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# 1

## Terminology, Classification, and History of Refractive Surgery

SHILPA GULATI, ANTONY M. POOTHULLIL, AND DIMITRI T. AZAR

### Introduction: Why Do Patients Choose Refractive Surgery?

Patients desire refractive surgery for a variety of reasons. For patients seeking laser in situ keratomileusis (LASIK) or surface ablation, the most common motivation is a desire to decrease contact lens or spectacle use.<sup>1-3</sup> Some individuals require improvement in their uncorrected visual acuity (UCVA) because of their careers. Others have ocular or medical conditions that make contact lens wear difficult or dangerous. Some prefer to be free of glasses or contacts when engaging in sports and recreation. Presbyopic patients may want to be able to read clearly without glasses. Still others have anisometropia or spectacle-related anisophoria such that corrective spectacle lenses result in prominent eyestrain and an unacceptable degree of discomfort. Cosmetic appearance may also be a reason for surgery.

The number of refractive surgical procedures available to patients has increased dramatically since the early days of radial keratectomy (RK) and keratomileusis. Recent developments are discussed in this textbook, including customized LASIK, small-incision lenticule extraction (SMILE), presbyopic implants, and multifocal IOLs. Patients who have had LASIK for the correction of myopia are generally very happy. In a survey by Miller et al., approximately 85% were at least "very pleased" with their refractive outcome and 97% said they would decide to have the procedure performed again.<sup>4</sup> Factors that correlated well with patient satisfaction were postoperative improvements in UCVA, decreased cylindrical correction, and absence of side effects, such as dry eye. While this may be comforting, it is important to remember that the vast majority of refractive surgery is performed on patients with excellent corrected visual acuity and a decrease in quality of vision is ultimately undesirable. With continued advancements of refractive procedures, we can minimize complications, improve outcomes, and educate our patients and ourselves.

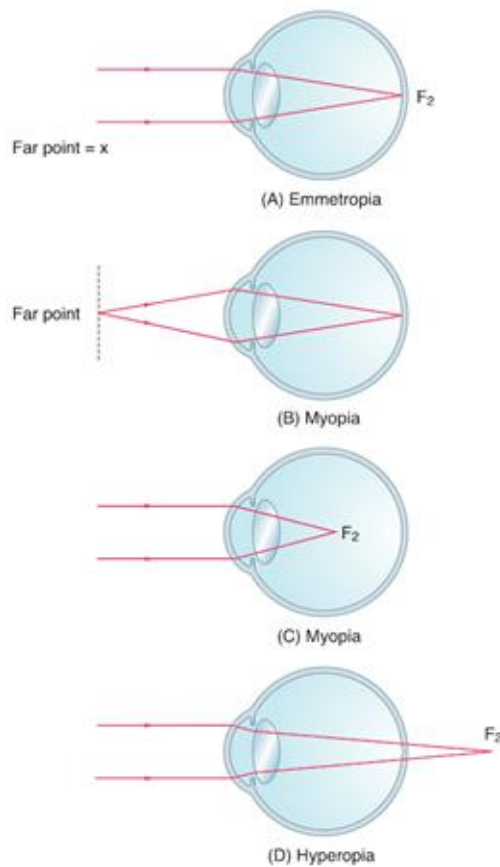
### Emmetropia, Ametropias, and Presbyopia

The successful performance of refractive surgery demands a thorough understanding of the optics of the human eye. The refractive power of the eye is predominantly determined by 3 variables: the power of the cornea, the power of the lens, and the length of the eye. In emmetropia, these 3 components combine in such a way as to produce no refractive error. When an eye is emmetropic, a pencil of light parallel to the optical axis and limited by the pupil focuses at a point on the retina (i.e., the secondary focal point of an emmetropic eye is on the retina; Fig. 1.1). The "far point" in emmetropia (defined as the point conjugate to the retina in the nonaccommodating state) is optical infinity.

Eyes with refractive errors can have abnormalities in one or more of the above variables, or all variables can be in the normal range but incorrectly correlated, resulting in a refractive error. For example, an eye with an axial length in the upper range of normal may be myopic if the corneal variable is also in the steeper range of normal. In a myopic eye, a pencil of parallel rays is brought to focus at a point anterior to the retina. This point, the secondary focal point of the eye, is in the vitreous. Rays diverging from the far point of a myopic eye will be brought to focus on the retina without the aid of accommodation.

