Federal Aviation Administration

Information for Pilots Considering Laser Eye Surgery

Currently, about 55% of the civilian pilots in the United States must utilize some form of refractive correction to meet the vision requirements for medical certification. While spectacles are the most common choice for aviators, recent studies show a growing number of pilots have opted for refractive surgical procedures, which include *laser refractive surgery*. The information in this brochure describes the benefits as well as possible pitfalls laser refractive surgery offers to those considering these procedures.

What is Refractive Error?

Refractive error prevents light rays from being brought to a single focus on the retina resulting in reduced visual acuity. To see clearly, refractive errors are most often corrected with ophthalmic lenses (glasses, contact lenses). The three principal types of refractive conditions are myopia, hyperopia, and astigmatism. Another ophthalmic condition that also results in blurred near vision is called presbyopia. *Presbyopia* is a progressive loss of accommodation (decreased ability to focus at near distance due to physiological changes in the eye's crystalline lens) that normally occurs around 40 years of age. Bifocals or reading glasses are necessary to correct this condition.

Myopia (nearsightedness, distant objects appear fuzzy) is a condition in which light rays are focused in front of the retina. About 30% of Americans are myopic.

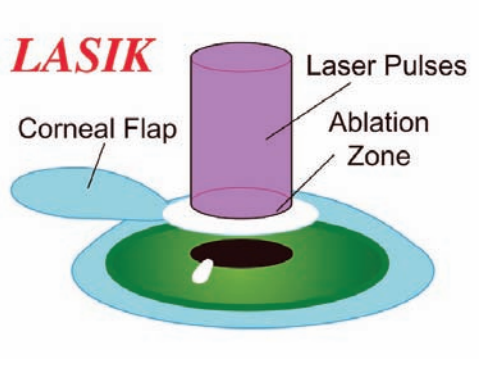
Hyperopia (farsightedness, near objects appear fuzzy) is a condition in which light rays are focused behind the retina. An estimated 40% of Americans are hyperopic. However, this number may not be accurate. Young hyperopes (< 40 years), who can compensate for their farsightedness with their ability to accommodate, are often not counted in this number and some studies incorrectly include presbyopes, who also require plus power lenses to see clearly.

Astigmatism is a condition often caused from an irregular curvature of the cornea. As a result, light is not focused to a single image on the retina. Astigmatism can cause blurred vision at any distance and may occur in addition to myopic or hyperopic conditions. Approximately 60% of the population has some astigmatism.

What is Laser Refractive Surgery?

In October 1995, the Food and Drug Administration (FDA) approved the use of the excimer laser to perform a refractive procedure called *Photorefractive Keratectomy (PRK)*. PRK improves visual acuity by altering the curvature of the cornea through a series of laser pulses. The laser photoablates (vaporizes) the corneal tissue to a predetermined depth and diameter. PRK can be used to correct myopia, hyperopia, and astigmatism. Reported PRK problems such as postoperative pain, prolonged healing period, increased risk of infection, and glare (halos) at night, has resulted in *Laser in situ Keratomileusis (LASIK)* becoming the preferred choice for refractive surgery by patients and eyecare practitioners. A survey in the United States found that the percentage of refractive surgeons performing PRK had decreased from 26% in 1997 to less than 1% in 2002.

LASIK is performed using two FDA approved devices: the *microkeratome* and *excimer laser*. During the LASIK procedure, the microkeratome slices a thin flap from the top of the cornea, leaving it connected by a small hinge of tissue. The corneal flap is folded aside and the excimer laser is used to reshape the underlying corneal stroma. The flap is then returned to its original position.



Is LASIK an Option for Me?

An eye care specialist should thoroughly evaluate your current ocular health and correction requirements to determine whether you are a suitable candidate for refractive surgery. Clinical trials have established the following selection criteria for LASIK.

