

DOT/FAA/AM-00/23

Office of Aviation Medicine
Washington, D.C. 20591

Gender Differences in a Refractive Surgery Population Of Civilian Aviators

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July 2000

Final Report

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U.S. Department
of Transportation
**Federal Aviation
Administration**

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Technical Report Documentation Page

1. Report No. DOT/FAA/AM-00/23		2. Government Accession No.		3. Recipient's Catalog No.	
4. Title and Subtitle Gender Differences in a Refractive Surgery Population of Civilian Aviators				5. Report Date July 2000	
				6. Performing Organization Code	
7. Author(s) Nakagawara, V.B. and Montgomery, R.W.				8. Performing Organization Report No.	
9. Performing Organization Name and Address FAA Civil Aeromedical Institute P.O. Box 25082 Oklahoma City, OK 73125				10. Work Unit No. (TRAIS)	
				11. Contract or Grant No.	
12. Sponsoring Agency name and Address Office of Aviation Medicine Federal Aviation Administration 800 Independence Ave, S.W. Washington, DC 20591				13. Type of Report and Period Covered	
				14. Sponsoring Agency Code	
15. Supplemental Notes This work was performed under task AM-A-99-TOX-203.					
16. Abstract INTRODUCTION. Refractive surgical procedures performed in the United States have increased in recent years and continued growth is projected. Postoperative side effects can affect the quality of vision and may be unacceptable in a cockpit environment. The scientific literature suggests certain females (pregnant, menopausal, elderly) are more likely to experience complications and have less than optimal visual performance after refractive surgery. This study reviews the civil aeromedical experience with refractive surgery by gender. METHODS. A list of airmen with Federal Aviation Administration (FAA)-specific pathology codes 130 (radial keratotomy) and 5179 (general eye pathology with surgical prefix), during the period 1 January 1994 through 31 December 1996, was generated from FAA medical databases. The records of airmen with pathology code 5179 were reviewed and those identified as having refractive surgery were collated into a database with those who had pathology code 130. The records were then stratified by class of medical certification and gender, and analyzed using demographic data extracted from FAA publications. RESULTS. There were 3,761 airmen identified as having had refractive surgical procedures during the study period. The prevalence rate for refractive surgery was found to be significantly higher ($p < 0.05$) for female (8.74/1,000) than for male (6.06/1,000) aviators. Prevalence rates for all classes of FAA medical certification were also found to be significantly higher for female aviators. CONCLUSIONS. Higher prevalence rates for female aviators with refractive surgical procedures suggest that they view refractive surgery to be a more viable alternative for correcting refractive error than do their male counterparts. With the more frequent post-surgical complications for selected females with these procedures, further research is recommended to investigate the potential for operational problems in the aviation environment. Continued monitoring may determine whether there is an increased risk of performance loss associated with normal age-related ocular changes.					
17. Key Words Aviation; Vision; Refractive Surgery; Gender; Aeromedical Certification; Occupational Health			18. Distribution Statement Document is available to the public through the National Technical Information Service, Springfield, Virginia 22161		
19. Security Classif. (of this report) Unclassified		20. Security Classif. (of this page) Unclassified		21. No. of Pages 11	22. Price

GENDER DIFFERENCES IN A REFRACTIVE SURGERY POPULATION OF CIVILIAN AVIATORS

INTRODUCTION.

Optimum vision is essential for pilots who must detect and identify airborne traffic as well as hazards that may be on runways and taxi lanes. Additionally, cockpit instruments and printed materials, such as flight manifests, charts, and maps, need to be clearly visible to ensure that proper flight procedures and safety are maintained.

Refractive error is an optical defect that prevents light rays from being focused as a clear, single image on the retina. Common refractive conditions that include myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (irregular corneal curvature) (see Figure 1) are normally corrected with ophthalmic lenses (eyeglasses, contact lenses). There are approximately 145 million Americans (54.6% of the U.S. population) who are dependent upon corrective lenses to achieve an acceptable quality of vision for their daily needs.

