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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 Surgery Preferred Practice Pattern guidelines (PPP). The PPP Panel members discussed and reviewed successive drafts of the document, meeting in person twice and conducting other review by e-mail discussion, to develop a consensus over the final version of the document.

Refractive Management/Intervention Preferred Practice Pattern Panel 2021–2022

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

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

Preferred Practice Patterns Committee 2022

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The Refractive Surgery PPP was then sent for review to additional internal and external groups and individuals in July 2022. All those returning comments were required to provide disclosure of relevant relationships with industry to have their comments considered. 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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In compliance with the Council of Medical Specialty Societies' Code for Interactions with Companies (available at <u>https://cmss.org/code-for-interactions-with-companies/</u>), relevant relationships with industry are listed. The Academy has Relationship with Industry Procedures to comply with the Code (available at <u>www.aao.org/about-preferred-practice-patterns</u>). A majority (100%) of the members of the Refractive Management/Intervention Preferred Practice Pattern Panel 2021–2022 had no related financial relationship to disclose.

Refractive Management/Intervention Preferred Practice Pattern Panel 2021–2022

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The disclosures of relevant relationships to industry of other reviewers of the document from January to October 2022 are available online at 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. During the panel's deliberations, and in the process of rating the strength of recommendations for care, explicit effort is made to consider the balance of potential benefits and possible harms of the medical interventions discussed.

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.

The intended users of the 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 Network¹ (SIGN) and the Grading of Recommendations Assessment, Development and Evaluation² (GRADE) group are used. GRADE is a systematic approach to grading the strength of the total body of evidence that is available to support recommendations on a specific clinical management issue. Organizations that have adopted GRADE include SIGN, the World Health Organization, the Agency for Healthcare Research and Policy, and the American College of Physicians.³

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

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

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

Good quality	Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Insufficient quality	Further research is very likely to have an important impact on our confidence 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 GRADE² as follows:

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

- The Highlighted Findings and Recommendations for Care section lists points determined by the PPP panel to be of particular importance to vision and quality of life outcomes.
- All recommendations for care in this PPP were rated using the system described above. Ratings are embedded throughout the PPP main text in italics.
- Literature searches for the PPP were undertaken in March 2021 and May 2022 in the PubMed database. Complete details of the literature search are available in Appendix 4.

HIGHLIGHTED FINDINGS AND RECOMMENDATIONS FOR CARE

Contraindications to refractive surgery include the following:

- 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
- Uncontrolled mental illness, including anxiety or depression
- Unrealistic patient expectations

It is recommended that corneal refractive surgery patients be provided with a record listing diagnosis, preoperative keratometry readings, and refraction, as well as postoperative refraction.

It is recommended that the refractive surgeon maintain a record including preoperative keratometry and refraction as well as postoperative refraction and provide that data if needed for future eye care, including cataract surgery.

As part of the informed consent process, it is recommended that the refractive surgeon review common adverse effects such as dry eye and eventual presbyopia with patients considering corneal refractive surgery.

Excimer laser ablations that result in very thin residual stroma increase the risk for ectasia. For laser in situ keratomileusis (LASIK) procedures, a minimum of 250 μ m is suggested as a safe residual stromal bed thickness. There is no absolute value that guarantees ectasia will not occur. Abnormal topography and percentage of tissue altered (PTA) higher or equal to 40% are also associated with higher ectasia risk.

Published studies have failed to demonstrate a relationship between pupil size and the quality of postop vision, minimizing the importance of pupillometry in the preoperative workup.

Persistent diffuse lamellar keratitis (DLK) unresponsive to corticosteroids should prompt consideration of microbial keratitis or interlamellar fluid due to increased intraocular pressure (IOP) measured peripheral to the LASIK flap, intraocular inflammation, or endothelial decompensation. For extensive DLK, the interface should be irrigated to minimize stromal loss and changes in refractive correction.

Surgical management of presbyopia includes keratorefractive surgery, corneal inlays, and intraocular lens implantation (multifocal, accommodative, and extended depth of focus lenses).

INTRODUCTION

PROCEDURE DEFINITION

Refractive surgeries are surgical procedures used to correct refractive errors such as myopia, hyperopia, astigmatisms, and presbyopia in order to improve the individual's daily function and to decrease dependency on glasses or contact lenses. There are two main refractive surgical approaches: one is by reshaping the cornea, and the other by implanting an intraocular lens.

PATIENT POPULATION

Individuals beyond the amblyogenic age with stable refractive error that when corrected results in improvement in visual acuity or function.

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 nonsurgical and surgical 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
- Inform patients about new and emerging technologies for treatment of their refractive errors
- Emphasize common adverse effects such as dry eye and eventual presbyopia with patients considering corneal refractive surgery (recommended as part of the informed consent process)
- Correct symptomatic refractive errors with eyeglasses, contact lenses, or surgery, as desired by the informed patient and as deemed appropriate by the physician
- Provide the patient with follow-up care and management of any side effects or complications resulting from the correction provided.
- Provide patients undergoing corneal surgery with a record⁴ that includes diagnosis, preoperative keratometry readings and refraction, as well as postoperative refraction.
- Maintain a record that includes preoperative keratometry and refraction as well as postoperative refraction, and provide that data if needed for future eye care including cataract surgery.

CARE PROCESS

PATIENT OUTCOME CRITERIA

The outcome criteria should be measured by best meeting individual patient's functional needs with minimum risks and side effects.

DIAGNOSIS

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

History

The patient's history should include refractive error progression; prior correction, including contact lens wear; medical history with the potential impact on eye health; and eye disease or eye problems.

Examination

Measuring Visual Acuity

Distance visual acuity is usually measured in a dimly lit room, typically at 20 feet (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 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 diopters (D) for spherical equivalent, spherical power, and cylindrical power.

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 not to provide excess minus power correction to the patient. In some cases, especially in younger patients, a cycloplegic refraction can be useful.

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

Cycloplegic refraction is 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 can allow a more accurate refraction but a longer duration of effect. A significant difference between manifest and cycloplegic refraction is observed frequently in children; in adults, a substantial difference between manifest and cycloplegic refraction is performed after full accommodation has returned.

Although most normal eyes should have a corrected acuity of 20/20 to 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 patients should have a comprehensive medical eye evaluation at the recommended intervals.

MANAGEMENT

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 used for 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.⁵

The ophthalmologist who is to perform the refractive surgery has the following responsibilities:^{6,7}

- 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), including any plan for postoperative co-management.⁵
- 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.^{6, 7}

A comprehensive medical eye evaluation should be performed before any refractive surgery procedure.⁶ Visual acuity determination and refraction require particular attention. In addition to the elements listed in the comprehensive adult medical eye evaluation⁸ (see Appendix 2), 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 intraocular refractive surgery examination includes the additional elements listed in Table 1.

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

TABLE 1 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

IOL = intraocular lens; OCT = optical coherence tomography; UBM = ultrasound biomicroscopy.

* 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.

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.⁹⁻¹⁴ Thus, the importance of pupillometry in the preoperative workup remains controversial.⁹ 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 high-order aberrations (HOAs), particularly spherical aberrations, 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.^{15, 16} 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.¹⁷ As a general guideline, spherical soft contact lenses should be discontinued for at least 3 days to 2 weeks.^{17, 18} 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 is 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.¹⁹⁻²²

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, to help identify the presence of keratoconus.²³

Excimer ablations that result in very thin residual stroma increase the risk for ectasia. In the case of LASIK procedures, a minimum of 250 μ m has been suggested as a safe residual stromal bed thickness,²⁴ but there is no absolute value that guarantees that ectasia will not occur since the posterior cornea exhibits weaker tensile strength than the anterior cornea.²⁵ 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, and topographic or tomographic analyses and indices, such as the Belin-Ambrosio enhanced ectasia display can be useful in identifying eyes at risk. In the context of normal preoperative topography or tomography, the percentage of tissue altered (PTA) higher or equal to 40% has been associated with higher ectasia risk.²⁶ 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 stromal bed thickness, and higher attempted corrections.¹⁹⁻²¹

Patients' preoperative expectations and psychological characteristics have been shown to affect satisfaction with LASIK.²⁷ Depressive symptoms have been associated with decreased patient satisfaction with visual quality after LASIK.²⁸ 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 a poor psychological or psychosocial outcome following surgery.²⁹

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,³⁰ insertion of intrastromal corneal ring segments,³¹ and historically, radial keratotomy (RK).³² It should be noted that the FDA approved the small-incision lenticule extraction (SMILE) technology initially in 2016 for low to moderate myopia and expanded the approval for -1.00 to -10.00 diopters of spherical refractive error and for cylinder -0.75 through -3.00 diopters in 2018.

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.³³⁻³⁵ A Cochrane review in 2016 found no difference in efficacy between LASEK and PRK in correcting myopia.³⁶ (*I-, insufficient, discretionary*) 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 LASEK and PRK.^{33, 34, 37} (*I-, insufficient, discretionary*) The latest 2020 Cochrane review confirmed that LASEK, PRK, and LASIK may be equally effective in correcting myopia and that there was no significant difference between wavefront-versus conventional excimer ablation or between wavefront-optimized versus wavefront-guided treatments.^{33, 34, 36-39} (*I-, insufficient, discretionary*) (#38 *I+, good, strong*) 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.⁴⁰ 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 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 of efficacy.⁴¹ 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.^{42, 43} Using 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.⁴⁴ Different laser platforms use different proprietary ablative patterns, which may affect the outcomes and 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, variable spot size, or flying-spot systems. Pupil-tracking technology is integrated into all of the current commercially available excimer laser systems, permitting the ablation to

remain centered on the pupil and neutralizing the impact of small ocular movements that occur during ablation. Newer tracking technologies now include pupillary offset centration to account for centroid shift and iris registration to eliminate supine positional cyclotorsion errors.

