correction.[423, 424] Subjective visual function and patient satisfaction do not always correlate with objective measurements.[425]

Laser in Situ Keratomileusis

Laser in situ keratomileusis is a surgical procedure in which a hinged flap consisting of corneal epithelium, the Bowman membrane, and superficial stroma is created. The corneal flap is reflected, a tissue-ablating excimer laser is used to reshape the exposed corneal stroma, and the flap is repositioned. The anterior corneal surface can be altered to modify a patient's refractive error by varying the pattern of corneal tissue removal beneath the flap.

Special considerations when evaluating patients for LASIK include the following:

◆ Abnormal corneal topography/tomography indicating forme fruste keratoconus
◆ Orbital, lid, or ocular anatomy that precludes proper function of the mechanical or femtosecond laser microkeratome
◆ Calculation of estimated residual stromal bed thickness
◆ Poor epithelial adherence, epithelial basement membrane dystrophy, or recurrent erosion syndrome
◆ Significant occupational or recreational risk for corneal trauma
◆ Significant dry eye

If one or more of these conditions are present, PRK or other surface ablation procedures may be considered.

Technique

All instrumentation must be checked and calibrated before the procedure. The surgeon must confirm the identity of the patient, the operative eye, and that the parameters are correctly entered into the laser's computer.[340] In the setting of significant astigmatism or a wavefront-guided treatment, the surgeon should take appropriate steps to ensure torsional alignment. Axis alignment is crucial and addressed in the same manner as in PRK (see Photorefractive Keratectomy under the Surface Ablation Techniques section).

In addition to mechanical microkeratome-based LASIK procedures, femtosecond lasers can be used to create a flap prior to excimer laser ablation. Femtosecond lasers refer to a group of solid-state lasers that operate mostly in the infrared spectrum. Photodisruption occurs when the laser beam is absorbed by the target tissue, free electrons are released, and plasma (electrically charged particles) is created.[426, 427] Plasma formation occurs and creates gas bubbles with cavitation. Femtosecond (10^{-15} second)-scale lasers have a short pulse duration, which allows them to be useful for corneal applications by reducing the size of the cavitation bubble formation and resultant shock wave.

The femtosecond lasers can be programmed to vary flap width, flap depth, hinge width, and side-cut angles, and they can perform other corneal procedures. Furthermore, resultant flaps may be inspected for imperfections prior to breaking the microadhesions and lifting. Table 3 lists femtosecond lasers that have been approved by the FDA for keratorefractive surgery and indications for their use.

TABLE 3   FDA-Approved Indications for Femtosecond Lasers

Model	Company	Indications
FEMTO LDV (formerly Da Vinci Femtosecond Surgical Laser) (K053511; 3/10/06)	Ziemer Ophthalmic Systems AG* (Port, Switzerland)	In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.
Horus Laser Keratome (K062314; 12/22/06)	Carl Zeiss Meditec AG (Jena, Germany)	In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.
iFS Laser System (K073404; 4/25/08) (K113151; 3/8/12)	Advanced Medical Optics, Inc.†	In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea; patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea; patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments; in lamellar keratoplasty and corneal harvesting; in the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and in the creation of a penetrating cut/incision for penetrating keratoplasty; in patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions, both penetrating and intrastromal.
IntraLase Fusion Laser (K063682; 2/9/07)	IntraLase Corp.†	
IntraLase FS Laser, IntraLase FS30 Laser, Models 1,2,3 (K060372; 8/16/06)	IntraLase Corp.†	
IntraLase FS Laser (K031960; 9/29/03)	IntraLase Corp.†	
Pulsion FS Laser Keratome (K013941; 2/27/02)	IntraLase Corp.†	
LenSx Laser System (K120732; 9/6/12)	Alcon LenSx, Inc. (Aliso Viejo, CA)	In the creation of corneal cuts/incisions, anterior capsulotomy and laser phacofragmentation during cataract surgery; each of these procedures may be performed either individually or consecutively during the same surgery; in the creation of a lamellar cut/resection for lamellar keratoplasty, and in the creation of a penetrating cut/incision for penetrating keratoplasty; in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.
Technolas Femtosecond Workstation Custom Flap (formerly FemTec Laser Microkeratome) (K033354; 2/18/04)	Technolas Perfect Vision GmbH‡	In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.
Victus Femtosecond Platform (K120426; 7/31/12)	Technolas Perfect Vision GmbH and Bausch & Lomb, Inc. (Rochester, NY)	In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.
VisuMax Femtosecond Laser (SMILE) (P150040 9/13/16)	Carl Zeiss Meditec (Dublin, CA)	For the SMILE procedure, an intrastromal lenticule is created with the femtosecond laser in a shape corresponding to the desired refractive correction in the intact cornea. The femtosecond incisions for the SMILE procedure consist of four separate cuts (posterior cut, side cut for the lenticule, cap cut, side cut for the opening incision), which are completed in succession in the integrated procedure. The lenticule is subsequently accessed and removed by the surgeon through the opening incision. The procedure is approved for myopia $\leq$-1.00 D and $\geq$-8.00 D with astigmatism $\leq$-0.50 D.
Victus Femtosecond Platform (K120426; 7/31/12)	Technolas Perfect Vision GmbH and Bausch & Lomb, Inc. (Rochester, NY)	In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

TABLE 3 FDA-APPROVED INDICATIONS FOR FEMTOSECOND LASERS (CONTINUED)

Model	Company	Indications
VisuMax Femtosecond Laser (SMILE) (P150040 9/13/16)	Carl Zeiss Meditec (Dublin, CA)	For the SMILE procedure, an intrastromal lenticule is created with the femtosecond laser in a shape corresponding to the desired refractive correction in the intact cornea. The femtosecond incisions for the SMILE procedure consist of four separate cuts (posterior cut, side cut for the lenticule, cap cut, side cut for the opening incision), which are completed in succession in the integrated procedure. The lenticule is subsequently accessed and removed by the surgeon through the opening incision. The procedure is approved for myopia $\leq$-1.00 D and $\geq$-8.00 D with astigmatism $\leq$-0.50 D.
VisuMax Laser Platform (K100253; 7/8/10)	Carl Zeiss Meditec AG (Jena, Germany)	In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea; in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea; in the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty; in the creation of a cut/incision for penetrating keratoplasty and corneal harvesting.
WaveLight FS200 Laser System (K101006; 10/21/10)	Alcon Laboratories, Inc. (Fort Worth, TX)	In the creation of a corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea; in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments; in the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty; in the creation of a penetrating cut/incision for penetrating keratoplasty and for corneal harvesting.

SOURCE: U.S. Food and Drug Administration. Available at: www.fda.gov. Accessed March 15, 2017.

Adapted with permission from Farjo AA, Sugar A, Schallhorn SC, et al. Femtosecond lasers for LASIK flap creation; a report by the American Academy of Ophthalmology. Ophthalmology 2013;120:e5-e20.

FDA = Food and Drug Administration; SMILE = small-incision lenticule extraction

* Da Vinci application filed by SIE Ltd. Surgical Instrument Engineering.

† Advanced Medical Optics, Inc. acquired IntraLase Corp. 4/27/07; Abbott Laboratories, Inc. acquired Advanced Medical Optics, Inc. 2/26/09 and renamed the company Abbott Medical Optics, Inc., Abbott Park, IL.

‡ Since 2009, in joint venture with Bausch & Lomb, Inc., Rochester, NY; FemTec application was filed by 20/10 Perfect Vision Optische Gerate GmbH.

A topical antibiotic or antiseptic may be applied preoperatively to the operative eye, and a topical NSAID eyedrop may also be applied to help ameliorate postoperative pain. The nonoperative eye should be occluded. Sterile instruments must be used for each patient. The operative eye is anesthetized topically, the surrounding skin and eyelashes of the operative eye are cleansed and/or isolated, and a lid speculum is placed to optimize corneal exposure. Marking the cornea facilitates flap reorientation at the end of the procedure, particularly in the event of a free cap.

The surgeon should confirm proper settings on the mechanical or femtosecond laser microkeratome. If a mechanical microkeratome is used to create the flap, a suction ring is placed on the eye to elevate the IOP and guide the mechanical microkeratome; the surgeon should confirm adequately elevated IOP.

The mechanical microkeratome is then passed across the corneal surface to produce a hinged corneal flap. If a femtosecond laser is used to create the flap, a suction ring is used to fixate the eye and the laser energy is applied intrastromally. Different hinge locations can be created using different mechanical microkeratomes.

In LASIK procedures, careful attention needs to be paid to ensure that the stromal bed diameter beneath the LASIK flap is large enough to accommodate the ablation. If a

femtosecond laser microkeratome is used, care needs to be taken to ensure the tear meniscus extends beyond the ablation zone.

The flap should be inspected and reflected, and the flap and stromal bed should be examined for size and regularity. Intraoperative central corneal thickness measurements may be performed to estimate residual corneal bed thickness. The advantages of such thickness rechecks include confirming the accuracy of the microkeratome and adequacy of the residual stromal bed thickness. A disadvantage includes prolonged surgical time with potential drying of the stromal bed. If the quality of the flap and stromal bed are adequate, the excimer laser ablation is performed centered on the entrance pupil. However, if there is inadequate stromal exposure or an irregular bed or flap, it may not be possible to perform the laser treatment safely. If the flap is noted to be visibly defective or grossly decentered after withdrawing the mechanical microkeratome, it may be more appropriate to abort surgery with as little flap manipulation as possible. The flap should be repositioned and allowed to heal. In many cases, surface ablation with or without mitomycin-C can then be performed.[428-430] In some cases, a recut and ablation after a period of months can be considered, although there can be significant complications.

An ablation of the stromal bed is performed in a manner similar to how it is performed for PRK. Following ablation, the flap is repositioned; the interface is usually irrigated with a balanced salt solution, and flap alignment is confirmed. The flap is given sufficient time to adhere and the eyelid speculum is removed, avoiding contact with the cornea. Before discharging the patient, the operative eye(s) should be examined under the slit-lamp in order to confirm proper flap position and appearance.

Results

A systematic review of 64 studies of LASIK published since 2000 found 17 studies that reported that 75% to 100% (median, 92%) of eyes with myopia or myopic astigmatism were within 1.00 D of the intended correction. Low to moderate myopia was corrected with a greater degree of predictability than higher degrees of myopia were.[431] A study with 10-year follow-up of patients who received LASIK for less than 10.00 D of myopia reported that 73% of eyes were within 1.00 D of the expected correction and 54.6% of eyes demonstrated an increase in BSCVA.[432] Based on data from 22 studies, the systematic review reported that a median 94% of eyes had a postoperative UCVA of 20/40 or better. Uncorrected visual acuity of 20/40 or better was achieved in 94% to 100% (median, 98%) of eyes with low to moderate myopia, and in 76% to 97% (median, 89%) of eyes with high myopia. In three studies of myopic astigmatism, 94% to 100% (median, 99%) of eyes achieved UCVA of 20/40 or better. In 25 studies that reported eyes with a loss of two or more lines of BCVA from pre-LASIK BCVA, a median rate of 0.6% (range 0%–3%) of eyes with myopia or myopic astigmatism lost two or more lines of BCVA.[317]

Laser in situ keratomileusis for hyperopia (preoperative refraction, 0.50 to 6.00 D of hyperopia) was reported to achieve within 1.00 D of the intended refraction in 86% to 91% (median, 88%) of eyes.[317] In hyperopic eyes, 94% to 100% had a postoperative UCVA of 20/40 or better. For eyes with hyperopic astigmatism, 88% to 89% (median, 88%) were within 1.00 D of the intended correction and 94% had UCVA of 20/40 or better.[317] A systematic review of LASIK found two studies of eyes with hyperopia or hyperopic astigmatism, and in these reports 2% to 5% (median, 3%) lost two or more lines of BCVA.[317]

Hyperopic LASIK (H-LASIK) has also been used successfully to treat overcorrected myopic LASIK.[433] A study[434] of H-LASIK and H-PRK reported that they were comparable in efficacy and safety for low to moderate hyperopia. However, H-PRK was associated with more postoperative pain, an initial and temporary myopic overcorrection, and delayed refractive stability than H-LASIK.

