

OPHTHALMOLOGY WAIVERS

CONDITION: CORNEAL REFRACTIVE SURGERY (ICD9 V 802A and V802B)

This policy establishes a medical process by which aviators (and flight school applicants) and other aircrew may obtain a medical waiver (or exception to policy) for the voluntary refractive surgery procedures laser in-situ keratomileusis(LASIK) or photorefractive keratectomy (PRK) in order to improve visual acuity. Additionally, this policy letter establishes the aviation Corneal Refractive Surgery Surveillance Program (CRSSP) in cooperation with the US Army Aeromedical Research Laboratory. All aviation personnel receiving corneal refractive surgery must be enrolled in the surveillance program. It is not the intent of this policy to obligate any resources not readily available.

AEROMEDICAL CONCERNS:

Corneal refractive surgery is a surgical treatment for the correction of refractive error (myopia, hyperopia or astigmatism). There are four surgical procedures: Radial Keratotomy (RK), Photorefractive Keratectomy (PRK), Laser in Situ Keratomileusis (LASIK), and Intra-Corneal Ring Implants (ICR). Civilian eye specialists are performing all procedures, but LASIK is currently the most common. PRK and LASIK have similar results in uncorrected visual acuity improvement at 6 months but differ in technique and immediate post-operative results.

RK involves a radial pattern of surgical incisions in the cornea. Military ophthalmologists determined that RK does not produce stable visual correction in operational environments and seriously weakens the integrity of the eye. This procedure is not waiverable for the Army or Army aviation.

PRK involves removing the corneal epithelium and then applying a series of fine laser ablations to re-sculpt the cornea. PRK lases through the basement membrane of the surgically removed epithelium and sculpts the corneal stroma to an average depth of 70 microns (typical corneal depth 550 microns). During the first weeks after the procedure the surface epithelium must repopulate the corneal surface and during this period there is discomfort and fluctuating vision. Some studies suggest there is increased risk of haze at the treated interface with increased ultraviolet exposure due to the destruction of the basement membrane even years later.

LASIK also uses the laser to sculpt the corneal stroma to a 70 micron depth but it differs from PRK in that a surgical blade is used to create a hinged flap approximately 160 microns thick. This flap is laid back and the stromal bed treated with the laser. When the flap is repositioned, vision is generally excellent immediately and there is no significant discomfort. LASIK has the theoretic risk of displacement of this flap, however preliminary basic science studies and clinical studies in the Airborne and Ranger student populations as well as the experience in the civilian population does not seem to support this concern as being of any operational or clinical relevance. The incidence of displacement of the flap is extremely low and the risk decreases with time.

ICR involves creating two channels in the corneal stroma and inserting plastic arcs which expand the peripheral cornea and flatten the central cornea resulting in a decrease in myopia. It is an incisional procedure and is not waiverable for the Army or Army aviation.

ADVANTAGES: Prior to FDA approval, extensive clinical studies were performed to assess PRK safety and efficacy. Ten year follow-up data is available from some of the studies conducted. More recently, the pool of those who may be eligible for treatment has expanded to include more severe forms of myopia, as well as hyperopia and astigmatism.

Potentially 80-90 percent of people who require glasses for distance vision may be eligible for PRK. It is an effective procedure, with up to 95 percent of treated patients not needing distance glasses to achieve 20/40 vision or better. Approximately 75 percent of patients achieve 20/20 vision. The results may not be quite as good among patients with more extreme forms of myopia, hyperopia or astigmatism. The visual improvement appears to remain stable after healing from the surgery. Developing wavefront technology holds the promise of custom corneal ablations to produce “super-vision” (20/10- the theoretic anatomic limit of vision- which statistically occurs naturally more frequently in aviators attending the Navy’s Top Gun Program).

DISADVANTAGES: As with any surgical procedure, there may be side affects and complications. Most of these are short term, and resolve within a few weeks following the procedure. But, some may take longer to resolve, or in a small percentage of cases, could be permanent. These include decreased night vision, glare sensitivity, and/or worsening of the pre-operation best vision due to scar formation and other effects of the healing process. With both PRK and LASIK, it is not uncommon for up to 10% of patients to require retreatment with the laser to ‘fine tune’ the desired corrective affects of the procedure.