Advanced

Wavefront-guided, wavefront-optimized, and topography-guided 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.⁴⁵ Wavefront-guided or wavefront-optimized techniques generally remove a greater volume of tissue than conventional procedures.⁴⁶⁻⁵³

An excimer laser ablation using wavefront aberrometry information can limit the induction of HOAs and, in some instances, reduce pre-existing HOAs.^{54, 55} 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 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.⁵⁶ Procedures used to treat regular astigmatism include PRK and its variants LASEK and epi-LASIK (collectively termed advanced surface ablation), LASIK, SMILE, and astigmatic keratotomy (AK). Customized treatments may be used to reduce irregular astigmatism in eyes with high degrees of aberration.⁵⁷ Topography-guided ablation uses keratometric data in the design of the ablation. Refractive and visual outcomes have been found to be inferior to manifest refraction data when used to determine the axis of ablation in topography-guided LASIK.⁵⁸

Indications

Table 2 and Table 3 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:

 $\frac{www.fda.gov/MedicalDevices/Products and MedicalProcedures/Surgery and LifeSupport/LASIK/ucm1686641.htm.$

MedWatch (<u>www.fda.gov/medwatch</u>) is the Safety Information and Adverse Reporting Program for drugs and other medical products regulated by the FDA. Adverse 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
- Uncontrolled mental illness, including anxiety or depression.
- Unrealistic patient expectations

Relative Contraindications

- Functional monocularity
- Ocular conditions that limit visual function, such that correction of refractive error would not improve visual function
- Excessively steep or flat corneas
- ◆ Abnormal corneal topography/tomography indicating possible 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
- ♦ Glaucoma⁵⁹
- ♦ History of uveitis⁶⁰
- ♦ Diabetes mellitus⁶¹
- ♦ Pregnancy or lactation⁶²
- ◆ Autoimmune or other immune-mediated diseases⁶³
- Certain systemic medications (e.g., isotretinoin, amiodarone, sumatriptan, levonorgestrel implants, colchicine)
- Age under 21 years (FDA labeling should be consulted for each laser platform)

Company (Model)	LASIK for Myopia and Astigmatism	LASIK for Hyperopia and Astigmatism	Mixed Astigmatism
Alcon (WaveLight	Myopia up to -12.00 D with or without astigmatism up to -6.00 D	Hyperopia up to +6.00 D with or without astigmatism up to +5.00 D	Mixed astigmatism up to 6.00 D at the spectacle plane
ALLEGRETTO WAVE)	(P020050; 10/07/03)	(P030008; 10/10/03)	(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 ≤-7.00 D with or without astigmatism ≤-3.00 D (P060004; 8/11/06)	Hyperopia \leq +5.00 D with or without astigmatism of >+0.50 D and \leq +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 ≤-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 <-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)	
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)	(, , , , , , , , , , , , , , , , , , ,	
	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)		
VISX, Inc. (Johnson & Johnson Surgical Vision) (VISX Star S4/S4IR & iDESIGN Refractive Studio) Wavefront-guided LASIK	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 April 6, 2022.

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

https://www.fda.gov/medical-devices/lasik/list-fda-approved-lasers-lasik, accessed April 6, 2022.

D = diopter; FDA = Food and Drug Administration; LASIK = laser in situ keratomileusis; 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.

Company (Model)	PRK for Myopia and Astigmatism	PRK for Hyperopia and Astigmatism	Mixed Astigmatism
VISX, Inc. (Johnson & Johnson Surgical Vision) (VISX Star S4/S4 IR & iDESIGN Refractive Studio)	Up to -8.00 D SE with or without astigmatism up to - 3.0 D		Mixed astigmatism from 1.00 to 5.00 D
Wavefront-guided PRK	(P930016/S057; 09/09/19)		(P930016/S20; 3/17/05)
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 <-4.50 D (P970056; 9/28/99)		
	Myopia from -0.75 to -13.00 D with astigmatism ≤-0.75 D and myopia -1.00 to -8.00 D with astigmatism		
Nidek EC-5000	-0.50 to -4.00 D (P970053/S9; 10/11/06)		

TABLE 3 FDA-APPROVED EXCIMER LASERS FOR PHOTOREFRACTIVE KERATECTOMY WITH INDICATIONS

SOURCE:

www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm168641.htm, accessed April 6, 2022.

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

https://www.fda.gov/medical-devices/lasik/fda-approved-lasers-prk-and-other-refractive-surgeries, accessed April 6, 2022.

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

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

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 to explain which may be transient and which may be permanent. The patient should be informed of the potential risks, benefits, and alternatives to the different refractive procedures prior to 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.^{6, 7} Elements of the discussion may include the following:

- Range of expected refractive outcomes
- Residual refractive error
- Reading and/or distance correction postoperatively
- Loss of or change to uncorrected habitual near vision in myopes
- 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.

- Effect on ocular alignment
- Development or exacerbation of dry eye symptoms, neuralgia
- Recurrent erosion syndrome
- Possibility that it may influence predictive accuracy of IOL calculations for subsequent cataract surgery
- Postoperative care plans (setting of care, providers of care)

Surface Ablation Techniques

Photorefractive Keratectomy

In PRK, the central corneal epithelium is removed and the excimer laser is used to ablate the Bowman layer and superficial corneal stroma centered over the entrance pupil. Because vision might be poor for some time after bilateral same-day PRK, the patient should be informed that activities such as driving may not be possible for weeks. The advantages and disadvantages of bilateral same-day versus sequential PRK should be reviewed as part of the patient education and consent process.

All instrumentation must be checked and calibrated before the procedure.⁶⁴ The surgeon should confirm the identity of the patient, the operative eye, and that the treatment parameters are correctly entered into the laser's computer.⁶⁴ 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.⁶⁵ These marks are then aligned intraoperatively with the laser reticle, thus compensating for ocular cyclotorsion. The use of a tracker or, when available, iris registration, may help to maximize accuracy as far as the axis 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 an eyelid speculum is placed to optimize corneal exposure.

The epithelium can be removed mechanically (by brush, blade, or epikeratome), chemically (most often with approximately 20% ethanol) or by laser.⁶⁶⁻⁷¹ Expeditious removal minimizes nonuniform or excessive drying of the stroma, thereby reducing the chance of an unanticipated treatment outcome. Enough epithelium should be removed to permit placement of the full, planned laser optical zone diameter as well as peripheral transition zones onto the exposed 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 often 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, pterygium excision, or penetrating keratoplasty.⁷²⁻⁷⁴ Most studies show no significant reduction of 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).^{75, 76}

A bandage contact lens is usually applied, and the eyelid speculum is removed. Postoperative regimens of topically applied antibiotics, corticosteroids, NSAIDs, and oral analgesic agents vary among practitioners.⁷⁷ 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-Laser in Situ Keratomileusis

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.⁷⁸ 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 layer. The epikeratome is similar in design to a mechanical microkeratome used for LASIK, but instead of using an oscillating sharp blade to incise the corneal stroma beneath the Bowman layer, 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 layer. 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.³⁶ 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 substantial difference between LASEK and LASIK for treating myopia.37 Epi-LASIK should be used only in eyes in which the Bowman layer is intact. Breaks in the Bowman layer (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.⁷⁹ Because LASEK and epi-LASIK are modifications of PRK, the potential for corneal haze to develop remains a concern.⁷⁴⁻⁷⁷ In an off-label application, mitomycin-C is often used to reduce the chance of corneal subepithelial haze developing, particularly in the setting of a high correction (e.g., deep ablation) or in eves that have undergone prior corneal surgery such as RK, LASIK, pterygium excision, or penetrating keratoplasty.⁸⁰⁻⁸²

Results

Photorefractive keratectomy reduces myopia, is most predictable for low to moderate myopia, and is less predictable for high myopia.⁴⁰ 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 uncorrected distance visual acuity (UCVA) of 20/20 and 20/40, respectively, at 12 or more months following PRK.⁴⁰ 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.⁴⁰ 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.⁴⁰ After PRK for high myopia, 6% of eyes lost two or more lines of BCVA.⁴⁰

In a study of wavefront-guided PRK for myopia and myopic astigmatism, 81% of patients achieved a UCVA of 20/20 or better.⁸³ 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).⁸⁴ Using wavefront-guided PRK, 1% of eyes lost one line of BCVA at 1 year (relative to presurgical BCVA).⁸³

Regression of the surgical effect was more common in patients with higher degrees of preoperative myopia.⁴⁰ Long-term studies examining 10- to 12-year results demonstrated excellent safety and efficacy of PRK for the treatment of myopia.⁸⁵⁻⁸⁸ 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).^{87,88} There is good evidence of the effectiveness of mitomycin C when used intraoperatively as prophylaxis against haze in higher myopic surface ablations.⁸⁹

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%).⁹⁰ 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.⁹¹ The efficacy and predictability of PRK retreatment are less than for primary procedures.⁹²⁻⁹⁶ However, a recent prospective comparison of wavefront-guided LASIK versus wavefront-guided PRK for residual

refractive error following previous myopic keratorefractive surgery found similar safety, efficacy, and predictability with comparable outcomes: 100% of LASIK eyes and 89.5% of PRK eyes were within + 0.50 D of emmetropia.⁹⁷

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.⁴⁰ A systematic review of 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.⁴⁰ 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.⁹⁸ In eyes with more than 3.50 D of hyperopia, 79% were within 1.00 D of the intended correction.⁹⁹ 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.¹⁰⁰ 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.⁴⁰ In a study of wavefront-guided PRK for hyperopia (mean preoperative refraction $\pm 2.90 \pm 0.80$ 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.¹⁰¹ Ninety percent of eyes were UCVA 20/40 or better 6 months after surgery.