Laser in situ keratomileusis is associated with more regression in hyperopic procedures than in myopic procedures.[435-437] The mechanisms of H-LASIK regression are not clearly defined, but epithelial hyperplasia and potential biomechanical causes may be some of the etiologies. Apparent regression after refractive surgery can be due to a natural age-related

hyperopic shift, or to the emergence of residual or incompletely treated hyperopia as latent hyperopia becomes manifest.[438]

As with myopic LASIK, many of the more serious complications of H-LASIK are associated with the creation of the corneal flap. Most microkeratomes are capable of making the larger flaps needed for hyperopic corrections, but thin flaps may be more difficult to create and larger flaps can be associated with more bleeding if limbal vascularization is present.[439, 440] There is a greater rate of loss of BCVA reported following H-PRK and H-LASIK compared with myopic corrections.[317]

In one study of LASIK for mixed astigmatism, 95% of eyes were within 1.00 D of the intended postoperative refraction and 94% had postoperative UCVA of 20/40 or better.[441]

More recently, Patient-Reported Outcomes with LASIK (PROWL) studies in the FDA's LASIK Quality of Life Collaboration Project revealed that at 3 months 99% of patients in PROWL-1 (Navy personnel) and 96% of patients in PROWL-2 (general population) had binocular UCVA of 20/20 or better. One eye of the 262 military patients in PROWL-1 and no eyes of the 312 civilian patients in PROWL-2 lost two or more lines of BCVA at 3 months. No eyes had BCVA worse than 20/40 nor more than a 2.00 D increase in cylinder.[442]

Postoperative Care

Postoperative management is integral to the outcome of any surgical procedure and is the responsibility of the operating surgeon.[287] Mild to moderate discomfort can be expected in the first postoperative day. Topical antibiotics are administered, and corticosteroids are generally used for a short time postoperatively.[311] Lubrication is typically used in the postoperative period and short-term use of a protective eye shield is recommended.

In the absence of complications, a postoperative examination should be performed within 36 hours following surgery. Visual acuity should be checked and the cornea should be evaluated with slit-lamp biomicroscopy. Specific features that should be noted include the presence of epithelial irregularity or staining, epithelial ingrowth into the flap interface; interface debris; corneal edema; diffuse or focal infiltrates in the flap, bed, periphery or interface; and the presence of microstriae or macrostriae. In the presence of corneal inflammation, the anterior chamber should also be evaluated. Patients with UCVA that has not yet met preoperative BCVA should be re-examined. The frequency of follow-up visits is individualized depending on the findings at the first postoperative visit. For the routine patient following uncomplicated LASIK, the second visit should be performed 1 to 4 weeks postoperatively and thereafter as appropriate.

It is recommended that patients be provided with a record (for example, the K Card) or that the ophthalmologist maintain a record that lists information about the patient's eye condition, including preoperative keratometry readings and refraction, as well as stable postoperative refraction, so that it will be available if the patient requires cataract surgery or additional eye care. (See Appendix 8.)

Retreatments

A stable refraction is usually achieved by 3 months after surgery, but more time may be required for higher corrections. Symptomatic residual refractive error may prompt consideration of retreatment (enhancement), but it should not be considered until refractive stability has been documented by repeat measurements.[443] Before retreatment, an eye evaluation that includes all relevant elements of the preoperative evaluation should be performed. It should be determined that residual refractive error is not due to accommodation or to pathologic conditions, such as cataract or corneal ectasia. Computerized corneal topography/tomography and central corneal thickness measurement should be performed before retreatment, and post-retreatment residual stromal bed thickness should be calculated. Anterior segment optical coherence tomography may be used to measure the residual stromal bed thickness. Intraoperative central corneal thickness measurement may also be used to measure the stromal bed before repeat ablation to ensure sufficient residual stromal bed.

The options for retreatment are relifting the original flap or performing a surface ablation (PRK with or without mitomycin-C, an off-label use).[444-446] If the original flap is lifted, care should be taken to preserve epithelium of the flap and to avoid incorporating epithelium in the interface to minimize the risk of epithelial ingrowth. If PRK is performed, care should be taken during epithelial removal to minimize the risk of flap disruption. If a new flap is cut, the intersection of the surgical planes can result in displaced stromal fragments, which can result in irregular astigmatism and loss of BCVA. The recutting of flaps has therefore become less popular.

Side Effects and Complications

Laser in situ keratomileusis procedures are associated with side effects and complications that are uncommon, sometimes permanent and, on rare occasion, debilitating. These side effects and complications include the following:

◆ Symptomatic undercorrection or overcorrection[447, 448]
◆ Partial regression of effect
◆ Loss of BCVA
◆ Visual symptoms, including transient or permanent glare or starburst/halo effect, especially at night
◆ Decreased contrast sensitivity
◆ Induced regular or irregular astigmatism
◆ Induced anisometropia
◆ Premature need for reading correction
◆ Corneal haze or scarring (early or delayed onset)
◆ Worsening corneal stromal dystrophy[449-455]
◆ Corneal infiltrates, ulceration, melting, or perforation (sterile or microbial)
◆ Corneal ectasia (progressive corneal steepening)
◆ Development or exacerbation of dry eye symptoms
◆ Decreased corneal sensitivity
◆ Recurrent corneal erosion
◆ Reactivation of HSV keratitis
◆ Corticosteroid-induced complications (e.g., ocular hypertension, glaucoma, cataract)
◆ Adverse effect on ocular alignment[414]
◆ Ptosis
◆ Artifactual reduction of IOP measured by applanation tonometry[456]
◆ Interface debris
◆ Interface fluid accumulation and associated artifactual underestimation of IOP (pressure-induced stromal keratitis)
◆ Epithelial ingrowth
◆ Flap necrosis
◆ Early or late onset diffuse lamellar keratitis (DLK)
◆ Pressure-induced sterile keratitis
◆ Transient-light sensitivity associated with femtosecond laser[457, 458]
◆ Rainbow glare associated with femtosecond laser[459, 460]
◆ Persistent flap edema
◆ Striae (microstriae and macrostriae)
◆ Traumatic flap dislocation

Although there are case reports of retinal abnormalities that have been recognized following LASIK, it is unclear if the incidence is different from that in a comparable myopic population.[416, 461]

In some cases, residual refractive error might be accompanied by a reduction in BCVA, often due to induced irregular astigmatism, and caution should be exercised when considering retreatment under these circumstances. Irregular astigmatism can be caused by LASIK flaps that are irregular, fragmented, truncated, buttonholed, or avulsed. There may be an increased risk of flap striae with thinner flaps compared with thicker flaps. Excessive

flap hydration or flap-bed contour mismatch can cause microstriae, and poor alignment or postoperative flap shift can cause macrostriae. Late-onset irregular astigmatism can result from corneal ectasia.

The quality of vision under low-light conditions can be reduced after LASIK. Smaller treatment-zone sizes, especially in high refractive corrections, may be associated with an increased likelihood of visually disturbing halo formation in low-light conditions.[396, 462]

Reduced BCVA, fluctuating vision, foreign-body sensation, and discomfort can be caused by post-LASIK epitheliopathy. Multiple factors have been implicated in this problem, including aqueous tear deficiency, accelerated tear-film break-up, and neurotrophic changes. Symptoms typically improve with time, but in certain cases they may persist for months or years. Supplemental lubrication, topical cyclosporine eyedrops, and punctal occlusion may be helpful in such cases.[463, 464]

Flap Striae and Displacement. If striae are present but are not visually significant, observation is appropriate. However, if visually significant striae are present postoperatively, the flap should be refloated and repositioned. Antitorque or interrupted 10-0 nylon sutures can be considered in cases of recalcitrant striae.[465] Flap dislocation has been observed most commonly within the first 24 hours following surgery, but it can also be seen many months to years after surgery as a consequence of trauma to the cornea.[466] A recent analysis of 41,845 consecutive adults who underwent LASIK surgery found that the incidence of flap displacements during a 12-month period was low at 0.012% (10 in 81,238 eyes) and that the number of flap displacements was higher after mechanical microkeratome surgery than with femtosecond laser.[466]

Epithelial Ingrowth. Epithelial ingrowth can follow primary LASIK procedures, but it is more common following flap-lift retreatments or trauma. Although minor peripheral epithelial ingrowth can be followed without intervention, more extensive epithelial ingrowth might require lifting the flap and debriding the interface. For persistent epithelial ingrowth, suturing the flap or placing tissue glue can be considered.[467] Other indications for lifting a flap with epithelial ingrowth include increasing astigmatism, increased growth towards the entrance pupil, flap melt, decreased BCVA, irregular astigmatism, or staining at the flap edge, which indicates active epithelial cell migration.

Diffuse Lamellar Keratitis. A characteristic pattern of interface inflammation can arise following LASIK, most commonly in the first few days after surgery. The eye shows little or no conjunctival hyperemia or anterior chamber inflammation, and the patient will generally have no discomfort.[468] Diffuse lamellar keratitis is a noninfectious aggregation of inflammatory cells confined to the lamellar interface in an otherwise uninflamed eye. It is initially characterized by a fine granular reaction in the lamellar interface and is more prominent if left untreated where it can progress to the "Sands of the Sahara" state.[468] It is frequently more prominent in the periphery and does not extend anteriorly into the flap or posteriorly into the stroma. Potential triggers include, but may not be limited to, interface debris from the mechanical microkeratome blade, gloves, drapes, cleaning solutions, meibomian gland secretions, bacterial antigens, endotoxins, or epithelial disruption, as well as energy-related DLK after femtosecond laser flap creation.[469]

The treatment of DLK is commonly guided by the severity of the inflammation.[470, 471] The mildest forms of inflammation are probably self-limited and of little visual consequence. Nevertheless, most surgeons will treat such cases by increasing the frequency of topical corticosteroid administration and with closer follow-up. More severe DLK may be treated by one or more of the following: more frequent and/or higher concentrations of topical corticosteroids, the administration of systemic corticosteroids, lifting of the flap with irrigation of the interface, or direct application of corticosteroids to the exposed stromal interface. Eyes with significant central involvement, rapidly progressing DLK, or at risk of stromal tissue loss from central toxic keratopathy should be considered for flap lift and irrigation. Data are not available to make an evidence-based treatment recommendation.

Persistent DLK that is unresponsive to corticosteroids should prompt consideration of microbial keratitis or interlamellar fluid due to increased IOP (pressure-induced stromal keratitis), intraocular inflammation, or endothelial decompensation.[472] Corticosteroids may

cause an IOP response that is not detected due to artifactually low measured IOP secondary to interface or interlamellar fluid accumulation. The appearance of the cornea can mimic DLK, which may prompt prolonged treatment with corticosteroids that actually worsens the condition. In these cases, the IOP should be measured peripheral to the flap edge to obtain a more accurate IOP reading.

The long-term complications of DLK are also related to the severity of inflammation. Interface opacification, tissue loss, and epithelial ingrowth can result in refractive shifts and irregular astigmatism. For moderate to extensive DLK, the interface should be irrigated sooner rather than later to minimize stromal loss and changes in refractive correction.

Postoperative Infection. Infection following LASIK is uncommon, but it has been reported following both initial procedures and retreatments. In contrast to DLK, clinical symptoms and signs of microbial keratitis after LASIK generally include pain, redness, and photophobia. Corneal infiltrates are usually focal in nature and often extend beyond the lamellar interface into deeper or more superficial stroma. An anterior chamber reaction is frequently present. Infection can present either early or late in the postoperative period. The time of onset and clinical severity vary greatly depending on the causative organism, especially if intensive topical corticosteroids have been used. Epithelial ingrowth may be a risk factor for the development of microbial keratitis.[473-475]

Scrapings should be obtained from the involved area and submitted for microbiological investigation. If the flap interface is involved but no surface ulceration is observed, the flap should be elevated to allow access for scrapings. Intensive broad-spectrum topical antibiotic therapy should be initiated and modified as appropriate. If the infiltrate involves the interface and prompts elevation of the flap, antibiotics can be applied directly to the flap interface. Severe infection of the flap or of the deep stroma may require flap amputation to control the infection. In addition to common bacterial isolates, unusual organisms such as atypical mycobacteria, methicillin-resistant *S. aureus*, nocardia, fungi, and HSV have been reported in these cases.[476-482] The microbiology of infections associated with LASIK is different from corneal infections associated with other risk factors.

Corneal Ectasia. Although the actual incidence of progressive corneal ectasia after LASIK remains undetermined, estimates range from 0.04% to 0.60%.[483-485] This variation may be due to differences in patient selection and detection of those who are at risk. Management options for ectasia after LASIK include contact lenses, corneal cross-linking (CXL), and intrastromal corneal ring segments (ICRS). In severe cases, corneal transplantation may be required.

Several studies have shown that CXL induced by topical riboflavin and ultraviolet irradiation may arrest keratectasia, as demonstrated by preoperative and postoperative corneal topography/tomography and a reduction in maximum keratometric readings.[486] Long-term stability after CXL therapy for treatment of postrefractive corneal ectasia has been reported and recently received FDA approval.[487, 488]

Ectasia after refractive surgery can often be treated with soft toric, rigid gas-permeable, scleral, piggyback, and hybrid (gas-permeable center with soft surround) contact lenses. Specialty lenses can be helpful for these patients who may have been intolerant of contact lens before refractive surgery.[485, 489-493]

Intrastromal corneal ring segments are FDA approved for use in keratoconus and have been used off label for ectasia after LASIK.[494-498] Reported techniques vary in the size, number, and symmetry of the implants as well as the location of the incision. Long-term efficacy for this procedure remains to be determined. Intrastromal channels can be created manually or with femtosecond laser.

