Aeromedical Certification Update

RK and Laser Visual Acuity Procedures

Warren S. Silberman, DO, MPH

WITH THIS ITERATION OF the *Bulletin,* I shall clear up some misperceptions of the procedures to correct refractive error.

Acceptable measures for airmen who have visual acuity correction by RK or laser procedures

The Federal Aviation Administration accepts the following Food and Drug Administration-approved procedures for visual acuity correction:

- Radial Keratotomy
- Epikeratophakia
- LASIK
- PRK

You are all aware that these procedures have potential adverse effects that could be incompatible with flying duties, including:

- corneal scarring or opacities
- worsening or variability of vision
- night-glare
- haziness of vision.

For more information, I refer you all to an excellent pilot safety brochure* on these procedures written by Dr. **Van Nakagawara** and distributed by AAM-400.

The FAA expects that airmen will not resume piloting aircraft until their treating health care professional determines that their postoperative condition has stabilized, they have no significant adverse effects or complications, and they meet the appropriate vision standards. This may take from one to six months.

When a determination has been made, the airman should have the treating health care professional document this by sending a report of post-operative visual acuities and a statement as to whether there were any complications. If the determination is favorable, the airman should send the form to the Aeromedical Certification Division in Oklahoma City, where we will review it and place it in the airman's record. The airman may resume and continue flight duties—unless informed otherwise by us.

We in the Office of Aviation Medicine hope that these regular updates in the *Bulletin* will allow you, the aviation medical examiner, to better inform the flying public so that they can be aware of medical certification issues. If there are topics that you would like for me to discuss in this space, please send them to me. My address is:

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**Laser Eye Surgery: Will It Fly?* (Publication # AM-400-98/ 1, available by request. Write to FAA Civil Aeromedical Institute, AAM-400, P.O. Box 25082, Oklahoma City, OK 73125.)

Dr. Silberman manages the Civil Aeromedical Institute's Aeromedical Certification Division.

LASIK Refractive Surgery: Clinical Considerations for the Pilot

Opthalmology, by Van B. Nakagawara, OD, Kathryn J. Wood, and Ron W. Montgomery, BS

APPROXIMATELY 145 MILLION Americans (54.6% of the US population) are dependent upon corrective lenses (glasses or contact lenses) to achieve a quality of vision satisfactory for their daily needs. These individuals have refractive conditions, i.e., myopia (nearsightedness), hyperopia (farsightedness), astigmatism (irregular corneal curvature), that prevent light rays from being focused as a clear, single image on the retina.

It is essential that pilots have optimum vision, since visual cues supply about 80% of all flight information. Pilots must detect and identify airborne traffic, as well as hazards that may be on runways and taxiways. Printed materials, such as flight manifests, charts, maps, and cockpit instruments need to be clearly seen to ensure that proper flight procedures are safely followed. In an aviation environment, where visual conditions are not always optimal, an aviator's choice of refractive correction becomes a serious consideration. Currently, more than 50% of the civil airman population use some form of visual correction to meet aeromedical certification standards.

Laser assisted in situ keratomileusis (LASIK) is an alternative method of refractive correction performed by ophthalmic surgeons for the treatment of myopia. LASIK is performed using two Food and Drug Administration (FDA) approved ophthalmic devices, the microkeratome and the excimer laser. The microkeratome is a planing scalpel that has been used for 30 years to perform other types of refractive surgery. The excimer laser, approved in October 1995, is used to perform a refractive procedure called photorefractive keratectomy (PRK) (see Figure 1). With PRK, the excimer laser emits a beam of light that vaporizes (photoablates) corneal tissue to a predetermined depth and diameter. The removal of corneal tissue reduces the cornea's curvature, which corrects or minimizes myopia.

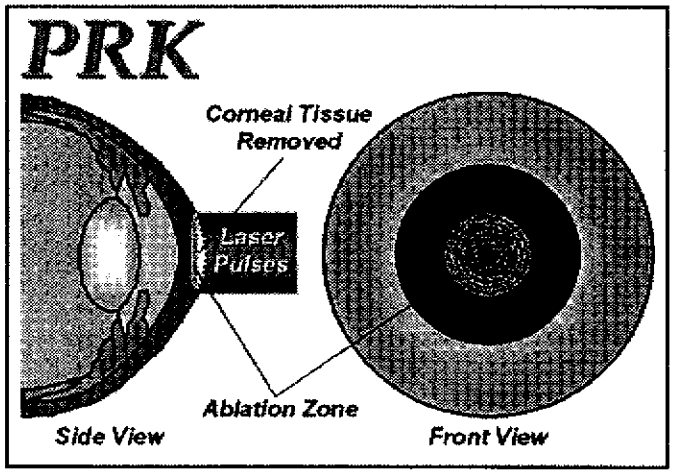

Figure 1

The clinical difference between the LASIK procedure and PRK is that LASIK reshapes an underlying layer of corneal tissue, while PRK ablates tissue on the surface of the cornea. LASIK involves the use of the microkeratome to slice 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 corneal flap is then returned to its original position (see Figure 2).