Although overall corneal haze was generally mild after H-PRK, there were moresignificant haze problems in the midperipheral ring, usually sparing the entrance pupil.¹⁰² 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 reduces decentrations. Optical zone centration using corneal fixation-based small-incision lenticular extraction (SMILE) was found to be comparable to eye tracker-based femtosecond laser-assisted LASIK for myopia.¹⁰³

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.¹⁰⁴ Higher regression in the PRK group was present even though the amount of hyperopic spherical equivalent was greater in the LASIK group (4.49 D vs. 2.85 D).

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.¹⁰⁵⁻¹⁰⁷

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.⁴⁰ 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.¹⁰⁸

Postoperative Care

Postoperative management is integral to the outcome of any surgical procedure and is the responsibility of the operating surgeon.⁷ 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 commonly be managed with topical therapy, but close monitoring is essential because IOP will become elevated in a significant proportion of patients with prolonged corticosteroid use.^{109, 110}

Postoperative pain is typically reduced by using a bandage contact lens and NSAID drops. Some patients may benefit from oral analgesics. Small quantities of dilute topical anesthetic are sometimes used but warrant close supervision. An Ophthalmic Technology Assessment on postoperative phototherapeutic keratectomy pain control concluded that systemic NSAIDs and opioid medications, topical NSAIDs, cold patches, bandage contact lenses, and topical anesthetics provide improved pain control over alternative strategies and allow PRK-associated pain to be more tolerable for patients.¹¹¹ Because anesthetic and NSAID drops may delay corneal epithelialization, they should be prescribed judiciously.¹¹²⁻¹¹⁶ Sterile corneal infiltrates associated with the use of NSAID drops without the concomitant use of topical corticosteroids have been described.¹¹⁷ Microbial keratitis, however, must be considered whenever a corneal infiltrate is seen.

Postoperative examination, including slit-lamp biomicroscopy of the cornea, is generally advisable on the day after surgery and every several days thereafter and ongoing 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. Although data are inconclusive, the topical corticosteroid regimen can be modified to attempt to modulate the treatment effect in the early postop period.^{118, 119}

It is recommended that patients be provided with a record⁴ and 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.

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 anything more than mild corneal haze should be carefully considered.⁹⁴ The off-label application of mitomycin-C at the time of retreatment has been reported to reduce the recurrence of haze.^{120, 121}

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 overcorrection¹²²⁻¹²⁵
- Partial regression of effect¹²⁶
- ◆ Loss of BCVA^{122-125, 127-133}
- Visual aberrations, including transient or permanent glare or starburst/halo effect, especially at night^{126, 134}
- Decreased contrast sensitivity¹³⁵⁻¹³⁷
- ◆ Induced regular or irregular astigmatism^{122, 125}
- ◆ Induced anisometropia¹²²⁻¹²⁵
- ◆ Need for reading correction¹²²⁻¹²⁵
- ◆ Corneal haze or scarring (early or delayed onset)¹³⁸
- ◆ Corneal infiltrates, ulceration, melting, or perforation (sterile or microbial)^{117, 132, 139}
- ◆ Central toxic keratopathy^{140, 141}
- ◆ Corneal ectasia (progressive corneal steepening)¹⁴²
- Development or exacerbation of dry eye symptoms
- ♦ Decreased corneal sensitivity¹⁴³
- ♦ Corneal neuralgia^{144, 145}
- ◆ Recurrent corneal erosion¹⁴⁶
- ♦ Reactivation of HSV keratitis¹⁴⁷
- ◆ Corticosteroid-induced complications (e.g., ocular hypertension, glaucoma, cataract)¹²⁵
- ♦ Adverse effect on ocular alignment¹⁴⁸
- ♦ Ptosis¹²⁴
- Artifactual reduction of measured IOP (due to corneal thinning)
- ◆ Complications related to mitomycin-C (e.g., endothelial cell decrease)¹⁴⁹

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.^{150, 151}

Patient Satisfaction

Patient satisfaction depends on both patient expectations and surgical outcome. Patients have generally been satisfied with the results of PRK.¹⁵²⁻¹⁵⁴ 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.^{155, 156}

Subjective visual function and patient satisfaction do not always correlate with objective measurements.¹⁵⁷ Questionnaires with superior psychometric properties have been developed to assess different aspects of quality of life in refractive surgery.^{158, 159}

Laser in Situ Keratomileusis

Laser in situ keratomileusis is a surgical procedure in which a hinged flap consisting of corneal epithelium, the Bowman layer, and superficial stroma is created. The corneal flap is manually 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 possible keratoconus
- Orbital, eyelid, or ocular anatomy that precludes proper function of the mechanical or femtosecond laser microkeratome
- Insufficient 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, other surface ablation procedures, or SMILE might be considered as approaches to mitigating the risks associated with creation of a LASIK flap, with the understanding that risks may be reduced but not eliminated entirely.

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 treatment parameters are correctly entered into the laser's computer.⁶⁴ 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).

Either mechanical microkeratomes or femtosecond lasers can be used to create a flap prior to excimer laser ablation.¹⁶⁰ (I+, *strong*, *good*)

The femtosecond lasers can be programmed to vary flap diameter, 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 mechanically breaking the micro-adhesions and lifting the flap. Table 4 lists femtosecond lasers that have been approved by the FDA for keratorefractive surgery and indications for their use.

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
IntraLase Fusion Laser (K063682; 2/9/07)	IntraLase Corp.†	 cornea; patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea; patients undergoing surgery or
IntraLase FS Laser, IntraLase FS30 Laser, Models 1,2,3 (K060372; 8/16/06)	IntraLase Corp.†	other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments; in – lamellar keratoplasty and corneal harvesting;
IntraLase FS Laser (K031960; 9/29/03)	IntraLase Corp.†	in the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and in the
Pulsion FS Laser Keratome (K013941; 2/27/02)	IntraLase Corp.†	 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.
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.

 TABLE 4
 FDA-Approved Femtosecond Lasers with Indications

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.
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.
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.

 TABLE 4
 FDA-Approved Femtosecond Lasers with Indications (continued)

SOURCE: U.S. Food and Drug Administration. Available at: <u>www.fda.gov</u>. Accessed April 6, 2022.

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; LASIK = laser in situ keratomileusis; 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 an eyelid speculum may or may not be used to optimize corneal exposure depending on the laser system and surgeon's technique. Marking the cornea facilitates flap reorientation at the end of the procedure, particularly in the event of a free cap. Corneal marking must be done prior to flap creation when using a mechanical microkeratome, as this will facilitate flap reorientation at the end of the procedure 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 at the level of the stroma. Different hinge locations can be created using different 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 that the tear meniscus extends beyond the flap diameter to avoid incomplete flaps.

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. 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 microkeratome, or if there is buttonhole of flap as rarely occurs with mechanical microkeratomes, 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 be performed at a later time.¹⁶¹⁻¹⁶³ In some cases, the flap can be lifted and ablation undertaken after a period of months or recut if cut initially with a femtosecond laser. Recut of a flap made with a mechanical microkeratome is subject to unpredictability, and significant complications, and has fallen out of favor.¹⁶⁴

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 to confirm proper flap position, appearance, and lack of interface debris.

Results

A systematic review of 64 studies on LASIK published since 2000 found 17 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.¹⁶⁵ A study with a 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.¹⁶⁶ Based on data from 22 studies, the systematic review reported that 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 values, a median rate of 0.6% (range, 0% to 3%) of eyes with myopia or myopic astigmatism lost two or more lines of BCVA.⁴⁰

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.⁴⁰ 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.⁴⁰ 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.⁴⁰

Hyperopic LASIK (H-LASIK) has also been used successfully to treat overcorrected myopic LASIK.¹⁶⁷ A study¹⁶⁸ 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 compared with H-LASIK.

Laser in situ keratomileusis is associated with more regression in hyperopic procedures than in myopic procedures.¹⁶⁹⁻¹⁷¹ The mechanisms of H-LASIK regression are not clearly defined, but epithelial hyperplasia and potential biomechanical causes may contribute. 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.¹⁷²

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.^{173, 174} There is a greater rate of loss of BCVA reported following H-PRK and H-LASIK compared with myopic corrections.⁴⁰

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.¹⁷⁵

In 2017, the 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.¹⁷⁶ The Patient-Reported Outcomes with LASIK Symptoms and Satisfaction (PROWL-SS) and Scoring Guide is available from the Academy. (https://www.aao.org/prowl-ss)

Postoperative Care

Postoperative management is integral to the outcome of any surgical procedure and is the responsibility of the operating surgeon.⁷ Mild to moderate discomfort can be expected during the first postoperative day. Topical antibiotics are administered, and corticosteroids are generally used for a short time postoperatively.³⁴ 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 documented 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. For the routine patient following uncomplicated LASIK, the second visit should be performed 1 to 4 weeks postoperatively and thereafter as appropriate. The frequency of follow-up visits is individualized depending on the findings at the first postoperative visit. Patients with UCVA that has not yet met preoperative BCVA should be seen until that discrepancy has resolved or is addressed.

