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REFRACTIVE SURGERY

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ABSTRACT

Refractive surgery encompasses a range of procedures aimed at changing the refraction of the eye by altering the cornea and/or crystalline lens, which constitute the principal refracting components. Refractive errors corrected by such procedures include myopia, hypermetropia and astigmatism. Non laser corneal refractive surgery, keratorefractive (corneal) procedures include radial keratotomy, astigmatic keratotomy (arcuate keratotomy (AK), limbal relaxing incisions and transverse keratomy). Laser refractive procedures consist of photorefractive keratectomy is performed with the excimer laser which can accurately ablate corneal tissue to an exact depth with minimal *disruption* of surrounding tissue. Laser epithelial keratomileusis is a relatively new procedure, its popularity is on the increase. It is associated with less pain, less haze and quicker visual recovery than PRK. Laser in-situ keratomileusis is currently the most frequently performed refractive procedure. It is more versatile than PRK and can correct hypermetropia of up to 4D, astigmatism of up to 5D and myopia of up to 12D depending on corneal thickness. Lens refractive surgery consist of phacoemulsification, anterior chamber phakic IOL implantation (claw lens), posterior chamber phakic IOL implantation (in which) the lens is injected between anterior lens capsule and iris. The field of refractive surgery is uniquely dependent on rapidly canging technology that dictats surgical tehnique.

Key words: lens, cornea, refractive surgery, excimer laser, phacoemulsification.

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INTRODUCTION

Refractive surgery encompasses a range of procedures aimed at changing the refraction of the eye by altering the cornea and/or crystalline lens, which constitute the principal refracting components. Refractive errors corrected by such procedures include myopia, hypermetropia and astigmatism.[1,2]

It may have begun in the 1870s. Ophthalmologists in Europe proposed and subsequently demonstrated that radial cuts on the cornea could reduce myopia and astigmatism. When the principles behind the cuts became more defined through the experimental and clinical studies in the Netherlands, Japan, Russia and the USA, work on refractive surgery gained momentum. Refractive surgery now encompasses an expanding list of procedures involving the cornea clear lens and sometimes the sclera as well as the use of auto and alloplasty implants and inlays.[3,4,5]

Waring in 1991, suggested a classification based on how the correction of ametropia is achieved. The settle any contact lens-induced corneal distortion, soft contact lenses should be discontinued 2 weeks before keratometry, and hard lenses for one week for each year of wear.

NON LASER CORNEAL REFRACTIVE SURGERY

Keratorefractive (corneal) procedures include radial keratotomy (RK), astigmatic keratotomy (arcuate keratotomy (AK), limbal relaxing incisions (LRIs) and transverse keratomy). By altering corneal shape, keratorefractive surgical procedures change the refractive altering corneal dimensions are relatively small. For instance, changing the refractive status of the eye by 2 D may require a shape change of less than 30 µm. Thus, achieving predictable result is sometimes problematic because minuscule changes in the shape of the cornea may produce large changes in refraction. Corn status of the eye. The tolerances involved ineal refractive procedures can be classified as lamellar, keratotomy, keratectomy, collagen shrinkage or penetrating keratoplasty. These procedures can alter the corneal biomechanics in several ways: incisional effect, tissue addition or subtraction, alloplastic material addition, collagen shrinkage.[1,2,4,5,6]

LASER REFRACTIVE PROCEDURES

Photorefractive keratectomy (PRK) is performed with the excimer laser which can accurately ablate corneal tissue to an exact depth with minimal disturption of surrounding tissue. Myopia is treated by ablating the central anterior corneal surface so that it becomes flatter; approximately 10m of ablation corrects 1D of myopia. Hypermetropia is treated by ablation of the periphery so that the centre becomes steeper. PRK is able to correct myopia up to 6D, astigmatism up to 3D and low hypermetropia.[1,2,5]

Technique

The visual axis is marked and the corneal epithelium removed, The patient fixates on the aiming beam of the laser, The laser is applied to ablate only bowman layer and anterior stroma this usually takes 30-60 seconds. The cornea usually heals within 48-72 hours aided by a bandage contact lens. A subepithelial haze invariably develops within 2 weeks and persists for 1-6 months. It rarely causes diminished visual acuity but may produce night glare.