Corneal transplantation is also an option for treatment of post-LASIK ectasia in patients who cannot be visually rehabilitated with any of the previously described treatments.

Patient Satisfaction

Patient satisfaction depends on both patient expectations and surgical outcomes.[305] Most patients are satisfied with the results of LASIK.[499-501] A review of 309 peer-reviewed LASIK articles published between 1988 to 2008 revealed that, on average, 95% of patients were satisfied with their outcome after LASIK surgery.[502] Well-informed candidates who understand normal biologic variability, the effect of lighting conditions on visual function, and presbyopia are more likely to be pleased with the outcome of surgery. Patients generally prefer the more rapid, less painful recovery that follows LASIK when compared with PRK.[503] Questionnaires have been developed and may be helpful to assess the functional and psychological impact of refractive error and its correction.[423, 424] Subjective visual function and patient satisfaction do not always correlate with objective measurements.[425] The most frequent complaints of patients dissatisfied with refractive surgery are blurred distance and/or near vision, glare, dry eyes, and night-vision problems. In many cases, dissatisfied patients had relatively good UCVA.[421, 422] Because a subset of patients have substantial and persistent symptoms after LASIK, studies are continuing to explore patient-satisfaction issues.[306]

Most recently, the FDA-conducted PROWL studies have addressed the aforementioned concerns. Most participants were satisfied with their postoperative vision and surgery; the rates of dissatisfaction with vision ranged from 1% to 4% and the rates of dissatisfaction with surgery ranged from 1% to 2%. Overall, visual and dry eye symptoms decreased, although 43% in the PROWL-1 study and 46% in the PROWL-2 study reported new symptoms at 3 months, such as glare and halos. Of those participants who reported visual symptoms at baseline, 46% in the PROWL-1 study and 34% in the PROWL-2 study reported no visual symptoms at 3 months. Double images were the most common complaint to resolve in both studies. With respect to the significance of these visual symptoms, difficulty performing usual activities was reported by less than 1% of the participants in each study.[442]

A recent prospective multicenter survey was conducted on 1800 subjects from age 16 to 60 years to compare contact lens wear with LASIK. The subjects included the control group of 694 (39%) who continued contact lens wear, LASIK group 1 of 819 (45%) wore contacts at baseline and had LASIK, and LASIK group 2 of 287 (16%) wore eyeglasses at baseline and had LASIK for over 3 years. The study found that patients from both LASIK groups (88% and 77%) had stronger satisfaction than the control contact lens group (54%) during the 3-year survey period. The LASIK groups did not report a higher rate of night driving difficulty nor a significant increase in dry eye symptoms.[504]

Other Procedures

Intrastromal Corneal Ring Segments

The ICRS procedure involves placing plastic arcuate segments into channels created in the stroma of the midperipheral cornea. The central corneal shape is altered by the configuration of the segments and their location in the cornea. Intrastromal corneal ring segment technology has FDA approval in the United States for the correction of -1.00 to -3.00 D of spherical equivalent at the spectacle plane, with 0 to 1.00 D of astigmatism. Approval by the FDA is for the thickness of the ring segments, which, as of 2010, ranges from 210 to 450 micrometers. This narrow range of approved correction and the inability to correct astigmatism have limited the application of this technology. Its advantages are that it spares the central cornea and that the segments can be removed.[505, 506] Intrastromal corneal ring segment technology is approved by the FDA for reducing the irregular astigmatism of keratoconus.[507-509] There are reports on the use of ICRS for correcting ectasia after keratorefractive surgery.[494-498]

The implant technique of ICRS requires a partial thickness entry corneal incision followed by the application of a suction ring and the use of a stromal separator, a circular instrument designed to create an arcuate intralamellar channel for the placement of the segments. Femtosecond laser dissection can also be used to create the incisions and channels.[510]

Arcuate plastic segments of prescribed thickness are then positioned within the channels and the incision is closed.[511] Side effects and complications of the ICRS procedure include

fluctuation of vision; under- or overcorrection; induced regular or irregular astigmatism; glare; haloes; anterior or posterior corneal perforation; segment malposition, migration or extrusion; corneal melting of the overlying stroma; pain; neovascularization; microbial keratitis; and lamellar channel deposits.[309, 511] A single retrospective within-patient comparison of topography after either LASIK or ICRS insertion reported that ICRS-treated eyes showed more corneal surface irregularity than LASIK-treated eyes.[512] Intrastromal corneal ring segments are now rarely used to correct myopia.

Radial Keratotomy

Radial keratotomy uses radial paracentral corneal incisions placed outside a central optical zone to flatten central corneal curvature.[513] The amount of central corneal flattening can be controlled by variations in surgical technique (e.g., the number, depth, and length of incisions; and the diameter of the central uncut optical zone).[310] The amount of correction also varies with patient characteristics, especially age. Reoperations (enhancements) are often used to improve the refractive result.[514, 515] Potential complications include glare, starburst, fluctuation of vision, regression, progression of refractive effect with subsequent hyperopia, inadvertent cuts into the visual axis, corneal perforation into the anterior chamber, microbial keratitis, and endophthalmitis.[310] Radial keratotomy has been largely replaced with contemporary procedures.

Thermal Keratoplasty

Thermal keratoplasty is an old concept in refractive surgery that dates to the work of Lans in 1898.[516] This technique steepens the central corneal curvature by means of heat-induced shrinkage of collagen fibers in the midperiphery of the cornea. Treatment can be applied by a noncontact laser or by contact probes. The amount of change depends on a number of variables including the total amount of energy delivered, number of pulses, pulse energy, spot size, and optical zone.

Conductive keratoplasty uses a contact probe to deliver radio frequency energy by inserting the tip sequentially in multiple locations of the peripheral cornea. The energy produces shrinkage of collagen lamellae that leads to steepening of the central cornea. Surgical technique appears to be an important variable in minimizing induced astigmatism.[517] Conductive keratoplasty has FDA approval for patients aged 40 years or older for the temporary reduction of 0.75 to 3.25 D of hyperopia and treatment of presbyopia, with a spherical equivalent of 0.75 to 3.00 D and 0 to 0.75 D of astigmatism. All refractive measurements are specified as being obtained under cycloplegia. Two-year results indicated that while 43% of the effect noted at 1 month was lost, the regression rate was approximately 0.25 D per year after 1 year.[518] Disadvantages include early overcorrection, regression, and induced astigmatism. Conductive keratoplasty, itself not used much these days, has replaced noncontact holmium laser thermokeratoplasty.

Incisional Astigmatic (Transverse or Arcuate) Keratotomy

Astigmatic keratotomy (AK) procedures are those in which either transverse or arcuate incisions are made in the paracentral cornea to change its curvature to reduce or eliminate corneal astigmatism. Limbal relaxing incisions are a variant of AK in which incisions are placed just inside the vascular limbal arcade in one or both hemimeridians of steepest astigmatic power to treat low to moderate degrees of astigmatism.[519] Limbal relaxing incisions have been performed alone or combined with phakic IOLs or cataract extraction and IOL implantation to reduce preoperative corneal astigmatism and to reduce surgical astigmatism following keratoplasty.[519, 520] Astigmatic keratotomy makes use of the coupling effect: a transverse or arcuate incision in the cornea flattens the meridian in which it is made and steepens the meridian 90 degrees away.[521, 522] These incisions are usually single or paired, typically maintaining an optical zone between 6.0 and 7.0 mm. Astigmatic keratotomy using smaller optical zones has been associated with a higher incidence of adverse visual symptoms.[523] This procedure may be performed alone or in conjunction with other refractive procedures.[524] Clinical experience suggests that the effect can be modulated by the depth and length of the incision and the distance from the corneal center. Incisions

can be created with blades designed to achieve consistent depth. Femtosecond lasers have been approved by the FDA to create arcuate incisions to achieve a refractive effect.[525, 526]

Although there are numerous reports of AK performed in animal eyes, in cadaver eyes, and in patients,[527-531] there are few well-controlled prospective clinical studies available on AK, either performed alone or in conjunction with other keratorefractive procedures. A prospective evaluation of AK demonstrated that it was capable of reducing 1.00 to 6.00 D of astigmatism but with limited predictability.[523] One study retrospectively examined LASIK versus AK to treat astigmatism.[532] The vector-corrected change and visual acuity achieved by LASIK and by AK were not significantly different, except that in eyes with compound myopic astigmatism over 2.00 D, 40% of LASIK patients compared with 7% of AK patients achieved UCVA of 20/20 or better. Of note is the paucity of head-to-head comparisons in the literature on this topic. Both methods had low rates of BCVA loss.[526, 532]

Complications of AK include corneal perforation, regression or progression of effect, fluctuation of vision, incision gape or dehiscence, microbial keratitis, irregular astigmatism, and fibrous scarring.[523, 533] Incision healing problems are more common if AK and RK incisions intersect.[523]

Automated Lamellar Keratoplasty

Automated lamellar keratoplasty (ALK) was a precursor of LASIK and SMILE. In this approach, the microkeratome is used create a corneal cap or flap. The flap is then folded back, and a thin lenticule of stromal tissue below is created with the microkeratome and then removed mechanically. The thickness and diameter of this lenticule determines the change in refractive error. Automated lamellar keratoplasty had only fair predictability. Complications included irregular astigmatism, thin flaps, free or displaced caps, corneal perforation, interface opacities, microbial keratitis, and epithelial ingrowth.[534] With the advent of LASIK, ALK creation of the lenticule has been largely abandoned. However, with the availability of femtosecond laser, the principles of ALK have re-emerged in SMILE.

Epikeratoplasty (Epikeratophakia)

In epikeratoplasty, a lathed donor corneal lenticule is sutured on top of a de-epithelialized recipient cornea, which changes its anterior curvature.[535, 536] Refractive results are variable and significant complications can occur.[537] These include poor incision healing, irregular astigmatism, interface haze, lenticule necrosis, and microbial keratitis. The procedure has been largely abandoned for refractive correction.

Intraocular Refractive Surgery

Intraocular refractive surgery is the elective use of an IOL in a phakic eye, or in the case of elective refractive lens exchange, to allow use of a pseudophakic IOL, to achieve a particular refractive outcome. Refractive IOLs are used in conjunction with cataract surgery and clear lens exchange. Intraocular lenses are discussed in the Cataract in the Adult Eye PPP.[538]

Indications

Intraocular refractive surgery can be considered for patients who desire to reduce their dependence on eyeglasses or contact lens wear. Table 4 lists the phakic IOLs that have been approved by the FDA for the correction of myopia. The FDA has not approved use of a pseudophakic IOL for the sole purpose of correcting refractive error in the absence of visually significant cataract.

MedWatch (www.fda.gov/medwatch) is the Safety Information and Adverse Reporting Program for drugs and other medical products regulated by the FDA. Adverse experiences of refractive surgery should be reported to MedWatch.

TABLE 4 FDA-Approved Indications for Phakic Intraocular Lenses

Model	Company	Indications	Typical Incision Size	Anterior Chamber Depth	Endothelial Cell Count
Visian ICL (Implantable Collamer Lens, MICL12.1, MICL12.6, MICL13.2, and MICL13.7) (P030016; 12/22/05)	STAAR Surgical Co. (Monrovia, CA)	To correct from 3.00 to 15.00 D of myopia with 0 to 2.50 D of astigmatism at the spectacle plane To reduce 15.00 to 20.00 D of myopia with 0 to 2.50 D of astigmatism at the spectacle plane	3.0–3.2 mm	≥3.0 mm	Age-dependent minimum* (2000–3350 cells/mm²)
Artisan (Model 206 And 204) Phakic Intraocular Lens/Verisyse (VRSM5US and VRSM6US) Phakic Intraocular Lens (P030028; 9/10/04)	Ophtec USA, Inc. (Boca Raton, FL) Abbott Medical Optics, Inc. (Abbott Park, IL)	To correct from 5.00 to 20.00 D of myopia with 0 to 2.50 D of astigmatism at the spectacle plane	6.0 mm	≥3.2 mm	Age-dependent minimum* (1900–3875 cells/mm²)

SOURCE: U.S. Food and Drug Administration. www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm. Accessed March 15, 2017.

Adapted with permission from Huang D, Schallhorn SC, Sugar A, et al. Phakic intraocular lens implantation for the correction of myopia. Ophthalmology 2009;116:2244-58.

D = diopter

* The minimum endothelial cell density was determined by the upper 90% confidence interval of the average cell loss for eyes with a specified anterior chamber depth in the FDA-authorized clinical trials. This was based on the minimum endothelial cell density criteria as a function of age that should result in at least 1000 cells/mm² at 75 years of age.