It is recommended that patients be provided with a record⁴ and 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.

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.¹⁷⁷ 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 obtained 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 include relifting the original flap or performing a surface ablation (PRK with or without mitomycin-C, an off-label use).^{164, 178, 179} 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. Mechanical recutting of flaps has fallen out of favor because the intersection of the surgical planes can result in displaced stromal fragments, resulting in irregular astigmatism and loss of BCVA. Flaps made with femtosecond laser can be recut due to more accurate and reproducible results as far as flap thickness.

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^{180, 181}
- 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 dystrophy¹⁸²⁻¹⁸⁸
- Corneal infiltrates, ulceration, melting, or perforation (sterile or microbial)
- Corneal ectasia (progressive corneal steepening)
- Development or exacerbation of dry eye symptoms
- Decreased corneal sensitivity

- Corneal neuralgia
- Recurrent corneal erosion
- Reactivation of HSV keratitis
- Corticosteroid-induced complications (e.g., ocular hypertension, glaucoma, cataract)
- ♦ Adverse effect on ocular alignment¹⁴⁸
- Ptosis
- ◆ Artifactual reduction of IOP measured by applanation tonometry¹⁸⁹
- 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
- Central toxic keratopathy
- Transient-light sensitivity associated with femtosecond laser^{190, 191}
- Rainbow glare associated with femtosecond laser^{192, 193}
- Persistent flap edema
- Striae (microstriae and macrostriae)
- Traumatic flap dislocation

Although there are case reports of retinal abnormalities following LASIK, it is unclear if the incidence is different from that in a comparable myopic population.^{150, 194}

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.^{126, 195}

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.^{196, 197} Chronic pain projected to the cornea, also called corneal neuralgia or neuropathic pain, has been reported after LASIK; multi-modal local and systemic treatment beyond what are typically used for dry eye disease are required.^{144, 145}

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.¹⁹⁸ 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.¹⁹⁹ 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.¹⁹⁹

Epithelial Ingrowth. Epithelial ingrowth is rare after primary LASIK procedures; 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.²⁰⁰ Other indications for lifting a flap with epithelial ingrowth include increasing astigmatism, increased growth towards the 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.²⁰¹ 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, when it can progress to the "Sands of the Sahara" state.²⁰¹ 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.²⁰²

The treatment of DLK is commonly guided by the severity of the inflammation.^{203, 204} 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.²⁰⁵ Corticosteroids may cause an IOP response that is not detected because of 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 exacerbates 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 extensive DLK, the interface should be irrigated sooner rather than later to minimize stromal loss and changes in refractive correction.

Central Toxic Keratopathy. Initially thought to be a variant of DLK, central toxic keratopathy is now thought to be a distinct entity, of unclear etiology. It is characterized by non-inflammatory central or pericentral amorphous corneal opacity involving the stroma, leading to reduced acuity in the affected eye, generally within nine days of LASIK. It can also occur after PRK. There is typically residual thinning, striae, and hyperopia. In contrast to DLK, steroids are not generally used in management and invasive intervention is generally not recommended.^{140, 141}

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.²⁰⁶⁻²⁰⁸

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.²⁰⁹⁻²¹⁵ 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%.²¹⁶⁻²¹⁸ 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 corneal ectasia after LASIK, as demonstrated by preoperative and postoperative corneal topography/tomography and a reduction in maximum keratometric readings.²¹⁹ Long-term stability after CXL therapy for treatment of corneal ectasia after refractive surgery has been reported.^{220, 221} Corneal cross-linking was FDA approved in 2016 for the management of corneal ectasia after refractive surgery.

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.^{218, 222-226}

Intrastromal corneal ring segments are FDA approved under a humanitarian device exemption for use in keratoconus and have been used off label for ectasia after LASIK.²²⁷⁻²³¹ 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 a 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.²⁷ Most patients are satisfied with the results of LASIK.²³²⁻²³⁴ 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.²³⁵ 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.²³⁶ Questionnaires have been developed and may be helpful to assess the functional and psychological impact of refractive error and its correction.^{237, 238} Subjective visual function and patient satisfaction do not always correlate with objective measurements.¹⁵⁷ 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.^{155, 156} Because a subset of patients have substantial and persistent symptoms after LASIK, studies are continuing to explore patient-satisfaction issues.²⁸

The FDA-conducted PROWL studies addressed many of these 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 with time, 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.¹⁷⁶

A recent 3-year 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, the LASIK group 1 of 819 (45%) who wore contacts at baseline and had LASIK, and the LASIK group 2 of 287 (16%) who wore eyeglasses at baseline and had LASIK. The study found that patients from both LASIK groups (88% group 1, 77% group 2) had greater 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.²³⁹

Small-Incision Lenticule Extraction

Small-incision lenticule extraction obviates the need for corneal flap creation and instead a small peripheral corneal incision is formed through which a stromal lenticule is extracted. The procedure entails docking of the cornea to the femtosecond laser apparatus for stabilization, femtosecond laser application, corneal lenticule dissection from the surrounding stroma, and lenticule extraction.²⁴⁰ A 2020 report on the outcomes of the U.S. FDA Premarket Approval Clinical trial found that SMILE for the treatment of myopia and astigmatism was safe and effective, and the reported adverse events had no significant impact on visual acuity.²⁴¹ By avoiding formation of a corneal flap, SMILE was hypothesized to improve corneal biomechanical strength by preserving the anterior stroma that accounts for 60% of the total corneal tensile strength.²⁴² It is also postulated to reduce exacerbation of dry eye disease by preserving the sub-basal nerve plexus, reducing postoperative corneal denervation and accelerating corneal nerve recovery relative to LASIK.²⁴³ A prospective, randomized contralateral study found that LASIK surgery led to a more profound decrease in corneal sensation in the early postoperative period compared with SMILE surgery, but there was no significant difference in self-reported dry eye symptoms between the two groups at any time point.²⁴⁴

Technique

The patient preparation for SMILE is similar to what is detailed for LASIK under Technique, including details specific to femtosecond laser flap creation. However, there are some notable differences between femtosecond laser platforms for LASIK and SMILE. First, the corneal coupling contact glass in SMILE is curved to minimize distortion caused by traditional flat applanation. Second, the suction ports lie over the peripheral cornea rather than the limbus, allowing for lower suction and lower IOP rise so that the patient's vision is maintained throughout the procedure.²⁴⁵

Docking, Suction, Laser

The corneal surface is cleaned with a balanced salt solution and excess fluid is removed so that the surface is moist but not wet. The patient supporting system is maneuvered so that the visual axis of the cornea is aligned with the center of the contact glass as the eye meets the contact glass. Upon confirming centration and suction, the patient is instructed to not move or talk, and the laser treatment is initiated. The entire laser procedure is observed by the surgeon through the surgical microscope or video display, and the treatment is halted immediately if the laser deviates from the intended treatment.

Rescue laser treatments can be attempted under the following guidelines:²⁴⁶

- If laser treatment is interrupted during the first 10% of the lenticule cut (underside of the lenticule), the entire procedure should be repeated.
- If laser treatment is interrupted between 10% and 100% of the lenticule cut or during the lenticule side cut, the case should be aborted.
- If treatment interruption occurs during the cap cut or cap side cut, this portion of the treatment should be repeated. Since the cap cut is refractively neutral, the

diameter of the cap cut can be increased so that the cap completely covers the lenticule.

Lenticule Removal

Upon careful inspection of the complete cap and lenticule cut, a sterile hook is used to open the superior incision and expose the lenticule edge. Then a sterile dissector is used first to separate the anterior surface of the lenticule from the overlying anterior stroma (the cap cut). Next, the lenticule's posterior surface is separated in similar fashion from the underlying stromal bed. A sterile nontoothed forceps is then used to remove the lenticule, which is placed on the corneal surface to ensure that the entire lenticule has been removed. The interface is irrigated with the balanced salt solution and the surface is swept with a surgical sponge to smooth out any microstriae and excess saline in the interface. Topical antibiotic and corticosteroid drops are instilled after the incision site is well approximated.

