Refractive surgery for myopia: Case selection and management options

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INTRODUCTION
Refraction is the change in direction of light rays when these pass from one medium to another with a different refractive index. Structures in the anterior segment of the eye, namely cornea and lens, function to focus the incoming rays of light onto the retina. Myopia (near-sightedness) is a refractive state of the eye where in a non-accommodating eye light rays from infinity are focused in front of the retina producing a blurred retinal image. Refractive errors account for 70%–90% of visual impairment in Asia,1,2 and of about 20% in the western world (USA, Europe and Australia).3 Spectacles and contact lenses are the principal methods for correction of refractive errors. The development of excimer laser in ophthalmology has opened a gamut of safe and effective treatment options for surgical correction of refractive errors. Much progress has been made in this field over the past two decades. This article focuses specifically on the surgical correction of myopia.

HISTORICAL EVOLUTION OF MYOPIA SURGERY
The first description of refractive surgery dates back to 1885 when corneal incisions were made for the correction of myopia.4 Jose Barraquer developed the first microkeratome and is considered the father of lamellar surgery. The initial techniques of epikeratophakia and keratophakia, done for aphakia and high myopia, involved making a lamellar corneal flap and then moulding the cap in a cryolathe, according to the degree of refractive error.5 The results of these procedures were unpredictable, and regression of the refractive correction was common; hence, these procedures were soon abandoned.

Radial keratotomy (RK) involves creation of radial corneal incisions of 90% depth to flatten the central cornea, thus correcting the myopia.6 In the Prospective Evaluation of Radial Keratotomy (PERK) trial,7 43% of patients showed a significant hyperopic shift at 10 years. Because of the problems of unpredictability and lack of stability, the number of these surgeries too declined drastically and the procedure is currently obsolete.

With the development of excimer laser systems in the 1990s, surgery for myopia has undergone a transition from incisional procedures to ablative procedures. Since then, procedures for laser vision correction (LVC) have been modified several times and are now the most commonly performed refractive procedures for the correction of myopia.

CLASSIFICATION OF VARIOUS SURGICAL PROCEDURES
Since cornea and lens are the two main refracting media in the eye, myopia can be corrected by surgery on either of these (Table I). The more commonly performed cornea-based procedures follow the principle of subtraction of tissue by laser ablation. Lens-based correction is reserved for patients in whom the refractive error is very high or the corneal thickness is inadequate for performing a corneal ablative procedure using laser.

SELECTION OF PATIENTS AND PREOPERATIVE WORK-UP
In view of the elective nature of refractive surgery, the selection of appropriate surgical candidates is of paramount importance.8

Patient’s history
Active infections or inflammatory conditions of the eye, past history of herpetic keratitis, glaucoma, uveitis, retinal detachment, or ocular trauma necessitating surgical repair are considered as contraindications for LVC procedures. In patients with history of dry eyes or allergic conjunctivitis, these coexisting conditions must be adequately managed before the procedure. Use of systemic drugs such as amiodarone and isotretinoin should be enquired.

Table I. Classification of refractive surgeries

<table>
<thead>
<tr>
<th>Corneal refractive surgeries</th>
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<tbody>
<tr>
<td>1. Photo-refractive keratectomy (PRK)</td>
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<td>2. Laser-assisted subepithelial keratomileusis (LASEK)</td>
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<td>3. Epithelial laser-assisted stromal in situ keratomileusis (Epi-LASIK)</td>
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<td>4. Laser-assisted stromal in situ keratomileusis (LASIK)</td>
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<th>Lenticular refractive surgeries</th>
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<tr>
<td>1. Femtosecond lenticule extraction (FLEX) and small incision lenticule extraction (SMILE)</td>
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about, since these are known to affect wound healing after surgery, as are connective tissue disorders. Patients above the age of 18 years who have stable refractive error (with variation of up to 0.5D) for at least a year are considered eligible for refractive surgery. Patients using contact lenses must discontinue their use for at least a week for soft contact lens and 3 weeks for rigid lenses.