Selection Criteria:

- Age 18 years or older
- Stable refractive error (less than .50 diopters [D] change within the last year) correctable to 20/40 or better
- Less than - 15.00 D of myopia and up to 6 to 7 D of astigmatism
- Less than + 6.00 D of hyperopia and less than 6 D of astigmatism
- No gender restriction, with the exception of pregnancy
- Pupil size less than or equal to 6 mm (in normal room lighting)
- Realistic expectations of final results (with a complete understanding of the benefits, as well as the possible risks)

In addition to conforming to the above criteria, it is important that you possess normal ocular health and be free of pre-existing conditions that may contraindicate LASIK.

Contraindications:

- Collagen vascular disease (corneal ulceration or melting)
- Ocular disease (dry eye, keratoconus, glaucoma, incipient cataracts, herpes simplex keratitis, corneal edema)
- Systemic disorders (diabetes, rheumatoid arthritis, lupus, HIV, AIDS)
- History of side effects from steroids
- Signs of keratoconus
- Use of some acne medication (e.g., Accutane and/or Cordarone)

Is LASIK Safe for Pilots?

Aviators considering LASIK should know that in initial FDA trials reporting high success rates (≥ 90%) and low complication rates (< 1%), the criteria for success varied. In most clinical studies, success was defined as 20/40 or better distant uncorrected visual acuity (UCVA) under normal room lighting with high contrast targets, not 20/20 or better UCVA. While the majority of patients do experience dramatic improvement in vision after laser refractive surgery, there is no guarantee that perfect UCVA will be the final outcome. Even successful procedures may leave many patients with a small amount of residual refractive error that requires an ophthalmic device (eyeglasses or contact lenses) to obtain 20/20 visual acuity. If overcorrection results, patients may need reading glasses.

Compared to its predecessor (PRK), LASIK requires higher technical skill by the surgeon because a corneal flap must be created. Although rare, loss of best corrected visual acuity (BCVA) can occur when there are surgical complications such as those summarized below.

Surgical Complications:

- Decentered or detached corneal flap
- Decentered ablation zone
- Button-hole flap (flap cut too thin resulting in a hole)
- Perforation of the eye

Operation of an aircraft is a visually demanding activity performed in an environment that is not always user friendly. This becomes particularly evident if the choice of vision correction is ill-suited for the task. While the risk of serious vision-threatening complications after having LASIK is low (< 1%), some complications could have a significant impact on visual performance in a cockpit environment.

Relative Risk of Post-Surgical Complications:

- Prolonged healing periods: 3 months or more
- Night glare (halos, starbursts): 1 in 50
- Under/over-correction: less than 1 in 100
- Increased intraocular pressure: non significant
- Corneal haze: 1 in 1,000
- Corneal scarring: non significant
- Loss of BCVA: 1 in 100
- Infection: 1 in 5,000
- Corneal flap complications (dislocated flap, epithelial ingrowth): less than 1 in 100

Following LASIK, patients are cautioned to avoid rubbing their eyes and to stay out of swimming pools, hot tubs, or whirlpools for at least a week. Contact sports should be avoided for a minimum of 2 weeks, and many eye surgeons recommend wearing safety eyewear while playing sports. Even after the patient's vision has stabilized and healing appears complete, the corneal flap may not be completely re-adhered. There have been reports of corneal flap displacement due to trauma up to 38 months after the procedure.

After surgery, patients are cautioned to not wear eye makeup or use lotions and creams around their eyes for a minimum of 2 weeks and to discard all previously used makeup to reduce the risk of infection.

In some instances, LASIK may be an option for patients with higher refractive error than can be safely corrected with PRK or those with conditions that can delay healing (e.g., lupus, rheumatoid arthritis). Since LASIK minimizes the area of the epithelium surgically altered, it reduces some of the risks associated with delayed healing. Additionally, ablation of the underlying stromal tissue results in less corneal haze and the tendency for the cornea to revert back to the original refractive condition during the healing process (refractive regression), which improves predictability. Most patients do not require long-term, postoperative steroid use, decreasing the possibility of steroid-induced complications (cataract, glaucoma).