Results

Since SMILE was approved for greater myopia and astigmatism treatment in 2018, several studies have investigated the efficacy and stability of myopic astigmatism treatment using SMILE. The U.S. FDA premarket clinical trial for SMILE was a prospective, multicenter clinical trial of 357 eyes of 357 patients (one eye per patient) who were followed for 12 months after surgery, with the preoperative spherical error ranging from -1.00 to -10.00 D and a refractive cylinder of up to -3.00 D. The mean spherical equivalent MSE was reduced from a preoperative -5.39 \pm 2.30 D to -0.01 \pm 0.24 D, and 95.3% of patients were within 0.50 D of emmetropia at 12 months. The refractive cylinder was reduced from a preoperative -1.53 \pm 0.70 D to -0.18 \pm 0.31 D, and the mean correction ratio of the refractive cylinder was 0.96 \pm 0.16. A slight undercorrection was noted for higher amounts of astigmatism. Eighty nine percent of eyes had UCVA of 20/20 or better at 12 months.²⁴¹ A 10-year follow-up of 56 of 92 eyes initially treated found that there was no significant change in the postoperative refractive error compared to 6 month results, with a mean spherical equivalent of -0.35 \pm 0.66 D.²⁴⁷

A prospective, randomized, paired-eye, single-masked clinical trial compared the safety and efficacy of SMILE with wavefront-optimized LASIK and reported 3- and 12-month postoperative results.²⁴⁸ For 70 consecutive patients treated, there was no difference in preoperative spherical equivalence between eyes (-5.3 \pm 1.8 D [SMILE] vs. -5.2 \pm 1.7 D [LASIK], P = 0.87). At 3 months postoperatively, 99% of SMILE eyes and 97% of LASIK eyes were within spherical equivalent \pm 1.0 D of attempted correction (0.97 \pm 0.20 vs. 0.99 \pm 0.20, P = 1.0) for SMILE and LASIK, respectively. One hundred percent of both groups had UCVA of 20/40 or better and 84% of SMILE and 87% of LASIK eyes had UCVA of 20/20 or better. At 12 months, 99% of both SMILE and LASIK eyes remained within \pm 1.0 D of attempted correction, and 85% of SMILE and 83% of LASIK eyes maintained UDVA of 20/20 or better. A meta-analysis finds that both femtosecond LASIK and SMILE are safe, effective, and predictable.²⁴⁹ Topographically guided myopic LASIK may achieve better effective centration than with myopic SMILE, which explains superior visual outcomes.²⁵⁰

Wavefront-guided LASIK may have advantages over SMILE. A prospective, randomized, paired-eye, single-masked clinical trial compared safety and efficacy of SMILE with wavefront-guided LASIK and reported 1-, 3-, 6-, and 12-month postoperative results.²⁵¹ Eighty-eight eyes of 44 patients with myopia were enrolled in the study. Seventy-four eyes of 37 patients had successful treatments and completed 12 months of follow-up. At postoperative month 12, there were a significantly higher proportion of WFG-LASIK eyes that had $\geq 20/20$ UDVA compared with SMILE eyes (94% vs 83%, P < .05). WFG-LASIK and SMILE both offered marked improvements in corrected distance visual acuity and excellent predictability in both eyes. Compared with SMILE, WFG-LASIK resulted in faster visual recovery, better low-contrast visual acuity, and greater gains in uncorrected visual acuity.²⁵¹ Studies comparing femtosecond LASIK and SMILE for high myopia suggest that there may be advantages to SMILE when refractive error is -6.00 diopters or worse.²⁵²⁻²⁵⁴

Side Effects and Complications

Intraoperative complications can occur during lenticule construction, dissection, and extraction. Suction loss, an opaque bubble layer, and black spots can complicate lenticule construction, which lead to cap-lenticule adhesions, difficulty in dissection, lenticule tears, and cap perforation. Retained lenticule fragments from incomplete dissection may induce irregular astigmatism. The majority of SMILE complications were found to be associated with surgeon inexperience. Compared with LASIK and surface ablation, longer learning curves are required for this technique.²⁵⁵

In the U.S. FDA premarket clinical trial, three intraoperative adverse events involving difficult lenticule removal and resultant cap tear were noted, and a total of 8 adverse events were reported, but none resulted in significant clinical consequences or reduction in visual acuity. Although SMILE appears to have a lower rate of ectasia than LASIK and even PRK, the cases reported since recent approval suggest that SMILE is not protective against ectasia.²⁵⁶

Retreatments

Over 3.5 million SMILE procedures have been performed, and long-term data are being collected and analyzed. Retreatments for postoperative residual refractive error from undercorrection, overcorrection, astigmatism induction, and regression have been attempted. These include surface ablation, thin-flap LASIK, secondary small-incision lenticule extraction, and the cap-to-flap procedure in which a femtosecond laser is used to create cuts to convert the original small-incision lenticular extraction cap into a LASIK flap.²⁵⁷

Patient Satisfaction

A systematic review and meta-analysis using Cochrane collaboration methodology identified 11 randomized controlled trials from a review of 102 studies comparing SMILE and femtosecond LASIK for myopia.³⁰ Among 1,101 eyes studied, 532 (48.3%) underwent SMILE and 569 (51.7%) underwent femtosecond LASIK. There was no statistically significant difference between the two procedures in resultant postoperative final refractive spherical equivalent error (P = 0.72), the proportion of eyes achieving uncorrected distance visual acuity of 20/20 or better (P = 0.35), or the proportion of eyes achieving a postoperative refractive spherical equivalent within +1.00 D of target values (P = 0.70). Signs and symptoms of ocular surface problems were identified less frequently in the SMILE cohort compared with the LASIK cohort. These findings were supported in a subsequent meta-analysis.²⁴⁹ (*I-, moderate, discretionary*)

Incisional Astigmatic (Transverse or Arcuate) Keratotomy

Astigmatic keratotomy 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 hemi-meridians of steepest astigmatic power to treat low to moderate degrees of astigmatism.²⁵⁸ Limbal relaxing incisions have been performed alone or combined with phakic IOLs, refractive lens exchange, or cataract extraction with IOL implantation to reduce preoperative corneal astigmatism and to reduce surgical astigmatism following keratoplasty.^{258, 259} 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.^{260, 261} 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.²⁶² This procedure may be performed alone or in conjunction with other refractive procedures.²⁶³ Clinical experience suggests that the effect can be modulated by the depth and length of the incision and by 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.264,265

Although there are numerous reports of AK being performed in animal eyes, in cadaver eyes, and in patients,²⁶⁶⁻²⁷⁰ there are few well-controlled, prospective clinical studies available on AK, performed either 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.²⁶² One study retrospectively examined LASIK versus AK to treat astigmatism.²⁷¹ 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 a UCVA of 20/20 or better. There exists a paucity of head-to-head comparisons in the literature on this topic. Both methods appear to result in low rates of BCVA loss.^{264, 271}

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.^{262, 272} Incision healing problems are more common if AK and RK incisions intersect.²⁶²

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 refractive error 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 from undergoing surgery and that the procedure is reversible, since the segments can be removed.^{273, 274} Intrastromal corneal ring segment technology is approved under a humanitarian device exemption by the FDA for reducing the irregular astigmatism of keratoconus.²⁷⁵⁻²⁷⁷ There are reports on the off-label use of ICRS for correcting ectasia after keratorefractive surgery.²²⁷⁻²³¹

The implant technique of ICRS requires a partial thickness entry corneal incision. This is 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.²⁷⁸

Arcuate plastic segments of prescribed thickness are then positioned within the channels and the incision is closed.²⁷⁹ 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.^{31, 279} 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.²⁸⁰ 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.²⁸¹ 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).³² The amount of correction also varies with patient characteristics, especially age. Reoperations (enhancements) are often used to improve the refractive result.^{282, 283} Transverse cuts are sometimes incorporated to address astigmatism. Radial keratotomy complications include glare, starburst, fluctuation of vision, irregular astigmatism, regression, progression of refractive effect with subsequent hyperopia, inadvertent cuts into the visual axis, corneal perforation into the anterior chamber,

microbial keratitis, and endophthalmitis.³² Radial keratotomy has largely been replaced with surface ablation, LASIK, and SMILE.

Thermal and Conductive Keratoplasty

Thermal keratoplasty is an old concept in refractive surgery that dates to the work of Lans in 1898.²⁸⁴ 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 several 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.²⁸⁵ 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.²⁸⁶ Disadvantages include early overcorrection, regression, and induced astigmatism. Conductive keratoplasty, rarely used these days, has replaced noncontact holmium laser thermal keratoplasty.

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.²⁸⁷ 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, changing its anterior curvature.^{288, 289} Refractive results are variable and significant complications can occur.²⁹⁰ These include poor incision healing, irregular astigmatism, interface haze, lenticule necrosis, and microbial keratitis. The procedure, performed for monocular aphakia prior to the introduction of IOL implants, 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 the replacement of the crystalline lens with an IOL, to achieve a particular refractive outcome. The devices used are referred to as phakic IOLs, although sometimes they are called Implantable Collamer Lenses or Intraocular Contact Lenses (ICL). 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.²⁹¹

Indications

Intraocular refractive surgery can be considered for patients who desire to reduce their dependence on eyeglasses or contact lens wear. Table 5 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 (<u>www.fda.gov/medwatch</u>) is the Safety Information and Adverse Reporting Program for drugs and other medical products regulated by the FDA. Adverse experiences of refractive surgery should be reported to MedWatch.

TABLE 5 FDA-Approved Phakic Intraocular Lenses with Indications

Model	Company	Indications	Typical Incision Size	Anterior Chamber Depth	Endothelial Cell Count
		To correct from 3.00 to 15.00 D of myopia with 0 to 2.50 D of astigmatism at the spectacle plane			
Visian ICL (Implantable Collamer Lens, MICL12.1, MICL12.6, MICL13.2, and MICL13.7) (P030016; 12/22/05)	STAAR Surgical Co. (Monrovia, CA)	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/mm ²)
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)
EVO ICL (EVO/EVO+ VISIAN Implantable Collamer Lens) for Myopia					
EVO TICL (EVO/EVO+ VISIAN TORIC Implantable Collamer Lens) for Myopia		To correct or reduce myopia with or without astigmatism with SE ranging from -3.0 to -20.0 D and cylinder from 1.0 to			Age-dependent minimum*
(P030016/S035; 3/25/22)	STAAR Surgical Co. (Monrovia, CA)	4.0 D at the spectacle plane	3.5mm or less	≥3.0mm	(1900-3875 cells/mm ²)

SOURCE: U.S. Food and Drug Administration. <u>www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm</u>. 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; SE = spherical equivalent.