**Ocular parameters and examination**

The following steps are mandatory before LVC:

- Recording of uncorrected and corrected distance visual acuity, and the power of the spectacles or contact lenses being used.
- Accurate refraction under cycloplegia and precise final subjective manifest refraction.
- Measurement of corneal curvature (keratomy) using either a manual or an automated keratometer; values below 39 dioptres (D) or above 47D should arouse suspicion of an abnormal cornea.
- Assessment of corneal topography along with pachymetry and precise final subjective manifest refraction.
- Assessment of corneal thickness (pachymetry) using an ultrasonic or slit-scanning technique. If it is below 500 μ, cautious evaluation may be needed to rule out ectatic corneal disorders.
- Contrast sensitivity and glare acuity.
- Mesopic pupil size; since large pupil size has traditionally been associated with night vision problems though recent studies have failed to find this association.9,10
- A thorough slit-lamp examination to look for adnexal problems, corneal dystrophy or scars, or lenticular opacities.
- Assessment of ocular surface and tear function using corneal staining, tear break up time and Schirmer test.
- Screening of retina using indirect ophthalmoscopy to rule out any peripheral treatable lesions as these predispose to retinal detachment.
- Detailed counselling of the patient, including discussion of the patient’s expectations and of the anticipated problems.

**Special investigation tools**

In addition to the above, the following specialized investigations are an integral part of the preoperative work-up.

- **Schiempflug imaging of the cornea (Pentacam):** Using the slit-scanning system, anterior and posterior elevation maps, and topographic and pachymetry maps are prepared. The Belin Ambrosio Display (BAD) map shows posterior elevation data relative to an enhanced best fit sphere along with corneal thickness spatial profile (CTSP) and percentage thickness increase (PTI). This enables early identification of ectasia in patients undergoing refractive surgery.
- **Anterior segment optical coherence tomography (ASOCT):** It allows imaging of the cornea with delineation of the flap and its morphology and thickness.
- **Aberrometry:** It allows study of optical aberrations of the entire ocular system and assessment of the wavefront in the form of Zernike polynomials. Conventional LASIK is known to induce spherical aberration. Hence, newer platforms that provide wavefront-optimized (aspheric ablation) and wavefront-guided ablation profiles, which reduce such aberrations after surgery, and hence provide better quality of vision.

**TYPES OF KERATO-REFRACTIVE SURGERY**

**Surface ablation procedures**

These include photo-refractive keratectomy (PRK), laser-assisted subepithelial keratomileusis (LASEK) and epithelial laser-assisted stromal in situ keratomileusis (Epi-LASIK), wherein ablation occurs just under the epithelium, including the Bowman layer and the superficial stroma. These procedures essentially lack the risks of flap-related conditions that are associated with LASIK. Hence, these procedures are preferred in persons working in armed forces and involved in contact sports. Patients with thin cornea and anterior epithelial basement membrane dystrophy are better treated using surface ablation. These procedures are approved for the treatment of mild-to-moderate myopia.

**PRK** involves removal of the overlying epithelium before stromal ablation using 15%–20% alcohol or manually using an electric toothbrush followed by ablation of the stroma using excimer laser, followed by application of a bandage contact lens.

**LASEK** involves removal of the epithelium as a sheet with 20% alcohol only to be placed back at the end of the procedure. The corneal epithelial sheet is considered essential in maintaining balanced epithelial stromal interaction and can produce inflammatory cytokines and fibroblast transformation when damaged.

**Epi-LASIK** is based on the same principle as LASEK except that the epithelial sheet is removed using epikeratome—an motorized machine similar to that used in LASIK.

Since the epithelial sheet is left behind intact in LASEK and Epi-LASIK, some workers claim that these procedures induce less discomfort than PRK, though this has not been proven consistently.11 Disadvantages of these surface ablation procedures over LASIK include the greater postoperative discomfort, longer period for visual recovery and corneal haze.

**Intrastromal corneal ring segments (ICRS)**

These were originally developed to correct low degrees of myopia (−1D to −3D) by an ‘arc-shortening effect’. These rings, made of polymethyl methacrylate (PMMA), are available in varying thicknesses from 250 μ to 450 μ (at 25 μ to 50 μ increments) and are implanted intrastromally at 80% depth in the channels created manually or using a femtosecond laser. Presently, the clinical use of ICRS is restricted to the treatment of keratoconus and post-LASIK ectasia.