While the final visual acuity results are identical for PRK and LASIK, there is a longer recovery time following PRK. Finally, though it is not anticipated that adverse complications will occur 10 or more years after the surgery, there is no data available to determine what, if any, changes may develop later in life.

WAIVERS:

All forms of corneal surgery are disqualifying. Class 1 applicants may be considered for an exception to policy to enter flight training under the USAARL research protocol “Evaluation of Refractive Surgery for Army Aviation.” Class 2F, 3 and 4 aviation personnel can be considered for waiver for PRK or LASIK on a case-by-case basis. Class

2 personnel (aviators) are not currently authorized to have any form of refractive surgery; this policy is currently under review pending outcome of ongoing research studies.

NEW ACCESSIONS New accession applicants having had PRK or LASIK (civilians, ROTC, Academy and enlisted accessions) may be granted an exception to policy for accession into aviation duty if they meet all the following criteria:

- a. Accepted into an Army-approved corneal refractive surgery study protocol for long-term follow-up.
- b. Pre-surgical refractive error was less than or equal to plus or minus 6.00 (total) diopters in any meridian with less than or equal to plus or minus 3.00 diopters of cylinder and anisometropia less than or equal to 3.50 diopters.
- c. Applicants must provide detailed pre-operative, operative, and post-operative refractive surgery follow-up records prior to acceptance into an Army approved study.
- d. At least 3 months have elapsed since surgery or re-treatment and evidence of stable refractive error is demonstrated by two separate examinations performed at least one month apart.
- e. Meet all other applicant entrance criteria as delineated in AR 40-501 and as specified by approved aviation study protocols.

ACTIVE AVIATION PERSONNEL Personnel electing the surgery must receive authorization from their commanding officer prior to the procedure. Commanders should be advised that the procedures have a six to twelve week recovery period before aviation duties can be resumed. Army aviation personnel (class 2F, 3 and 4), upon approval by their commanding officers, may seek acceptance into the Army aviation CRSSP program. A waiver to return to flight duties will be recommended if they meet all surveillance requirements and all other physical standards as delineated in AR 40-501.

FOLLOW-UP: The annual flight physical must include an optometry/ophthalmology consult for completion of a slitlamp examination of the cornea, manifest refraction, corrected visual acuity and 5% contrast sensitivity test. The 5% contrast test is not required for follow-up for classes 2F, 3, and 4, but will be completed if available.

TREATMENT: (Refer to the CRSSP protocol)

DISCUSSION:

Corneal refractive surgery will optimally result in less optometric support before and during deployment to Stability and Support Operations as well as combat operations. There is a significant medical logistics “footprint” of combat health support activities providing corrective lenses and protective mask inserts that may be lessened. This is

especially important in current rapid deployment, high op tempo environments. Corneal refractive surgery is an additional benefit in the continuous development of new man-machine interfaced weapons based on routinely updated detailed vision parameters. This is especially important for increasingly complex flight environments where corrective lenses would be a hindrance.

This is a new technology and long-range ramifications are not fully understood. Therefore, central to this policy is the aviation Corneal Refractive Surgery Surveillance Program (CRSSP) at the US Army Aeromedical Research Laboratory (USAARL). All aviation personnel who undergo corneal refractive surgery must be enrolled in the surveillance program and follow its established protocols.

Advantages and disadvantages for both LASIK and PRK have been identified and will be further elucidated by the CRSSP. In order to do this, there are two study arms in the CRSSP, one looking at civilian accessions into aviation and one looking at active aviation personnel who desire the procedure. The civilian accession arm will follow subjects who have had either LASIK or PRK and who meet criteria specified in the CRSSP protocol. The other arm will include trained aviation personnel upon whom LASIK or PRK has been performed at the US Army Aeromedical Center or a DOD medical treatment facility (IAW AR 40-3, Chapter 2-11). USAARL will be responsible for providing study results and any required documentation to the Department of Defense Accessions Medical Standards Analysis and Research Activity (ASMARA) at CHPPM.

APPENDIX 1. CRSSP protocol

APPENDIX 2. Informed Consent Form