Contraindications

Contraindications for intraocular refractive surgery are as follows:

◆ Unstable refraction
◆ Visually significant cataract in the case of phakic IOLs
◆ Shallow anterior chamber in the case of phakic IOLs
◆ Corneal endothelial disease, including Fuchs dystrophy
◆ Uncontrolled glaucoma
◆ Uncontrolled external disease
◆ Active or recently active uveitis, or uveitis that requires ongoing treatment or is recurrent in nature
◆ Uncontrolled autoimmune or other immune-mediated disease
◆ Unrealistic patient expectations

Relative Contraindications

The use of intraocular refractive surgery to correct refractive errors may not be advisable when there are pre-existing systemic or ocular conditions that may increase the relative risk of intraocular surgery, including the following:

◆ Significant eyelid, tear film, or ocular surface abnormalities related to keratoconjunctivitis sicca, blepharoconjunctivitis, acne rosacea, conjunctival cicatrization, corneal exposure, neurotrophic keratitis, or other corneal abnormalities
◆ Inflammation of the anterior segment
◆ Presence of a filtering bleb
◆ Pseudoexfoliation
◆ Functional monocularity
◆ History of uveitis
◆ Autoimmune or other immune-mediated disease
◆ Diabetes mellitus

◆ Shallow anterior chamber
◆ Pregnancy or lactation[338]

Preoperative Evaluation

A comprehensive medical eye evaluation should be performed before any refractive surgery procedure.[286] In addition to the elements listed in the comprehensive adult medical eye evaluation[176] (see Appendix 4), the intraocular refractive surgery examination includes the elements listed in Table 5.

Computerized corneal topography/tomography is important for assessing the optical state of the cornea. It is also relevant if a keratorefractive surgical procedure is necessary to optimize the refractive result after the lens surgery or for toric IOL implantation.

TABLE 5   ELEMENTS OF THE INTRAOCULAR REFRACTIVE SURGERY PREOPERATIVE EVALUATION

Element	Phakic IOL Implantation	Refractive Lens Exchange
Computerized corneal topography/tomography	Yes	Yes
Central corneal thickness measurement	Yes	Yes
Axial length	Optional*	Yes
White-to-white measurement of the limbus (or estimations of the sulcus diameter by anterior segment OCT and UBM)	Yes	Optional
Specular microscopy/confocal microscopy	Yes	Optional
Anterior chamber depth	Yes	Yes
Pupil size	Yes	Yes

* The surgeon should be prepared to implant a pseudophakic IOL in the event that there is significant damage to the lens during phakic lens implantation.

Informed Consent

The patient should be informed of the potential risks, benefits, and alternatives to and among the different refractive procedures before surgery. The informed consent process should be documented, and the patient should be given an opportunity to have all questions answered before surgery. The surgeon is responsible for ensuring the patient's informed consent.[286, 287] Elements of the discussion include the following:

◆ Range of expected refractive outcomes and possible residual refractive error
◆ Procedures for possible reduction of residual refractive error (i.e., enhancement procedures)
◆ Loss of accommodation following refractive lens exchange and the possible need for reading and/or distance correction postoperatively
◆ Corneal endothelial damage leading to corneal edema
◆ Loss of BCVA
◆ Side effects and complications (e.g., irregular pupil, microbial keratitis, endophthalmitis, intraocular inflammation, cystoid macular edema [CME])
◆ Retinal detachment (especially with myopic refractive lens exchange)
◆ Changes in visual function not measured by visual acuity testing (e.g., glare and function under low-light conditions)
◆ Night-vision symptoms (e.g., glare, haloes) developing or worsening. Careful consideration should be given to this issue for patients with high degrees of ametropia or for individuals who require a high level of visual function in low-light conditions.
◆ Monovision advantages and disadvantages (for patients of presbyopic age)
◆ Postoperative care plans (setting of care, providers of care)

Anesthesia

Intraocular refractive surgery may be performed using a variety of anesthesia techniques that include general and local (regional) anesthesia (e.g., retrobulbar, peribulbar, sub-Tenons injection, topical, and intracameral). The planned mode of anesthesia should be discussed with the patient so that she or he will know what to expect in terms of pain, discomfort, consciousness level, visual experiences, and complications.

Depending on the type of implant, topical or local (regional) anesthesia, along with sedation, is generally used. Intravenous access is generally recommended to treat potential adverse events when sedation/analgesic agents are administered.[539] Given the lack of evidence for an optimal anesthesia strategy during anterior segment intraocular surgery, the type of anesthesia management should be determined by the patient's needs and the preferences of the patient and surgeon.[540]

Issues for Decision

Intraocular refractive surgery is one of several alternatives for the correction of ametropia. Phakic IOLs allow correction of up to 20.00 D of myopia and are approved for reduction of myopia up to 20.00 D. They have optical and structural advantages compared with keratorefractive surgery at high levels of intended refractions.[541] Patients with thin corneas or atypical topography may be at increased risk of corneal complications with keratorefractive surgery. In these situations, intraocular refractive surgery may be considered as an alternative to keratorefractive surgery. Risks include those complications generally associated with intraocular surgery and must be considered carefully.

Retinal detachment following refractive lens exchange in the setting of high myopia has been described to occur in 2% to 8% of eyes, and the risk is cumulative over time.[542, 543] Phakic IOLs have not been associated with increased risk of retinal detachment compared with other intraocular interventions in highly myopic patients.[417, 544, 545] In highly myopic eyes, the relative risk of loss of BCVA was less for phakic IOLs than for refractive lens exchange in patients between the ages of 30 and 50.[546]

Phakic Intraocular Lens Implantation

Specially designed IOLs may be surgically placed in the anterior chamber, attached to the iris, or placed in the posterior chamber anterior to the crystalline lens in the phakic eye to correct refractive error.[547-552] Advantages include rapid visual recovery, stability of achieved correction, preservation of accommodation, and the ability to correct high myopic refractive errors. Potential complications include endophthalmitis, endothelial cell loss, chronic iridocyclitis, cataract formation, iris distortion, pigment dispersion, elevated IOP, glaucoma, and IOL dislocation.[553, 554] Two styles of phakic IOLs have been approved by the FDA for use in the United States and other designs are in clinical trials. (See Table 4.) Prototypes of multifocal phakic IOLs have demonstrated potential for the treatment of presbyopia.[555, 556]

Both types of phakic IOLs require a peripheral iridectomy or iridotomy to prevent pupillary block. The iridectomy may be performed either before surgery or at the time of lens insertion. Neodymium yttrium-aluminum-garnet (Nd:YAG) laser iridotomy is most frequently performed 7 to 14 days before surgery. Single or paired iridotomies, approximately 0.2 to 0.5 mm in size, are placed superiorly, with care to avoid straddling the lid margin to lessen the risk of postoperative glare and ghosting.

The IOL power is determined using standard biometry similar to IOL power calculation methods for cataract surgery. Insertion of a phakic IOL is an intraocular procedure that requires the same sterile technique and surgical setting as cataract surgery. In the case of posterior chamber phakic IOLs, adequate dilation is required. Anterior-chamber-style, iris-fixated, or angle-supported phakic IOLs are inserted with a nondilated pupil with or without the use of pharmacologic miosis. The FDA-approved iris-supported lens is held in place through a process called enclavation in which a knuckle of iris is brought anteriorly within the haptic portion of the IOL on either side. Care must be taken when dilating with either type of phakic IOL in place because of the risk of lens dislocation.[557]

Results

A Cochrane review presented a meta-analysis of three clinical trials that compared keratorefractive surgery and phakic IOL implantation for patients with myopia ranging from -6.00 to -20.00 D with up to 4.00 D of astigmatism. At 1 year, the authors found that the percentage of eyes with UCVA of 20/20 was not significantly different between the groups and that there was significantly less loss of BSCVA for the group receiving phakic IOLs.[558] This can be considered with other data on long-term safety. In a long-term study of anterior chamber iris-fixated phakic IOLs, the mean spherical equivalent after 10 years was -0.70 ± 1.00 D (range, -4.00 to +2.00 D), with no significant change in mean spherical equivalent at 1, 6, or 10 years. At 10 years, 68.8% of all eyes were within 1.00 D of the intended correction. The mean IOP remained stable and the mean endothelial cell loss was -8.90 ± 16.00% at 10 years.[559]

Higher order aberrations and contrast sensitivity changes were similar for phakic IOLs and LASIK in one study.[560] However, another study reported that eyes undergoing LASIK had three times more induced spherical aberration and two times more induced coma than phakic IOL eyes with similar preoperative corrections.[561]

Toric anterior and posterior chamber phakic IOLs have shown improved clinical results in European trials compared with spherical phakic IOLs.[562] The term "bioptics" has been used to describe the combination of a phakic or pseudophakic IOL with keratorefractive surgery for residual refractive error.[563, 564]

Postoperative Care

Postoperative management following phakic IOL implantation is similar to that for cataract surgery. (See Appendix 9.)

Side Effects and Complications

◆ Symptomatic undercorrection or overcorrection
◆ Loss of BCVA
◆ Visual aberrations, including transient or permanent glare or starburst/halo effect, especially at night
◆ Induced anisometropia
◆ Corticosteroid-induced complications (e.g., ocular hypertension, glaucoma, cataract)
◆ Adverse effect on ocular alignment
◆ Ptosis
◆ Cataract formation
◆ Endothelial cell loss
◆ Corneal decompensation
◆ Pupil ovalization
◆ Pigmentary glaucoma
◆ Acute angle-closure glaucoma
◆ Malignant glaucoma
◆ Lens dislocation with subsequent need for repositioning, exchange, or removal

Information on complications compiled from the manufacturers' submissions to the FDA is in Table 6.

TABLE 6   INCIDENCE OF COMPLICATIONS WITH PHAKIC INTRAOCULAR LENSES FROM FDA SUBMISSIONS

Model	No. of Eyes	Glare/Haloes	Hyphema	Mean Endothelial Cell Loss	Cataract	Iritis	IOP Elevation
Artisan (Model 206 and 204) Phakic Intraocular Lens/Verisyse (VRSM5US and VRSM6US) Phakic Intraocular Lens (P030028; 9/10/04)	662	18.2% at 12 months (n=472)	0.2% at 12 months	4.75% at 3 years (n=353)	Visually significant 1.1% at 36 months	0.5% at 12 months	0% at 12 months
Visian ICL (Implantable Collamer Lens) (P030016; 12/22/05)	526	3 years' glare: worse 9.7%; better 12.0%; haloes worse 11.4%; better 9.1%	0% at 36 months	Cumulative loss of 12.8% approaching stability at 5 years	Visually significant ASC 0.4%; NS 1.0% at 36 months	NR	0.4% No cases of visual field loss or nerve damage at 36 months

Adapted with permission from the American Academy of Ophthalmology Basic and Clinical Science Course Subcommittee. Basic Clinical and Science Course. Refractive Surgery: Section 13, 2013–2014. Table 8-3. San Francisco, CA: American Academy of Ophthalmology; 2012.

ASC = anterior subcapsular cataract; IOP = intraocular pressure; NR = not reported; NS = nuclear sclerosis

Cataract formation has been identified as a potential risk of phakic IOLs.[565-567] Additional factors, such as intraoperative trauma and patient age greater than 50 at the time of implantation, have been associated with an increased risk of lens opacification following posterior chamber implantation.[568] The incidence of cataract formation with posterior chamber phakic IOLs has been linked to surgeon experience.[569] Most lens opacities are observed in the early postoperative period and are thought to be due to surgical trauma.[569] Posterior chamber phakic IOLs are designed to vault over the natural crystalline lens, but peripheral contact between the posterior chamber phakic IOL and crystalline lens has been demonstrated by ultrasound biomicroscopy in 72% of cases.[570] Subtle changes in lens design can influence the incidence of cataract formation.[571] Iris-fixated phakic IOLs have been associated with a transitory increase in IOP.[572] Anterior location of the crystalline lens apex relative to the plane of the iris may predispose the eye to this complication.[573] Endothelial cell loss and pigment dispersion remain a concern for both anterior- and posterior-chamber-style phakic IOLs.[574] Long-term loss of endothelial cells has been reported for angle-, iris-, and sulcus-supported phakic IOL styles.[541] Pupil ovalization has been associated with various styles of phakic IOLs.[575-577] Slower pupil reaction and decreased resting pupil diameter have been reported following posterior chamber phakic IOL implantation.[578]

Indefinite long-term follow-up is recommended for all phakic IOL patients.

Patient Satisfaction

Subjective assessment of patient satisfaction with visual quality has been evaluated as part of the Phase III clinical trials conducted for the FDA-approval process.[579, 580] In general, a high proportion of patients rate their visual acuity as good to excellent. Rapid recovery of visual acuity with phakic IOLs was typical. Similar rates of patient satisfaction have been reported with both anterior and posterior chamber phakic IOLs.

