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THE EFFECT OF LASER REFRACTIVE SURGERY ON VISUAL PERFORMANCE AND ITS IMPLICATIONS FOR COMMERCIAL AVIATION

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THE EFFECT OF LASER REFRACTIVE SURGERY ON VISUAL PERFORMANCE AND ITS IMPLICATIONS FOR COMMERCIAL AVIATION

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Executive Summary

Introduction

Due to the rapidly increasing popularity of refractive surgery as an alternative to spectacle or contact lens correction, the Civil Aviation Authority (CAA) is likely to encounter an ever increasing proportion of prospective pilots who have undergone such a procedure. It is therefore important to implement an up to date policy on refractive surgery based on the visual performance requirements of commercial aviation. With the rapid developments in laser surgery technology now taking place, there is great potential for treated individuals to achieve excellent visual performance and avoid some of the pitfalls of conventional vision correction. The traditional methods of refractive error correction are not without their problems: spectacles suffer from the collection of dirt and scratches and if candidates with >–5.00D are considered by the Joint Aviation Authorities (JAA) in the future, spectacles for such corrections lead to minification of the retinal image and below average acuity. Contact lenses are often uncomfortable in the dry atmosphere of the cockpit and are known to cause corneal swelling and therefore reduced visual performance due to an increase in intraocular light scatter.

The piloting of an aircraft is visually demanding and any significant reduction in visual performance under the specific visual conditions experienced in aviation would be unacceptable. Following extensive investigation, the armed services in the United States of America are considering refractive surgery as an option for personnel.

The aim of the project was to investigate the effect of excimer laser surgery on the visual performance of the eye with reference to the implications for commercial pilots. The CAA originally expressed concern about the suitability of laser surgery for pilots because of the published evidence linking laser surgery with glare disability and compromised night vision. Disability glare results from an increase in intraocular light scatter, causing a veil of stray light to be superimposed over the retinal image. Compromised night vision is more likely to be related to the reported increase in ocular aberrations which cause the deviation of light rays, particularly those passing through the edge of the pupil. Both scatter and aberrations have the effect of reducing the contrast of the retinal image.

Refractive Surgery Techniques

An ever increasing range of surgical procedures is available to treat refractive errors. The refractive status of the eye can be modified by changing the corneal shape using a diamond blade (radial keratotomy), an excimer laser (photorefractive keratectomy and laser assisted in-situ keratomileusis) or a perspex implant (intra-stromal rings). Alternatively, the insertion of additional lenses into the eye has the effect of altering the refractive power of the eye.

Radial keratotomy (RK) was developed by Fyodorov in the early 1970s and uses a micrometer blade to produce radial cuts in the mid-peripheral and peripheral cornea, through approximately 95% of the corneal thickness, leaving a central untreated area of 3–4mm in diameter. The incisions substantially weaken the tissue, causing the peripheral cornea to bulge, resulting in a relative flattening of the central cornea and a reduction in myopia. Permanent radial corneal scars are visible following this procedure.

Although a small number of UK licensed pilots have successfully undergone this procedure, its suitability for aviation is questionable. A hyperopic shift in refractive error greater than 1.00D has been reported in 43% of eyes between 6 months and 10 years post-RK and visually disturbing shifts of –0.50D or more from morning to evening, are not uncommon. Ongoing glare disability is cited by the French Airforce, as being a significant reason for excluding radial keratotomy patients from flying training.

Radial keratotomy is rarely performed in the United Kingdom today with most surgeons believing that the risks are too high and that the procedure has been superseded by the advances in excimer laser technology.

Photorefractive keratectomy (PRK) was first performed on a human cornea in 1988. The procedure involves removing the corneal epithelium to expose Bowman's membrane. An Argon Fluorine excimer laser (193nm) is used to remodel the anterior corneal surface by the ablation of stromal tissue. Reprofiling the cornea to treat myopia requires the ablation of more tissue centrally than peripherally, producing a flatter refracting surface. The amount of tissue removed for low myopia is in the region of approximately 50μm – less than 10% of the overall corneal thickness. Studies have indicated that ocular integrity is not compromised. A subepithelial opacification referred to as haze develops over the first 2–4 weeks and peaks in intensity at 2–3 months, gradually subsiding by approximately 12 months. Once the haze has disappeared, there may be no visible signs that the eye has undergone PRK on slit lamp examination. Topography and retinoscopy may aid identification of a treated eye.

For myopia < –6.00D treated with a 6mm ablation zone, 85–88% achieve an uncorrected acuity of 6/12 or better and 40–58% achieve 6/6 or better at 12 months. Studies suggest that the refraction stabilises by approximately 3 months. For myopia >–6.00D treated with a 5.6 or 6mm zone, 68% achieve 6/12 acuity or better with only 26% obtaining 6/6 at 12 months. Stabilisation of the refractive error occurs between 6–12 months post-PRK. Significant regression can occur after the treatment of higher degrees of myopia (>–6.00D) and tends to become apparent within a few weeks of surgery, with the appearance of dense haze.

Glare sensitivity appears to be significantly increased for the first month post-surgery related to the increase in forward light scatter, poor optical heterogeneity of the cornea and induced aberrations. Studies consistently indicate that visual performance under dilated pupil conditions (low illumination) remains compromised for a year or more, particularly for low contrast acuity tasks. Forward light scatter in the direction of the retina, increases during the first 2 weeks post-PRK, peaks at 3 months and tends to return to normal levels comparable to spectacle wearers and soft contact lens wearers by 12 months. A significant reduction in visual performance can occur if there is a mismatch between ablation zone size and entrance pupil, resulting in halos caused by the refraction of light by the untreated paracentral cornea. Halos are more common under low illumination when the pupil is dilated, particularly in eyes that have undergone small diameter ablations, and in patients with naturally large pupils, up to 7.0mm in diameter. Ablation diameters of 6.0mm have eliminated halo problems in the majority of patients, although larger diameter ablations are indicated for "at risk" groups, i.e. young patients with large pupils, those with deep anterior chambers and patients in occupations where glare is a serious problem, such as pilots.

As the technology develops, the predictability and accuracy of PRK improves along with a reduction in the risk of complications. Since this procedure was first used on a human eye in 1988, the long-term consequences are unknown but there is no evidence to suggest anything significant to date. Ideally, PRK treatment should be restricted to the lower degrees of myopia because of the increased risk of haze and regression, and the slow stabilisation of the refraction following treatment for myopia greater than –4.00D.

Laser assisted in-situ keratomileusis (LASIK) was developed in 1990 after the introduction of the excimer laser to ophthalmology. It was based on a procedure called automated lamellar keratectomy (ALK), developed in 1966, which used a microkeratome to cut a thin cap of tissue and a second cut to flatten the cornea by a predetermined amount. The ALK cases have remained stable over 30 years. The LASIK procedure involves placing a suction ring on the peripheral cornea, which momentarily increases the intraocular pressure to >65mmHg as the volume of the globe is reduced and the cornea squeezed into the small aperture in order to ensure a regular cut. The microkeratome is inserted into the tracks of the suction ring and activated to pass across the cornea and back, cutting the flap. The vacuum is released and the flap reflected back, exposing the underlying stroma. The ablation is carried out on the dry stromal bed and the flap is repositioned.