The hyperopic eye, on the other hand, brings a pencil of parallel rays of light to focus at a point behind the retina. Accommodation of the eye may produce enough additional plus power to allow the light rays to focus on the retina. Rays converging toward the far point farther behind the eye will be focused on the retina while accommodation is relaxed.

For full correction of myopia and hyperopia, a distance corrective lens placed in front of the eye must have its secondary focal point coinciding with the far point of the eye so that the newly created optical system focuses parallel rays onto the retina.



• **Fig. 1.1** Schematic diagrams of emmetropia, myopia, and hyperopia. (A) In emmetropia, the far point is at infinity, and the secondary focal point ( $F_2$ ) is at the retina. (B and C) In myopia, the far point is in front of the eye and the secondary focal point,  $F_2$ , is in the vitreous. (D) In hyperopia (bottom), the secondary focal point,  $F_2$ , is located behind the eye. (Modified with permission from Azar DT, Strauss L. *Principles of applied clinical optics*. In: Albert D, Jakobiec F, eds. *Principles and Practice of Ophthalmology*. Philadelphia: WB Saunders; 1994.)

Astigmatism may be caused by a toric cornea or, less frequently, by astigmatic effects of the native lens of the eye. Astigmatism is regular when it is correctable with cylindrical or spherocylindrical lenses so that pencils of light from distant objects can be focused on the retina. Otherwise, the astigmatism is irregular. Visual acuity is expected to decline for the different degrees of astigmatism. Astigmatism of 0.50 to 1.00 diopters (D) usually requires some form of optical correction. An astigmatic refractive error of 1.00 to 2.00 D decreases uncorrected vision to the 20/30 to 20/50 level, whereas 2.00 to 3.00 D may decrease UCVA to the 20/70 to 20/100 range.<sup>5</sup>

Presbyopia is the age-related loss of accommodation. Onset of presbyopia will vary with the refractive error and its method of correction. For example, myopes corrected

**TABLE 1.1** Classification of Lenticular and Scleral Refractive Procedures

	M	MyA	H	HA	MxA	A	P
CLE	+			+			
PIOL	+			+			
Bioptics	+	+	+	+	+	+	
Multifocal	+		+				+
Accommodative IOL	+		+				+
Phaco-Ersatz							+
Scleral relaxation, expansion							±

A, Aphakia; CLE, clear lens extraction; H, hyperopia; HA, hyperopic astigmatism; IOL, intraocular lens; M, myopia; MxA, mixed astigmatism; MyA, myopic astigmatism; P, presbyopia; PIOL, phakic intraocular lenses.

with spectacles can simply remove their glasses for improved reading vision. Latent hyperopes, on the other hand, use their accommodative reserve for clear distance vision; as the amplitude of accommodation wanes with age, reading difficulties emerge.

### Classification of Refractive Procedures

Refractive surgery procedures are undergoing constant development and modification. In the late 1990s, LASIK has essentially replaced RK as the preferred treatment for patients with myopia. More recently, SMILE and multifocal IOLs have gained increasing popularity and phakic intraocular lenses (PIOLs) have undergone numerous modifications for the treatment of higher degrees of myopia or hyperopia. With an expanding repertoire of options, it is important to have an organized understanding of the surgical techniques that are available to the refractive surgeon.

Refractive surgery procedures for the correction of myopia, hyperopia, presbyopia, and astigmatism achieve emmetropia by modifying the optical system of the eye. In this chapter, we have divided surgical techniques into 2 broad categories: keratorefractive (corneal-based) and lenticular or scleral surgical procedures. Keratorefractive techniques surgically alter the cornea without entering the anterior chamber and are the main type of refractive surgery performed today. The lenticular or scleral refractive procedures include intraocular techniques, such as the insertion of multifocal, accommodating, and adjustable lenses, and extraocular methods, such as scleral relaxation or expansion procedures for presbyopia (Table 1.1).