**LASIK**

LASIK is the most commonly performed refractive surgery and is the preferred technique in the low and moderate myopes (<6D) where appropriate preoperative screening has been done. The surgery involves creation of a lamellar corneal flap (which includes the epithelium and superficial stroma) followed by excimer ablation of the stroma using the argon fluoride laser (193 nm). The flap is repositioned at the end of the surgery allowing it to adhere by functioning of the endothelial pump, although the flap no longer provides any biomechanical strength to the cornea.

**Femtosecond LASIK.** Femtosecond (FS) has nearly replaced mechanical microkeratomes for flap creation in LASIK. It is an Nd-YAG solid-state laser that uses a near-infrared (1053 nm) scanning pulse which is focused to 3 μm spots at a preset depth of 1 μm, thus allowing formation of precise lamellar flaps by photodisruption.12 Each laser pulse creates a tiny 2–3 μm bubble of carbon dioxide and water vapour. In this procedure, the eye is fixed with a suction ring through which the cornea is applanated with a disposable contact lens that couples the eye to the laser system during the procedure. The software in the LASER system
first creates a canal and then the laser pulses are delivered to the stroma in a raster pattern from the hinge across the cornea for the set diameter of the flap (Fig. 1).

**Microkeratome versus femtosecond flap.** Femtosecond flaps are planar compared to the meniscus-shaped flaps created with a microkeratome. The flap thickness is consistently within 10 µm of intended thickness. The flap can be created over a wide range of thickness profiles compared to only a few modifications that are possible with the microkeratome. The increased side cut angle in femtosecond flaps act as a barrier to epithelial cells preventing complications, such as flap displacement and epithelial ingrowth. In various studies, the final visual outcome with these procedures have been comparable.

**Newer ablation profiles**

Conventional LASIK or standard profile applies a simple sphero-cylindrical correction and is known to induce positive spherical aberrations dependent on the amount of intended correction. Ablation profiles have been developed to reduce this complication and provide better postoperative visual outcome. Wavefront-optimized profile designed to reduce or eliminate the induced spherical aberration of conventional LASIK removes additional tissue from the periphery to provide smoother transition zones. The excimer LASER system can be coupled to patient’s topography map or wavefront map to generate a complementary ablation profile; this is referred to as the topoguided LASIK and wavefront-guided LASIK, respectively. Topoguided LASIK is specifically used in patients with higher amounts of astigmatism or for enhancement procedures. Wavefront-guided ablation profile aims to correct all the optical aberrations of the eye and not just the sphero-cylindrical refractive error. The complications of LASIK are listed in Table II.

**Refractive lenticule extraction**

This is the latest development in the field of keratorefractive surgery where an intrastromal lenticule corresponding to the degree of myopia is carved using femtosecond laser and the same removed after creation of a flap as was described first (femtosecond lenticule extraction; FLEX) or through a 2 mm side cut incision (small incision lenticule extraction; SmILE). It is an all femtosecond procedure and the excimer platform for the stromal ablation is not required. It is a viable option for patients with myopia –2 to –8D with astigmatism of <1D and is presently available only in Visumax femtosecond laser platform (Carl Zeiss Meditec AG). Since the femtosecond is not coupled with a registration system, patient fixation throughout the procedure is extremely important. The specific advantages of the SmILE procedure include probably less dry eye and better biomechanical effects as no flap is created. It is considered safer than LASIK/ReLEX for people in the armed forces and those playing contact sports as there is no risk of displacement of the flap.