Bowman's layer remains intact and therefore there is often a complete absence of post-operative haze and scar formation. Pain is minimal due to the limited disruption to the epithelium and useful vision returns almost immediately after surgery. The eye stabilises more quickly than after PRK and there is minimal tissue proliferation resulting in a transparent interface and rapid recovery of corneal sensitivity. In vivo microscopy has revealed corneal flap interface particles in all LASIK patients with microfolds in Bowman's layer in 96.8% of patients but these problems tend to be clinically insignificant. Post-operatively, a C-shaped ring is visible corresponding to the edge of the flap, which fades with time.

The percentage of LASIK patients achieving 6/12 vision or better, (uncorrected), has been quoted as 71.4% and 50% respectively for corrections of <–12.00D and >–12.00D at 6 months follow-up. Spatial contrast sensitivity recovers by 3 months in 78% of patients.

To perform a LASIK procedure there must be sufficient corneal thickness to prevent the ablation encroaching within 200μm of the endothelium, which may result in keratectasia. This is a rare condition in which induced corneal thinning leads to protrusion of the corneal tissue, severe irregularity and consequently a reduction in visual performance. To date, 57 out of more than 3 million procedures world wide, have resulted in keratectasia. This severe complication is usually associated with treatment for high myopia (>–10.00D) and has generally been attributed to a mis-calculation of the remaining stromal bed after flap creation, due to the limited accuracy of microkeratomes, (standard deviation of 30μm).

The treatment of astigmatism using either PRK or LASIK is less satisfactory than for spherical procedures since axis alignment is critical, with a 10° error leading to correction of only 65% of the astigmatic error. Higher degrees of initial astigmatism are unlikely to achieve 6/6 unaided and only a limited number achieve 6/12. There is also an increased risk of losing best corrected visual acuity with increasing astigmatism, resulting from induced irregularity. The treatment of hyperopia is in its infancy since it is more difficult to induce controlled steepening of the central cornea than to flatten the tissue. Results are still somewhat unpredictable and the laser algorithms require refinement.

Analysis of Visual Tasks and Lighting Conditions

A questionnaire was completed by a group of commercial pilots to assess the relative importance of visual tasks and determine the most demanding visual conditions encountered in aviation. The information gained from this process guided the detailed analysis that was made of the instrumentation and ambient illumination within the average cockpit. The only significant glare source identified by the pilots was a low sun. This was reported to be disabling by all pilots and required the use of sunglasses and tinted or opaque screens. Other potential glare sources such as the instrumentation alpha-numerics or approach/airport lights were not generally considered to be significant. When alternating between observation of the instrumentation and runway, the approach lights could cause a temporary reduction in the visibility of the instrumentation while the retina recovered from adapting to the bright approach lighting, but this was not reported as a problem in the questionnaire.

Cockpit display measurements indicated high contrast vector graphics with the smallest, critical tasks subtending between 12 and 18 minutes of arc at the eye, (approximately 3 times average acuity). The minimum angle of resolution was therefore 2.5 to 3 minutes of arc over an eccentricity range of +/– 5°.

Design of Experimental Program

Intraocular Light Scatter

The City University Scatter Test, based on the direct compensation technique, was used to assess the quantity and distribution of scattered light within the eye. The subject fixated the central black target while the luminance of a white scatter annulus was modulated sinusoidally. The subject reported flickering over the central target due to stray light from the annulus, superimposed over the retinal image. The luminance of the test target was then modulated in counterphase to that of the scatter source and the amplitude increased using decreasing step sizes until the subject identified the point at which the flicker appeared to be neutralised. This gave an estimate of the retinal luminance resulting from the glare annulus at a particular eccentricity. The test was repeated six times for each of five glare angles, allowing the scatter function of the eye to be plotted and the scatter index, n (distribution of scattered light) and straylight parameter, k (quantity of scattered light) to be calculated.

Visual Search Performance and Glimpse Duration

A dynamic visual search task was designed to assess suprathreshold visual performance over a range of contrast levels, mimicking the visual tasks of search and recognition regularly employed within the cockpit. Both the stimulus and distractors were composed of Landolt rings displayed over a circular field of 20° diameter, with 15 randomly positioned, vertically orientated distractor elements, and a single, obliquely orientated target. The distractors varied in contrast between 6–64% and the target was presented at one of 5 pre-selected contrast levels. The target presentations were randomly interleaved with each repeated an average of 36 times. On finding the target, the subject pressed a response button to indicate identification of the target and allow a measure of search time. The average glimpse duration was also investigated using a infra-red pupillometer system. Glimpse duration was defined as the average time taken for the subject to saccade from one possible target to another within the field. Subjects suffering from visual degradation would be expected to take longer to process the information gained during a fixation and therefore exhibit a longer average glimpse duration.

The results of this test displayed significant inter-subject variability and the experimental procedure was very time consuming. Consequently, a computer model of the task was developed to enable investigation of the importance of individual factors in determining the outcome of the test and potentially to predict visual performance. The influence of target contrast on visual performance was reduced by a significant learning effect, fatigue and the use of search strategies by some subjects.

Contrast Threshold Measurements

In order to analyse the contrast element in search performance, two further computer-based tests were developed:

(i) Contrast detection thresholds – measurement of the contrast threshold required to detect the presence of a single Landolt ring target at a particular eccentricity.

(ii) Contrast acuity thresholds – measurement of the contrast threshold required to detect and identify the orientation of a single Landolt ring target at a particular eccentricity

The stimulus for both experiments consisted of a Landolt ring with an orientation of 45°, (visual angle: diameter 72 mins of arc, gap 7.7 mins of arc). The subject was required to fixate the central red target and respond to the presentation of a stimulus, flashed up for 250ms duration at one of three, randomly interleaved eccentricities over a circular field of 10° radius. Target contrast was varied in ever decreasing steps until the threshold had been crossed 6 times. For both threshold measurements, the contrast threshold increased with target eccentricity, reflecting the reduced resolving power of the retina away from the fovea and the reduction in the optical quality of the eye for images away from the visual axis.

These threshold measurements formed important assessments of visual performance in their own right. Both scatter and aberrations are known to reduce the effective retinal image contrast and therefore cause an increase in contrast thresholds, particularly for detection of the gap (contrast acuity thresholds).

Visual Acuity Measurements

Visual acuity was assessed using a logMAR chart at both high and low contrast levels in order to determine the effectiveness of such a measurement.

Subjects

The study was performed retrospectively with subjects recruited from two laser clinics within London. All subjects underwent a full ophthalmic examination to assess the health of the eye and the refractive status. Those with any form of ocular or systemic disease were excluded. Unfortunately due to logistical constraints, it was not possible to assess the majority of laser patients both before and after the surgery. Data have been collected for 53 control, 51 LASIK and 32 PRK subjects. The average follow-up times for the two refractive surgery groups differed significantly, (LASIK 16.3 weeks and PRK 135.6 weeks) but the groups were matched for age and pre-operative refractive error. The effect of age, follow-up time and pre-operative refractive error were assessed but the size of the data sets available meant that the power to detect any effects were limited. Age is known to influence visual performance due to a combination of increased intraocular light scatter, reduced retinal illuminance and neuronal degeneration. Few changes occur before the age of 45 years and the greatest reduction tends to occur much later on in life. Therefore the subjects in each group were divided into two sections: <45 years and > 45 years for analysis. A one–way analysis of variance, (ANOVA) was used to examine the effect of age on each experiment, for each of the three subject groups. Age was identified as a statistically significant factor for some measures of performance however the significance was limited by the small number of subjects over the age of 45 years.

