

Summary Recommendations for Keratorefractive Laser Surgery

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Background

Laser assisted in-situ keratomileusis (LASIK) surgery is the most commonly performed keratorefractive surgery; altering the cornea of the eye. Other keratorefractive procedures to correct low to moderate myopia include variations of photorefractive keratectomy (PRK) – collectively termed surface ablation techniques – insertion of intrastromal corneal ring segments, and radial keratotomy (RK). Highlighted below are general summary recommendations for elective keratorefractive laser surgery based on expert opinion and consensus. The practices outlined are designed to promote the patient's best interests and safety.

Recommendations

Training

Ophthalmologists performing keratorefractive laser surgery should have:

- Appropriate training and certification on the laser and laboratory experience with the microkeratome
- Proctoring for the first several keratorefractive laser surgery cases

Marketing

Promotional materials are monitored and regulated by the Federal Trade Commission (FTC) and should provide accurate information about the safety, efficacy, and benefits of keratorefractive laser surgery based on reliable scientific evidence or consensus expert opinion (not anecdotal evidence or testimonials), including any material information about risks and limitations. For example, the FTC notes that, "It is important to keep in mind that the fact that the FDA has approved the excimer laser for use in PRK does not, by itself, necessarily provide adequate substantiation for all specific claims about the success of the procedure."

Patient Selection

In general, suitable candidates for keratorefractive laser surgery should meet the following criteria:

- Meet the FDA-approved guidelines for degree of myopia, hyperopia, and astigmatism
- Demonstrate refractive stability for a twelve month period, at least
- Be at least 18 years old. FDA labeling should be consulted for each laser. (For PRK procedures, the Summit Laser FDA indication is for patients 21 years and older)
- Express realistic expectations about the outcome of surgery. Assessment of a patient's preoperative expectations and psychological characteristics may be helpful¹
- Demonstrate a willingness to discontinue contact lens use due to the possibility of contact-lens-induced corneal warpage and corneal edema before the preoperative examination and procedure. (Generally, soft contact lenses should be discontinued for at least three days to two weeks. Toric soft contact lenses and rigid contact lenses should be discontinued for longer as they're associated with greater corneal warpage and refractive instability, which takes longer to resolve)

- Demonstrate a stable refraction and topography. In rigid contact lens wearers, stability may be documented on successive readings (at least one week apart)
- Have no contraindications to treatment; such as unstable refraction, certain abnormalities of the cornea, insufficient corneal thickness for the proposed ablation depth, significant cataract, uncontrolled glaucoma, uncontrolled external disease, uncontrolled autoimmune or other immune-mediated disease, and unrealistic patient expectations

Preoperative Patient Examination

A comprehensive medical eye evaluation should be performed before any refractive surgery procedure.² In determining suitability, a baseline eye evaluation should include:

- Distance visual acuity with and without correction
- Manifest and, when appropriate, cycloplegic refraction
- Evaluation of corneal topography for evidence of irregular astigmatism, corneal warpage or abnormalities suggestive of keratoconus or other corneal ectasias. All of these conditions may be associated with unpredictable refractive outcomes, and keratoconus and the ectasias with ectasia progression following keratorefractive surgery³⁻⁶
- Central corneal thickness measurement. In the case of LASIK procedures, 250µm is recommended as a safe residual stromal bed thickness,⁷ to help protect against ectasia. (Abnormal topography is the most significant risk factor for postoperative ectasia.)
- Evaluation of tear film and ocular surface
- Diluted fundoscopic examination
- Measurement of intraocular pressure (IOP)
- Evaluation of ocular motility and alignment⁸
- For PRK, retreatments should generally not be performed until manifest refraction, corneal haze, and corneal topography have stabilized, which usually requires at least six months healing after primary surgery. For LASIK, retreatments should generally not be performed until refractive stability has been achieved

Note: Importance of pupillometry in the preoperative workup remains controversial. Measurement of pupil size is not required in the preoperative examination.