Complications

Include slow-healing epithelial defects, corneal haze and haloes, poor night vision and regression of refractive correction. Uncommon problems include decentered ablations, scarring, abnormal epithelial healing, irregular astigmatism, hypoaesthesia, sterile infiltrates, infection and acute corneal necrosis.[1,2,5]

LASER EPITHELIAL KERATOMILEUSIS

Although LASEK is a relatively new procedure, its popularity is on the increase. It is associated with less pain, less haze and quicker visual recovery than PRK. LASEK works well with low corrections and for patients who are unsuitable for LASIK such as those with very thin corneas. The tehniques are as follows: alcohol 20% is applied for 30-40 seconds and an epithelial sheet is cleaved at the basement membrane, laser is applied, the epithelial flap is re-positioned. Functional vision is usually archived within 4-7 days and the procedure has a low risk of serious complications. The main disadvantages over LASIK are the unpredictability of postoperative pain and epithelial healing.[1,2,4,5]

LASER IN-SITU KERATOMILEUSIS

LASIK is currently the most frequently performed refractive procedure. It is more versatile than PRK and can correct hypermetropia of up to 4D, astigmatism of up to 5D and myopia of up to 12D depending on corneal thickness. To prevent corneal ectasia, a residual corneal base of 250m thickness must remain after the flap has been cut and tissue ablated. The amount of tissue removed and the total treatment is therefore limited by the original corneal thickness (on pachymetry). The thickness of the flap can be varied but thinner flaps are more difficult to handle and are more prone to wrinkling.[1,2,4,5]

Technique

A suction ring is applied to the globe which raises the intraocular pressure to over 65 mmHg. This may

temporarily occlude the central retinal artery and extinguish vision. The ring is centered on the cornea and provides a guide track into which an automated microkeratome is inserted. The keratome is mechanically advanced across the cornea to create a very thin flap, which is reflected. Suction is released and the bed is treated with the excimer laser as for PRK. The flap is repositioned and allowed to settle undisturbed for 30 seconds. Compared with LASEK, the procedure offers the advantages of minimal discomfort, faster visual rehabilitation, rapid stabilization of refraction and minimal stromal haze.

Complications

Operative

Complications include buttonholes, thin flaps, flap amputation, incomplete or irregular flaps, and rarely corneal perforation.[5,6]

Postoperative

Dry eyes are almost universal and may require treatment. Wrinkling, distortion or dislocation of the flap. Subepithelial haze that may cause glare at night. Epithelial defects that may predispose to epithelial in growth under the flap. Diffuse lamellar keratitis (sands of sahara) may develop 1-7 days following LASIK. It is characterized by granular deposits at the flap interface. Treatment is with intensive topical antibiotics and steroids. Bacterial keratitis is rare.

LENS REFRACTIVE SURGERY

Phacoemulsification, the first phacoemulsification was performed on a human in 1967 by Dr. Charles Kelman of New York. The tehnique of ultrasonic fragmentation was brought to his attention by a dentist who used an ultrasonic cleaner for the removal of dental plaque. As the machine have become more powerful and reliable, the technique has been refined so the length of the operation in experienced hand is no longer than 15 minutes. Other techniques consist of anterior chamber phakic IOL implantation (claw lens), posterior chamber phakic IOL implantation (in which) the lens is injected between anterior lens capsule and iris.[6,7]

INTRAOCULAR LENS SURGERY

In its first two decades, refractive surgery was synonymous with corneal surgery, which compensates for refractive error by altering the contour of the anterior surface of the eye. Several factors expanded the range of refractive surgery to include intraocular lens surgery. Ophthalmologists became accustomed to cataract patients not only expecting to see clearly after their operation, but also becoming less dependent on glasses as a consequence of IOL surgery. Technology has helped to achieve this goal. Small-incision cataract surgery with self-sealing, astigmatism-neutral wounds has all but eliminated the high postoperative astigmatism that was previously common. New formulas and software have made IOL power selection more accurate. Foldable IOLs, multifocal IOLs, toric IOLs, and accommodating IOLs are now reality. These technological advances have led to a renewed interest in clear lens surgery, particularly for correction of hyperopia in the presbyopic patient.

