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# **JAMA Insights**

# Refractive Surgery in the US in 2021

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Refractive surgery, which corrects high degrees of refractive error (the reason most people wear glasses), is one of the most rapidly evolving fields in ophthalmology. In the past decade, the field has evolved beyond excimer laser surgery. Newer platforms, such as the femtosecond laser, have improved outcomes of traditional procedures and allowed the emergence of novel ones, such as small incision lenticule extraction. Presbyopia, the loss of accommodation in virtually all adults older than 40 years, can be addressed with various strategies. The various types of surgical procedures are described in the Figure.

## **Corneal-Based Refractive Surgery**

#### Laser In Situ Keratomileusis

Laser in situ keratomileusis (LASIK) is considered the reference standard of laser refractive surgery. It remains the most popular refractive procedure in the US, with approximately 800 000 procedures performed annually. A 2016 review showed that 99.5% of patients who undergo LASIK achieve spectacle independence and 98.6% are within ±1.0 diopter of the attempted correction. The transition from mechanical to femtosecond laser flaps has reduced the risk of complications. Careful patient screening remains the most important factor in patient satisfaction. Patients with thin corneas are at higher risk of post-LASIK ectasia, a weakening of corneal biomechanics that leads to progressive corneal curvature changes and severe refractive errors (eg., myopia, irregular astigmatism) that may

not be amenable to spectacle correction. Fortunately, new imaging modalities, such as Scheimpflug imaging, and artificial intelligence algorithms have improved screening of patients at risk of ectasia and reduced its incidence to roughly 1 in 5000 cases.<sup>3</sup>

#### Photorefractive Keratectomy

Photorefractive keratectomy (PRK) is a safe alternative for many patients who may not qualify for LASIK, including those with thin corneas or those at risk for trauma, such as military or law enforcement personnel. A systematic review found no difference in long-term refractive outcomes between LASIK and PRK. Low-dose topical mitomycin C (0.02%-0.04%), an antimetabolite that modulates stromal keratocyte activation, has reduced the incidence of post-PRK corneal haze, a potential complication of the procedure.

## **Wavefront Refractive Laser Surgery**

Conventional excimer laser ablation (LASIK and PRK) can induce higher-order aberrations (HOAs), such as spherical aberration, coma, and trefoil, which can result in unwanted visual effects, such as halos, glare, and starbursts. Wavefront technology and 3-dimensional corneal imaging have allowed for better ablation profiles, improving contrast sensitivity and visual quality. Wavefront-guided ablations are based on preoperative measurements of HOAs to reduce existing HOAs. Wavefront-optimized ablations are designed to minimize

Figure. Common Refractive Surgical Procedures in the US

	Procedure name	Technique	Advantages	Disadvantages	Refractive range	Contraindications
CORNEAL-BASED PROCEDURES	Laser-assisted in situ keratomileusis (LASIK)	Creation of corneal flap followed by excimer laser ablation of flap bed; repositioning of flap	Fast visual recovery; minimal postoperative pain	Flap-related complications; risk of corneal ectasia; traumatic flap dislocation; dry eyes	Up to -11.00 D of myopia; up to +5.00 D of hyperopia; up to +5.00 D of astigmatism	Thin corneas; dry eyes; corneal dystrophies; autoimmune disease; pregnancy; herpetic eye disease; advanced diabetes
	Photorefractive keratectomy (PRK)	Epithelial debridement followed by excimer laser ablation; application of contact lens until complete re-epithelialization	No flap creation; possible with thinner corneas; possible with some anterior corneal dystrophies; less risk of dry eyes; resistant to trauma	Slower recovery time; more postoperative discomfort; corneal haze; infections; dry eyes	Up to -11.00 D of myopia; up to +5.00 D of hyperopia; up to +5.00 D of astigmatism	Severe dry eyes; stromal corneal dystrophies; autoimmune disease; herpetic eye disease; advanced diabetes
	Small incision lenticule extraction (SMILE)	Cutting of intracorneal lenticule with femtosecond laser; extraction of lenticule manually via small corneal incision	No flap creation; minimal discomfort; quicker visual recovery (compared with PRK); more resistant to trauma than LASIK; less dry eyes	Cost and availability; lenticule extraction complications; relative lack of long-term outcomes; not available for patients with hyperopia	Up to -8.00 D of myopia; up to +3.00 D of astigmatism	Hyperopia; severe dry eyes; autoimmune disease; uncontrolled diabetes; pregnancy; keratoconus; herpetic eye disease
LENS-BASED PROCEDURES	Phakic implants	Insertion of intraocular lens (IOL) in the presence of natural crystalline lens; can be placed between iris and natural lens (Visian ICL) or iris-fixated lens (Artisan)	Correction of high degrees of myopia; quick visual recovery; excellent visual quality; preservation of accommodation; reversible	Intraocular surgery with risks of endophthalmitis and hemorrhage; glaucoma; formation of cataracts; endothelial cell density loss	Visian ICL up to -20.00 D of myopia; up to +4.00 D of astigmatism Artisan up to -23.00 D of myopia; up to +2.50 D of astigmatism	Shallow anterior chamber; cataract; low endothelial cell count; endothelial dystrophies; glaucoma; uveitis
	Refractive lens exchange	Removal of clear crystalline lens followed by implantation of posterior chamber IOL	Correction of high degrees of refractive error; option to correct presbyopia with multifocal IOL; toric IOL for astigmatism	Intraocular surgery with risks of endophthalmitis and hemorrhage; risk of retinal detachments in high myopes; loss of accommodation	All refractive errors, including extremes of myopia and hyperopia; up to +4.50 D of astigmatism with toric IOL	Prepresbyopic patients; high myopia; retinal degeneration or detachment