Patient Education

Patient satisfaction depends on patient expectations and surgical outcome. Although there is a high probability for successful outcomes with keratorefractive laser surgery, potential adverse events or complications, either transient or permanent, may occur. The operating ophthalmologist has the responsibility to emphasize these risks, in addition to discussing benefits, and must:

- Inform patients about alternatives for vision correction, including glasses, contact lenses, and other types of refractive surgery
- Obtain informed, documented consent
- Explain the risks, possible complications, and side effects, including: over or under-correction; corneal scarring and inability to wear contact lenses; corneal infection; loss of best-corrected visual acuity (BCVA); loss of contrast sensitivity; flap problems; discomfort; blurry vision; dryness; glare; haloes; and light sensitivity
- Inform patients that there is a risk for night vision symptoms after keratorefractive surgery. Most studies of conventional and wavefront-guided LASIK have not shown a relationship between the diameter of the low light pupil and night vision symptoms postoperatively⁹⁻¹³

- Caution that high myopia is less likely to be fully corrected by laser surgery than low to moderate myopia,¹⁴ and that regression is more likely to occur postoperatively
- Discuss monovision in presbyopic and pre-presbyopic patients, and other limitations of keratorefractive surgery with respect to presbyopia
- Determine if expectations of patients are realistic
- Discuss postoperative care plans
- Discuss the costs associated with the surgery

Performance of Keratorefractive Laser Surgery

The operating ophthalmologist has the following responsibilities:

- Confirm the identity of the patient, the operative eye, and that the parameters are correctly entered into the laser's computer

Comparisons of Laser Technologies

In general different laser platforms use different proprietary ablative patterns, which may affect the outcomes of long-term stability of the refractive procedures. (See Refractive Errors and Refractive Surgery PPP for more detailed information.) Some notable differences between laser technologies include:

- Surface ablation techniques – i.e., PRK, laser epithelial keratomileusis (LASEK), and epi-LASIK -- preserve more residual posterior stromal tissue and there are no flap complications, but include more discomfort and slower recovery of vision when compared to LASIK¹⁵
- Compared with conventional LASIK, both wavefront-guided and aspheric laser ablations may lead to improved quality of vision under dim lighting conditions¹⁶
- Refractive outcomes may be less stable with PRK, as evidenced by a statistically significant regression at two years in the PRK group compared to no significant regression in the LASIK group^{17, 18}

Note: PRK keratectomy using wavefront-guided technology is considered an off-label use of an FDA-approved device.

Postoperative Management

Postoperative management is integral to the outcome of any surgical procedure and is the responsibility of the operating surgeon.^{19,20} The operating ophthalmologist or a designated ophthalmologist should:

- For PRK, perform the first postoperative visit within 48 hours following surgery and every two to three days thereafter until epithelium is healed. For LASIK, perform a postoperative examination within 36 hours following surgery and conduct a second visit within one to four weeks
- Provide follow-up care throughout the patient's at-risk period or arrange for this to be done by another appropriately trained ophthalmologist or optometrist
- Prescribe topical anesthetics where needed to help control postoperative pain
- Administer topical antibiotics to minimize the risk of postoperative infection
- Monitor corticosteroid-related side effects, such as elevated IOP

- Provide patient with a record that lists information about the patient's preoperative keratometry reading and refraction as well as stable postoperative refraction, in case the patient requires subsequent cataract surgery or additional eye care

Note: MedWatch (<http://www.fda.gov/Safety/MedWatch/default.htm>) is the Safety Information and Adverse Reporting Program for drugs and other medical products regulated by the FDA. Adverse experiences of keratorefractive laser surgery should be reported to MedWatch.

Co-management

The ophthalmic surgeon has the primary responsibility for the preoperative assessment and postoperative care of his/her patients, **regardless of the type of surgery performed**. The decision to co-manage should be the result of a determination of what is best for the patient and not economic considerations. If the co-management of patients is done on a routine basis for predominantly financial reasons, it represents unethical behavior and may be illegal. **Above all, patients' interests must never be compromised as a result of co-management.**

In the event that the ophthalmologist needs to co-manage with an optometrist(s), the ophthalmologist should:

- Verify and document that the optometrist(s) has the appropriate education, training, and skills to follow patients postoperatively
- Develop standardized guidelines and protocols regarding postoperative care of patients, particularly concerning communications
- Prior to surgery, inform the patient if there are any prearranged postoperative management plans. The patient must voluntarily consent to any prearranged postoperative management plans in writing
- Inform the patient of the financial implications resulting from the co-management arrangement, particularly with regard to the patient's payment obligations, and the postoperative provider's reimbursement
- Follow the patient until postoperatively stable. There is no fixed time when the patient is sent back to the referring provider
- Reassure the patient that he/she has access to the surgeon, if necessary, during the postoperative period at no additional cost

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