* 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-regulated 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 (e.g., blepharitis, dry eye syndrome, atopy/allergy)

- Active or recently active uveitis, or uveitis that requires ongoing treatment or is recurrent in nature
- Uncontrolled autoimmune or other immune-mediated disease
- Uncontrolled mental illness, including anxiety or depression.
- 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:

- ◆ Functional monocularity
- Ocular conditions that limit visual function such that correction of refractive error would not improve visual function.
- 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
- ♦ History of uveitis
- Autoimmune or other immune-mediated disease
- Diabetes mellitus
- Shallow anterior chamber
- Pregnancy or lactation⁶²

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.^{6, 7} 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)
- Retinal detachment (especially with myopic refractive lens exchange)
- Development and/or progression of cataract
- 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.²⁹² 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.²⁹³

Considerations

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.²⁹⁴ 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.^{295, 296} Phakic IOLs have not been associated with increased risk of retinal detachment compared with other intraocular interventions in highly myopic patients.^{151, 297, 298} 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 years.²⁹⁹ The refractive stability (10 years) of phakic IOLs over LASIK was corroborated by another study, at the expense of reduced endothelial cell counts.³⁰⁰

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.³⁰¹⁻³⁰⁶ 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.^{307, 308} Three 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 5.) Prototypes of multifocal phakic IOLs have demonstrated potential for the treatment of presbyopia.^{309, 310}

The earliest two FDA-approved 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 newest FDA-approved phakic IOL incorporates a central hole, minimizing the risk of pupillary block, and eliminating the need for peripheral iridectomy or iridotomy.³¹¹

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.³¹²

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.³¹³ 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 \pm 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 \pm 16.00% at 10 years.³¹⁴

Higher order aberrations and contrast sensitivity changes were similar for phakic IOLs and LASIK in one study.³¹⁵ 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.³¹⁶

Toric anterior and posterior chamber phakic IOLs have shown improved clinical results in European trials compared with spherical phakic IOLs.³¹⁷ The term bioptics has been used to describe the combination of a phakic or pseudophakic IOL with keratorefractive surgery for residual refractive error.^{318, 319}

Most recently, a prospective cohort study of a new presbyopic posterior chamber phakic IOL implanted in highly myopic patients showed promising results. The mean distance refraction improved from -6.9 D (range, -8.6 to -5.3D) preoperatively to -0.35 D (range, -0.55 to -0.15D) with less than -0.5 D residual myopia in 11 of 17 eyes. Fifteen of 17 eyes had improved uncorrected near visual acuity to J1 at 2 years follow-up.³²⁰

Postoperative Care

Postoperative management following phakic IOL implantation is similar to that for cataract surgery. (See Appendix 3.)

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
- Complications of intraocular surgery (e.g. endophthalmitis, cystoid macular edema, retinal detachment, malignant glaucoma)
- Corticosteroid-induced complications (e.g., ocular hypertension, glaucoma, cataract)
- Adverse effect on ocular alignment
- Ptosis
- Cataract formation
- ◆ Endothelial cell loss
- Corneal decompensation
- Pupil ovalization
- Diplopia related to optical effects of iridectomy/iridotomy
- Pigmentary glaucoma
- ♦ Acute angle-closure 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.

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
EVO ICL (EVO/EVO+ VISIAN Implantable Collamer Lens) for Myopia							No instances over 6 months related to blockage of aqueous flow
EVO TICL (EVO/EVO+ VISIAN TORIC Implantable Collamer Lens) for Myopia		One eye (1/629, 0.02%) underwent ICL explantation due to a subjective		Mean loss of	NS (1/629,		throughout the central port, anterior chamber angle narrowing, pigment dispersion, or
(P030016/S035; 3/25/22)	629	report of halo and glare.	0% at 6 months	2.3% at 6 months	0.02%) at 6 months	0% at 6 months	intraocular inflammation.

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.³²¹⁻³²³ 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.³²⁴ The incidence of cataract formation with posterior chamber phakic IOLs has been linked to surgeon experience.³²⁵ Most lens opacities are observed in the early postoperative period and are thought to be due to surgical trauma.³²⁵ 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.³²⁶ Subtle changes in lens design can influence the incidence of cataract formation.³²⁷ Iris-fixated phakic IOLs have been associated with a transient increase in IOP.³²⁸ Anterior location of the crystalline lens apex relative to the plane of the iris may predispose the eye to this complication.³²⁹ Endothelial cell loss and pigment dispersion remain a concern for both anterior and posterior chamber-style phakic IOLs.³³⁰ Long-term loss of endothelial cells has been reported for angle-, iris-, and sulcus-supported phakic IOL styles.²⁹⁴ As of 2022, there is no FDA approved angle-supported phakic IOL. Pupil ovalization has been associated with various styles of phakic IOLs.³³¹⁻³³³ Slower pupil reaction and decreased resting pupil diameter have been reported following posterior chamber phakic IOL implantation.³³⁴ In a retrospective review of 240 explanted phakic IOLs, the main indication was found to be

cataract formation (132 eyes, 55%), followed by endothelial cell loss (26 eyes, 11%), corneal decompensation (22 eyes, 9%), phakic IOL dislocation/decentration (16 eyes, 7%), inadequate phakic IOL size or power (12 eyes, 5%) and pupil ovalization (10 cases, 4%).³³⁵ Cataract formation affected mainly posterior chamber phakic IOL patients, whereas endothelial cell loss was observed mainly in patients who received angle-supported and iris-fixated implants.

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.^{336, 337} 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. A recent meta-analysis of middle- and long-term results after iris-fixated phakic IOL implantation in myopic and hyperopic patients found that visual and refractive results were positive with low complication rates, although greater caution was recommended for hyperopic eyes because of increased risk for endothelial cell loss and pigment dispersion.³³⁸

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.³³⁹ 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, cystoid macular edema, and the increased risk of retinal detachment, particularly in patients with high axial myopia.²⁹⁵ 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.²⁹¹

Biometry and Intraocular Lens Power Calculation

Principles guiding biometry and IOL power calculation are the same as those required in cataract surgery. (See Appendix 3 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 iris prolapse and 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
- ◆ Use of a light-adjustable 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 intermediate or near vision when used with refractive lens exchange. Toric IOLs may be used to correct preoperative regular keratometric astigmatism.^{340, 341}

Because there is a potential compromise in quality of vision with some IOLs (e.g., multifocal compared with spheric monofocal IOLs³⁴²), 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 \pm 1.00 D of the intended refraction,^{339, 343-346} and 58% to 70% of eyes within \pm 0.50 D.^{343, 345, 346} Postoperative UCVA of 20/40 or better was reported in 77% to 100% of eyes.^{339, 345, 346} Loss of BSCVA was reported in 0% to 10% of eyes.³⁴³⁻³⁴⁶

One study that compared refractive lens exchange with phakic IOLs found that visual outcomes after phakic IOLs were better than after refractive lens exchange.³⁴⁷

Postoperative Care

Postoperative management following refractive lens exchange is similar to that for cataract surgery. (See Appendix 3.)

Side Effects and Complications

No large-scale investigations on complications of refractive lens exchange have been reported. An important complication to consider in refractive lens exchange for myopia is retinal detachment, with reported incidence ranging from 1.5% to 8.1% (see Considerations section).³⁴⁸ with thorough posterior segment evaluation and follow-up warranted.³⁴⁹ Other complications that may result in a permanent loss of vision are rare but include infectious endophthalmitis, intraoperative suprachoroidal hemorrhage, cystoid macular edema, corneal edema, and IOL dislocation.

Refractive Surgery for Presbyopia

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.

The management of presbyopia can be divided into 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), as well as pharmaceutical treatment by stimulating ciliary muscle contraction and miosis.³⁵⁰ Topical therapy for treatment of presbyopia has been approved by the FDA (Pilocarpine HCL 1.25%). 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.

Surgical management of presbyopia includes corneal inlays; IOLs with aspheric, multifocal, or accommodative design or monovision strategies; and scleral surgery, 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. Although two corneal inlays have been approved by the FDA, the Raindrop inlay that was approved in 2015 was withdrawn from the market because of complications. The remaining inlay, Kamra, an aperture inlay approved in 2016, is available but rarely used. Corneal inlays that either enhance depth of focus or establish corneal multifocality in the setting of presbyopia remain an area of active investigation.^{351, 352} Conductive keratoplasty and laser thermokeratoplasty have been used to treat presbyopia by achieving a monovision result.³⁵³

The best candidates for monovision using these approaches 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.^{354, 355} Distance correction is usually performed for the dominant eye and near correction is performed for the nondominant eye.³⁵⁶ Evidence exists to suggest that near correction in the dominant eye may also be successful and even preferable in some patients.^{356, 357} Caution should be used in considering monovision in 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.³⁵⁸ 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 has been explored to treat presbyopic patients with preoperative myopia or hyperopia but is not approved by the FDA.^{359, 360}

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, accommodative, extended depth of focus, and light-adjustable 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.³⁴² Multifocal IOLs did result in reduced contrast sensitivity and an increased incidence of haloes, however.³⁴²

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.³⁶¹ Biometric studies of IOL shift in response to accommodative effort have shown little if any lens movement with single-optic designs.³⁶² 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.³⁶³

Future Directions for Management of Presbyopia

Scleral surgery has been advocated for the treatment of presbyopia.^{350, 364} In anterior ciliary sclerotomy, deep radial scleral incisions are made posterior to the limbus in the area overlying the ciliary muscle.³⁶⁵ 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.³⁶⁶ This procedure is not widely used because of complications, including anterior segment ischemia, regression, intraoperative anterior chamber perforation, and decreased ocular integrity.³⁶⁶⁻³⁶⁹

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. One prospective, multicenter trial showed a modest improvement in near vision in about half of the patients by using subjective testing methods.³⁷⁰ 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.^{369, 371}

As detailed in the Refractive Errors PPP,³⁷² presbyopia is a global challenge affecting nearly 2 billion people worldwide. Additional pharmaceutical options are under development.³⁷³ Innovative IOL optics as well as optoelectronic adjustable IOLs are being tested. Lenticular softening approaches also offer hope to change the human lens elasticity to delay onset of presbyopia.