As with any invasive procedure, there are surgical risks, and the recovery process often varies with each individual. Post-LASIK patients report experiencing mild irritation, sensitivity to bright light, and tearing for a few days after surgery. For most, vision stabilizes within 3 months to near-predicted results, and residual night glare usually diminishes within 6 months. In rare cases, symptoms have lingered longer than a year. Earlier versions of LASIK used a smaller ablation zone which sometimes resulted in glare problems at night. Ablation zones have an area of transition between treated and untreated corneal tissue. As the pupil dilates and becomes larger than the ablation zone, light (car headlights, streetlights, and traffic signals lights) entering through these transition areas becomes distorted, resulting in aberrations perceived as glare. These patients often complain of difficulties seeing under low-light conditions.

Patients that develop postoperative haze during the healing process have complained of glare (halos and starbursts). Furthermore, it has been reported that exposure to ultraviolet radiation or bright sunlight may result in refractive regression and late-onset corneal haze. It is therefore recommended that all refractive surgery patients wear sunglasses with UV protection and to refrain from using tanning beds for several months after surgery.

For those with larger amounts of refractive correction, the predictability of the resulting refractive correction is less exact. This can lead to under-correction (requiring an additional laser *enhancement* procedure and/or corrective lenses) or over-correction of the refractive error. In the case of overcorrection, premature presbyopia and the need for reading glasses can result.

It has been reported that there can be a slower recovery of BCVA and UCVA with hyperopic LASIK compared with those having myopic LASIK. This is especially true for older patients who may be even less likely to achieve UCVA of 20/20 or better. (Note: Loss of BCVA is reportedly 5 to 15 times more likely with refractive surgery than from the use of extended-wear contact lenses.)

Older patients with presbyopia may opt for monovision LASIK, which corrects the dominant eye for distant vision and the other eye for near vision. The procedure is intended to eliminate the need for a patient to wear corrective lenses for near and distant vision. Anisometropia (difference in correction between the eyes) induced

by monovision may result in decreased binocular vision, contrast sensitivity, and stereo acuity. After an adaptation period, patients are often able to see and function normally. Patients who report blurred vision, difficulty with night driving, and other visual tasks in low-light conditions typically do not adapt to monovision and may require an enhancement on their non-dominant eye so that both eyes are fully corrected for distant vision. Airmen who seek monovision correction should consult an eye care practitioner to assist them in compliance with standards outlined in the "Guide for Aviation Medical Examiners (see below):

Airmen who opt for monovision LASIK must initially wear correction (i.e., glasses or contact lens) for near vision eye while operating an aircraft. After a 6-month period of adaptation, they may apply for a Statement of Demonstrated Ability (SODA) with a medical flight test. If the airman is successful, the lens requirement is removed from their medical certificate.

Advances in Refractive Surgery

Wavefront LASIK

Eye care specialists have traditionally used standard measurement techniques that identify and correct lower-order aberrations, such as nearsightedness, farsightedness, and astigmatism. However, no two people share the same eye irregularities or have similar refractive needs. Vision is unique and as personal as fingerprints or DNA.

Wavefront technology allows eye surgeons to customize the LASIK procedure for each eye, providing the possibility of even better vision. The FDA approved the first system for general use in October 2002. A laser beam is sent through the eye to the retina and is reflected back through the pupil, measuring the irregularities of the light wave (wavefront) as it emerges from the eye. This process produces a three-dimensional map of the eye's optical system. Measuring the cornea's imperfections or aberrations in this way allows the refractive surgeon to develop a personalized treatment plan for the patient's unique vision needs. Correcting the patient's specific imperfections can result in sharper vision, better contrast sensitivity, and reduces problems associated with higher-order aberrations after surgery, such as haloes and blurred images. Studies indicate that 90-94% of patients receiving

wavefront LASIK achieved visual acuity of 20/20 or better. However, those with thin corneas, high degrees of aberrations, severe dry eyes, or conditions affecting the lens and vitreous fluid inside the eye may not be good candidates for wavefront LASIK.