**LENS-BASED REFRACTIVE SURGERIES**

Lens-based refractive surgeries are indicated mainly for patients with marked myopia who may not be suitable candidates for corneal ablation procedures.
TABLE II. Complications of LASIK14–20

**Intraoperative**
- Flap-related: tear, buttonhole, free cap, eccentric flap
- Epithelial defect at flap edge
- Suction loss
- Decentered ablation
- Femtosecond-related: air bubble in anterior chamber, persistent opaque bubble layer (OBL)

**Early postoperative**
- Dry eyes
- Diffuse lamellar keratitis
- Pressure-induced stromal keratopathy
- Infectious keratitis
- Flap striae
- Under- or over-correction
- Transient light sensitivity syndrome: with femtosecond LASIK

**Late postoperative**
- Dry eyes
- Night vision problems: glare, haloes
- Epithelial ingrowth
- Keratectasia
- Regression
- Loss of best corrected visual acuity (BSCVA)

LASIK laser-assisted stromal in situ keratomileusis

1. **Phakic** intraocular lens (IOL) is the most commonly performed surgery wherein the patient’s crystalline lens is retained and another IOL corresponding to the amount of refractive error is implanted in the eye either in the angle, fixed to the iris or in the sulcus just above the anterior lens capsule. The natural crystalline lens is left behind compared to cataract surgery where it is extracted and replaced with an IOL.

2. **Refractive lens exchange**: Clear lens extraction with implantation of a multifocal IOL/accommodative IOL. It is not done in pre-presbyopic myopic patients in whom accommodation is still retained. This procedure has a high risk of retinal detachment (0%–8%) and hence is rarely done.22

The currently available phakic IOL models classified on the basis of their site of placement are as follows:

**Angle-supported phakic IOLs**
1. PMMA IOLs: These require a larger incision and may cause surgically induced astigmatism. These models are no longer in use.
2. Foldable angle-supported IOLs
   a. Acrysof Cachet
   b. Kelman Duet

**Iris fixated anterior chamber IOLs**
1. PMMA iris claw IOL: Veriseye/Artisan
2. Foldable iris claw IOL: Veriflex/Artiflex

**Posterior chamber phakic IOLs**
1. Implantable collamer lens (ICL)
2. Phakic refractive lens (PRL)

Of all the designs described, ICL is the most commonly used because of ease of implantation and established safety profile.

**ICL description**
The ICL (STAAR Surgical Co, Monrovia, California) is biocompatible, made from a combination of copolymer (pHEMA, water, benzophenone) and collagen; hence, called Collamer. It is a foldable lens which can be inserted into the eye through a 3.2 mm incision and has a plate haptic design with the haptics being tucked behind the iris to be placed in the ciliary sulcus (Fig. 2). It is available in the following range of powers: –18D myopia, +10D hyperopia and +6D cylinder. The latest design of ICL version V4c has a central hole of 0.3 mm which allows the flow of aqueous from the posterior to anterior chamber obviating the need of a laser iridotomy before the surgery.

**Patient selection for phakic IOLs**
The preoperative work-up is done as described for a corneal refractive procedure. The specific investigations required are the specular count of the corneal endothelium as patients with cell count <2500 cells/mm² are contraindicated for the procedure. The patient’s anterior chamber depth must be adequate (>2.8 mm) and the white-to-white diameter measured on Orbscan or digital caliper should be symmetrical in both eyes.

**OUTCOMES OF KERATO-REFRACTIVE SURGERIES**
The results of kerato-refractive surgeries are gauged by their efficacy, stability and safety.

- The efficacy of the procedure is ascertained by the proportion of patients achieving postoperative uncorrected visual acuity (UCVA) of 6/6 or better, and the proportion of eyes with postoperative manifest refractive spherical equivalent (MRSE) within ±0.5D or ±1.0D of the intended refractive correction.
- Stability is an important parameter to assess as epithelial and stromal tissue remodelling is known to cause regression of the refractive effect. It is measured by determining the mean change in MRSE over a defined time interval.
- Safety is measured by the percentage of eyes with postoperative loss of two or more lines of best corrected visual acuity (BCVA) on the Snellen chart and the incidence of surgical complications.