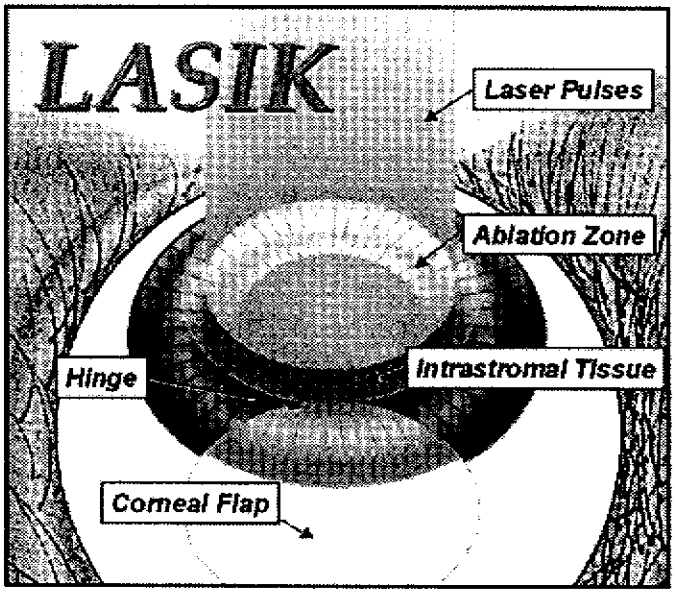

Figure 2

The patient selection criteria for LASIK are similar to those of PRK (see Table 1). Clinical studies indicate that LASIK can be used to correct mild to moderate (up to 15 diopters [D]) myopia and a substantial amount of astigmatism with greater predictability and decreased probability of refractive regression, compared with PRK. LASIK is an option for patients who have conditions that can delay healing for which PRK is contraindicated, including lupus, severe dry eyes, and rheumatoid arthritis. LASIK minimizes the area of the epithelium that must heal, reducing the risks associated with the healing process. However, other contraindications associated with PRK still

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Table 1: Selection Criteria for LASIK

- Normal ocular health
- Age 18 years or older
- Stable refractive error and correctable to 20/40 or better
- > -1.00 to -15.00D of myopia and < 8.00D of astigmatism
- Pupil size ≤ 6mm (in room light)
- Realistic expectations of the final results

Table 2: Surgical Complications of LASIK

- Decentered ablation zones resulting in monocular diplopia
- Decentered or detached corneal flap
- Epithelial ingrowth in the corneal flap
- Perforation of the eye
- Subconjunctival hemorrhages
- Technical problem with the surgical instruments

apply for LASIK including collagen vascular disease (corneal ulceration or melting), ocular disease or abnormalities (dry eye, keratoconus, glaucoma), pregnancy, or a history of side effects from steroids.

A pilot considering refractive surgery should know that there are advantages of LASIK over PRK. For example, surgery on the fellow eye may be performed within 2-3 days of the initial procedure, and the patient may return to normal work activities within a few days after surgery. Some surgeons feel comfortable performing bilateral LASIK procedures during the same visit. Also, ablation of the underlying stromal tissue results in less corneal haze and refractive regression during the healing process. As a result, the LASIK patient usually does not require long-term post-operative steroid use, decreasing the possibility of steroid-induced complications (cataract, glaucoma). Furthermore, studies have shown that the risk of vision-threatening complications is reduced with LASIK. (Note: PRK patients are 5 times more likely to develop an infection, 10 times more likely to develop haze, and 10 to 20 times more likely to have corneal scarring.) In the majority of LASIK patients, their vision stabilizes within 3 months to near predicted results, and residual night glare usually diminishes within 6 months. However, as with PRK, the final results are a combination of the surgeon's ability to perform the laser procedure proficiently and the patient's ability to heal.

LASIK may have complications for a small number of patients. Some individuals experience mild irritation, sensitivity to bright light, and tearing for a few days. If infection occurs, it can result in corneal scarring that may reduce sharpness of vision. Additional complications include: under- or over-correction of refractive error (requiring an additional laser "enhancement" procedure or corrective lenses); reduced contrast sensitivity, best-corrected visual acuity or acuity in low light levels; and myopic regression (may be exacerbated by exposure to ultraviolet radiation or bright sunlight). Following LASIK, patients should be cautioned to avoid vigorous rubbing of the eyes, contact sports, etc., as it can take up to 6 months for the corneal flap to completely re-adhere. LASIK has an increased surgical risk over PRK, since it requires a corneal flap to expose the inner layers of the corneal tissue. Therefore, the ophthalmic surgeon needs more technical skill and training. The surgical complications from LASIK are summarized in Table 2.

A recent study for the period 1 Jan 1994 to 31 Dec 1996, identified 3,761 civil airmen who carried pathology codes for refractive surgery. Of this population, an estimated 372 (9.9%) had PRK and 64 (1.7%) had LASIK. While the number of pilots with LASIK may appear to be low, U.S. market projections indicate that more than one million laser procedures will be performed annually by the year 2000. Presently, LASIK accounts for about 29% of all laser refractive procedures, but it is expected to increase to 90-95% of all refractive surgical procedures in the future. Therefore, it is reasonable to assume that a substantial number of pilots will elect to have laser refractive surgery.

Civil airmen with refractive surgical procedures, such as PRK and LASIK, can obtain a medical certificate without a waiver. They must meet the visual acuity standards for the class of medical certificate requested, and an eye specialist must verify that surgical healing is complete, visual acuity is stable, and no significant glare intolerance is present. Most major air carriers allow their pilots to fly after having had refractive surgical procedures. However, active duty and reserve military forces consider refractive surgery a disqualifying condition for flying. Pilots contemplating refractive surgery should consult an eyecare specialist to learn how a particular procedure could correct their refractive condition and how it may affect their occupational or avocational aeromedical certification status.