Phakic IOLs (PIOLs) represent a new category of IOL that expands the range of keratorefractive surgery, offering surgeons and their patients new options for vision correction. The combination of corneal and intraocular refractive surgery, so-called bioptics, may ultimately allow patients at the extremes of refractive errors to achieve predictable outcomes by combining the advantages of the PIOL in treating large corrections with the adjustability of keratorefractive tehnique. In addition, the optical quality may be improved by dividing the refractive correction between two different locations.

This chapter discusses the intraocular surgical techniques that are now or expected to be soon within the armamentarium of the refractive surgeon.[2,4,7]

PHAKIC IOL (PIOL)

Background

The history of the PIOL to correct refractive error began in Europe in the 1950s with Strampelli, Dannheim, and Barraquer each separately attempting to design a PIOL that would be well tolerated in the eye. The lack of modern IOL-manufacturing capability, microsurgical tehniques, and knowledge about the fragility of anterior segment structures resulted in a high incidence of corneal edema, iritis, cataract, and glaucoma. Ultimately, many of these IOLs were removed and, by tha late

1960s, interest in PIOL implantation had waned.[1,6] In the middle 1980s there was renewed interest in PIOLs. Improvements in IOL manufacture, development of modern microsurgical technique, viscoelastic and topical corticosteroid availability, and improved knowledge of the corneal endothelium and anterior segment structures led to greater success. Worst modified his aphakic, iris-fixated "claw" IOL to correct both myopia andhyperopia. Baikoff worked on variations of the open-loop, flexible anterior chamber IOL to correct myopia, while Fyodorov experimented with a plate-heptic IOL for use in the posterior chamber. Different PIOL designs were associated with different types of complications. Early versions of the Baikoff anterior chamber PIOLs were associated with significant endothelial cell loss. The PIOL placed in the ciliary sulcus over a clear lens was associated with pupillary block and cataract. Refinements in IOL design have reduced the incidence of complications, which has resulted in increasing the popularity of these PIOLs outside the United States. Within the United States, the availability of PIOLs is currently limited by their investigational status. Representative lenses in each category will be discussed.

Advantages

PIOLs have the advantage of treating a much larger range of myopic and hyperopic refractive errors than can be achieved with keratorefractive surgery. The skills required for insertion are, with a few exceptions, similar to those used in cataract surgery. The equipment is significantly less expensive than an excimer laser, and most or all of it is already used for cataract surgery.

The PIOL is removable; therefore the refractive effect should theoritically be reversible. However, any intervening pathology caused by the PIOL would most likely be irreversible.[2,6,7]

Disadvantages

PIOL insertion is an intraocular procedure with all the potential risks associated with intraocular surgery. Each PIOL style has its own set of associated risks. In the case of PIOLs with polymethylmethacrylate (PMMA) optics, insertion requires a larger wound that may result in unintended posoperative astigmatism. There is less flexibility then with LASIK for fine-tuning the refractive outcome. If patient eventually developes a visually significant cataract, the PIOL will have to be explanted at the time of cataract surgery, possibly through a larger-than-usual wound.

THE REFRACTIVE ERROR CORRECTION

Correction Of Myopia

Correction Of Myopia consist of photorefractive keratectomy (PRK), laser epithalial keratomileusis (LASEK), laser in-situ keratomileusis (LASIK). Clear lens extraction, gives very good visual result but carries a small risk of retinal detachment. Iris clip (lobster claw), implant is attached to the iris, complications include subluxation and an oval pupil. Phakic posterior-chamber implant (implantable contact lens), is inserted behind the iris in front of the crystalline lens and supported in the cilliary sulcus. The lens is composed of material derived from collagen with a power of -3D to -20.50D. Short term visual results are promising: however, this procedure should be used with caution because it may be assocoiated with uveitis, glaucoma, endothelial cell loss and cataract formation.