Results and Discussion

For each of the three subject groups, the outliers were identified and removed prior to analysis. The method chosen for exclusion of the outliers assumed a non-normal distribution for all tests. Outliers were defined using a standard technique for non-normal data in which individuals whose results fell outside 1.5x (inter-quartile range) above the upper quartile were considered an outlier.

For each experiment, the means were corrected for the effects of age, refractive error and follow-up time, to overcome the differences between groups for each of these variables. A three-way ANOVA was used to compare the corrected means of the three groups for each experiment. The hypothesis in each case was that the corrected means were the same for all three data sets. The level of significance was set at 5% for all tests ($p=0.05$ or less). In some cases, a further two-way analysis was needed to identify which particular set of data was significantly different from the other two.

Comparison of the intraocular light scatter functions of the three groups indicated no statistically significant difference between the groups. In other words, light scatter was not elevated following either PRK or LASIK compared to the control group for the follow-up times considered. This is not surprising since the literature suggests that the rise in intraocular light scatter is only significant in the first few weeks following PRK and very few PRK subjects with a short follow-up were available for examination. Two PRK subjects were identified as outliers for light scatter. Both exhibited stromal haze greater than grade 1 associated with < 10 weeks follow-up.

The experiments to assess visual performance produced variable responses. The contrast detection thresholds for the two refractive surgery groups did not differ significantly from the control group. This is to be expected since the effect of scatter and aberrations would be minimal for such large retinal images.

The contrast acuity test indicated a small but statistically significant increase in contrast threshold, relating to a reduction in visual performance for the LASIK group and a slightly greater reduction in the PRK group. This test appeared to be the most sensitive assessment of visual performance but the small reduction in average performance is unlikely to be significant in the real world. This experiment also identified the greatest number of outliers, many of whom suffered mild symptoms.

The visual search program revealed a small but statistically significant increase in search times for the high contrast targets only. The effect may have been masked at lower contrasts by the larger standard deviation at this contrast level. The LASIK data did not differ significantly from the control group. Measurement of both glimpse duration and high and low contrast logMAR acuity did not reveal any difference from the control group for either refractive surgery group.

Significant outliers exhibiting a notable reduction in visual performance existed in both refractive surgery groups. The reduced performance of these individuals was not always related to an increase in intraocular scattered light and was therefore attributed to an increase in the irregular aberrations of the eye.

Conclusions

Following removal of the outliers, the data suggests that in general, neither PRK nor LASIK cause a significant reduction in visual performance. The statistically significant reduction in visual performance following both PRK and LASIK suggested by the contrast acuity test, requires further investigation. However, the small difference between the refractive surgery data and the control data suggests that this reduction in performance is unlikely to be of significance in aviation and the data suggest that a test based on contrast acuity would be the most sensitive technique from which to develop a screening test. Such a test should be based on the target parameters and light levels found in the flight deck so as to determine whether or not the small reduction in performance is relevant to the visual tasks involved in commercial aviation. The test should enable detection of the 12–17% of outliers that suffer from significantly compromised vision and are therefore also likely to have substandard flying performance.

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1 PROJECT AIMS

Due to the rapidly increasing popularity of refractive surgery as an alternative to spectacle or contact lens correction, the Civil Aviation Authority (CAA) is likely to encounter an ever, increasing proportion of prospective pilots who have undergone such a procedure. It is therefore essential to implement an up to date policy on refractive surgery based on the visual performance requirements of commercial aviation. Scientifically based aeromedical certification decisions on unsuitable applicants who have undergone refractive surgery, are easier to justify to the individuals involved.

Until July 1999, the medical certification policy of the CAA considered individuals who had undergone refractive surgery for less than 5.00D of myopia, following confirmation of a successful outcome by an Ophthalmologist. Since July 1999, this policy has been superseded by the Joint Aviation Authorities of Europe (JAA) policy, which rejects all refractive surgery applicants. Previously certificated pilots with a history of refractive surgery maintain "grandfather" rights.

With the rapid developments in laser surgery technology now taking place, there is great potential for treated individuals to achieve excellent visual performance and avoid some of the pitfalls of conventional vision correction. However, the piloting of an aircraft is visually demanding and any significant reduction in visual performance under the specific visual conditions experienced in aviation would be unacceptable.

The aims of the project have been to:

1. Analyse the visual tasks involved in piloting a commercial aircraft through measurement, discussion and the use of a questionnaire.
2. Examine the literature on excimer laser surgery and its effect on visual performance.
3. Measure levels of intraocular straylight using the City University Light Scatter Program, and determine the effect of Photorefractive Keratectomy and Laser Assisted in-situ Keratomileusis on light scatter.
4. Develop computer-based suprathreshold measures of visual performance, relevant to common visual tasks in aviation.
5. Examine the visual performance of refractive surgery patients using these tests, and hence determine the suitability of excimer laser surgery for use in commercial aviation.

2 CORRECTION OF REFRACTIVE ERROR

2.1.1 *Spectacles*

Glasses are capable of correcting spherical and astigmatic errors and generally allow good visual quality. However, lenses of any power can become dirty, scratched or broken. Under emergency conditions, glasses may fog or become covered in water droplets, severely reducing the quality of vision.

Lenses for the correction of higher refractive errors lead to minification or magnification of the image with associated restrictions of the field of view. Patients who undergo a successful refractive surgery procedure for the correction of myopia greater than about –5.00D, tend to demonstrate an increase in the best corrected visual acuity following surgery, as the retinal image is no longer minified. To reduce such optical effects and also for cosmetic reasons, many high-powered spectacle lenses are made from high index materials with aspheric surfaces. The trade-off is a reduction in acuity away from the optical centre of the lens.

2.1.2 *Contact Lenses*

The problems of contact lenses in aviation are well known from the outcome of numerous military studies. The main difficult for contact lens wearers is the dry atmosphere within the cockpit, reducing tear quality and causing drying of the contact lens and anterior ocular surface. Both soft and rigid lenses are affected by this problem which may lead to symptoms of asthenopia (eye-strain), frontal headache, and reduced visual quality due to poor wetting of the lens surface. Starbursts and reduced contrast sensitivity have been reported, particularly in soft lens wearers. Deposition of the lens surface also degrades the optical performance further.

Rigid lenses can cause temporary disability if small particles, such as dust, become trapped beneath the lens, resulting in excessive lacrimation and discomfort. Many rigid lens wearer also report flare and halos (bright annulus in periphery of vision) when driving at night, due to a mis-match between the pupil and optic zone of the lens.

Nowadays, the majority of patients are fitted with soft lenses but such lenses are generally unable to correct the small degrees of astigmatism commonly found among the population. The quality of the vision will depend on the hydration of the lens material, the level of fatigue of the wearer and their sensitivity to blur.