Refractive Lens Exchange

Removal of a clear crystalline lens without visually significant cataract, with or without IOL implantation, has been performed to correct refractive errors.[581] Advantages include rapid rehabilitation and predictability of refractive outcome. Disadvantages include loss of accommodation in younger patients and the risk of complications inherent to any intraocular procedure. These include endophthalmitis, CME, and the increased risk of retinal detachment, particularly in patients with high axial myopia.[542] Since the steps of

refractive lens exchange are very similar to, if not identical to, cataract surgery, the potential postoperative complications are similar to those of standard cataract surgery.[44]

Biometry and Intraocular Lens Power Calculation

Principles guiding biometry and IOL power calculation are the same as those required in cataract surgery. (See Appendix 9 for details.)

Surgical Techniques

The surgical technique of refractive lens exchange is functionally indistinguishable from cataract surgery. The preferred method to remove the lens is extracapsular extraction by phacoemulsification.

The ideal technical elements of a successful refractive lens exchange procedure currently include the following:

◆ Capsular bag fixation of an appropriate posterior chamber IOL
◆ Minimization of trauma to the corneal endothelium, iris, and other ocular tissues
◆ A secure, watertight incision that minimizes surgically induced astigmatism or reduces pre-existing corneal astigmatism

The following are special considerations that are relevant to conditions typically encountered during refractive lens exchange:

◆ In eyes with high axial myopia, the depth and stability of the anterior chamber are abnormal during phacoemulsification.
◆ In short hyperopic eyes, there is an increased risk of choroidal effusion.
◆ In eyes with high axial length, there is an increased risk of perforation with retrobulbar injections.

Control of astigmatism is important in achieving the UCVA desired by the refractive lens exchange patient. The following means can be used to control astigmatism:

◆ Strategic placement of the corneal incisions
◆ Use of limbal relaxing incisions and AK
◆ Use of a toric IOL
◆ Secondary keratorefractive surgery

Intraocular Lenses

Posterior chamber lenses are the most frequently used implants and the implant of choice. If there is inadequate capsular or zonular support, a suture-fixated or appropriately sized anterior chamber IOL may be required.

The surgeon should have access to a variety of styles to select an appropriate IOL for an individual patient. Variations in the preoperative state of the eye, the surgical technique, patient expectations, and surgeon experience and preference affect the decision.

Multifocal, extended depth-of-focus, or accommodative IOLs may increase functional near vision when used with refractive lens exchange. Toric IOLs may be used to correct preoperative regular keratometric astigmatism.[582]

Because there is a potential compromise in quality of vision with some IOLs (e.g., multifocal compared with spheric monofocal IOLs[583]), surgeons should understand the individual patient's lifestyle and expectations so that the best IOL option can be selected.

Results

Refractive lens exchange for myopia and hyperopia has been demonstrated to be predictable and effective, with studies reporting that from 68% to 100% of eyes were within ± 1.00 D of the intended refraction,[581, 584-587] and 58% to 70% of eyes within ± 0.50 D.[584, 586, 587] Postoperative UCVA of 20/40 or better was reported in 77% to 100% of eyes.[581, 586, 587] Loss of BSCVA was reported in 0% to 10% of eyes.[584-587]

Postoperative Care

Postoperative management following refractive lens exchange is similar to that for cataract surgery. (See Appendix 9.)

Side Effects and Complications

No large-scale investigations on complications of refractive lens exchange have been reported. Complications that may result in a permanent loss of vision are rare. Major complications of lens extraction that are potentially sight threatening include infectious endophthalmitis, intraoperative suprachoroidal hemorrhage, CME, retinal detachment (see Issues for Decision section), corneal edema, and IOL dislocation.

REFRACTIVE 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.

Refractive surgery for presbyopia includes corneal inlays; IOLs with aspheric, multifocal, or accommodative design or monovision strategies; and scleral surgeries, including anterior ciliary sclerotomy, and scleral expansion bands.

Keratorefractive Surgery

At present, the most widely used surgical approach to compensate for presbyopia is excimer laser photoablation to achieve the desired refractive outcome for each patient. Similar to the approach for monovision using contact lenses, the desired refractive correction can be achieved by surface ablation (PRK, LASEK, epi-LASIK) or flap procedures (LASIK, refractive lenticule extraction) and intrastromal corneal inlays.[588, 589] Conductive keratoplasty and laser thermokeratoplasty have been used to treat presbyopia by achieving a monovision result (see Thermal Keratoplasty).[590] The best candidates for monovision are patients over 40 years old who place a high premium on maximizing their freedom from optical aids and are willing to sacrifice uncorrected distance stereoacuity to achieve this goal. Larger degrees of anisometropia produce better visual function at near, but smaller degrees of anisometropia may be better tolerated and are a viable option for some patients willing to accept a compromise.[591, 592] Distance correction is usually performed for the dominant eye and near correction is performed for the nondominant eye.[593] Evidence exists to suggest that near correction in the dominant eye may also be successful and even preferable in some patients.[593, 594] Caution should be used in considering monovision in patients who have had previous strabismus surgery, phorias, or intermittent tropias, as these patients may develop postoperative diplopia. A preoperative trial with contact lenses is a useful test to determine the desired refractive endpoint for each patient based on the intended refractive outcomes.

Patients with monovision who function well for most of their daily activities may still benefit from the use of eyeglass correction, especially in dim-light conditions while driving. Many patients with a low degree of monovision will be able to drive without difficulty. Patients with monovision correction may experience a decrease in contrast sensitivity and stereopsis compared with bilateral distance correction.[595] When the eye corrected for near vision is corrected for distance vision using eyeglasses, distance visual acuity and depth perception are optimized.

Multizone excimer photoablation to create a multifocal effect in the cornea is being investigated to treat presbyopic patients with preoperative myopia or hyperopia.[596] Excimer laser software is not approved by the FDA for multifocal ablation for presbyopia. In order to achieve a multifocal cornea, the central cornea can either be flatter or steeper than the midperipheral cornea. The ablation profile is designed to achieve either center distance/periphery near vision or center near/periphery distance vision. Early reports with small numbers of presbyopic patients who have myopia or hyperopia treated with multifocal LASIK have shown variable

results.[596, 597] Additional studies to refine ablation profiles, improve predictability, and assess the role of pupil size are ongoing.

Numerous strategies are being pursued to improve near and intermediate function in the setting of presbyopia through the implantation of corneal devices that either enhance depth of focus or establish corneal multifocality.[598] One particular device is a corneal implant of less than 4 mm with a central pinhole of less than 2 mm that creates a pinhole effect, thereby increasing depth of focus. Another approach is to create a multifocal cornea by implanting a transparent lens of appropriate curvature so that it creates focal elevation over the center of the pupil. Yet another approach to achieve multifocality is to implant a lens within the intracorneal stroma that increases the refractive index of the center of the pupil. The shape-changing inlay has been shown to enhance near and visual performance.[599]

Intraocular Surgery

Lenticular surgery using a variety of IOL implants has also been used to address presbyopia. After the crystalline lens is removed, the IOL can be used to provide functional distance vision as well as near vision through monofocal, aspheric multifocal, and accommodative IOLs. There are advantages and disadvantages to each of these modalities, and the selection of the specific IOL depends on the patient's visual needs, expectations, motivation to be less dependent on eyeglasses, and willingness to accept potential compromises.

Monofocal and extended depth of focus IOLs can be used to address presbyopia by using monovision strategies. It can be difficult, however, to assess which eye is the dominant eye in a preoperative patient who has blurred vision due to cataracts. Before cataract surgery, it is also difficult to demonstrate the proposed results of monovision IOLs using contact lenses. Patients who have demonstrated success with monovision contact lenses before the development of cataracts may be well suited for this modality.

Multifocal IOLs offer additional options to provide distance, intermediate, and near vision with less dependence on eyeglasses. Multifocal IOLs achieve their effect by dividing incoming light into two or more focal points and can be classified as refractive or diffractive. A Cochrane systematic review concluded that multifocal IOLs were effective at improving near vision when compared with monofocal IOLs, and that unaided distance visual acuity was similar in the two groups.[583] (I+, *moderate quality, strong recommendation)* Multifocal IOLs did result in reduced contrast sensitivity and an increased incidence of haloes, however.[583]

Accommodative lenses have been designed to change position in the eye with near-focusing effort. The amplitude of lens movement varies among lens designs and patients.[600] Biometric studies of IOL shift in response to accommodative effort have shown little if any lens movement with single-optic designs.[601] These lenses may offer an alternative to allow patients to see well at distance with a modest improvement in near and intermediate vision when compared with monofocal lenses. The mechanism of improved distance and intermediate vision may involve pseudoaccommodation (increased depth of focus) and possibly a small degree of lens-position shift.[602]

Scleral Surgery

In anterior ciliary sclerotomy, a series of 8 to 12 deep radial scleral incisions approximately 2.5 mm long are made posterior to the limbus in the area overlying the ciliary muscle, but stopping short of the pars plana.[603] The proposed, but highly controversial, mechanism of this procedure is the creation of additional space in the region of the ciliary body, thus increasing the distance between the ciliary body and the equatorial lens to allow greater zonular tension and to potentially allow a greater accommodative effect during ciliary muscle contraction. No peer-reviewed data exists to support the efficacy of anterior ciliary sclerotomy, and a prospective comparative study of anterior ciliary sclerotomy in one eye, using the contralateral eye as a control, showed no statistically significant increase in accommodation after surgery.[604] This procedure is not widely used because of complications, including anterior segment ischemia, regression, intraoperative anterior chamber perforation, and decreased ocular integrity.[604-607] However, the concept has been resurrected by laser biomechanical manipulation of the ciliary scleral complex.

To increase the effect of scleral expansion surgery, some researchers have proposed implanting a silicone expansion plug within the scleral incision, but no peer-reviewed data have been published to show improved results. Another approach has been the use of scleral expansion band segments. In this surgery, four PMMA segments measuring about 1.4 x 0.9 x 5.5 mm in size are inserted beneath partial-thickness scleral incisions (scleral belt loops) in each of the oblique quadrants. One prospective, multicenter trial showed a modest improvement in near vision in about half of the patients by using subjective testing methods.[608] Many investigators dispute the proposed mechanism of scleral expansion to treat presbyopia, and the results of these various surgeries have not shown predictable or consistent effects on distance-corrected near acuity or accommodative amplitude.[607, 609]

PROVIDER AND SETTING

Patients with refractive errors should be examined and evaluated for treatment by an ophthalmologist or an optometrist. Although many of the elements of the preoperative refractive surgery evaluation can be delegated to appropriately trained optometrists, it is the overall responsibility of the operating ophthalmologist to ensure that it is properly performed.[287] Only an appropriately trained ophthalmologist should perform surgical treatment of refractive errors, including excimer and femtosecond laser surgery. The operating ophthalmologist has the ultimate responsibility for the preoperative assessment and postoperative care of the patient, beginning with the determination of the need for surgery and ending with completion of the postoperative care contingent on medical stability of the patient. Postoperative care responsibilities may be ethically delegated to another nonoperating healthcare practitioner, whether as part of a co-management arrangement or as a transfer of care, under appropriate circumstances.[279, 287]

COUNSELING AND REFERRAL

Any decisions about surgical correction of a refractive error should be made by an informed patient and an ophthalmologist.[286] Information and discussion about the planned procedure should be available sufficiently in advance of the proposed surgical date so that the patient can carefully consider the risks, benefits, and alternatives to the procedure.[286, 287]

SOCIOECONOMIC CONSIDERATIONS

Global Burden of Uncorrected Refractive Error

Uncorrected refractive error is a common cause of visual impairment and blindness throughout the world. The World Health Organization estimates that 153 million people have vision worse than 20/60 due to uncorrected refractive error, with the burden of disease greatest in developing countries.[610] Globally, uncorrected refractive error accounts for 42% of persons with visual impairment worse than 20/60 and 18% of persons with vision worse than 20/400, making it the leading cause of visual impairment and second leading cause of blindness.[611] A 2016 report estimates that within the United States, up to 8.2 million people have a vision impairment due to uncorrected refractive error.[612] The global burden of refractive error increases when presbyopia is taken into account. An estimated 1.04 billion people are estimated to have presbyopia, and nearly half of these do not wear presbyopic correction.[613] Uncorrected presbyopia causes visual impairment for 410 million people worldwide, with the vast majority of cases (94%) occurring in developing countries.