Correction of Hypermetropia

PRK and LASEK cant correct low degrees of hypermetropia**.** LASIK can correct up to 4D**.** Conductive keratoplasty with a radiofrequency probe can correct low hypermetropia. Burns are placed in one or two rings in the corneal periphery. The resultant thermally induced stromal shrinkage is accompanied by increase in central corneal curvature. This change decays over time but the procedure can be repeated. Laser thermal keratoplasty with a holmium laser can correct low hypermetropia. Laser burns are plasced in one or two rings in the corneal periphery. The resultant thermally induced stromal shrinkage is accompanied by increase in central corneal curvature. This change decays over time but the procedure can be repeated.[3,4,6]

Correction of Astigmatism

Limbal relaxing incision/arcuate keratotomy involves making paired arcuate incisions on opposite sides of the cornea in the axis of the correcting 'plus'

cylinder (the steep meridian). The resultant flattening of the steep meridian coupled with a smaller steepening of the flat meridian at 90 to the incisions reduces astigmatism. The desired result can be controlled by varying the length and depth of the incisions and their distance from the optical centre of the cornea. Arcuate keratotomy may be combined with compression sutures placed in the perpendicular meridian, when treating large degrees of astigmatism such as may occur following penetrating keratoplasty.[3,4,6]

PRK and LASEK can correct up to 3D, LASIK can correct up to 5D. Lens surgery involves using a toric intraocular implant at the time of cataract extraction. However, postoperative rotation of the implant away from the desired axis may occur.

PATIENT SELECTION

Indications

Patients who are near or beyond the FDA-approved limits for laser correction may be candidates for a PIOL. Although the programmable upper limit of myopic excimer laser treatment is as high as -14.0 D, some surgeons have further reduced the upper limit of LASIK and PRK in their refractive practice because of reduced predictability, high rate of regression, increased incidence of microstriae, and night-vision problems that can occur with treatment of the high myope. Similarly, LASIK and PRK for hyperopia above +4.0D and astigmatism correction above 4.0 D of cylinder are less accurate than at lower corrections. If PIOLs are approved by the FDA and surgeons become familiar with their use, it is possible that surgeons may choose to implant the PIOLs for revractive powers significantly lower then the programmable excimer laser limits.

Most myopic PIOLs can correct up to -20.0 D. the 6 mm optic Artisan iris-fixation PIOLs can (manufactured by ophtec; to be distributed as the verisyse PIOL by AMD) can correct up to -23.5 D. All three categories of PIOL are available for correction of hyperopia of at least +10.0 D. Ophtec and CIBA Vision are conducting clinical trials of toric PIOLs.

PIOLs can be an attractive alternative if PRK or LASIK is contraindicated if the resultant residual corneal stromal bed thickness would be <250m, because this could increase the risk of developing corneal ectasia. Because extremes of corneal curvature lead to indiced aberrations and degradation of optical quality, a final corneal curvature flatter than 34.0 D in myopic corrections or steeper than 50.0 D in hyperopic corrections is also undesirable. More sophisticated measurement and treatment planning based on wavefront analysis may refine these limits.

Contraindications

PIOLs have specific contraindications. They should not be used if there is preexisting intraocular disease such as compromise of the corneal endothelium, iritis, significant iris abnormality, rubeosis iridis, cataract, or glaucoma. When compared with clear lens extraction, the PIOL has the advantage of preserving natural accommodation and may have a lower risk of postoperative retinal detachment because of the preservation of the crystalline lens and the lack of vitreous destabilization. The anterior chamber diameter, anterior chamber depht, and pupil size must be appropriate for the specific PIOL being considered.

Surgical Technique

Topical anasthesia with intracameral supplement is suitable if the patient can cooperate and the PIOL can be inserted through a small incision. If the patient cannot cooperate for topical anesthesia or if a large incision. If the patient cannot cooperate for topical anesthesia or if a large incision is required, peribulbar anesthesia is preferable. Retrobulbar anesthesia should be used with caution in patients with a high axial length because of the increased risk of perforation. Pupil dilation may occur after anesthetic injection. This may be undesireble in the case of anterior chamber PIOL and iris-fixated PIOL insertion. Topical pilocarpine 1% or 2% administered preoperatively can block this dilation effect but may decenter the pupil.

A peripheral iridotomy is recommended for each of the PIOL categories in order to reduce the risk of pupillary block and angle closure.