### Keratorefractive Surgery

Keratorefractive surgeries rely on at least five major methods to reshape the corneal surface: lasers, incisions, corneal implants, thermal procedures, and nonlaser lamellar surgery.

All procedures induce corneal changes by affecting the corneal stroma. Excimer lasers are used to subtract tissue from the stroma and modify corneal shape. With incisional surgery, a blade is used to make precise cuts into the stroma. These incisions result in wound gape, altering the corneal surface contour, resulting in changes in the refractive power of the cornea. Corneal implants can be placed into the corneal stroma to change corneal shape. Thermal techniques cause focal changes in stromal collagen architecture in order to change corneal contour. At present, thermal methods are limited to the correction of hyperopia or presbyopia. Non-laser lamellar surgeries add or subtract tissue from the cornea in order to reshape it. With lamellar addition procedures, donor corneal tissue is transplanted to the host cornea. Lamellar subtraction procedures involve two stages: (1) lamellar stromal dissection and (2) removal of stromal tissue. Many of these procedures have the unintended side effect of reducing corneal tensile strength. Our understanding of corneal biomechanics has increased and has allowed us to develop safer keratorefractive procedures for our individual patients.<sup>6-9</sup>

### Keratorefractive Procedures: Myopia and Myopic Astigmatism

Myopia is the most common visually significant refractive error, with a rising prevalence of 25% to 40% in Western countries.<sup>10,11</sup> In the United States, the prevalence of myopia has doubled in the last 30 years and pathologic myopia (over 8.00 D) has risen eightfold.<sup>12</sup> Numerous procedures have been developed to treat myopia by altering the corneal curvature. The cornea is responsible for 60% of the eye's refractive power; small changes in curvature can produce significant refractive changes. Corneal procedures correct myopia by flattening the anterior curvature or changing the index of refraction of the cornea. All keratorefractive procedures for the treatment of myopia modify the corneal thickness to produce anterior curvature alterations except for RK, in which the corneal curvature is flattened by tectonic weakening without changing the central thickness.<sup>13</sup>

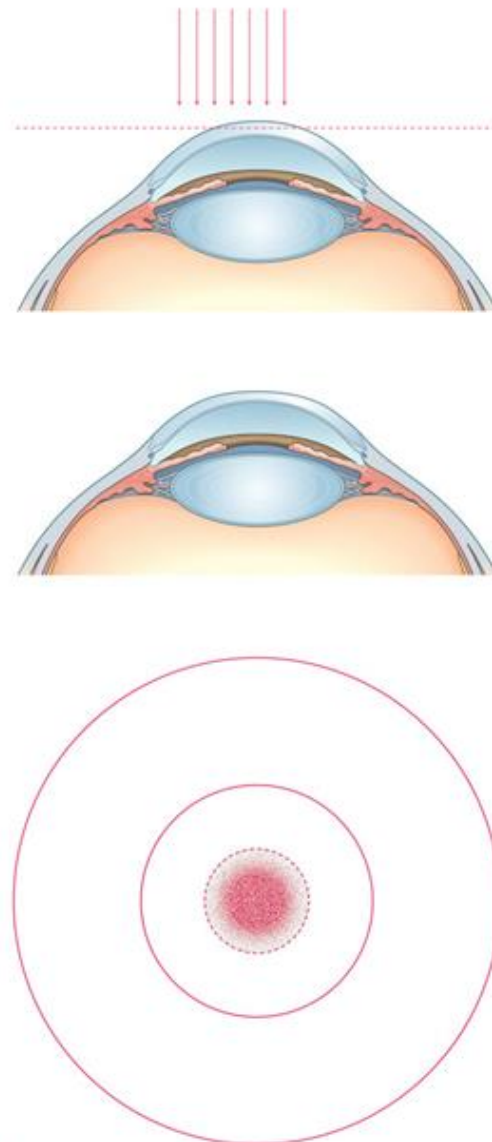
### Laser Procedures

The excimer laser, a 193-nm argon fluoride (ArF) beam, has become the technology of choice for keratorefractive surgeons worldwide. A major advantage of the laser is its ability to precisely ablate tissue with submicron pulses. The excimer laser-ablated surface has the potential of being smoother than that obtainable by other surgical techniques. Since its introduction in 1983 by Trokel and Srinivasan for linear keratectomy, the excimer laser procedure has undergone a rapid evolution.<sup>14</sup> Myopic excimer laser treatments achieve their effect by flattening the central cornea. The laser can reshape the cornea by ablating the anterior corneal surface, as in *photorefractive keratectomy* (PRK) or *laser-assisted subepithelial keratectomy* (LASEK or epi-LASEK).