PROVIDER AND SETTING

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.⁷ 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.⁷

COUNSELING AND REFERRAL

Any decisions about surgical correction of a refractive error should be made by an informed patient and an ophthalmologist.³⁷⁴ 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.^{374, 375}

SOCIOECONOMIC CONSIDERATIONS

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.³⁷⁶ In a European study, more than half of pseudophakic patients who wore eyeglasses after cataract surgery would be willing to pay more than $\notin 0.50$ per day to be free from wearing eyeglasses.³⁷⁷

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%.¹⁷⁶ 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; 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%).²³⁹ 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).

Numerous patient-reported outcomes instruments have been developed to estimate quality of life specifically in the context of refractive error.³⁷⁸ Vision-related quality of life has been found to increase after refractive surgery in multiple cohorts of patients.³⁷⁹⁻³⁸¹ A trial comparing refractive lens exchange with monovision LASIK found no difference in quality of life between the two groups, although in subgroup analysis the moderate-to-high myopes randomized to monovision LASIK had a higher quality of life.³⁸² In nonrandomized studies, contact lens wearers had a higher vision-related quality of life than eyeglass wearers³⁸³ and LASIK patients had quality of life scores closer to emmetropes than did those who wore eyeglasses or contact lenses.³⁸⁴ 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, although a separate randomized trial found improved quality of life in participants fitted with toric as opposed to spherical contact lenses.^{385, 386} A systematic review estimated satisfaction among 95% of patients who underwent LASIK.²³⁵ 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.^{381, 387}

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.³⁸⁸ Worldwide, the burden of uncorrected refractive error has substantial economic repercussions. The global productivity loss of \$244 billion has been estimated for uncorrected myopia alone—a far greater cost than the estimated \$20 billion that would be required to correct the world's refractive error. ^{389, 390} 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.^{391, 392} The long-term cost savings for refractive surgery results from fewer doctors' appointments and fewer prescriptions for contact lenses or eyeglasses. Similarly, toric and multifocal IOLs were shown to be more cost-effective than conventional IOLs because of lower long-term costs of postoperative contact lenses or eyeglasses as well as higher quality of life.^{393, 394} 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 alternate 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 respond in an adequate and timely manner.

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

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APPENDIX 2. EXCERPT OF THE COMPREHENSIVE ADULT MEDICAL EYE EVALUATION PPP⁸ - CARE PROCESS

A comprehensive medical eye evaluation includes a history, examination, diagnosis, and initiation of management.⁸ The examination includes a careful and thorough detection and diagnosis of ophthalmic disorders, implementation of appropriate therapy for refractive error and for both ocular and systemic disease. The items listed are basic areas of evaluation or investigation and are not meant to exclude additional elements when appropriate. For example, because history-taking is an interactive process, the patient's responses may guide the clinician to pursue additional questions and evaluation.

HISTORY

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

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

OCULAR EXAMINATION

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

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

- Fundus examination: mid and posterior vitreous, retina (including posterior pole and periphery), vasculature, and optic nerve
- Assessment of relevant aspects of patient's mental and physical status

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

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

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

Additional diagnostic testing may include the following:

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

APPENDIX 3. CATARACT IN THE ADULT EYE PPP²⁹¹ EXCERPT

BIOMETRY AND INTRAOCULAR LENS POWER CALCULATION

Optical biometry refers to highly accurate and non-invasive methods for measuring anatomical characteristics of the eye by optical methods. Optical biometry devices for measuring axial length initially used partial coherence interferometry as a replacement for ultrasound. If a signal-to-noise ratio is adequately high, interferometry is significantly more accurate and consistent than contact (applanation) A-scan biometry.³⁹⁵⁻³⁹⁷ In applanation A-scan, an ultrasound probe compresses the cornea, causing both a variable and artificial shortening of axial length. The accuracy and overall consistency of applanation ultrasound techniques are highly dependent on the skill and experience of the operator.^{396, 398, 399} When the immersion A-scan ultrasound technique is used, the probe does not come in direct contact with the cornea, making the measurements more consistent and accurate.

Optical biometry was once considered comparable to immersion A-scan biometry, but it has since been shown to produce better refractive outcomes. The patient's postoperative spherical equivalent is also more likely to be closer to the target refraction.⁴⁰⁰⁻⁴⁰² Optical biometry has also been shown to give user-independent results.⁴⁰³ Other advantages over A-scan ultrasonography include ease and speed of automated operation and the ability to measure to the fovea when proper fixation is achieved. Optical biometry can also obtain additional measurements required for newer and potentially more accurate IOL formulas. A newer form of optical biometry, swept-source OCT, allows for measurement through an even greater percentage of cataracts and other media opacities than partial coherence interferometry.⁴⁰⁴⁻⁴⁰⁸

A shortcoming of optical biometry is that it currently assigns a global refractive index to the entire eye rather than adjusting 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 using standard formulas. To compensate for this effect, approaches such as the Wang-Koch adjustment can be applied to the axial length for eyes longer than 25 mm.⁴⁰⁹ However, the Wang-Koch adjustment is not to be used with newer-generation formulas such as the Barrett Universal II or Hill-RBF formulas, or with any of the specialized formulas 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.⁴¹⁰ Additionally, it is easier to use optical biometry than ultrasound when a patient has silicone oil in the posterior segment.^{411, 412} Despite recent advances in optical biometry that allow the measurement of axial length through increasingly dense cataracts, ^{404-408, 413} A-scan biometry may be necessary to measure axial length in certain dense cataracts or when a patient is unable to fixate properly.^{414, 415} The measurement and comparison of axial length for both eyes is advisable, even if surgery is not planned for the fellow eye.

Formulas for calculating IOL power rely on keratometry to determine the net refractive contribution of the cornea. These measurements can be obtained by manual or automated keratometers, biometers, topographers, Scheimpflug tomographers, and anterior segment OCT devices (see Table A3-1). Following keratorefractive surgery, the determination of true central corneal power is particularly challenging (see Cataract Surgery Following Refractive Surgery in the Combined Surgery and Special Circumstances section).

TABLE A3-1 INTRAOCULAR LENS POWER CALCULATION	
Formulas	

Formula	Variables in Addition to Keratometry and Axial Length	Notes			
Barrett Universal II	Anterior chamber depthLens thicknessWhite-to-white	 Uses a theoretical ray-tracing formula with data-driven enhancement Model eye correlates axial length and keratometry to anterior chamber depth Includes location of the principal plane of refraction of the IOL 			
Haigis	Anterior chamber depth	Uses double regression analysis to optimize three variables			
Hill-RBF	Anterior chamber depthLens thicknessWhite-to-white	Uses artificial intelligence for pattern recognition and data interpolation			
Hoffer Q ⁴¹⁶⁻⁴¹⁸	• None	Optimizes equation constant (personalized anterior chamber depth)			
Holladay 1	• None	• Optimizes surgeon factor to derive anterior chamber depth			
Holladay 2	 Anterior chamber depth Lens thickness Age White-to-white Preoperative refraction 	 Adds additional variables to Holladay 1 Updated with nonlinear regression model 			
Kane ^{419, 420}	 Anterior chamber depth Biological sex Lens thickness Central corneal thickness 	 Based on theoretical optics incorporating regression and artificial intelligence components 			
Olsen ⁴²¹	Anterior chamber depthLens thickness	• Uses ray tracing and thick lens calculations to derive the C constant			
SRK/T ⁴²²	• None	 Combines theoretical optics with regression analysis T2 formula uses regression analysis to update SRK/T 			

IOL = intraocular lens

Although IOL manufacturers supply 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 actually used. Optimization of lens constants for a specific IOL based on an individual surgeon's actual refractive outcomes may be helpful, as may online databases pooling information from multiple surgeons.⁴²³

The surgeon should consider the patient's desires and needs when selecting an appropriate postoperative refractive target. Patients with high myopia may require unique lens constants for plus and minus power IOLs that are quite different from those recommended by the manufacturer because of IOL geometry.^{424, 425} For patients with extreme hyperopia who require an IOL beyond the available power range, piggybacking two posterior chamber IOLs is possible, including as a staged procedure.⁴²⁶⁻⁴³⁰ When this is indicated, it is highly preferable to place one IOL in the capsular bag and one in the sulcus to reduce the risk of interlenticular membrane formation.^{431, 432}

Corneal relaxing incisions can correct small amounts of preoperative corneal astigmatism, but for larger amounts, toric IOLs should be considered.⁴³³⁻⁴³⁵ A 2016 systematic review and meta-analysis found that toric IOLs provided lower amounts of residual astigmatism than nontoric IOLs, even when corneal relaxing incisions were used.⁴³⁴ (*I*+, *Good, Strong*) Toric lenses available in the United States are designed for implantation within the capsular bag. Toric calculators require preoperative measurement of the corneal cylinder and a knowledge of surgically induced astigmatism. Adding the contribution of the posterior cornea has been shown to improve outcome accuracy, whether by nomogram or by measuring the posterior cornea directly.⁴³⁶⁻⁴³⁹ The power of the toric component should be adjusted for the effective lens position of the IOL.