Civil airmen with radial keratotomy (RK) refractive surgical procedures have been allowed to obtain Federal Aviation Administration (FAA) medical certificates since the early 1980s. RK requires a surgeon

to make a series of spoke-like incisions around the periphery of the cornea that, once healed, flattens the cornea and reduces myopia. In 1995, the Food and Drug Administration (FDA) approved the use of the excimer laser to perform refractive surgical procedures (1). Laser procedures, such as photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK), are being performed on a rapidly growing number of people, including civilian pilots. PRK reshapes the cornea through a process called photoablation, which utilizes the excimer laser to vaporize the cornea's outer tissue. LASIK uses a specially designed surgical scalpel (microkeratome) to slice a thin horizontal flap from the top of the cornea, leaving it connected by a small hinge of tissue. The flap is folded aside, and the excimer laser is used to remove tissue from the corneal stroma. The corneal flap is then returned to its original position (see Figure 2).

There was an approximate 100% increase in the number of U.S. laser refractive procedures from 1996 to 1997 (from 94,500 to 200,000 procedures). It is estimated that one million laser refractive surgical procedures will be performed annually in this country by

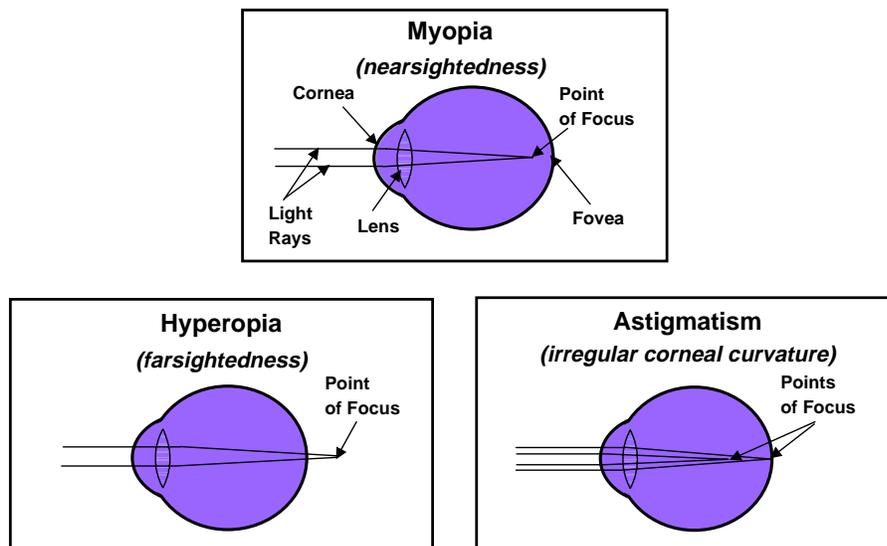


Figure 1: The diagrams above illustrate the three most common forms of refractive error.

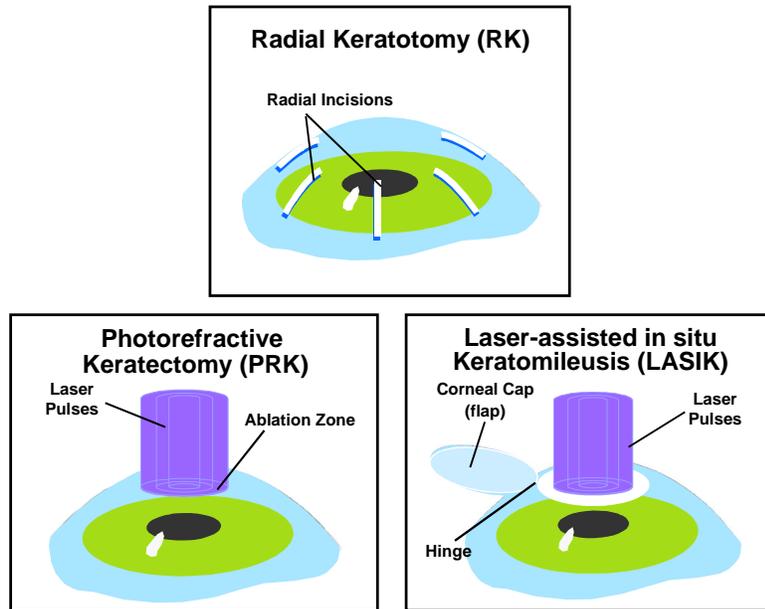


Figure 2: The diagrams above illustrate the most common forms of refractive surgery.

the year 2000. Presently, applicants with refractive surgery may obtain a medical certificate without a waiver for a particular class provided they meet the vision standards for that class, and an eye-care specialist verifies that their vision is stable, healing is complete, and no glare intolerance is present.