More commonly, the laser is used to perform corneal stromal ablation under a lamellar flap, termed *laser in situ keratomileusis* (LASIK).

### Laser Procedures for Myopia

In PRK, the excimer laser is applied to the anterior surface of the cornea for reshaping (Fig. 1.2). The laser may be used

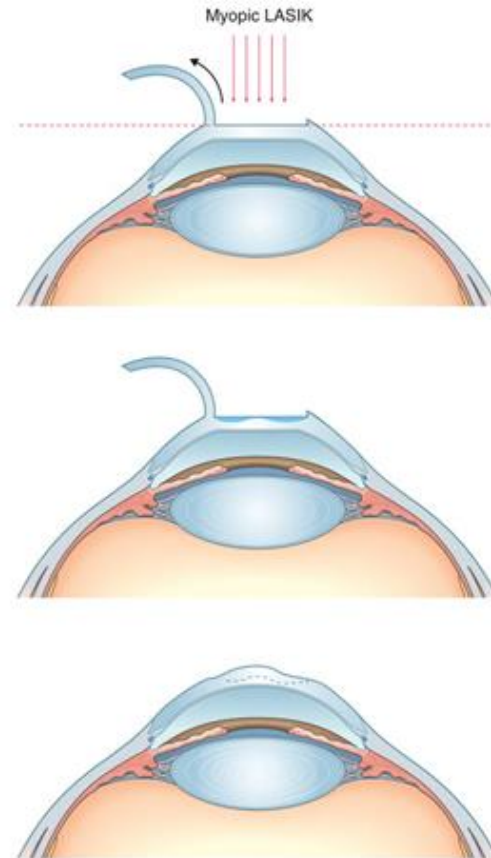


• **Fig. 1.2** Schematic illustration of myopic photorefractive keratectomy. The shaded area refers to the location of tissue subtraction. More stromal tissue is removed in the central as compared to the para-central region.

to remove the corneal epithelium. Alternatively, the epithelium may be removed by scraping with a surgical blade or by using dilute ethanol and a cellulose sponge. For myopia of 1 D to 7 D, PRK has been shown to result in a high rate of preservation of best corrected visual acuity (BCVA) and minimal complications. In most series, 90% of patients achieve 20/40 or better uncorrected acuity and are within 1 D of emmetropia. In this moderate myopia group, the initial overcorrections generally regress toward emmetropia over several months, with stabilization after 6 to 12 months. Highly myopic patients often regress 6 to 12 months after surface PRK, presumably because of stromal regeneration and/or epithelial hyperplasia, which cause re-steepening of the ablated zone.<sup>15</sup> Dense subepithelial haze occurs rarely but is greater in PRK treatments exceeding 6 D and may reduce the BCVA. Mitomycin C has been applied during PRK treatments in order to decrease the incidence of haze formation.<sup>16</sup> Artola et al. found that induced corneal aberrations after PRK for myopia created a multifocality that enhanced near acuity, which may delay the onset of presbyopic symptoms. However, this multifocality also reduced the quality of the retinal image for distance at low contrast.<sup>17</sup>

LASEK and epi-LASIK are modifications of the PRK procedure in which the corneal epithelium is preserved, displaced prior to surface ablation, then replaced after laser application. Advantages over PRK include decreased postoperative discomfort, reduced postoperative scarring, and faster visual recovery. Prior to laser application, the epithelium is treated with 15% to 20% ethanol. This treatment weakens hemidesmosomal attachments between the corneal epithelium and the underlying Bowman membrane. The epithelial sheet can then be easily displaced and protected by moving it outside of the ablation zone. Following stromal ablation, the epithelial sheet is returned to its original location, covering the ablated area.<sup>18</sup> Pallikaris et al. have described epi-LASIK, using an automated blade to remove the corneal epithelium mechanically, without the application of alcohol. They suggest that this technique should provide improved comfort and decreased haze formation compared to PRK, and histologic studies show better preservation of the corneal epithelial sheet when compared to LASEK.<sup>19,20</sup>