Quality of Life

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.[614] 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.[501] 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.[615]

Several studies have assessed symptoms that affect quality of life following LASIK. The PROWL studies found that the prevalence of dry eye symptoms 3 months after LASIK was approximately 35% and the prevalence of visual symptoms was 50% to 60%.[442] Although both

of these estimates were improvements compared with the preoperative visit, roughly 25% of those without dry eye symptoms preoperatively reported dry eye symptoms at 3 months, and approximately 45% of patients without visual symptoms at baseline reported visual symptoms at 3 months. A prospective nonrandomized cohort study compared contact lens wearers who had LASIK with those who continued contact lens wear, and at the 3-year study visit the LASIK group was more likely to strongly recommend their correction method to a close friend or family member (88% vs. 54%), to have no difficulty driving at night (60% vs. 40%), and to have no symptoms of dry eye (50% vs. 29%).[504] Furthermore, this study found a similarly low proportion who had felt depressed in the previous 2 weeks in each group (7% in the LASIK group vs. 6% in the contact lens group).

Vision-related quality of life has been assessed after treatment for refractive error.[616-619] Various quality-of-life instruments have been used, including several designed specifically for refractive error: the Refractive Status and Vision Profile (RSVP), the National Eye Institute Refractive Quality of Life (NEI-RQL), and the Quality of Life Impact of Refractive Correction (QIRC).[567,572,573] In nonrandomized studies, contact lens wearers had a higher vision-related quality of life than eyeglass wearers[620] and LASIK patients had quality of life scores closer to emmetropes than did eyeglass- or contact lens-wearers.[621] A randomized study found no significant difference in quality of life related to refractive error when comparing astigmatic patients undergoing toric IOL implantation with aspherical IOL implantation.[622] A systematic review estimated satisfaction among 95% of patients who underwent LASIK.[502] It is important to point out that persons willing to pay for refractive surgery are likely a biased group, with several studies showing that preoperative vision-related quality of life scores in patients having refractive surgery are lower than in patients with equivalent refractive error who wear eyeglasses or contact lenses.[619, 623]

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.[624] Worldwide, the burden of uncorrected refractive error has substantial economic repercussions, with conservative analyses estimating a societal cost of $121.4 billion in lost productivity.[172] According to these analyses, a net economic gain would result from treatment of uncorrected refractive error if eyeglasses could be provided to each affected individual for less than $1000. At the individual level, several cost-effectiveness studies have compared refractive surgery with contact lenses. Although the results depend on the assumptions used in the models, these studies have generally found that refractive surgery has higher up-front costs compared with contact lenses but becomes more cost-effective in the long term.[625, 626] The long-term cost savings for refractive surgery results from fewer doctors' appointments and fewer prescriptions for contact lenses or eyeglasses. Similarly, toric IOLs were shown to be more cost-effective than conventional IOLs, mostly because toric lenses reduced long-term costs of postoperative contact lenses or eyeglasses.[627] More research on the cost-effectiveness of various treatments for refractive error would be helpful for insurers as well as for clinicians counseling their patients on services not covered by health insurance.

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.

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	H52.0–
Myopia (axial) (congenital)	H52.1–
Astigmatism, regular	H52.22–
Astigmatism, irregular	H52.21–
Astigmatism, postkeratoplasty	T86.848
Astigmatism, postoperative, surgically induced	T88.8–
Presbyopia	H52.4
Specified NEC	H52.6

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. EPIDEMIOLOGY OF REFRACTIVE ERRORS

Over half of Americans over the age of 40 have ametropia of sufficient magnitude to require refractive correction.[47] It has been estimated that 93 million Americans aged 12 years and older use some form of eyewear to correct refractive errors in distance.[48] About 41 million people in the United States used contact lenses in 2005.[49] It has been estimated that over 8.5 million people in the United States have undergone refractive surgery since 1995[51] and it is estimated that over 13 million LASIK procedures have been performed in the United States.[52]

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.[628] A meta-analysis of population-based studies found a prevalence of 25% in persons over age 40.[56] 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.[47] A number of population-based studies have shown that the prevalence of myopia is lower in older than in younger persons, 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.[57-59] Individuals who develop nuclear sclerosis, however, tend to undergo a myopic shift over time.[60-62]

MYOPIA

Studies of ethnic Chinese in Taiwan documented an increase in the prevalence and severity of myopia over two generations.[115-118] Genetics alone are unlikely to account for such a rapid change. One study has speculated that genetic factors do not preclude such a change.[119] A study of successive cohorts of enlistees in the Israeli army showed a marked increase in prevalence of myopia over a 13-year period.[120] A study in Finland showed that the prevalence of myopia doubled among teenagers and young adults over the course of the 20th century.[121] 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.[122] Several additional studies have reported that the prevalence of myopia is increasing.[88, 123, 124] In one report from East Asia, the prevalence of myopia was found to be rapidly increasing (now 80%–90%) in school-aged children.[125]

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.[47] 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%.[56, 629] A similar pattern was reported in Australia[126, 630] and in populations of African descent in Baltimore and Barbados.[58, 631] The prevalence of myopia in Chinese Americans aged 50 years and older has been estimated at 35.1% (at least 0.5 D of myopia), and high myopia (at least 5 D of myopia) was found in 7.4%.[632] 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);[633] in Indonesia, the prevalence was 26%;[634] in Beijing, the prevalence was 23% (40 years and older).[635] In Chinese people aged 30 years and older, the prevalence was 26.7%,[636] and the prevalence was 9.5% in persons living in southern China aged 50 years and older.[637] A study of Japanese persons aged 40 years and older found a prevalence of myopia (0.50 D or more) of 41.8%.[638] 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 students[639] to 85% in 19- to 23-year-old medical students in Singapore,[640] to 30.7% in persons of Malay ethnicity aged 40 to 80 years.[641] Studies in South Asian countries found prevalences of 13% for persons aged 30 or older living in rural India,[642] 37% for persons living in Andhra Pradesh state (India),[643] and 36% for persons aged 30 and older in Pakistan.[644]

The prevalence of myopia in American children aged 12 to 17 was estimated to be approximately 25% in the early 1970s.[628] In one study, myopia (0.75 D or more) was found in 9% of children aged 5 to 17 years.[53] 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%.[54] For African American children it was 6.6% and for Hispanic children it was 3.7%.[55] 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 8- to 10-year-olds, and 14% among 11- to 12-year-olds.[134] 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.[115] 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;[645] 10% to 34% in Malaysia;[646] 5% to 17% in southern China;[647] 7% in New Delhi;[648] and 9% to 40% in Malaysia and Singapore.[649] 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).[83, 116, 650, 651] A survey in Nigeria found that the prevalence of myopia in persons aged 40 years or older was 16.2%.[652]

HYPEROPIA

Less is known about the epidemiology of hyperopia and astigmatism than about myopia. 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.[57, 58, 126] A meta-analysis of population-based studies found the prevalence of hyperopia was 10% in the United States and increased with increasing age.[56] 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.[47] A similar pattern of higher prevalence of hyperopia in older ages was observed in a U.S. population-based study.[47] In a population of rural Chinese persons aged 50 and older, the prevalence of hyperopia was 8.9%[637] and in another rural Chinese population aged 30 and older, the prevalence was 15.9%.[636] A similar prevalence and association with age were seen among African Americans in Baltimore.[58] In Australian children aged 6 years and 12 years, the prevalence of hyperopia was 13.2% and 5.0%, respectively.[653] 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.[654] 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.[60] A study in Salisbury, Maryland, also found that nuclear sclerosis was associated with myopia,[655] consistent with a report from a Latino population.[62] In contrast to myopia, hyperopia was associated with fewer years of formal education in the same populations.[57, 58] African American men in Baltimore, Maryland, had half the prevalence of hyperopia that women had[58] and female Mexican American participants in the Proyecto Ver study were more likely than their male counterparts to have hyperopia,[56] but this gender difference was not observed among individuals of European descent.[56-58] A study of persons aged 30 or older in rural India found a prevalence of hyperopia (0.50 D or more) of 18%[642] and a study of persons of similar age in Pakistan found a prevalence of 27%.[644] A study of persons of Malay ethnicity in Singapore, aged 40 to 80, found a prevalence of hyperopia of 27%.[641] In Japanese persons aged 40 and older the prevalence of hyperopia was 28%.[638] 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%.[54] In Chinese kindergartners, the prevalence of hyperopia greater than 2.0 D was 14.3%.[656] In adult populations, the prevalence of hyperopia greater than 0.5 D ranged from 31.5% in Singapore[657] to 31.8% in Germany,[658] and 41.8% in Korea.[659] For hyperopia of 1.0 D or less, prevalence was reported as 25.2% in Europeans aged 25 to 90 years[660] and 22.1% in Latinos 40 years and older in the United States.[661]

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.[127] Kleinstein et al[53] 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%.[662] 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,[645] to 7% in New Delhi,[648] to 6% in Chinese children.[146] The prevalence of high astigmatism in Native American children was reported as 23% to 29% in those aged 2 to 7 years.[663] In Taiwanese preschoolers, the prevalence of astigmatism was 13.3%.[664] One or more diopters of astigmatism is common among older adults (31% in persons aged 40 and older) and the prevalence is higher in older-age groups.[47, 58] This increase with age was also seen among African Americans, although the prevalence was about 30% lower than among Caucasians at every age.[58] 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.[47, 58] Astigmatism was found in 7.6% of Chinese subjects aged 50 and older[637] and in 24.5% of subjects aged 30 and older.[636] A study of persons of Malay ethnicity aged 40 to 80 living in Singapore reported a prevalence of astigmatism of 33%.[641] In Japanese persons aged 40 and older the prevalence of astigmatism was 54%.[638] A study of persons aged 30 and older in Pakistan found a prevalence of astigmatism of 37%.[644] There have been conflicting data about the association of astigmatism with prematurity or low birth weight and with retinopathy of prematurity.[128-131]

These studies cannot be directly compared because the definitions of myopia, hyperopia, and astigmatism.

HYPEROPIA

Less is known about the epidemiology of hyperopia and astigmatism than about myopia. In a population of rural Chinese persons aged 50 and older, the prevalence of hyperopia was 8.9%[637] and in another rural Chinese population aged 30 and older, the prevalence was 15.9%.[636] In Australian children aged 6 years and 12 years, the prevalence of hyperopia was 13.2% and 5.0%, respectively.[653] 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.[654] 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.[60] A study in Salisbury, Maryland, also found that nuclear sclerosis was associated with myopia,[655] consistent with a report from a Latino population.[62]

African American men in Baltimore, Maryland, had half the prevalence of hyperopia that women had[58] and female Mexican American participants in the Proyecto Ver study were more likely than their male counterparts to have hyperopia,[56] but this gender difference was not observed among individuals of European descent.[56-58] A study of persons aged 30 or older in rural India found a prevalence of hyperopia (0.50 D or more) of 18% [642] and a study of persons of similar age in Pakistan found a prevalence of 27%.[644] A study of persons of Malay ethnicity in Singapore, aged 40 to 80, found a prevalence of hyperopia of 27%.[641] In Japanese persons aged 40 and older the prevalence of hyperopia was 28%.[638] 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%.[54] In Chinese kindergartners, the prevalence of hyperopia greater than 2.0 D was 14.3%.[656] In adult populations, the prevalence of hyperopia greater than 0.5 D ranged from 31.5% in Singapore[657] to 31.8% in Germany,[658] and 41.8% in Korea.[659] For hyperopia of 1.0 D or less, prevalence was reported as 25.2% in Europeans aged 25 to 90 years[660] and 22.1% in Latinos 40 years and older in the United States.[661]

ASTIGMATISM

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These studies cannot be directly compared because the definitions of myopia, hyperopia, and astigmatism vary.