Success rates of 90% or better have been reported for patients with low-to-moderate myopia who have had laser refractive procedures. However, the criteria for success used in many of these studies permit uncorrected visual acuity (VA) as low as 20/40 (2). While VA in this range may be adequate for the general population, professional pilots, who must safely perform a wide variety of vision-related flight operations under visually demanding environmental conditions, may find these results unacceptable. Aviation safety concerns remain regarding the quality of the resulting vision correction, side effects, and the potential for surgical complications.

Before choosing refractive surgery, a pilot should be aware of the possible problems associated with these procedures (3). Complaints following refractive surgery include reduced contrast sensitivity, increased glare sensitivity, and loss of best corrected visual acuity (2). Some patients, who report seeing well in normal lighting conditions, have found night driving to be difficult or impossible due to halos, aberrations, and glare from oncoming head lights (4).

These complaints may be associated with residual corneal haze and/or de-centered ablation zones. Furthermore, under-correction of the refractive condition can result in poor distant vision, while over-correction can produce “premature” presbyopia (i.e., the need for reading glasses).

Clinical studies have suggested that a number of factors can influence the results of refractive surgical procedures, including the magnitude of refractive correction, age, and gender. Several studies have concluded that the predictability of the resulting refractive correction decreases with increased refractive error (5,6,7). Other research has suggested that the outcome of refractive procedures performed on older patients can differ significantly from those of younger patients who have had similar procedures to correct equivalent refractive error (8). Furthermore, some studies suggest that females may not respond as favorably to surgical correction when compared with males who have undergone similar surgical procedures to correct comparable amounts of refractive error. The reasons for these gender-specific results may be associated with oral contraceptive use and hormonal changes during pregnancy and menopause (6,9,10). Finally, clinical trials suggest poorer outcomes for older women who undergo laser vision correction (11).

This epidemiological study reviewed the prevalence of civil aviators who fly with refractive surgical procedures by gender and class of medical certification for the study period, 1994-96.

METHODS

A list was generated of active airmen with FAA-specific pathology codes 130 (radial keratotomy) and 5179 (general eye pathology with surgical prefix) for the period from 1 January 1994 through 31 December 1996. This information was extracted from the Consolidated Airman Information System medical database, maintained by the FAA's Application Systems Division at the Mike Monroney Aeronautical Center in Oklahoma City, OK. Medical records of airmen with pathology code 5179 were reviewed to identify those airmen who had refractive surgery. (Note: The 5179 code is assigned to applicants with various eye surgeries, including refractive surgery.) Data from the medical records of airmen identified as having had refractive surgery and those with pathology code 130 were collated into a common database and stratified by gender and class of medical certification. The refractive surgery data were then compared with airman population data extracted from the Aeromedical Certification Statistical Handbook, which is published annually by the Civil Aeromedical Institute's Aeromedical Certification Division (12). Frequency, prevalence, and average age were calculated

for both the refractive surgery and general civil airman populations. Hypothesis testing was performed to determine whether the prevalence rates for refractive surgery differed significantly for male and female airmen.

RESULTS

A total of 3,708 airmen with pathology code 130 and 202 airmen with pathology code 5179 were identified. A review of the medical records for those with pathology code 5179 found 53 airmen had refractive surgical procedures. When these were combined with those who carried pathology code 130, a total of 3,761 airmen (3,454 males, 307 females) had refractive surgery from 1 January 1994 through 31 December 1996. During the study period, the average total civil airman population was 605,296 (570,185 males; 35,111 females). Figures 3 and 4 show both the refractive surgery and average total airman populations by class of FAA airman medical certificate.

The prevalence rate of refractive surgery per 1,000 airmen by class and gender are presented in Figure 5. Females had higher prevalence rates for refractive surgery in all three classes of medical certification for the study period. Utilizing the Chi-square test, the total prevalence of female aviators (8.74/1,000) with refractive surgery was found to be significantly higher ($p < 0.05$) than that of males (6.06/1,000). Further statistical analysis using the Cochran-Mantel-

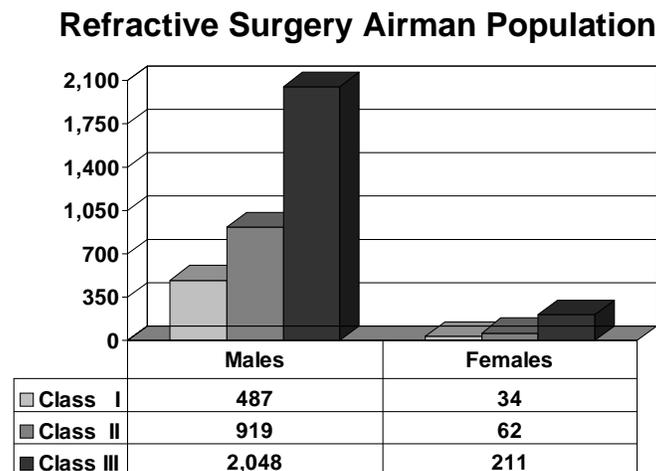


Figure 3: This chart presents the frequency of refractive surgery in the civil airman population by class of medical certification and gender for the period 1994-96.