Long-haul pilots often wear their lenses for 12 hours or more. With the exception of some rigid lens materials and two new soft lens materials, (marketed for extended wear at sea level), the majority of contact lenses do not allow enough oxygen to reach the cornea to prevent swelling at altitude. Four percent corneal swelling is considered an acceptable level since this occurs in the normal closed eye overnight when at sea level and the reduced partial pressure of oxygen at altitude results in the presence of daytime swelling of this magnitude. However the nature of some flight schedules and the tendency for some pilots to sleep in their lenses during long flights, results in a vicious circle in which the cornea is not given the chance to return to acceptable levels of swelling. Corneal oedema is known to cause an increase in scattered light and hence a reduction in contrast sensitivity. This effect occurs on top of the increase in scattered light noted in contact lens wearers without significant corneal swelling, (Lohmann *et al.*, 1993; Hennelly, 1997; Woodward, 1996; Woodward, 1996), which has been attributed to chronic microscopic tissue changes.

2.2 The Implications Of Refractive Error Restrictions

If the current refractive restrictions on individuals over –5.00D remain in force, refractive surgery may provide a method of correcting the eyes of highly trained personnel who no longer meet the visual standards for commercial aviation. It may also increase the pool of potential candidates, although this is not believed to be a particular necessity.

If the restriction on higher refractive errors is lifted, refractive surgery may be a less attractive option. However it has been shown to improve visual performance in some individuals with large degrees of short-sight (myopia).

The armed services in the United States of America are considering extending the refractive requirements for many military positions to include myopia up to –8.00D. Following considerable research, they are also seriously considering PRK surgery as an option for personnel. LASIK is still under investigation as some believe the corneal flap may be compromised by high G-forces.

3 VISUAL TASK ANALYSIS

When piloting an aircraft, visual information provides a critical part of the sensory input. The introduction of Cathode Ray Tube (CRT) or Liquid Crystal Display (LCD) based digital displays has greatly simplified the cockpit instrumentation, allowing for the presentation of only the most critical information at any one time. Colour cues have increased but are always associated with shape features. Although the Auto-pilot continues to become increasingly more sophisticated and can therefore be relied upon to perform a large proportion of the aircraft’s manoeuvres, pilots still need to be able to rapidly detect visual information and respond appropriately.

3.1 Questionnaire

An initial questionnaire was designed to aid our understanding of the most vision-critical tasks involved in commercial aviation, and the most challenging visual conditions which pilots are subjected to, (see Appendix 1).

Questionnaires were completed by 23 pilots, (12 flying with digital instrumentation, 9 with analogue instrumentation, 2 helicopter pilots with digital instrumentation). The average age of the pilots was 40 years and only 5 pilots required prescription spectacles. Sunglasses were regularly used by 20 pilots, out of which 4 commented that the tint reduced the visibility of the digital instrumentation.

Additional information was gained from observation and discussion during a number of flights.

To summarise the information collected, the most difficult visual tasks were consistently listed as the approach, landing and take off, because of the need to constantly monitor the instrumentation and the requirement to judge the position of the aircraft in relation to the runway. As expected, the visual difficulty of tasks was increased by conditions of poor visibility, whether due to poor weather, low sun or low light levels. Loss of peripheral contrast information due to snow or water made the approach and landing more difficult.

Glare was noted as a concern with the sun forming the only significant glare source, particularly when positioned low in the sky. Prolonged low sun, as found on east/west flights, was reported as a cause of both discomfort and disability glare. Sensitivity to glare appeared to be related to both tiredness and time zone transitions. Most pilots found that direct glare from a low sun was impossible to combat with sunglasses and tinted visors – blinds, maps and newspapers were often used to block out the sun.

Other potential glare sources such as the instrumentation alpha-numerics or approach/airport lights were not generally considered to be significant. The approach lights, although adjustable on demand, could result in adaptation glare when the pilot was required to alternate fixation between the runway and the instrumentation. In other words, the visibility of the instrumentation would be momentarily reduced while the retina recovered from adaptation to the bright approach lighting.

Surprisingly few pilots complained of any difficult seeing under low illumination although complaints did increase slightly with age as would be expected. The cockpit illuminance was generally kept low for night landings and take-off. Younger pilots sometimes complained that the cockpit background illumination was too high at night, reducing the visibility of the instrumentation. In these cases, the luminance level had been determined by an older captain.

Pilots spent the majority of the flight observing the two primary flight screens, depicting information on altitude, airspeed, orientation etc. Due to the excellent design of the modern CRT and LCD screens, with adjustable contrasts of 200% or more, no other problems were reported regarding the visibility of the digital instrumentation. Even veiling glare had no significant effect. The move from analogue to LCD based displays, has made the assembling of critical information from the instrumentation, one of the easiest visual tasks. Of the pilots flying on analogue instruments, 4 complained of reduced instrumentation visibility at night due to poor cockpit illumination.

Introduction of the Airborne Collision Avoidance System (ACAS) has reduced the importance of searching the visual field for other aircraft. However it is still ultimately the pilots' responsibility to be aware of other traffic, particularly small planes that do not carry a ACAS transponder. During the approach and landing, it was common for pilots to alternate fixation between the instrumentation at an intermediate distance and the runway at a far distance.

3.2 Analysis Of An Airbus 320 Flight Deck

The detailed analysis was undertaken during a daytime flight between Heathrow and Edinburgh and a night time return flight.

Figure 1 Airbus 320 LCD Instrumentation

The A320 allows the pilot to select the presentation of one from 13 screens on the central Primary Engine Display. The Primary Flight Screens allow the additional selection of weather radar information and the enhanced Ground Proximity Warning System. The emergency warning lights consist of large, red flashing buttons, located above the Primary Flight Display for each pilot. Such warnings are usually accompanied by an audible signal, and the pilots must then examine the central Primary Engine Display screen for information regarding the nature of the warning.

Both pilots were seated such that their eye to Primary Flight Display distance was 0.75m and 0.85m. The alpha-numerics employed on the LCD screens can be categorised into one of three sizes: small (3mm, such as the small altitude characters), medium (4mm, such as the numbers on the directional heading) and large (5.5mm, such as the headings on the screens and important figures). Assuming an average viewing distance of 0.8m, the smallest critical characters, (3mm in size) subtend approximately 12 minutes of arc (minimum angle of resolution 2.5 minutes of arc). This is approximately three times the average resolution of the eye.

All the LCD display screens on the A320, measure 0.16 x 0.16m square, therefore subtending approximately 10° at 0.8m, (+/–5° either side of the visual axis).

3.2.1 *Luminance Levels*

Luminance measurements were taken by pointing a light meter directly at the relevant object, (see appendix C). During the day, luminance levels within the cockpit ranged from less than 0.2 cd/m^2 (LCD background), to more than 50 cd/m^2 (alpha-numerics at brightest setting). The luminance of the sky varied from 730 cd/m^2 (overcast), to more than 300,000 cd/m^2 (maximum reading on luminance scale when pointing at the sun). The pupil size is determined by the average illuminance in the plane of the pupil. Under these bright photopic conditions, the pupil tends to be between 3 and 4mm in diameter.

At night, the luminance levels within the cockpit ranged from less than 0.1 cd/m^2 (LCD background) to 3.8 cd/m^2 (alpha-numerics at brightest setting). Localised lighting for examining airport maps etc. tended to provide lower luminance values.