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

A comprehensive medical eye evaluation includes a history, examination, diagnosis, and initiation of management. [176] 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)
◆ 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, with a 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, version and duction assessment)
◆ 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
◆ Schirmer testing and ocular surface dye staining
◆ Corneal sensation
◆ Gonioscopy
◆ Functional evaluation of the nasolacrimal tear drainage system
◆ Extended 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 (pachymetry, corneal tomography)
◆ Corneal endothelial cell analysis
◆ External, slit-lamp, or fundus photography
◆ Anterior and posterior segment imaging (e.g., optical coherence tomography, anterior segment optical coherence tomography, ocular photography, high-frequency ultrasonography, or confocal microscopy)
◆ 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
◆ Fluorescein or indocyanine green 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. PREVENTION OF MYOPIA PROGRESSION

Most myopic refractive errors develop and progress during childhood and adolescence.[139] Slowing progression of myopia has a considerable public health impact, and thus the field of myopia control has been born in the recent years. Treatments proposed to prevent or reduce the progression of myopia (i.e., myopia control) include optical correction, use of antimuscarinic eyedrops, contact lenses, and other approaches. A Cochrane review assessed the effects of several types of interventions (eye drops, undercorrection of nearsightedness, multifocal eyeglasses, and contact lenses) 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, they are not commercially available, and they have a lesser effect than multifocal eyeglasses.[45] 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 outside time that is the controlling factor.[113, 665]

A multifocal soft lens has been found to slow myopia progression in Hong Kong Chinese schoolchildren.[190]

OPTICAL CORRECTION OF REFRACTIVE ERROR

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.[666] Furthermore, undercorrection of human myopia is myopigenic.[667]

In a study, bifocal eyeglasses were found to slow myopia progression in children to an annual progression rate of at least 0.50 D after 3 years.[668]

Further randomized controlled clinical trials have compared the use of bifocal eyeglasses (with add powers ranging from +1.00 D to +2.00 D) with single-vision distance eyeglasses in myopic children, and have failed to demonstrate any significant differences in myopic progression.[137, 139, 669, 670] One 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.[671] Among the children completing the 30 months of follow-up, myopia progression was statistically significantly lower for bifocals than for single-vision eyeglasses (1.00 to 1.24 D).[671] In a study comparing the use of multifocal eyeglasses to single-vision distance eyeglasses in myopic children, there was no statistically significant difference in the rate of myopia progression.[145] One 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.[672] The authors concluded that the small magnitude of the effect does not warrant a change in clinical practice. Another study of 138 Hong Kong children ages 7 to 10.5 years found no evidence of retardation of myopia progression by wearing progressive addition lenses after 2 years.[673] Thus, with the exception of one small trial, optical correction has not been shown to prevent progression of myopia.[137, 139, 669, 670]

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.[674-676]

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.[144, 145, 677, 678] 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.[183, 184] A more significant myopic rebound was noted after 0.5% atropine treatment cessation compared with 0.01%.[187]

There is emerging evidence from Hong Kong, Australia, and Spain that there is a role for orthokeratology in the control of myopia,[185, 679] with reduction of peripheral hyperopic defocus as the likely mechanism.[680] Whether these results will apply to broader populations remains to be proven. The risk of microbial keratitis must be considered. Soft contact lenses with multifocal or aspheric features might reduce axial elongation via a similar mechanism. As of yet, there is no contact lens that is FDA approved for myopia control. The safest way to incorporate contact lens into clinical practice for reduction of axial elongation in young children remains to be determined.

It has also been shown that atropine eyedrops are effective in populations in the West where children generally have less rapid rates of progression of myopia than in Taiwan.[184, 681-683] 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% eyedrops over a 5-year period.[184] It is now also known that the beneficial effects remain once the use of atropine is discontinued.[683] 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 the effect on 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 recordings of multifocal electroretinograms in children.[684] Other potential disadvantages include the possible need for bifocal or multifocal eyeglasses (depending on the concentration of atropine administered), photosensitivity and glare, and the inconvenience of using daily eyedrops.

Cyclopentolate 1% administered nightly was evaluated in one study in school children in Taiwan. It was found to slow the rate of progression of myopia compared with controls (mean myopic progression of –0.60 D/year compared with –0.90 D/year, which is statistically significant), but not as much as atropine did (mean myopic progression of –0.20 D/year).[677] Tropicamide 1% was evaluated in a study of monozygotic twins, and no significant difference in progression of myopia was noted compared with controls.[685]

Pirenzepine hydrochloride has been evaluated in two multicenter, double-masked, placebo-controlled parallel studies to slow the progression of myopia in school-aged children. Unlike atropine, which affects both accommodation and mydriasis, pirenzepine has a relatively selective effect on accommodation. The U.S. study examined 174 children ages 8 to 12 years,[686] and the Asian study examined 353 children ages 6 to 13 years.[687] Both studies found 2% pirenzepine ophthalmic gel effective and relatively safe in slowing myopia progression over a 1-year treatment period.

A network meta-analysis based on 30 randomized controlled trials involving 5422 eyes, compared the efficacy of 16 interventions for myopia control in children, and concluded muscarinic antagonists, such as atropine and pirenzepine, were the most effective in reducing myopia progression, followed by specially designed contact lenses.[46]

CONTACT LENSES

Soft contact lens wear was evaluated in a randomized clinical trial in the United States.[688] 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 positive spherical aberration were compared with the spherical design and were found to slow axial growth in children following 1 to 2 years of treatment; however, spherical equivalent cycloplegic autorefraction was not significantly affected in concordance.[186]

It has long been postulated that rigid contact lens wear could slow the progression of myopia in children.[689, 690] Previous studies published were limited by methodological difficulties.[691-696] A 2-year randomized clinical trial evaluating the effect of rigid contact lenses on myopia progression in school children was conducted in Singapore,[697] and another study concurrently in the United States.[698] The study of 428 Singaporean children ages 6 to 12 years found that rigid gas-permeable contact lenses did not slow the rate of myopia progression over 2 years, even among children who used them regularly and consistently.[697] The U.S. study compared the effects of rigid gas-permeable contact lenses and soft contact lenses on myopia progression in 116 children ages 8 to 11 years. They found that rigid contact lens wearers experienced less myopia progression than soft contact lens wearers, and that the corneal curvature of the soft lens group steepened more than the rigid lens group, but the axial growth was not statistically significantly different between the groups. Because some of the effect was likely influenced by transient corneal curvature changes, the authors concluded that the results indicate that rigid gas-permeable contact lenses should not be prescribed primarily for myopia control.[699]

Although it has been suggested that orthokeratology can slow the progression of myopia in children, there is no randomized controlled trial evidence to support this.[697, 700] A 2-year pilot study was conducted to determine whether orthokeratology can effectively reduce and control myopia in children. Thirty-five Hong Kong children ages 7 to 12 years undergoing orthokeratology treatment were compared with 35 children wearing single-vision eyeglasses from an earlier study (control). The study found a statistically significant change in axial length for the orthokeratology group and the control group (0.29 ± 0.27 mm and 0.54 ± 0.27 mm, respectively). However, there are substantial variations in changes in eye length among children and there is no way to predict the effect for individual subjects.[700] Another orthokeratology myopia progression study (SMART, Stabilizing Myopia by Accelerating Reshaping Technique) enrolled 172 subjects to study progression of myopia in children ages 8 to 14 wearing soft silicone hydrogel contact lenses compared with corneal reshaping contact lenses.[701] This multicenter longitudinal study over a 3-year period showed that myopia progressed at a significantly less degree in subjects wearing corneal reshaping contact lenses. In this study, the efficacy, safety, and dropout rate of subjects were comparable in the two groups. The effect that overnight orthokeratology lens wear has on axial length growth was found comparable to that of gas permeable lenses in a prospective randomized study of 26 myopic East Asian children.[185]

A meta-analysis of nine clinical trials comparing the effects of multifocal and single-vision contact lenses in school-aged children found that multifocal contact lenses with powers ranging from +1.50 to +2.00 D were associated with a significant decrease in myopia progression compared with single-vision contact lenses.[702] (I-, *moderate quality, strong recommendation*)

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 administration of 0.25% timolol maleate with the use of single-vision eyeglasses failed to show any retardation of progression of myopia.[669, 703] Therefore, this treatment is not recommended.

Visual Training

Visual training purported to reduce myopia includes exercises such as near-far focusing change activities.[704-706] There are no scientifically acceptable studies that document that these treatments are clinically effective, and, therefore, this therapy is not recommended.[704, 707, 708]

Acupressure and Nutrition

In a Cochrane review, acupuncture was studied for slowing the progression of myopia in children. However, no conclusions could be drawn for the benefit of co-acupressure for slowing progress of myopia in children.[709] (II++, *moderate quality, strong recommendation*)

Information about the effects of nutritional changes on the progression of myopia is largely anecdotal and no scientifically valid studies are available.

APPENDIX 6. 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 like 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 PPP[142]).

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.[710] 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.[711]

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.[711] 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:

- 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 7. 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.[712] 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.

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 >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 of Wear (also called 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 wear is defined as less than 24 hours of continuous wear. Extended wear is defined as under closed eyelids, but to the lay person, 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 for 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.[8] Reports from the United Kingdom[11] and Australia[4] in 2008 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. *(strong recommendation)* 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.[250] 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.[25, 28, 37] 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,[14, 30, 251, 257] and damaged or cracked cases should be discarded.

The American Academy of Ophthalmology (www.aao.org/store) and the Contact Lens Association of Ophthalmologists ((www.clao.org/publications) have patient information brochures for contact lens care. Also, the FDA and CDC have issued recommendations.[250, 251]

Daily-Wear Soft Contact Lenses

Daily disposable soft contact lenses should not be worn longer than manufacturers' recommendations, nor should they be reused. At the time of removal of all other daily-wear soft contact lenses, a contact lens cleaner or multipurpose solution should be used daily 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.[21, 28, 37] 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.[713] Hydrogen peroxide systems may be superior to preserved disinfecting solutions in reducing pathogen binding and cysticidal disinfection, but they require more complex care regimens.[38]

Periodic enzymatic cleaning may be useful for some patients. Manufacturers' recommendations for contact lens care and replacement should be followed.

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.[7, 714] Disposable contact lenses for extended

wear should also be discarded on a regular basis consistent with manufacturers' recommendations or the specific instructions of their eye care professional. 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; 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.[248, 281] Cases for soft 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.[715]

Specialized Uses of Contact Lenses

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

APPENDIX 8. THE K CARD

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Information

Patient name: _____

Date of surgery or retreatment: _____

Refractive surgeon name: _____

Surgeon phone: _____

Date of pre-operative readings: _____

Right eye pre-operative refraction: _____ sphere _____ cylinder _____ axis

at vertex distance _____ mm

Left eye pre-operative refraction: _____ sphere _____ cylinder _____ axis

at vertex distance _____ mm

Right eye pre-operative keratometry: _____ (D)K1 _____ (D)K2

Left eye pre-operative keratometry: _____ (D)K1 _____ (D)K2

Intended refractive correction: _____ right eye _____ left eye

Right eye post-operative refraction: _____ sphere _____ cylinder _____ axis

Left eye post-operative refraction: _____ sphere _____ cylinder _____ axis

A fillable PDF form for downloading is available at http://isrs.aao.org/resources.

APPENDIX 9. CATARACT IN THE ADULT EYE PPP[538] EXCERPT

BIOMETRY AND INTRAOCULAR LENS POWER CALCULATION

Accurate measurement of axial length and central corneal power, combined with an appropriate IOL selection based on a power calculation formula, is the minimal requirement to achieve the targeted postoperative refraction. *(III, good quality, strong recommendation)* A-scan ultrasonography or optical biometry is used to measure axial length. A-scan ultrasonography is performed using either an applanation or immersion technique. In A-scan ultrasonography by applanation, the ultrasound probe compresses the cornea by variable amounts and there is both a variable and artificial shortening of axial length; the accuracy and overall consistency of this method are highly dependent on the skill and experience of the operator.[716-718] When the immersion technique is used, the ultrasound probe does not come in direct contact with the cornea, making the measurements more consistent and accurate.

Optical biometry is a high-resolution noncontact method for measuring axial length that uses partial coherence interferometry rather than ultrasound. It is significantly more accurate and consistent than contact (applanation) A-scan biometry.[716, 719, 720] Optical biometry was initially considered comparable to immersion A-scan biometry, but it has since been shown to produce improved refractive outcomes. The patient's spherical equivalent is also more likely to be closer to the target refraction.[721-723] Optical biometry has also been shown to give user-independent results.[724] Other advantages over A-scan ultrasonography include ease and speed of automated operation and the ability to measure to the center of the macula when proper fixation is achieved. A shortcoming of optical biometry is that currently it assigns a global refractive index to the entire eye rather than adjusting it according to the specific optical elements (e.g., cornea, aqueous humor, lens, and vitreous humor) through which light passes. In a highly myopic eye measured using an optical biometer, the axial length of the vitreous gel relative to the other structures results in an overestimation of the true axial length, causing an underestimation of IOL power with standard formulas. To compensate for this effect, approaches such as the Wang-Koch adjustment can be applied for eyes longer than 25 mm.[725] The Wang-Koch adjustment is unreliable in conjunction with the Barrett Universal II formula, or with any of the many specialized formulas, when used to calculate IOL power in eyes with a history of keratorefractive surgery.

Because optical biometry measures the refractive axial length rather than the anatomical axial length, this method is more accurate than standard forms of ultrasound A-scan biometry when the fovea is located on the sloping wall of a posterior staphyloma.[726] Additionally, it is easier to use optical biometry than ultrasound when the patient has silicone oil in the posterior segment. [727, 728] Despite recent advances in optical biometry that allow the measurement of axial length through increasingly dense cataracts,[729] A-scan biometry may be necessary to measure the axial length in certain cataracts or when patients are unable to fixate properly.[730, 731] The measurement and comparison of axial length for both eyes is advisable, even if surgery is not planned for the other eye.

Formulas for calculating IOL power rely on keratometry to determine the net refractive contribution of the cornea. These measurements can be obtained by either manual or automated keratometry, or by corneal topography. Following keratorefractive surgery, the determination of true central corneal power is particularly challenging (see Cataract Surgery Following Refractive Surgery section). All devices that measure corneal power by standard methods are unable to accurately determine the total central corneal power following keratorefractive surgery to correct myopia because the posterior curvature may be unaltered. The use of standard keratometry in this setting without a compensatory adjustment will typically result in an unanticipated under- or overcorrection.