THE ROLE OF THE FDA IN REFRACTIVE SURGERY[8]

The field of refractive surgery is uniquely dependent on rapidly changing technology that dictats surgical tehnique. Many of the investigational devices discussed in the following chapters will

Table 1. Phakic IOLs

Position	Model	Available Power	Optic Size	Length	Material	Manufacturer
Angle-Supported	NuVita MA 20	7-20 D myopia	5.0 mm mm effective (4.5 diameter)	12.0, 12.5, 13.0, 13.5mm	PMMA	Bausch & Lomb
	Vivarte	7-20 D Myopia	5.5 mm	12.0, 12.5, 13.0 mm	Acrylic	CIBA Vision
	93 A or ZSAL-4	6-22 D myopia	5.5 mm diameter) (5.0 mm effective	13.0 mm	PMMA	Morcher
Iris-supported	Artisan model 204	3-15.5 D myopia	5.0 or 6.0 mm	8.5 mm	PMMA	Ophtec
	Artisan model 206	3-23.5 D myopia	5.0 or 6.0 mm	8.5 mm	PMMA	Ophtec
	Artisan model 203	3-12 D hyperopia	5.0 or 6.0 mm	8.5 mm	PMMA	Ophtec
	Artisan toric IOL	Custom combination up to +7.0 D	5.0 or 6.0 mm	8.5 mm	PMMA	Ophtec
Sulcus-Supported	ICL (for myopia)	3-23 D myopia	4.65-5.5 mm	11.0, 11.5, 12.0, 12.5, 13.0, 13.5 mm	Collamer	STAAR
	ICL (for hyperopia)	3-23 D hyperop	5.5 mm	11.0, 11.5, 12.0, 12.5, 13.0, 13.5 mm	Collamer	STAAR
	ICL (toric for myopia)		4.65-5.5 mm	11.0, 11.5, 12.0, 12.5, 13.0, 13.5 mm	Collamer	STAAR

receive food and drug administration (FDA) approval by the time this book is published. Other “promising” devices or tehniques may have already fallen out of favor.

Because of the continual introduction of new devices to the US market, the FDA approval process has particular influence in refractive surgery. Therefore we have included this brief introduction to the FDA approval process. Table 1 gives a list of FDA-approved lasers for refractive surgery, as of March 2005.

The FDA

The scope of the FDA's work is established by legislation. The food, drug, and cosmetic act passed by congress in 1938 required for the first time that companies prove the safety of new drugs before putting them on the market and required regulation of cosmetics and therapeutic devices. The medical device amandements of 1976 authorized the FDA to ensure that medical devices are safe and effective before they come to market in the United States. This amandement also provided for classification of medical devices into three categories depending on potential risk of the device, established three pathways to market, and established advisory panels to assist the FDA in the review of devices. The ophthalmic devices panel reviews, and votes on approval of, marketing applications for ophthalmic devices with new tehnologies, devices with new indications for use, or those devices that rise significant issues of safety and effectiveness, before such devices are granted FDA approval.[8]