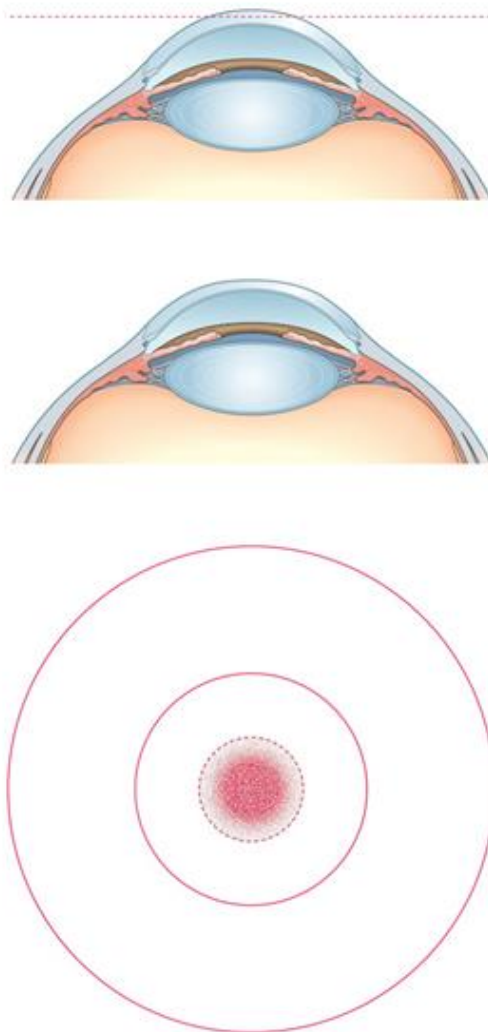
LASIK is a two-stage procedure that combines lamellar surgery with laser application. It has become the most widely performed refractive procedure in the United States. Its main advantages over surface ablation procedures include faster visual recovery, less postoperative discomfort, and decreased incidence of postoperative corneal scarring or haze in patients with higher refractive errors. During LASIK, an anterior corneal flap is created and then is lifted, the excimer laser is applied to the stromal bed, and the flap is returned to its original position (Fig. 1.3). The corneal flap can be created with either a microkeratome or an intrastromal laser. Microkeratomes are affixed to the globe via a suction device and the blade is passed via a manual or automated mechanism. The femtosecond (FS) laser is a solid-state laser with a 1053-nm wavelength that can be



• **Fig. 1.3** Schematic illustration of myopic and hyperopic laser in situ keratomileusis. A superficial corneal flap is raised. The shaded area refers to the location of tissue subtraction under the flap. After treatment, the flap is repositioned.

used to photodisrupt the corneal stroma with a preset depth and pattern. When used for LASIK, the laser creates the corneal flap prior to excimer laser application.<sup>21</sup>

Customized corneal ablations use Q-based or "wave-front" aberrometers to detect and treat both spherocylindrical error and higher-order aberrations (HOAs) that can affect visual acuity. At the time of publication, these devices are approved in the United States for the treatment of myopic and astigmatic refractive errors. These custom lasers offer the possibility of improved vision compared to traditional excimer lasers because they address additional factors that may be contributing to blur in an individual's optical system.<sup>22</sup> A study of 132 eyes undergoing LASIK using the NIDEK Advanced Vision Excimer Laser (NIDEK) showed that fewer HOAs were induced when compared to non-custom LASIK, and 93% achieved uncorrected vision of at least 20/20. Preoperative sphere and cylinder ranged to  $-8.25$  D and  $-3$  D, respectively.<sup>22</sup>



• Fig. 1.4 Small-incision lenticule extraction (SMILE).