Most modern IOLs contain aspheric optical surfaces. These lenses improve mesopic and scotopic contrast sensitivity and visual quality by reducing or eliminating spherical aberration.⁴⁴⁰⁻⁴⁴⁴ However, they are less tolerant of tilt and decentration and might not be the best choice in patients with zonulopathy.⁴⁴⁵ Some surgeons choose the asphericity of an IOL to match the asphericity of the cornea to maximize visual quality under mesopic and scotopic conditions.^{446, 447}

Intraocular lens power can be confirmed or refined intraoperatively in the aphakic and pseudophakic states using intraoperative aberrometry. Aberrometry can assist with toric IOL axis alignment as well.⁴⁴⁸ Intraoperative aberrometry can be useful in eyes with a history of keratorefractive surgery such as photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK), although it is not as useful after radial keratotomy.^{449, 450} It is not clear that intraoperative aberrometry always improves outcomes.⁴⁵¹⁻⁴⁵⁴

POSTOPERATIVE MANAGEMENT

The operating ophthalmologist has the ultimate responsibility for the preoperative assessment⁶ and postoperative care of the patient, beginning with determining the need for surgery and ending with completing the postoperative care contingent on medical stability of the patient.^{5, 455} 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. 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.^{5, 456} Co-management is a relationship between an operating ophthalmologist and a nonoperating practitioner for shared responsibility in the postoperative care. Co-management occurs when the patient consents in writing to multiple providers, the services being performed are within the providers' respective scopes of practice, and there is written agreement between the providers to share patient care. Transfer of care takes place when there is transfer of responsibility for a patient's care from one qualified health care provider functioning within his or her scope of practice to another who also functions within his or her scope of practice.

The ophthalmologist who performs surgery has an obligation to inform patients about medication instructions, activity restrictions, postoperative eye protection, required visits, signs and symptoms of possible complications, and information for accessing emergency care. The ophthalmologist should also inform patients of their responsibility to follow the advice and instructions provided during the postoperative phase and to notify the ophthalmologist promptly if problems occur. Patients should always have access to an ophthalmologist for appropriate care if serious problems arise.

(See the Comprehensive Guidelines for the Co-Management of Ophthalmic Postoperative Care for detailed information.⁵)

Postoperative medication regimens vary among practitioners; use of topical antibiotics for infection prophylaxis and of topical corticosteroids NSAIDs for cystoid macular edema prophylaxis are discussed earlier in this PPP. Topical corticosteroids and NSAIDs are also used for control of postoperative inflammation, but there is insufficient high-level evidence to compare these interventions,⁴⁵⁷ (*I*+, *Moderate, Discretionary*) making it the decision of the operating surgeon to use one or both of these medication classes. 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, are rare complications of topical ocular NSAID use.⁴⁵⁸⁻⁴⁶⁰

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 promptly and accurately diagnosing and treating the complications of surgery, providing satisfactory optical correction, educating and supporting the patient, and reviewing postoperative instructions. Postoperative patients with low-risk surgeries and with no signs or symptoms of possible complications following cataract surgery should be seen within the first 48 hours of surgery. Studies have reported that, for the routine patient, omitting an examination on the day after uncomplicated cataract surgery is associated with a low frequency of serious ocular complications.⁴⁶¹⁻⁴⁶⁵ Functionally monocular patients and those at high risk of early postoperative complications should be seen within the first 24 hours of surgery.

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. In patients with low-risk, uncomplicated cataract surgery who are seen within 1 day of surgery and remain asymptomatic, a subsequent visit 1 week later rarely serves to change management;⁴⁶⁶ however, this visit may increase medication compliance. 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.

Components of each postoperative examination should include the following:

- Interval history, including use of postoperative medications, new symptoms, and selfassessment 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
- Provision of a 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 RD. However, dilation is often critical in assessing anterior ocular concerns, such as capsular contracture and IOL malposition and in evaluating retinal issues, such as cystoid macular edema.

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 neuroophthalmic abnormality. Other testing may be conducted if appropriate.

A final visit should be made to provide an accurate refractive prescription to allow for the patient's optimal visual function. Optical correction can usually be prescribed between 1 and 4 weeks after small-incision cataract surgery⁴⁶⁷ and between 6 and 12 weeks after sutured large-incision cataract extraction surgery.

APPENDIX 4. LITERATURE SEARCHES FOR THIS PPP

Literature searches of the PubMed database were conducted in March 2021. The search strategies were as follows. Specific limited update searches were conducted after May 2022. The searches had added filters for randomized controlled trials and systematic reviews and date limiters to capture literature published since 2017. The panel examined 3284 studies of which 53 were included in the PPP.

Keratorefractive Surgery:

("keratomileusis, laser in situ"[MeSH Terms]) OR ("photorefractive keratectomy"[MeSH Terms]) OR ("keratectomy, subepithelial, laser assisted"[MeSH Terms]) OR (epi-LASIK[tiab]) OR (epi-laser in situ keratomileusis[tiab]) OR (epi-laser in situ keratomileusis[tiab]) OR (epi-LASEK[tiab]) OR (epi-Laser-Assisted Sub-Epithelial Keratectomy[tiab]) OR (epi-Laser-Assisted Subepithelial Keratectomy[tiab]) Laser Epithelial Keratomileusis[tiab] AND ((Quality of Life[MeSH Terms]) OR (Patient Satisfaction[MeSH Terms]))

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

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

Scleral Surgery: "scleral surgery"[tiab] OR sclerotomy[tiab] OR "scleral expansion surgery"[tiab] OR "scleral expansion"

Femtosecond Laser Surgery: "femtosecond laser surgery"[tiab] OR (femtosecond[tiab] OR femtosecond laser[tiab]) AND cataract[tiab])

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

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

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

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

LASIK: (keratomileusis, laser in situ/adverse effects[MAJR]) OR (keratomileusis, laser in situ[MAJR]) AND (Treatment Outcome[MeSH Terms]) OR (keratomileusis, laser in situ[MAJR]) AND (Time Factors[MeSH Terms]) OR (keratomileusis, laser in situ[MAJR]) OR (lasik[tiab] OR laser in situ keratomileusis[tiab]) AND (outcome*[tiab] OR adverse[tiab] OR long-term[tiab] OR effect*[tiab] OR complication*[tiab] OR safety[tiab] OR trial[tiab] OR random*[tiab] OR review[tiab] OR comparative[tiab]) NOT (rabbit*[tiab] OR mouse[tiab] OR mice[tiab] OR animal*[tiab])

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

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

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

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

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

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

Refractive Surgery for Presbyopia: "presbyopia/surgery"[MeSH Terms] OR ((photoablation[tiab]) OR (ablation[tiab])) AND (presbyop*[tiab]) OR (anterior ciliary sclerotomy[tiab]) OR ((Sclerostomy[MeSH Terms]) AND (Ciliary Body[MeSH Terms])) OR (scleral expansion[tiab]) OR (presbyop*[tiab]) AND (surg*[tiab])

(sclerostomy[tiab]) AND (ciliary[tiab] OR scleral expan*[tiab])

Surface Ablation: (Surface ablation*[tiab])

Socioeconomic: "refractive errors" [MeSH Terms] AND "refractive surgical procedures" [MeSH Terms] AND ("economics" [MeSH Terms] OR "quality of life" [MeSH Terms] OR "cost effectiveness" [tiab])

RELATED ACADEMY MATERIALS

Basic and Clinical Science Course

- Clinical Optics (Section 3, 2022-2023)
- Refractive Surgery (Section 13, 2022-2023)

Focal Points

- Intracameral Medications for Cataract Surgery (2018)
- Management of Postoperative Refractive Surprises After Cataract Surgery (2019)
- Management of Cataract Surgery and Uveitis (2020)
- Micro-Invasive Glaucoma Surgery and Cataract Surgery Synergy (2018)

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

- Effectiveness of Laser Refractive Surgery to Address Anisometropic Amblyogenic Refractive Error in Children (2022)
- Femtosecond Laser-Assisted Cataract Surgery (2022)

• Intraocular Lens Power Calculations in Eyes with Previous Excimer Laser Surgery for Myopia (2021)

Patient Education Downloadable Handout

- Contact Lenses (2022)
- Laser Eye Surgery (2022)
- LASIK (2022)
- Laser Surgery of the Eye (2022)
- Photorefractive Keratectomy (PRK) (2022)
- Refractive Errors (2022)
- Refractive Surgery (subscription) (2022)
- Wavefront-Guided LASIK (2022)

Patient Education Video

- Microkeratome LASIK
- Femto LASIK
- PRK

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

- Cataract in the Adult Eye (2021)
- Comprehensive Adult Medical Eye Evaluation (2020)

To order any of the Related Academy Materials, except for the free materials, please contact the Academy's Customer Service at 866.561.8558 (U.S. only) or 415.561.8540 or <u>www.aao.org/store</u>.

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