Table 2. FDA-approved lasers for refractive surgery

FDA-Approved Lasers for LASIK (as of March 9, 2005)		
Company and Model	**Approval Number and Date**	**Approved Indications (D = diopters)**
Alcon-LADARVision	P970043/S5; 5/9/00	Myopia <-9.0D with or without astigmatism from -0.5 to -3.0D
Alcon-LADARVision	P970043/S7; 9/22/00	Hyperopia <0.6D with or without astigmatism <-6.0D
Alcon-LADARVision	P970043/S10; 10/18/02	Wavefront-guided LASIK: Myopia up to -7.0D with or without astigmatism <0.5D
Alcon-LADARvision	P970043/S15; 6/29/04	Wavefront-guided LASIK: Myopic astigmatism from -0.5 to 4.0 D
Alcon-Apex Plus	P930034/S13; 10/21/99	Myopia <-14.0 D with or without astigmatism from 0.5 to 5.0 D
Bausch & Lomb Surgical-Technolas 217a	P990027; 2/23/00	Myopia from -1.0 to -7.0D withor without astigmatism <-3.0D
Bausch & Lomb Surgical-Technolas 217a	P990027/S2; 5/15/02	Myopia from -11.0 D with or without astigmatism<-3.0D
Bausch & Lomb Surgical-Technolas 217a	P990027/S4; 2/25/03	Hyperopia between 1.0 and 0.4 Dwith or without astigmatism up to 2.0 D
Bausch & Lomb Surgical-Technolas 217z	P990027/S6; 10/10/03	Wavefront-guided LASIK: Myopiaup to -7.0 D with or without astigmatism between -0.3D
Dishler	P970049; 12/16/99	Myopia from -0.5 to -13.0 D with or without astigmatism between -0.5 to -4.0 D
Kremer	P970005; 7/30/98	Myopia from -1.0 to -15.0 D with or without astigmatism up to -5.0 D
laserSight-LaserScan LSX	P980008/S5; 9/28/01	Myopia from -0.5 to -0.6 D with or without astigmatism up to 4.5 D
Nidek-EC5000	P970053/S2; 4/14/00	Myopia from -1.0 to -14.0D with or without astigmatism <4.0 D
VISX-Star S2 & S3	P930016/S12; 4/27/01	Hyperopia between 0.5 and 5.0 D with or without astigmatism up to 3.0 D
VISX-Star S2 & S3	P930016/S14; 11/16/01	Mixed astigmatism up to 6.0 D; Cylinder is greater Than sphere and of opposite sign
VISX-Star S2 VISX-Star S3 (eye tracker)	P990010; 11/19/99 P990010/S1; 4/20/00	Myopia <-14.0 D with or without astigmatism between -0.5 and -5.0 D Same as S2, but w/ eye tracker
VISX-Star S4 & Wave Scan Wave Front System	P930016/S16; 5/23/03	Wavefront-guided LASIK: Myopia up to -6.0D with or without astigmatism up to -3.0 D
VISX-Star S4 & Wave Scan Wave Front System	P930016/S17; 12/14/04	Wavefront-guided LASIK: Myopia up to 3.0 D with or without astigmatism up to 2.0 D
Wavelight-ALLEGRETTO WAVE	P020050; 10/07/09	Myopia up to -12.0 D with or without astigmatism up to -6.0 D
Wavelight-ALLEGRETTO WAVE	P030008; 10/10/03	Myopia up to 6.0 D with or without astigmatism up to 5.0 D

FDA-Approved Lasers for PRK and other Refractive Surgeries (as of March 9, 2005)		
Company and Model	**Approval Number and Date**	**Approved Indications (D = diopters)**
Alcon-LADARVision	P970043; 11/2/98	PRK; Myopia from -1.0 to - 10.0 D with or without astigmatism <-4.0 D
Alcon-Apex & Apex Plus	P930034; 10/25/95	PRK; myopia from -1.5 to -7.0D
Alcon-Apex plus	P930034/S9; 3/11/98	PRK; Myopia from -1.0 to -6.0D with or without astigmatism from -1.0 to -4.0 D
Alcon-Apex Plus	P930034/S12; 10/21/99	PRK; Hyperopia from 1.5 to 4.0D with or without astigmatism <-1.0D
Bausch & Lomb Surgical – KERACOR 116	P970056; 9/28/99	PRK; Myopia from -1.5 to -7.0 D with or without astigmatism <-4.5 D
LaserSight-LaserScan LSX	P98008; 11/12/99	PRK; Myopia from -1.0 to -6.0 Dwith or without astigmatism <1.0 D
Nidek-EC5000	P970053; 12/17/98	PRK; Myopia from -0.75 to -13.0 D
Nidek-EC5000	P970053/S1; 9/29/99	PRK; Myopia from -1.0 to -8.0 D or without with Astigmatism from up to -0.5 to -0.4 D