3.2.2 *Night Vision*

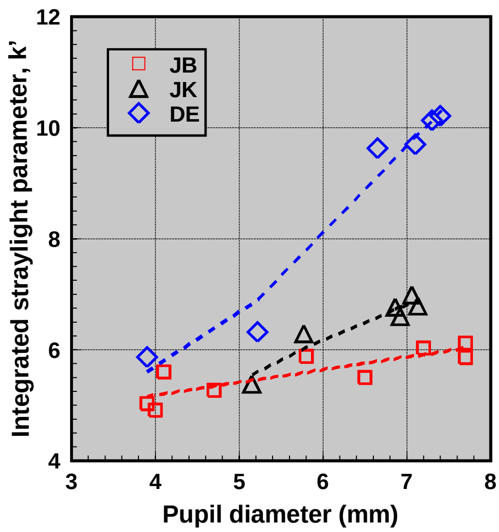
Under the mesopic conditions found in the cockpit at night, the retina shifts from exhibiting a predominantly cone function to a mostly rod function for the majority of the visual field. Some cone function remains, providing sharp central vision at the fovea due to the high contrast of the digital displays and the higher luminance of the grey surround etc. Consequently, good colour vision is maintained centrally.

Night-time illumination levels vary between crews and with the different stages of the flight. The pupil size is determined by the average retinal illuminance and hence a large pupil size is to be expected. Under such low illumination, the pupil can dilate from an average of 3 to 4mm under daylight conditions, up to 6 to 8mm under low level light conditions.

For visual tasks such as searching for an airport runway or scanning for other air traffic, the low illumination has a number of other consequences. Scattered light within the eye, either from a glare source or more commonly from the object of regard itself, causes a reduction in the visibility of the target if the irradiance of the scattered light is similar to or exceeds that of the retinal image. A veil of light is superimposed on or around the retinal image of the object of interest, reducing the contrast of the image. Back scattered light (e.g. haze after PRK), can be assessed directly but it is only weakly correlated with the quantity of forward scattered light, since the proportion of light scattered forward and back depends on the physical characteristics of the scatter source. Forward light scatter can be assessed indirectly using low contrast and glare tests or using tools such as the straylightmeter.

Under low illumination, the influence of scattered light on visual performance increases significantly. This is partly because the contrast between low contrast objects and bright glare sources is greater at night than during the day, but also because scattered light increases with increasing pupil size (see figure 2). In addition, the Stiles-Crawford effect

Figure 2 Effect of pupil size on the integrated stray-light parameter, k' (measure of overall quantity of light scatter)



Scattering of light is non-uniform across the pupil. The far periphery appears to contribute the most. As the pupil dilates, the overall quantity of scattered light increases.

becomes less dominant as the influence of the cones is reduced. Rod receptors are less discerning with regard to the direction of light rays and hence are more likely to detect scattered light than the cone receptors.

The eye naturally possesses higher order aberrations (optical irregularities), which are exacerbated by corneal refractive surgery. Spherical aberration results in light rays that pass through the peripheral pupil focussing at a different point along the visual axis than the paraxial rays, (either in front or behind the retina). Coma results in peripheral rays focussing at a point laterally displaced from the focal point of the paraxial rays, due to alterations in refractive power of the eye across the pupil. Both have the effect of reducing the clarity of the retinal image and they are highly dependent on pupil size. Large increases in these axial aberrations significantly reduce the ability of the optical components to produce a good quality retinal image for large pupil diameters, (as assessed by the modulation transfer function of the eye). In an average eye, these aberrations increase 30-fold as the pupil dilates from 3 to 7mm (Applegate *et al.*, 1998; Martinez *et al.*, 1998). As a consequence, aberrations have significantly more influence on visual performance under low illumination since the pupil is dilated.

Scattered light, aberrations and a reduction in the signal-to-noise ratio of the visual stimulus due to photon noise, all have the effect of reducing image contrast.

Further reductions in image contrast as a result of any of these factors are likely to render the image invisible since the image contrast will be closer to threshold due to the predominance of the rod function.

The visual performance of an individual is less predictable under low illumination, not just because of variations in the optical quality of the eye (scatter, aberrations, pupil size) but also because of the variation between individuals in the state of adaptation of the eye for a particular light level.

4 SUMMARY OF REFRACTIVE SURGERY

An ever increasing range of surgical procedures are available to treat refractive errors. The refractive status of the eye can be modified by changing the corneal shape using a diamond blade (radial keratotomy), an excimer laser (photorefractive keratectomy and laser assisted in-situ keratomileusis) or a perspex implant (intra-stromal rings). Alternatively, the insertion of additional lenses into the eye has the effect of altering the power of the eye.

The specific remit of this study was to examine the effects of excimer laser surgery on the visual performance of the eye. A brief mention is made of radial keratotomy since thousands of procedures were performed in the United Kingdom and a small number of licensed commercial pilots underwent the procedure. It is important for the CAA to continually update its knowledge of refractive surgery as it is a rapidly developing field.

4.1 Radial Keratotomy (RK)

Radial Keratotomy (RK) was developed by Fyodorov in the early 1970's, (Fyodorov and Durnev, 1979), and uses a micrometer blade to produce radial cuts in the mid-peripheral and peripheral cornea, through approximately 95% of the corneal thickness, leaving a central untreated area of 3–4mm in diameter, (Waring *et al.*, 1985) (figure 3). The incisions substantially weaken the tissue, causing the peripheral cornea to bulge, resulting in a relative flattening of the central cornea and a reduction in myopia. The Prospective Evaluation of Radial Keratotomy (PERK) study, ran in the United States from 1980–1985 to investigate the safety, efficacy, predictability and stability of a standardised, 8 incision radial keratotomy procedure. It assessed 793 eyes with a range of pre-operative myopia between –2.00 and –8.75 D with 88% of eyes followed for 10 years, (Waring *et al.*, 1994).

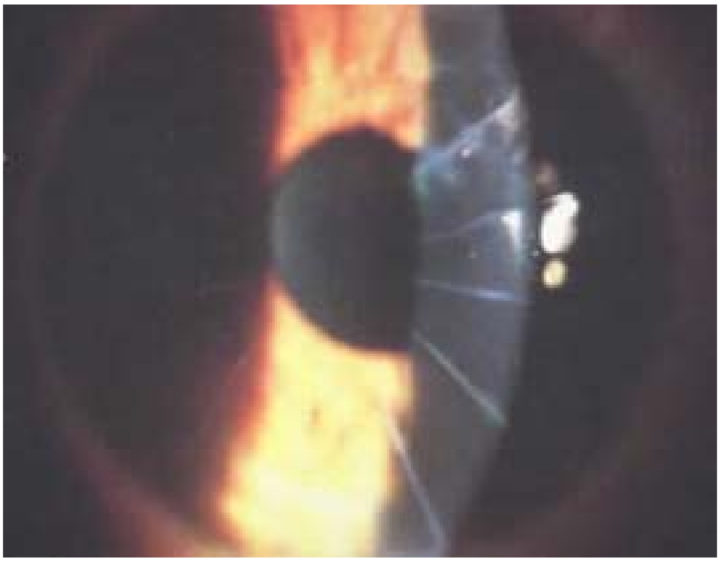


Figure 3 Corneal scars resulting from Radial Keratotomy

4.1.1 *Recovery*

Disruption to the corneal epithelium results in some pain in the early post-operative period but this subsides within a few days. The deep nature of the corneal incisions leads to an inherently unstable cornea.