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induction of new HOAs while preserving naturally occurring aberrations of the eye. Topography-guided ablations use the corneal curvature map to guide treatment and are particularly beneficial for patients with irregular corneas (eg, decentered treatments, LASIK flap complications).

#### **Small Incision Lenticule Extraction**

Advancements in femtosecond laser technology have allowed the development of a new refractive procedure, small incision lenticule extraction, that is rapidly gaining popularity in the refractive marketplace. More than 80 000 procedures have been performed worldwide.<sup>5</sup>

#### **Lens-Based Refractive Surgery**

#### Phakic Intraocular Implants

Phakic implants are intraocular lenses implanted without removing the patient's natural lens. Two phakic implants are available in the US. The Visian Implantable Collamer Lens (ICL; STAAR Surgical) is a foldable lens injected through a 3.0-mm corneal incision in the posterior chamber (between the iris and the crystalline lens). More than 1 000 000 ICLs have been implanted.  $^6$  In a 2018 comparative multicenter study, 97% of 351 patients with moderate to high myopia achieved an uncorrected distance visual acuity of 20/20 or better after ICL implantation.  $^6$ 

The Artisan lens (Ophtec) has claws that attach it to the iris. Although many patients can preserve excellent vision over many years, a 2018 10-year follow-up study showed significant corneal endothelial cell loss of 20% after Artisan implantation, 7 risking corneal decompensation and loss of clarity.

#### Refractive Lens Exchange

The removal of the crystalline lens without the presence of a cataract is known as *refractive lens exchange*. It can correct many types of refractive errors and is a particularly useful option for patients with hyperopia with presbyopia.

## **Treatments for Presbyopia**

Presbyopia, age-related loss of near vision, is due to loss of elasticity of the aging lens with time. Reading glasses and contact lenses remain the safest and cheapest remedy. Although surgical options exist, a treatment that can prevent its development or replace the full accommodative range of the natural lens is not yet available.

#### Monovision

Monovision, in which one eye is targeted for distance and the other for near vision, remains a reliable approach to managing presbyopia and can be achieved with LASIK, PRK, small incision lenticule extraction, or refractive lens exchange. One drawback is that not all patients tolerate the disparity between eyes; therefore, careful screening or testing with a trial of contact lenses prior to surgery is recommended.

#### Multifocal Intraocular Lenses

Multifocal intraocular lenses (IOLs) divide incoming light into several focal points, allowing improved range of focus with functional vision at near, intermediate, and far distance. To date, only 1 true trifocal implant is available in the US, the AcrySof PanOptix (Alcon), which was approved by the US Food and Drug Administration (FDA) in 2019. The main drawback of all multifocal lenses is reduced contrast sensitivity and night vision and increased HOAs, which can make them unsuitable for many patients, warranting an IOL exchange in up to 5% of cases.

#### **Corneal Inlays**

Corneal inlays are miniature devices implanted in the cornea to alter its refractive power. Two inlays were approved by the FDA to manage presbyopia. The Raindrop inlay (ReVision Optics) was recalled in 2019 due to high rate of corneal haze. The Kamra inlay (Acufocus) is a miniature (3.8 mm) implant placed over the pupil in the cornea of the non-dominant eye, acting as a pinhole to improve range of vision. In the FDA trial, 95% of 373 treated eyes achieved near vision of 20/40.8 However, associated complications include glare, halos, and reduced peripheral vision, requiring removal of 3% to 9% of implanted devices.

#### **Conclusions**

Patients often ask physicians whether there are safe and effective surgical alternatives to glasses or contact lenses. The field of refractive surgery is constantly evolving and will continue to improve the quality of life of patients. With a focus on improving safety, new minimally invasive treatments may become available. Drops to alter the refractive indices of the cornea and lens to manage presbyopia are under investigation. Multifocal and accommodative IOL technology continue to evolve to offer a wider range of vision without visual aberrations. Additionally, treatment to alter biomechanics of the cornea, such as corneal collagen crosslinking, may find a new role in the correction of refractive errors.

## ARTICLE INFORMATION

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