FDA-Approved Lasers for PRK and other Refractive Surgeries (as of March 9, 2005)		
Company and Model	**Approval Number and Date**	**Approved Indications (D = diopters)**
Refractec- ViewPoint CK System	P010018; 4/11/02	Conductive keratoplasty; Hyperopia from +0.75 to +3.25D with or without astigmatism <0.75 D
Refractec- ViewPoint CK System	P010018/S5; 3/16/04	Conductive keratoplasty; monovision in patients with presbyopia with or without hyperopia
Sunrise-Hyperion	P990078; 6/30/00	Laser thermokeratoplasty (LTK); hyperopia from 0.75 to 2.5 D with or without astigmatism <0.75 D
VISX-Model B & C (Star & Star S2)	P930016; 3/27/96	PRK; Myopia from 0 to -6.0 D
VISX-Model B & C (Star & Star S2)	P930016/S3; 4/24/97	PRK; Myopia from 0 to -6.0 D withor without Astigmatism from -0.75 to -0.4 D
VISX-Model B & C (Star & Star S2)	P930016/S5; 1/29/98	PRK; Myopia from 0 to -12.0 Dwith or without astigmatism from 0 to -4.0 D
VISX-Model Star S2	P930016/S7; 11/2/98	PRK; Hyperopia from 1.0 to 6.0 D
VISX-Model Star S2 & S3	P930016/S10; 10/18/00	PRK; Hyperopia from 0.5 to 5.0 D with or without astigmatism 0.5 to 4.0 D
VISX-Model Star S2 & S3	P930016/S13; 3/19/01	Add myopia blend zone; increase overall ablation zone from 6.5 to 8.0 mm

Device classification

Class I devices (eg, refractometers, perimeters, wavefront aberrometers, sunglasses) are usually considered minimal-risk devices. These devices are subject to general controls by the FDA, such as current good manufacturing practice regulations and prohibitions against adulteration and misbranding.

Class II devices (eg, phacoemulsification units, glaucoma shunts, tonometers, daily wear contact lenses) are usually considered moderate-risk devices. These devices, in addition to general controls, are subject to special controls, which may include the requirement for submission of performance data (clinical and/or bench testing) to the FDA. With few exceptions, class II devices require premarket review by the FDA before they can go to market.

Class III devices (eg, excimer lasers, IOLs, extended-wear contact lenses, intraocular fluids and gases) are considered significant-risk devices that present a potential unreasonable risk of illness or injury. Class III devices cannot be marketed in the United States until the FDA determines that there is a reasonable assurance that the device is safe and effective. Most require an extensive review by the FDA before approval is granted for marketing. Class III devices with new tehnologies, devices with new indications for use, or those devices that rise significant issues of safety and effectiveness are brought before the advisory panel for a review and recommendation before the FDA makes a decision on the application. Class III devices that have been modified and that do not raise new issues of safety or effectiveness, or devices that are similar to other Class III devices that have already been reviewed by the panel, do not require a riview and recommendation by the advisory panel before the FDA makes its marketing decision. With rare exceptions, Class I and Class II devices do not need a review and recommendation by the advisory panel.[8]

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Alcon-LADARvision	P970043/S15; 6/29/04	Wavefront-guided LASIK: Myopic astigmatism from -0.5 to 4.0 D
Alcon-Apex Plus	P930034/S13; 10/21/99	Myopia <-14.0 D with or without astigmatism from 0.5 to 5.0 D
Bausch & Lomb Surgical-Technolas	P990027; 2/23/00	Myopia from -1.0 to -7.0D with or without 217aastigmatism <-3.0D
Bausch & Lomb Surgical-Technolas 217a	P990027/S2; 5/15/02	Myopia from -11.0 D with or without astigmatism <-3.0D
Bausch & Lomb Surgical-Technolas 217a	P990027/S4; 2/25/03	Hyperopia between 1.0 and 0.4 D with or without astigmatism up to 2.0 D
Bausch & Lomb Surgical-Technolas 217z	P990027/S6; 10/10/03	Wavefront-guided LASIK: Myopia up to -7.0 D with or without astigmatism between -0.3D
Dishler	P970049; 12/16/99	Myopia from -0.5 to -13.0 D with or without astigmatism between -0.5 to -4.0 D
Kremer	P970005; 7/30/98	Myopia from -1.0 to -15.0 D with or without astigmatism up to -5.0 D
laserSight-LaserScan LSX	P980008/S5; 9/28/01	Myopia from -0.5 to -0.6 D with or without astigmatism up to 4.5 D
Nidek-EC5000	P970053/S2; 4/14/00	Myopia from -1.0 to -14.0D with or without astigmatism <4.0 D
VISX-Star S2 & S3	P930016/S12; 4/27/01	Hyperopia between 0.5 and 5.0 D with or without astigmatism up to 3.0 D
VISX-Star S2 & S3	P930016/S14; 11/16/01	Mixed astigmatism up to 6.0 D; Cylinder is greater Than sphere and of opposite sign
VISX-Star S2	P990010; 11/19/99	Myopia <-14.0 D with or without astigmatism between -0.5 and -5.0 D
VISX-Star S3 (eye tracker)	P990010/S1; 4/20/00	Same as S2, but w/ eye tracker
VISX-Star S4 & Wave Scan Wave Front System	P930016/S16; 5/23/03	Wavefront-guided LASIK: Myopia up to -6.0D with or without astigmatism up to -3.0 D