4.1.2 *Refractive Results*

The initial predictability of the residual refractive error is reasonable for low degrees of pre-operative myopia with 84% of the –2.00 to –3.12D group and 62% of the –3.25 to –4.37D group achieving a refractive result within +/–1.00D of emmetropia, at 1 year post-surgery. However, only 38% of the –4.50 to –8.00D group were found to achieve a refractive result within +/–1.00D of emmetropia at 1 year, (Waring *et al.*, 1985), suggesting that RK should be restricted to the treatment of low myopia only.

4.1.3 *Stability*

The long-term stability of the refractive result has been questioned following the detection of a drift towards hyperopia in up to one third of patients after 4 years, (Waring *et al.*, 1991). The 10 year follow up of the PERK study revealed an alarming 43% of eyes with a hyperopic shift greater than 1.00D from the refractive result measured at 6 months post-RK, (Waring *et al.*, 1991; Waring *et al.*, 1994).

4.1.4 *Visual Performance*

High Contrast Acuity
The only assessment of visual quality undertaken by the majority of surgeons is a measure of the high contrast acuity when any residual refractive error is corrected. A loss of 2 or more lines of Best Corrected Visual Acuity (BCVA) is considered significant. A loss of 1 – 2 Snellen lines of visual acuity occurred in 13% of cases (PERK) at one year, and 3% of eyes at the 10 year follow up. A common complication is a diurnal fluctuation in refractive error and hence visual acuity due to the structurally weakened cornea, (Bores *et al.*, 1981; Cowden and Bores, 1981; Hoffer *et al.*, 1981; Kwitko *et al.*, 1992). The PERK researchers encountered an increase in myopia greater than 0.50D in 30% of eyes, (Bourque *et al.*, 1986). A study of a group of firefighter applicants who had undergone radial keratotomy, found a myopic shift occurring between the morning and afternoon of –0.41 +/– 0.33D compared to +0.06+/–0.42D in the control group. The refractive change caused 3 out of 10 subjects to fail to meet the visual standard in the afternoon despite passing in the morning, (Bullimore *et al.*, 1994).

Contrast Sensitivity
The data are inconclusive with some studies indicating no significant loss of function, (Olsen and Andersen, 1991; Applegate *et al.*, 1987), while others show a transient loss in some patients that tended to recover by 10–24 months, (Ginsburg *et al.*, 1990; Krasnov *et al.*, 1988; McDonald *et al.*, 1983). Although contrast sensitivity testing should be one of the better ways of assessing visual performance, there is little consistency between the results from commercially available tests. The majority of studies test contrast sensitivity under photopic conditions, causing the pupil to constrict so that the influence of the mid-peripheral cornea on visual performance remains undetected.

Glare Testing
The consequence of a glare source for any eye is to increase intraocular light scatter and hence reduce contrast sensitivity. This effect is magnified following radial keratotomy. Bullimore and colleagues (Bullimore *et al.*, 1994) assessed contrast sensitivity, both with and without a glare source, for dilated pupils and natural pupils. A reduction in contrast sensitivity was noted for dilated pupils only. However, the design of the glare source can affect the results of any glare test since a point glare source similar to car headlights, causes pupil constriction and masks some of the effects of increased corneal aberrations, (Boxer *et al.*, 1999).

4.1.5 *Corneal Aberrations And Their Implications For Visual Performance*

Studies have shown an alteration in the optical aberrations of the cornea following radial keratotomy. After RK, the central cornea becomes flatter and the paracentral area steepens. This multi-focal effect results in a larger blur circle and decreases the eyes sensitivity to defocus which tends to mean that the eye achieves a better uncorrected acuity than would be expected for the residual refractive error, (Holladay *et al.*, 1991; Santos *et al.*, 1987). However, the other consequence of a multifocal cornea is a myopic shift with pupil dilation. This effect has been reported in about 19% of radial keratotomy patients and can have serious implications for night vision, (Holladay *et al.*, 1991). Applegate and colleagues (Applegate *et al.*, 1998) considered the effect of induced corneal aberrations on contrast sensitivity for 3mm and 7mm pupils. For the RK eyes with a 3mm pupil there was a significant and permanent surgical-induced change to the corneal aberrations, which increased to 30 times pre-operative values for a 7mm pupil. There was no significant change in high contrast visual acuity for either pupil size.

4.1.6 *Rare Complications*

More serious but rare complications of radial keratotomy include a 2.2% risk of sight-threatening corneal perforation, (Waring *et al.*, 1985) due structural weakening of the cornea. The continuity of collagen fibrils is not restored following RK and so the tensile strength of the cornea is reduced. Many surgeons believe that the radial wounds never completely heal and keratitis has been reported many years after surgery.

4.1.7 *Conclusions*

Radial Keratotomy is rarely performed in the United Kingdom today with most surgeons believing that the risks are too high and that the procedure has been superseded by the advances in excimer laser technology.

On going glare disability is sighted by Corbe and colleagues (Corbe *et al.*, 1993), as being significant reason for excluding radial keratotomy patients from the French airforce. Enzenauer et al. (Enzenauer *et al.*, 1993) also concluded that radial keratotomy was unsuitable for the Soldier-Aviator. Any assessment of the suitability of a radial keratotomy patient for commercial aviation should include a measurement of the stability of refraction as well as the visual assessment.

4.2 **Photorefractive Keratectomy (PRK)**

This was first performed on a human cornea in 1988. The procedure involves removing the corneal epithelium to expose Bowman's membrane. An Argon Fluorine (ArF) excimer laser (193nm) is used to remodel the anterior corneal surface by the ablation of stromal tissue, (Trokel *et al.*, 1983) (figure 4). Reprofiling the cornea to treat myopia requires the ablation of more tissue centrally than peripherally, producing a flatter refracting surface. The amount of tissue removed for low myopia is in the region of approximately 50µm – less than 10% of the overall corneal thickness. Studies have indicated that ocular integrity is not compromised, (Galler *et al.*, 1995).

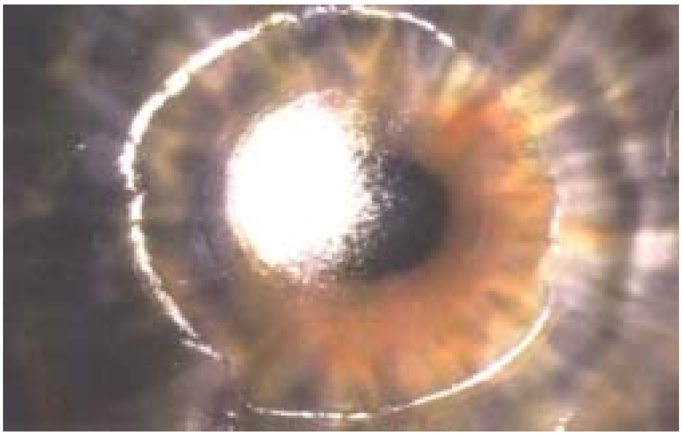


Figure 4 Corneal surface after PRK showing the ablation pattern on the stroma and the limit of the epithelium

4.2.1 *Recovery*

Post-operative care involves the management of pain and the prevention of ocular infection. Pain can be severe for the first 24 hours, and continues until re-epithelialisation occurs in 4.6 +/– 0.2 days, (McDonald *et al.*, 1991). Functional vision returns upon re-epithelialisation with 83% of low myopes (< –6D) and 61.4% of high myopes (>–6D) achieving an unaided vision of $^{6}/_{12}$ at 1 week, (Reich *et al.*, 1996). The initial refraction tends to be slightly hyperopic followed by a gradual drift towards emmetropia or myopia.