SMILE is a refractive procedure in which an FS laser is used to create a corneal stromal lenticule, which is extracted whole through a 2- to 3-mm incision (Fig. 1.4). Outcomes have been noted to be similar to those of LASIK: in a meta-analysis by Zhang et al.<sup>23</sup> comparing SMILE and FS-assisted LASIK (FS-LASIK) in 1101 eyes, no significant difference was found in refractive outcomes. SMILE was found to result in higher postoperative corneal sensitivity but fewer dry-eye symptoms than FS-LASIK. The biomechanical stability after SMILE surgery is expected to be greater than that after LASIK and may be comparable to PRK and LASEK. Fig. 1.5 compares RK, PRK, LASIK, and SMILE

corneal biomechanics. Long-term follow-up has demonstrated a reduction in HOAs and minimal refractive regression, though some potential advantages, such as improved biomechanical stability and postoperative inflammation, have yet to be established.

#### Lasers Procedures for Myopic Astigmatism

Compound myopic astigmatism can be treated with negative or positive cylinder ablation. Negative cylinder ablation flattens the central cornea in both the flat and the steep meridians. Positive cylinder ablation may allow a larger optical zone with no change in the central depth of ablation.<sup>24</sup> One study examined 74 eyes with compound myopic astigmatism treated with the Meditec MEL 10 G-Scan (Zeiss) excimer laser. Patients were followed for 1 year and had myopia from  $-4.50$  D to  $-9.88$  D and astigmatism up to  $4.00$  D. At 1 year, mean postoperative spherical equivalent was  $-0.49$  and mean cylinder refraction was  $0.59$ .<sup>25</sup>

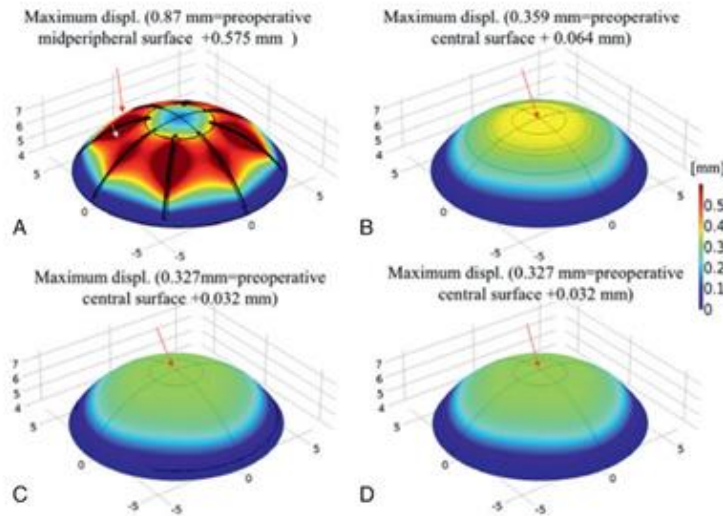
#### Incisional Procedures: A Historical Perspective

In the early 1970s, RK was performed by ophthalmologists in the Soviet Union, including Beliaev,<sup>26</sup> Yenaliyev,<sup>27</sup> and Fyodorov and Durnev.<sup>28-31</sup> RK was performed for the first time in the United States in 1978.<sup>32,33</sup> The RK procedure for myopia places deep, radial, corneal stromal incisions, which weaken the paracentral and peripheral cornea and flatten the central cornea. Refractive power of the central cornea is reduced and myopia is decreased (Fig. 1.6). The surgeon can control the refractive effect by adjusting three variables: central optical zone, incision number, and incision depth.

#### Incisional Procedures for Myopia

RK achieves the best results in patients with low and moderate degrees of myopia (up to 5 D). In patients with higher amounts of myopia (6–10 D), the response to surgery is much more variable<sup>34-43</sup> and undercorrection is more common. The age of the patient partially determines the upper limit of attainable correction. Older patients achieve a greater correction by approximately 0.75 D to 1.00 D per 10 years of age exceeding 35 years.<sup>44</sup> Other patient variables may affect outcomes but are difficult to quantitate. For example, reports show that a premenopausal female with a flat cornea, low intraocular pressure, and a small corneal diameter may achieve less correction than would be generally predicted for a particular RK technique.<sup>45-47</sup>