FDA-Approved Lasers for LASIK (as of March 9, 2005)		
Company and Model	**Approval Number**	**Approved Indications and Date(D = diopters)**
VISX-Star S4 & Wave Scan Wave Front System	P930016/S17; 12/14/04	Wavefront-guided LASIK: Myopia up to 3.0 D with or without astigmatism up to 2.0 D
Wavelight-ALLEGRETTO WAVE	P020050; 10/07/09	Myopia up to -12.0 D with or without astigmatism up to -6.0 D
Wavelight-ALLEGRETTO WAVE	P030008; 10/10/03	Myopia up to 6.0 D with or without astigmatism up to 5.0 D
Alcon-LADARVision	P970043; 11/2/98	PRK; Myopia from -1.0 to - 10.0 D with or without astigmatism <-4.0 D
Alcon-Apex & Apex Plus	P930034; 10/25/95	PRK; myopia from -1.5 to -7.0D
Alcon-Apex plus	P930034/S9; 3/11/98	PRK; Myopia from -1.0 to -6.0D with or without astigmatism from -1.0 to -4.0 D
Alcon-Apex Plus	P930034/S12; 10/21/99	PRK; Hyperopia from 1.5 to 4.0D with or without astigmatism <-1.0D
Bausch & Lomb Surgical – KERACOR 116	P970056; 9/28/99	PRK; Myopia from -1.5 to -7.0 D with or without astigmatism <-4.5 D
LaserSight-LaserScan LSX	P98008; 11/12/99	PRK; Myopia from -1.0 to -6.0 D with or without astigmatism <1.0 D
Nidek-EC5000	P970053; 12/17/98	PRK; Myopia from -0.75 to -13.0 D
Nidek-EC5000	P970053/S1; 9/29/99	PRK; Myopia from -1.0 to -8.0 D or without with Astigmatism from up to -0.5 to -0.4 D
Refractec-ViewPoint CK System	P010018; 4/11/02	Conductive keratoplasty; Hyperopia from +0.75 to +3.25D with or without astigmatism <0.75 D
Refractec-ViewPoint CK System	P010018/S5; 3/16/04	Conductive keratoplasty; monovision in patients with presbyopia with or without hyperopia
Sunrise-Hyperion	P990078; 6/30/00	Laser thermokeratoplasty (LTK); hyperopia from 0.75 to 2.5 D with or without astigmatism <0.75 D
VISX-Model B & C (Star & Star S2)	P930016; 3/27/96	PRK; Myopia from 0 to -6.0 D
VISX-Model B & C (Star & Star S2)	P930016/S3; 4/24/97	PRK; Myopia from 0 to -6.0 D with or without Astigmatism from -0.75 to -0.4 D
VISX-Model B & C (Star & Star S2)	P930016/S5; 1/29/98	PRK; Myopia from 0 to -12.0 D with or without astigmatism from 0 to -4.0 D
VISX-Model Star S2	P930016/S7; 11/2/98	PRK; Hyperopia from 1.0 to 6.0 D
VISX-Model Star S2 & S3	P930016/S10; 10/18/00	PRK; Hyperopia from 0.5 to 5.0 D with or without astigmatism 0.5 to 4.0 D
VISX-Model Star S2 & S3	P930016/S13; 3/19/01	Add myopia blend zone; increase overall ablation zone from 6.5 to 8.0 mm