Unlike Radial Keratotomy, PRK involves treating the centre of the cornea therefore changes in corneal clarity are of concern. A subepithelial opacification referred to as haze develops over the first 2–4 weeks and peaks in intensity at 2–3 months, gradually subsiding by approximately 12 months, (Lohmann *et al.*, 1991; Seiler *et al.*, 1990; McDonald *et al.*, 1989; McDonald *et al.*, 1990a; McDonald *et al.*, 1990b).

4.2.2 *Refractive Results*

For myopia < –6.00D treated with a 6mm ablation zone, 85–88% achieve an uncorrected acuity of 6/12 or better and 40–58% achieve 6/6 or better at 12 months. By 12 months, 56–87% achieve within +/–1.00D of emmetropia and the refraction stabilises by approximately 3 months, (Tuunanen and Tervo, 1998; Pallikaris *et al.*, 1996).

For myopia >–6.00D treated with a 5.6 or 6mm zone, 68% achieve 6/12 acuity or better with only 26% obtaining 6/6 at 12 months. At this point, 79–90% are within +/–1.00D of emmetropia and stabilisation occurs between 6–12 months post-PRK, (Tuunanen and Tervo, 1998; Williams, 1996). Since the development of LASIK, PRK is rarely used to treat more than –4.00D of myopia. Significant regression can occur after the treatment of higher degrees of myopia (>–6.00D) and tends to become apparent within a few weeks of surgery, with the appearance of dense haze. Regression has been shown to be 13.5 times more likely in females taking oral contraceptives, with other risk factors being solar radiation, sun beds and ocular surface disorders.

Retreatments or enhancement procedures can be performed to correct residual refractive error but predictability is not as good as for the initial procedure.

4.2.3 *Visual Performance*

High Contrast Visual Acuity: It is rare for those undergoing PRK for myopia of <–6.00D to experience a loss in best corrected acuity by 12 months post-surgery, but 6–14.4% of patients treated for >–6.00D lose 2 or more lines of best corrected acuity. Unlike RK, diurnal variations resulting from PRK are clinically insignificant and any shift tends to be in the hyperopic direction, (Goldberg *et al.*, 1997; Goldberg and Pepose, 1996).

Contrast Sensitivity
Opinions regarding the effect of PRK on contrast sensitivity vary significantly, probably because of the wide range of methods employed by different investigators. Some studies have shown no reduction in contrast sensitivity, (Sher *et al.*, 1991; Sher *et al.*, 1992), whereas Essente and colleagues (Essente *et al.*, 1993) found that contrast sensitivity only returned to pre-operative levels at 3 months in eyes treated for <–6.00D. For eyes with a preoperative refraction >–6.00D, contrast sensitivity returned to normal by 6 months. A similar result was noted by Pallikaris and co-workers (Pallikaris *et al.*, 1996) for myopia –1.0 to –6.0D with a reduction in contrast sensitivity at 1 month that returned to pre-operative levels by 3 months. Beade and Haight (Beade and Haight, 1996), recorded a statistically significant decrease in contrast sensitivity at 12 months post-operatively and Ficker et al. (Ficker *et al.*, 1993), noted a general reduction in contrast sensitivity that recovered by 1 year post-surgery.

Perhaps of more relevance to aviation, Ambrosio and colleagues (Ambrosio *et al.*, 1994) assessed the effect of PRK on both static and dynamic contrast sensitivity, along with glare sensitivity. They found that glare did not affect visual acuity although night-time conditions and hence dilated pupil conditions were not considered. The contrast sensitivity function was reduced at 1 month and 3 months follow-up. Low and moderate degrees of myopia showed a recovery of static contrast sensitivity by 6 months but a slight loss of sensitivity for dynamic patterns. No reduction in visual acuity at high contrast was detected at any point in time.

Glare sensitivity appears to be increased for the first month post-surgery related to the increase in forward light scatter. Normal levels return by about 3 months with undilated pupils and 12 months with dilated pupils. The recovery is slower in those who have undergone correction of larger degrees of myopia, (Seiler and Wollensak, 1991). The reduction in visual performance is not just caused by an increase in intraocular light scatter but by the poor optical heterogeneity of the cornea and induced aberrations, (Niesen *et al.*, 1997; Verdon *et al.*, 1996).

Studies consistently indicate that visual performance under dilated pupil conditions (low illumination) remains compromised for a year or more, particularly for low contrast acuity tasks, (Strolenberg *et al.*, 1996). Therefore, it is essential to assess performance under conditions that will cause dilation of the pupil.

4.2.4 *Causes Of Reduced Visual Performance*

Intraocular Light Scatter

Forward light scatter increases during the first 2 weeks post-PRK, peaks at 3 months and tends to return to normal levels comparable to spectacle wearers and soft contact lens wearers by 12 months, (Miller and Schoessler, 1995; Veraart *et al.*, 1995; Lohmann *et al.*, 1993).

Corneal Aberrations

In recent years, researchers have realised that an increase in irregular aberrations (similar to spherical aberration and coma) may have significant implications for visual performance. The eye is designed to have a prolate corneal shape but present algorithms tend to produce an oblate cornea, leaving the cornea with an increase in positive spherical aberration. Seiler and colleagues (Seiler *et al.*, 2000) found that the total wavefront error increased by a factor of approximately 17.65 at 3 months post-operatively. This increase correlated with a reduction in high and low contrast acuity and increased glare sensitivity. Schwiegerling and Snyder (Schwiegerling and Snyder, 2000) noted that the degree of induced spherical-like aberration increased as the level of treated myopia increased.

One of the greatest challenges remaining for laser companies is the race to produce technology that can correct or at least minimise corneal aberrations. In simple terms, this requires increased flattening of the peripheral cornea. Exact centration and large ablation zones can help to minimise the increase in aberrations following PRK, (Applegate and Howland, 1997).

A significant reduction in visual performance can occur if there is a mismatch between ablation zone size and entrance pupil, resulting in halos caused by the refraction of light by the untreated paracentral cornea. An extreme version of positive spherical aberration occurs, with myopic blur circles superimposed over the retinal image, (O'Brart *et al.*, 1994b; O'Brart *et al.*, 1994a). Halos are more commonly a problem under low illumination when the pupil is dilated, particularly in eyes that have undergone small diameter ablations, and in patients with naturally large pupils, up to 7.0mm in diameter, (Koch *et al.*, 1991). Ablation diameters of 6.0mm have eliminated halo problems in the majority of patients, although Roberts and Koester (Roberts and Koester, 1993) suggested the use of even larger diameter ablations for "at risk" groups, i.e. young patients with large pupils, those with deep anterior chambers and patients in occupations where glare is a serious problem, such as pilots.

4.2.5 *Conclusions*

As the technology develops, the predictability and accuracy of PRK improves along with a reduction in the risk of complications. Since this procedure was first used on a human eye in 1988, the long-term consequences are unknown but there is no evidence to suggest anything significant to date. Ideally, PRK treatment should be restricted to the lower degrees of myopia because of the increased risk of haze and regression, and the slow stabilisation of the refraction following treatment for myopia greater than –4.00D. Those presently holding a medical certificate should be monitored in the unlikely event that long-term regression occurs.