Recent-generation theoretical IOL-power calculation formulas such as Hoffer Q, Holladay, and SRK/T should be used in the IOL-selection process.[732-737] Some newer generation formulas, such as Haigis, Holladay 2, Olsen, and Barrett Universal II incorporate additional measurements such as anterior chamber depth, lens thickness, and horizontal corneal diameter in an attempt to predict more accurately the effective lens position of the IOL to be implanted.[738-740] Theoretical formulas rely on numerical constants that allow the formula to predict the effective lens position within the eye. The Haigis formula uses three separate constants that are highly specific to the individual characteristics of a specific IOL model across its power range. Although the IOL manufacturer supplies lens constants to be used with calculation formulas, these numbers are generally considered to be only a

recommendation and may not correspond to the biometry method being used. Optimization of lens constants for a specific IOL based on an individual surgeon's actual refractive outcome is recommended.

The surgeon should consider the patient's individual desires and needs in selecting an appropriate postoperative refractive target. *(III, good quality, strong recommendation)* Several extended-range high-plus and high-minus IOL powers are available. Patients with high myopia, where very low-power IOLs straddle both sides of plano, may require unique lens constants for plus and minus powers that are quite different than those recommended by the manufacturer.[741, 742] For the patient with extreme hyperopia requiring an IOL power in excess of the available range, piggybacking two posterior chamber IOLs has been used.[743] When this is indicated, it is preferable to use lens optics of different materials in different locations rather than inserting both IOLs inside the capsular bag. This reduces the risk of interlenticular (between the IOLs) membrane formation.[744, 745] If implantation of a sulcus piggyback IOL can be delayed until the in-the-bag lens has a stable anterior chamber depth, it may improve refractive accuracy and reduce the incidence of interlenticular opacification. Intraocular lens power calculations for piggybacked IOLs as a primary procedure may be less accurate than for a single IOL because it is difficult to predict the combined effective IOL position.[746] Refractive results with piggybacking IOLs have been favorable in two small case series.[747, 748] Sulcus piggyback implantation in the setting of zonular laxity may result in an unexpected hyperopic refractive result if the piggyback lens pushes the lens within the capsular bag posteriorly, thus reducing its effective power.

A corneal relaxing incision can correct small amounts of astigmatism, but for 1.0 diopter (D) or more of preoperative corneal astigmatism, toric IOL implantation should be considered.[749-751] Most toric lenses are designed for implantation within the capsular bag. Many company-specific online and machine-based calculators are available to calculate the power of the toric component of the optic. They require the input of preoperative keratometry values and the anticipated surgically induced astigmatism. Adding the contribution of the posterior cornea has been shown to improve outcome accuracy.[752-754] The final resting location of the IOL within the eye influences the effective power of the toric component of the optic, just as it does for a purely spherical lens.[755] Online formulas that calculate the effective lens position of a toric IOL require the user to input the axial length of an eye in addition to keratometry values and surgically induced astigmatism. The spherical power of a toric IOL is calculated in the usual manner.

Most modern IOLs have aspheric optics. These lenses improve mesopic and scotopic contrast sensitivity and visual quality by reducing depth of focus caused by spherical aberration.[756-760] Some surgeons match the asphericity of the IOL to be implanted to the asphericity of the cornea to maximize visual quality under dilated-pupil conditions.[761]

Intraocular lens power can be confirmed or refined intraoperatively in the aphakic and pseudophakic states through the use of intraoperative aberrometry.[762] These devices can be used to assist with axis alignment of a toric IOL as well.[763] Intraoperative aberrometry can be especially useful in eyes with a history of keratorefractive surgery, such as PRK and LASIK, although it is not as useful following radial keratotomy.[764]

POSTOPERATIVE MANAGEMENT

The operating ophthalmologist has the ultimate responsibility for the preoperative assessment and postoperative care of the patient, beginning with the determination of the need for surgery and ending with completion of the postoperative care contingent on medical stability of the patient.[285] The ophthalmologist who performs the cataract surgery has a unique perspective and thorough understanding of the patient's intraoperative course, postoperative condition, and response to surgery. The postoperative period is the time in which most complications occur and within which stable visual function is achieved. The operating ophthalmologist has an ethical obligation to the patient that continues until postoperative rehabilitation is complete.

The operating ophthalmologist should also provide those aspects of postoperative eye care that are within the unique competence of the ophthalmologist. *(III, good quality, strong recommendation)* These do not necessarily include those aspects of postoperative care permitted by law to be performed by auxiliaries. If such follow-up care is not possible, the operating ophthalmologist must make arrangements before surgery to refer the patient to another ophthalmologist for postoperative care with the prior approval of the patient and the ophthalmologist.[287, 765] Comanagement is a relationship

between an operating ophthalmologist and a nonoperating practitioner for shared responsibility in the postoperative care when the patient consents in writing to multiple providers, the services being performed are within the providers' respective scope of practice, and there is written agreement between the providers to share patient care. Transfer of care occurs when there is transfer of responsibility for a patient's care from one qualified health care provider operating within his or her scope of practice to another who also operates within his or her scope of practice.

The ophthalmologist who performs surgery has an obligation to inform patients about appropriate signs and symptoms of possible complications, eye protection, activities, medications, required visits, and details for access to emergency care. *(III, good quality, strong recommendation)* The ophthalmologist should also inform patients of their responsibility to follow advice and instructions provided during the postoperative phase and to notify the ophthalmologist promptly if problems occur. *(III, good quality, strong recommendation)* Patients should always have access to an ophthalmologist for appropriate care if serious problems arise. *(III, good quality, strong recommendation)*

Most ophthalmologists provide all postoperative care in their offices. Other members of a team of eye care professionals may also participate in the comanagement of postoperative care. The operating ophthalmologist is responsible to the patient for those aspects of postoperative care delegated to other eye care professionals.[287] Economic considerations should never influence the decision to comanage or the timing of a patient's transfer of care after surgery; such quid pro quo arrangements are unethical and often illegal.[285] Any delegation of a surgeon's postoperative responsibilities to another nonoperating practitioner and any payments to either party should be completely transparent to the patient and only done after obtaining the patient's informed consent in writing. Routine comanagement or transfer of care-referral arrangements are not appropriate. Instead, comanagement and transfer of care arrangements should be conducted pursuant to written patient-specific protocols. (See the Comprehensive Guidelines for the Co-Management of Ophthalmic Postoperative Care for detailed information.[285])

Postoperative regimens of topically applied antibiotics, corticosteroids, NSAIDs, and oral analgesic agents vary among practitioners.[353] There are no controlled investigations that establish optimal regimens for the use of topical agents. Therefore, it is the decision of the operating surgeon to use any or all of these products singly or in combination. Complications of postoperative medications include elevated IOP with corticosteroids and allergic reactions to antibiotics. Significant corneal reactions, including epithelial defects and stromal ulceration and melting, have rarely been reported for topical ocular NSAIDs.[766-768]

Postoperative Follow-up

The frequency of postoperative examinations is based on the goal of optimizing the outcome of surgery and swiftly recognizing and managing complications. This requires prompt and accurate diagnosis and treatment of complications of surgery, providing satisfactory optical correction, educating and supporting the patient, and reviewing postoperative instructions. Table A9 provides guidelines for follow-up based on consensus in the absence of evidence for optimal follow-up schedules. Prospective studies from the United Kingdom have reported that omitting an examination on the day after uncomplicated cataract surgery for the routine patient was associated with a low frequency of serious ocular complications.[769-772]

TABLE A9   POSTOPERATIVE FOLLOW-UP SCHEDULE

Patient Characteristics	First Visit	Subsequent Visits
Without high risks or signs or symptoms of possible complications following small-incision cataract surgery	Within 48 hours of surgery	Frequency and timing dependent upon refraction, visual function, and medical condition of the eye
Functionally monocular; intraoperative complications; high risk of immediate postoperative complications, such as IOP spike	Within 24 hours of surgery	More frequent follow-up usually necessary

IOP = intraocular pressure

Patients should be instructed to contact the ophthalmologist promptly if they experience symptoms such as a significant reduction in vision, increasing pain, progressive redness, or periocular swelling, because these symptoms may indicate the onset of endophthalmitis. *(III, good quality, strong recommendation)*

In the absence of complications, the frequency and timing of subsequent postoperative visits depend largely on the size or configuration of the incision, the need to cut or remove sutures, and when refraction, visual function, and the medical condition of the eye are stabilized. More-frequent postoperative visits are generally indicated if unusual findings, symptoms, or complications occur. The patient should have ready access to the ophthalmologist's office to ask questions or seek care. *(III, good quality, strong recommendation)*

Components of each postoperative examination should include the following:

◆ Interval history, including use of postoperative medications, new symptoms, and self-assessment of vision
◆ Measurement of visual function (e.g., visual acuity, including pinhole testing or refraction when appropriate)
◆ Measurement of IOP
◆ Slit-lamp biomicroscopy
◆ Counseling/education for the patient or patient's caretaker
◆ Management plan

A dilated fundus examination is indicated if there is a reasonable suspicion or higher risk of posterior segment problems. In the absence of symptoms or surgical complications, no study has demonstrated that a dilated fundus examination results in earlier detection of retinal detachment. However, dilation is often critical in assessing anterior ocular concerns, such as capsular contracture or IOL malposition and other retinal issues, such as CME.

When postoperative visual improvement is less than anticipated, the ophthalmologist may perform additional diagnostic testing to evaluate the cause. For example, if maculopathy is suspected, OCT or fluorescein angiography would be appropriate to diagnose cystoid or diffuse macular edema, epiretinal membranes, or AMD. Likewise, corneal topography could help diagnose irregular corneal astigmatism. Automated visual fields may help diagnose a neuro-ophthalmic abnormality. Other testing may be conducted if appropriate.

A final refractive visit should be made to provide an accurate prescription for eyeglasses to allow for the patient's optimal visual function. *(III, good quality, strong recommendation)* The timing and frequency of refraction will depend on patient needs and the stability of the measurement. Sutures, if used, may be cut or removed by the ophthalmologist to reduce astigmatism. Optical correction can usually be prescribed between 1 and 4 weeks after small-incision cataract surgery[773] and between 6 and 12 weeks after sutured large-incision cataract extraction surgery.

APPENDIX 10. LITERATURE SEARCHES FOR THIS PPP

Literature searches of the PubMed and Cochrane databases were conducted in May 2016 and July 2017. The search strategy can be found at www.aao.org/ppp.

RELATED ACADEMY MATERIALS

Basic and Clinical Science Course

- Clinical Optics (Section 3, 2017-2018)
- Refractive Surgery (Section 13, 2017-2018)

Clinical Statement -
Free download available at http://one.aao.org/guidelines-browse?filter=clinicalstatement**.**

- Appropriate Management of the Refractive Surgery Patient (2012)
- Extended Wear of Contact Lenses (2013)
- Laser Surgery (2015)
- Unapproved Lasers and Software for Refractive Surgery (2014)
- Summary Recommendations for Keratorefractive Laser Surgery (2013)

FemtoCenter -
Available at http://one.aao.org/femtocenter**; scroll down to Journals & News; enter required login.**

- AAO/ASCRS Guidelines for Billing Medicare Beneficiaries When Using the Femtosecond Laser (December 4, 2012)

Focal Points

- Innovations in Advanced Surface Laser Refractive Surgery (2010)
- Surgical Treatment of Presbyopia (2009)
- Wavefront-Guided LASIK (2008)

Ophthalmic Technology Assessment -
Published in *Ophthalmology***, which is distributed free to Academy members***;* **links to abstracts and full text available at** www.aao.org/ota**.**

- Intrastromal Corneal Ring Segments for Low Myopia (2001; reviewed for currency 2009)
- LASIK for Hyperopia, Hyperopic Astigmatism, and Mixed Astigmatism (2004; reviewed for currency 2009)
- Laser In-Situ Keratomileusis (LASIK) for Myopia and Astigmatism: Safety and Efficacy (2002; reviewed for currency 2009)
- Wavefront-Guided LASIK for the Correction of Primary Myopia and Astigmatism (2008)

Patient Education Downloadable Handout

- Contact Lenses (2017)

- Laser Eye Surgery (2017)

- LASIK (2017)

- Laser Surgery of the Eye (2017)

- Photorefractive Keratectomy (PRK) (2016)

- Refractive Errors (2016)

- Refractive Surgery (subscription) (2016)

- Wavefront-Guided LASIK (2016)

Patient Education Video

- Microkeratome LASIK – 2015

- Femto LASIK - 2015

- PRK – 2015

Preferred Practice Pattern® Guidelines - Free download available at www.aao.org/ppp**.**

- Cataract in the Adult Eye (2016)

- Comprehensive Adult Medical Eye Evaluation (2015)

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