Other Advances in Refractive Surgery

The eye's optical system creates a limit as to how wide and deep the laser ablation should be, i.e., the wider the ablation, the deeper the laser must ablate into the cornea, which may result in delayed healing and prolonged visual recovery. The development of new lasers allows the creation of a wider ablation zone while removing the least amount of tissue. Studies have shown that this reduces problems with night vision and other side effects associated with laser refractive surgery.

Laser technology that provides variable optical zone sizes and beam shapes with scanning capabilities allows the eye surgeon greater flexibility in developing a more personalized laser vision procedure. A spot laser may be adjusted so minimal spherical aberrations are produced and a larger optical zone is created. Results from clinical trials indicate that 67% of eyes had UCVA of 20/16 or better and 25% had 20/12.5 or better. Additionally, there was an overall improvement in nighttime visual function and night driving, which is achieved by preserving the optical zone size and better shaping of the ablation profile.

During traditional LASIK, the corneal flap is created with a mechanical microkeratome manipulated by the surgeon's hand. While this method has worked well over the years, the performance of these devices can be unpredictable and is the source of a majority of surgical complications. These difficulties result in irregularities in thickness between the central and peripheral areas of the flap that can induce postoperative astigmatism.

The IntraLase Femtosecond Laser Keratome, which received FDA approval in December 1999, is the first blade-free technology for creating the corneal flap. The laser keratome beam passes into the cornea at a predetermined depth, producing a precise cut that is reportedly more accurate than the microkeratome. Corneal flaps made with the laser keratome appear to adhere more tightly to the corneal bed at the end of the procedure, which may eliminate problems with long-term flap displacement. A reported disadvantage to this new technology is that surgical time is increased, leaving the stroma exposed several minutes longer, which has led to reported complaints of photophobia and eye irritation for up to two days after surgery. While it may take longer (4 to 7 days) to recover good vision, the approach appears to be associated with a lower incidence of dry eyes, corneal complications, and enhancement procedures compared with traditional LASIK.

The FAA requires that civil airmen with refractive surgical procedures (e.g., PRK, LASIK) discontinue flying until their eyecare specialist has determined that their vision is stable and there are no significant adverse effects or complications. The airman should submit one of two documents to the FAA (a report from their eyecare specialist or "Report of Eye Evaluation" [FAA-8500-7]). These reports can be submitted directly to the Aerospace Medical Certification Division when released from care, or to their Aviation Medical Examiner during their next flight physical. This report should state:

". . . . that the airman meets the visual acuity standards and the report of eye evaluation indicates healing is complete, visual acuity remains stable, and the applicant does not suffer sequela, such as glare intolerance, halos, rings, impaired night vision, or any other complications. . . ." (Guide for Aviation Medical Examiners, July 2005)

If you are a pilot contemplating refractive surgery, consult an eyecare specialist to determine if you are a good candidate for laser refractive surgery. Although the FAA and most major air carriers allow laser refractive surgery, professional aviators should consider how it could affect their occupational and certification status. As with any invasive procedure, there are many variables that can influence the final outcome. You should understand all risks as well as the benefits before electing to have a procedure performed that could compromise your visual performance in the cockpit.

MEDICAL FACTS FOR PILOTS

Publication OK-06-148

Written by:
Van B. Nakagawara, O.D., F.A.A.O.
Kathryn J. Wood, CPOT
Ron W. Montgomery, B.S.

For additional copies, download from our Web site:
www.faa.gov/pilots/safety/pilotsafetybrochures/

Or contact:
FAA Civil Aerospace Medical Institute
Aerospace Medical Education Division
AAM-400, P.O. Box 25082
Oklahoma City, OK 73125