Average Airman Population

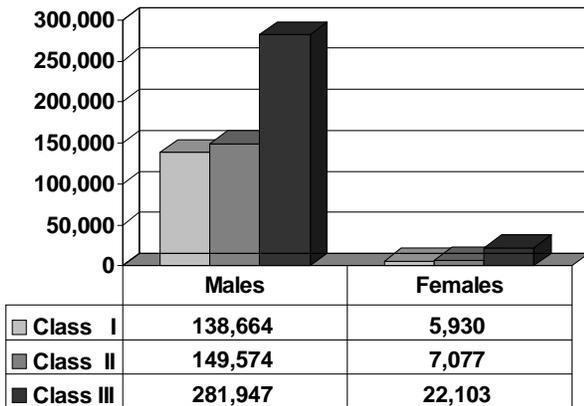


Figure 4: This chart presents the average airman population frequency by class of medical certification and gender for the period 1994-96.

Prevalence of Refractive Surgery

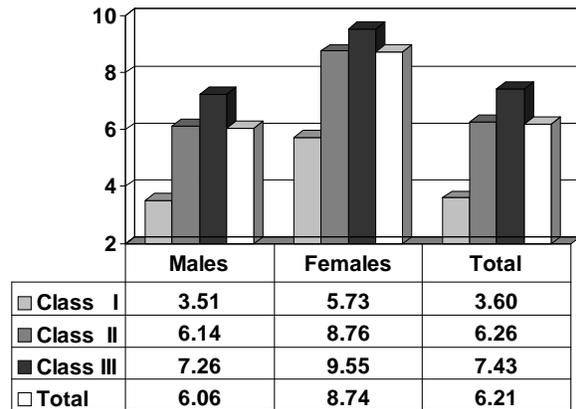


Figure 5: This chart presents the prevalence of airmen with refractive surgery in the civil airman population (per 1,000 airmen) by class and gender for the period 1994-96.

Average Age of Refractive Surgery Airmen

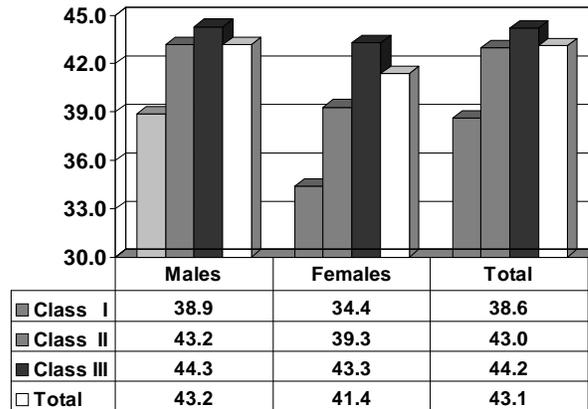


Figure 6: This chart presents the average age of airmen with refractive surgery in the civil airman population by class and gender for the period 1994-96.

Haenszel method found the association between female airmen and refractive surgery to be significantly higher ($p < 0.05$) for all classes of medical certification when compared with that of males.

The average age of the refractive surgical population by class of medical certificate and gender is reported in Figure 6. The average age of females (41.4) in the refractive surgery population was slightly less than two years younger than their male counterparts (43.2) (mean difference = 1.8; Std. Dev. = 1.9).

DISCUSSION

The use of eyeglasses to correct refractive problems may have disadvantages for pilots. Spectacle frames can reduce the field of vision, be uncomfortable, become displaced due to G-forces encountered during flight maneuvers, and may be incompatible with communication and protective breathing equipment. Spectacle lenses can also be dislodged in flight, and fogging may occur with sudden changes in humidity and air temperature.