RK has been studied thoroughly, most notably by the National Eye Institute (NEI)-funded, multicenter Prospective Evaluation of Radial Keratotomy (PERK) study, a collaborative effort of 9 clinical centers. Predictability of results remains problematic.<sup>35-45</sup> Early studies of predictability showed that about 70% of eyes have a residual refractive error within  $\pm 1$  D of the predicted result and 90% within  $\pm 2$  D.<sup>45-49</sup> Later studies, with a staged approach, report 80% to 90% of eyes within 1 D of emmetropia.<sup>49-51</sup> Stability of refraction after radial keratotomy is also inadequate.<sup>52-54</sup> The 10-year PERK results revealed long-term



• **Fig. 1.5** Simulated displacements in corneal shape on the surface resulting from the four refractive surgical procedures at a normal intraocular pressure of 15 mm Hg. The dark-red areas involve maximum displacements ( $>0.5$  mm) outwards (body expansion), and the dark-blue areas involve zero displacement near the constrained boundary of the models. The "preoperative surface" is displacement of the normal cornea. (A) Radial keratotomy: maximum displacements located at middle incisions; (B) photorefractive keratectomy: maximum displacement at central cornea; and (C) LASIK and (D) SMILE: maximum displacements located around the central cornea (unit: mm). (From Shih P-J, Wang I-J, Cai W-F, Yen J-Y. Biomechanical simulation of stress concentration and intraocular pressure in corneas subjected to myopic refractive surgical procedures. *Sci Rep.* 2017;7(1):13906. doi:10.1038/s41598-017-14293-0.)

instability of refractive errors; 43% of eyes changed refractive power in the hyperopic direction by 1 D or more (hyperopic shift) between 6 months and 10 years.<sup>52</sup>

RK has essentially been replaced by newer excimer laser keratorefractive procedures. In 2003, one survey showed that 4% of cataract and refractive surgeons performed RK, down from 46% in 1996.<sup>53</sup>

#### Incisional Procedures for Myopic Astigmatism

Naturally occurring astigmatism is very common and up to 95% of eyes may have some clinically detectable astigmatism in their refractive error.<sup>55</sup> Between 3% and 15% of the general population has astigmatism greater than 2 D.<sup>56</sup> Although there is some variability, approximately 10% of the population can be expected to have naturally occurring astigmatism greater than 1 D, where the quality of UCVA might be considered unsatisfactory.<sup>57</sup> Surgically induced astigmatism can occur following cataract surgery. The incidence of astigmatism following extracapsular cataract extraction greater than 2 D is approximately 25% to 30%.<sup>58,59</sup> With clear corneal incision phacoemulsification procedures, the incidence of astigmatism is much less. Beltrame et al. showed 0.66 D to 0.68 D of surgically induced astigmatism 3 months after phacoemulsification through a 3.5-mm clear cornea incision.<sup>60</sup>

Astigmatic keratotomy (AK) involves performing transverse (also called tangential, or T) cuts in an arcuate or

straight fashion perpendicular to the steep meridian of astigmatism (Fig. 1.7A). AK offers the patient a very good chance of significant improvement by correcting astigmatic errors.<sup>61-63</sup> In general, patients with greater than 1.5 D of astigmatism may be candidates for AK. Deeper and longer incisions closer to the center of the cornea produce greater effect, but cuts beyond 75 degrees are not recommended. Effects of cuts increase dramatically with age. This procedure is now performed with the femtosecond laser and, rarely, with a diamond blade.

Relaxing incisions in the steep meridian were developed by Troutman (Fig. 1.7B). These decrease astigmatism in the steep meridian, but the results can be unpredictable.<sup>64,65</sup> This procedure may be combined with wedge resection or suturing in the flat meridian. These techniques have been used to correct postkeratoplasty astigmatism and surgically induced astigmatism at the time of cataract surgery.<sup>65-67</sup> A study of 52 eyes showed a mean astigmatic change of  $-0.8$  D in patients who had clear cornea cataract surgery with placement of limbal relaxing incisions (LRIs). The control group of 47 eyes had a mean astigmatic change of  $+0.50$  D.<sup>68</sup>

The Ruiz procedure, now rarely used, employs trapezoidal cuts, four transverse cuts inside two radial incisions (Fig. 1.7C). Although important in its time, stacking multiple rows of astigmatic incisions is no longer felt to be prudent because of poor predictability. A pair of tangential