**Outcomes of PRK and LASIK**

**Efficacy.** Most studies of PRK have reported an efficacy of 70% of patients achieving MRSE within ±1D.21–23 A postoperative UCVA of 6/12 or better was achieved by more than 80% of patients in these studies but outcomes were lower in patients with higher myopia. A Cochrane review reported no significant differences in efficacy outcomes between PRK and LASIK or for low-to-moderate myopia versus high myopia subgroup.26

**Stability.** The amount of myopic regression postoperatively is more frequent and severe with high myopic eyes.24 Post-LASIK MRSE gets stabilized within 3–6 months.27

**Safety.** In PRK, around 3.2% of eyes lost two or more lines of BCVA. The mean percentage reported for LASIK is 1.0%–2.3%.28 Post-PRK subepithelial haze peaks at 3–6 months postoperatively and clears by 12 months. Comparing LASIK versus PRK with regard to safety, the percentage of eyes losing two or more lines of BCVA were significantly lower in LASIK studies than in PRK studies indicating that LASIK had superior safety.23 A Cochrane review found no significant difference in safety between the two techniques.26

**Femtosecond LASIK versus microkeratome LASIK**
A recent meta-analysis by Zhang et al.29 analysed various randomized controlled trials and individual studies comparing the femtosecond technology with mechanical microkeratomes. The refractive outcomes were comparable as were the safety
profile except that diffuse lamellar keratitis was more likely in the femtosecond group and the flap buttonhole more in the microkeratome group. Total higher order aberrations and spherical aberrations were more common in the microkeratome group owing to the meniscus-shaped flap resulting in peripheral steepening and central flattening with the induced spherical aberration.

**Wavefront-guided LASIK versus conventional LASIK**

Though the wavefront-guided treatment seemed to offer advantages over other profiles theoretically, studies show that higher-order aberrations are increased after the procedure; however, less higher-order aberrations occur after the conventional LASIK. In another study, there was no significant difference between wavefront-optimized and wavefront-guided treatment profiles and it was recommended that the wavefront-guided profile be reserved for those with higher-order aberration profiles of $>0.3 \mu$ RMS error preoperatively.

**Low-to-moderate myopia versus high myopia**

The results of trials approved by the US Food and Drug Administration for low-to-moderate myopia versus high myopia are given in Table III. The efficacy of LASIK in high myopes is evidently less compared with low-to-moderate myopes and hence alternative surgical options are usually provided to these patients.

**Quality of life after LASIK**

The overall patient satisfaction rate after primary LASIK surgery is reported to be around 95%.

**TABLE III. Outcomes of low-to-moderate myopia versus high myopia**

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<thead>
<tr>
<th>Parameter</th>
<th>Low-to-moderate myopia (≤6D)</th>
<th>High myopia (&gt;6D)</th>
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<tbody>
<tr>
<td>MRSE within ±1D</td>
<td>96%</td>
<td>80%</td>
</tr>
<tr>
<td>MRSE within ±0.5D</td>
<td>81%</td>
<td>61%</td>
</tr>
<tr>
<td>UCVA ≥20/40</td>
<td>96%</td>
<td>89%</td>
</tr>
<tr>
<td>UCVA ≥20/20</td>
<td>72%</td>
<td>48%</td>
</tr>
</tbody>
</table>

MRSE manifest refractive spherical equivalent    UCVA uncorrected visual acuity

**OUTCOMES OF LENS-BASED REFRACTIVE PROCEDURES**

Since ICL implantation is the most common procedure among phakic IOLs, we have discussed only its safety and efficacy. Numerous studies have proved the efficacy of ICL with the mean postoperative SE range from 0.02 to –2 and 80%–100% of patients within ±1D and 60%–100% patient having UCVA of ≥0.5%. Common complications include anterior subcapsular cataract formation, pupillary block glaucoma and pigment dispersion. A patent iridotomy or centraflow technology (in ICL V4c) and an adequate postoperative vault (distance between the posterior surface of ICL and anterior lens capsule) of 500–750 µ prevents most of these complications. Studies comparing the previous versions of ICL with V4c show good and comparable optical quality with safe intraoperative control.

**CONCLUSION**

The surgical options for treatment of myopia appear to be safe and effective subject to the amount of refractive error and corneal thickness, in the absence of any other pre-existing ocular illness.
A thorough preoperative screening and counseling regarding patient expectations can improve outcomes and minimize complications.

REFERENCES