Contact lenses can have inherent advantages for pilots over spectacle correction, including more natural vision, full field of vision, no lens fogging or water droplet accumulation, no discomfort due to weight, and no annoying obstruction from the frame or distracting reflections from the lenses. However, difficulties have also been reported with contact lens use in the aviation environment. Contact lenses have been displaced off the cornea and even ejected from the eye in flight. Airmen have also reported having to remove a contact lens while in flight due to dryness or a foreign body beneath the lens (13). Furthermore, the aviation environment includes low barometric pressure and relative humidity, which may affect contact lens wear. Corneal edema has been reported in seemingly well-fit contact lens wearers who experience altitude hypoxia (14). With the use of soft contact lenses in the 10-15% relative humidity of an aircraft, there is evidence of less lens movement and increased conjunctival injection (redness), both indications of an excessively tight fit (15). Soft contact lenses can dehydrate in low humidity, resulting in a vision performance (reduced low-contrast visual acuity) loss (16).

The frequent need to meet strict occupational or recreational vision standards, not normally required of the general population, can be a powerful motivating factor in a pilot's choice of refractive correction.

Civilian pilots may also be more likely to consider such surgical procedures due to an actual or perceived operational concern accompanying the use of spectacles and contact lenses in the aviation environment.

In this study, female aviators were approximately 30% more likely to have had refractive surgery than male pilots and had significantly higher ($p < 0.05$) prevalence rates for refractive surgery for all classes of medical certification. This suggests that female aviators consider refractive surgery a more viable alternative for refractive correction than do their male counterparts. It also contradicts one study, which found that males generally express a greater interest in refractive surgery than did females (17). Social-economic factors may influence the decision to have refractive surgery, since female pilots may be more financially capable of affording these relatively expensive procedures than females who do not fly.

Females, especially the elderly, may have poorer results following refractive surgery. According to the Ophthalmic Device Panel of the FDA's Medical Device Advisory Committee, women of middle age and older tend to have less favorable results with laser vision correction for reasons that are not totally understood (11). The predictability of refractive procedures may be more complicated for older females due to hormonal shifts associated with menopause (18). However, according to other studies, hormone replacement therapy may have little or no influence on the outcome of laser refractive procedures. The poorer outcomes seen in older female laser patients appear to be age-related (19). Additional clinical research involving older female patients has been recommended, which may result in revised guidance for laser refractive surgery for this population. Further research may also help determine whether menopause and the use of hormone supplements in the years following refractive surgery have any adverse effects on vision performance or if age-related changes in vision (cataracts, corneal dystrophies, keratoconjunctivitis sicca) are exacerbated by the presence of refractive surgery (20,21).

Younger women should be aware that pregnancy is a contraindication for refractive surgery (22,23). Women undergoing hormonal changes during pregnancy can experience relatively large shifts in refractive error, and hormonal changes may also affect the corneal healing process. If this occurs, surgery could result in an increased incidence of under- or over-correction of refractive error, corneal haze, glare

disability, and myopic regression (9,10). Furthermore, oral contraceptives have been associated with increased myopic regression after PRK (6). This study found female aviators with refractive surgery to be relatively young (34.4 to 43.3 years of age); therefore, many of these women would still be in their child-bearing years and possibly using oral contraceptives for birth control.

Long-term effects of newer laser refractive surgical procedures are still unknown. However, the long-term effects observed for RK may provide some clues regarding possible problems that female aviators with laser refractive surgical procedures may face in the future. At ten years after RK, women were found to have benefited less from their refractive surgery than men. The study also showed that women had poorer uncorrected and best-corrected visual acuity with less preoperative myopia, suggesting a possible biologic gender effect (24). In addition, women have been shown to have a higher prevalence of dry eye syndrome (25). This may adversely influence corneal healing and interfere with optimal results following refractive surgery, due to the reduction in the tear film layer (21). Since the average age of female airmen with refractive surgery in this study was 41.4 years of age, it is likely that these aviators will continue to fly for decades. Over time, it is conceivable that vision problems could develop as a direct result of refractive surgery, which may affect operational performance.

In summary, if the increase in the number of civilian pilots who elect to have refractive surgical procedure follows that projected for the general population, such procedures will become substantially more prevalent. Female pilots have significantly higher prevalence rates for refractive surgery, suggesting that they consider it a more viable alternative for correcting refractive error than do their male counterparts. Given their higher prevalence and the reports of gender-specific post-surgical complications women may experience, further research is recommended to investigate the potential for operational problems in the aviation environment. Instability of refractive correction associated with normal age-related ocular changes could also become an issue, as aviators with surgical correction mature. Special monitoring is warranted to evaluate whether unknown long-term side effects associated with laser refractive surgery could adversely affect aviation safety.

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