4.3 Laser Assisted In Situ Keratomileusis (LASIK)

LASIK was developed in 1990 after the introduction of the excimer laser to ophthalmology, (Pallikaris *et al.*, 1991). It was based on a procedure called Automated Lamellar Keratectomy (ALK), developed in 1966, which used a microkeratome to cut a thin cap of tissue and a second cut to flatten the cornea by a predetermined amount, (Barraquer, 1980).

To perform LASIK, a 9mm suction ring is placed on the peripheral cornea and suction is applied to momentarily increase the intraocular pressure to >65mmHg. This ensures that the eyeball is firm enough to allow a regular cut through the cornea. The microkeratome is inserted into the tracks of the suction ring and activated to pass across the cornea and back, cutting the flap. The vacuum is released and the flap reflected back, exposing the underlying stroma (figure 5). The ablation is carried out on the dry stromal bed and the flap is repositioned. Post-operative care includes the application of antibiotics for 3–4 days.

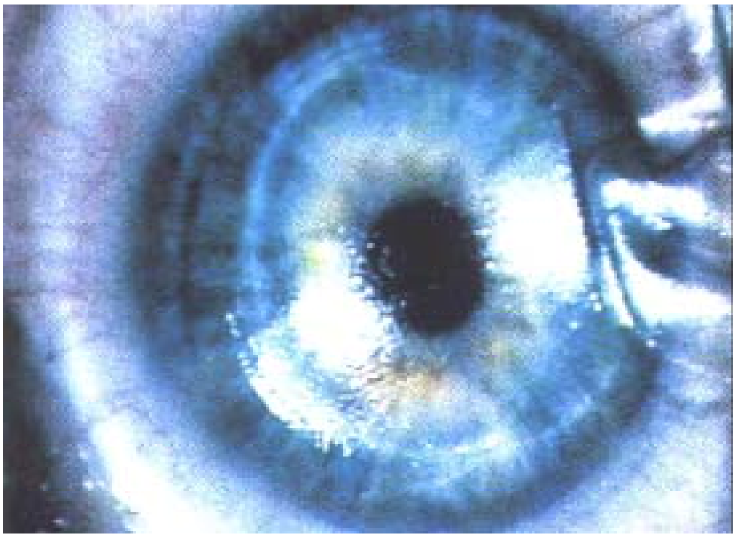


Figure 5 LASIK: stromal bed and reflected corneal flap

4.3.1 *The Advantages Of LASIK Over PRK*

Bowman's layer remains intact and therefore there is often a complete absence of post-operative haze and scar formation, (Helmy *et al.*, 1996). Pain is minimal due to the limited disruption to the epithelium, (Buratto *et al.*, 1993) and useful vision returns almost immediately after surgery. The eye stabilises more quickly than after PRK and long term stability is likely to be very good, judging from the first lamellar keratectomies performed more than 30 years ago. Wound healing occurs faster than following PRK, with minimal tissue proliferation resulting in a transparent interface and rapid recovery of corneal sensitivity. In vivo confocal microscopy has revealed corneal flap interface particles in all LASIK patients with microfolds in Bowman's layer in 96.8% of patients, (Vesaluoma *et al.*, 2000) but these problems tend to be clinically insignificant. Post-operatively, a C-shaped ring is visible corresponding to the edge of the flap, which fades with time.

LASIK is certainly more successful than PRK for myopia greater than –6.00D, but the majority of surgeons now refrain from treating myopia greater than –12.00D due to the increased risk of complications and the small optic zones required to prevent excessive tissue removal, (Puk *et al.*, 1996). To correct a certain degree of myopia, the cornea is reshaped to a particular curvature. For high myopia, achieving the correct curvature over a large zone results in the removal of too much stromal tissue. Consequently, the zone size tends to be reduced to minimise the risk of corneal thinning.

4.3.2 *Refractive Results*

As for PRK, the predictability of patients achieving an uncorrected vision of 6/12 is greater for lower degrees of myopia. The percentage achieving 6/12 vision or better has been quoted as 71.4% and 50% respectively for corrections of <–12.00D and >–12.00D at 6 months follow-up, (Guell and Muller, 1996). Studies of LASIK on lower levels of myopia have produced 6/6 unaided vision for between 17.5–36% of patients, (Wang *et al.*, 1997; Helmy *et al.*, 1996). The percentage of eyes achieving a residual refractive error within +/–1.00D of emmetropia at 12 months is between 68–86% for less than –12.00D of treatment, and 40–50% for greater than –12.00D of treatment, (Pallikaris and Siganos, 1994; Kremer and Blumenthal, 1995). The refraction tends to stabilise within 3–6 months, (Pallikaris and Siganos, 1994). Retreatment is a much simpler option following LASIK than PRK. Undercorrection can be managed by lifting the initial flap and reablating the stromal bed. Lifting the flap requires careful dissection of the flap margin from beneath the healed epithelial layer and the stromal healing processes mean that the flap can only be lifted up to 6–9 months after the first procedure.

4.3.3 *Visual Performance*

High Contrast Visual Acuity

For the loss of 2 or more lines of acuity on the Snellen chart, results vary between zero and 9.5% with a greater loss in the high myopia groups, (Salah *et al.*, 1996; Knorz *et al.*, 1996; Marinho *et al.*, 1996).

Contrast Sensitivity

Limited study has been made of the effects of LASIK on visual performance, but early work suggests that problems are less common and less severe than those resulting from PRK. Spatial contrast sensitivity recovers by 3 months in 78% of patients, (Alanis *et al.*, 1996; Perez-Santonja *et al.*, 1998).

Night Vision And Glare

Guell (Guell, 1997), noted problems in 60% of patients after one month, 30% after three months but 0% after six months.

4.3.4 *Complications*

Complications can arise from either the flap or less commonly the laser ablation. Surgeon experience is a key factor in the outcome. Complications generally manifest themselves within the first 6 weeks and are likely to be evident before a candidate is examined for medical certification. Flap complications include those that occur at the time of surgery, such as an incomplete or decentred flap, which tend to lead to night vision problems, and complications that present after surgery. These include flap striae and epithelial ingrowth, (nests of trapped epithelial cells beneath the flap, leading to corneal irregularity and glare or rarely corneal melt).

LASIK requires sufficient corneal thickness to prevent the ablation encroaching within 200µm of the endothelium, increasing the risk of inducing keratectasia. This is a rare condition in which induced corneal thinning leads to protrusion of the corneal tissue, severe irregularity and consequently a reduction in visual performance. Some cases require a corneal graft to achieve functional vision. To date, 57 out of more than 3 million procedures world wide, have resulted in keratectasia. This is a severe complication that may not present for a number of years post-surgery but is usually associated with treatment for high myopia. Seiler and colleagues (Seiler *et al.*, 1998) reported 3 eyes that had undergone LASIK for myopia between –10.00 and –13.50D and exhibited central steepening 1 to 8 months after surgery. Joo and Kim (Joo and Kim, 2000) reported 2 cases that followed LASIK for less than –12.00D that were detected using topography.

Keratectasia has generally been attributed to a mis-calculation of the remaining stromal bed after flap creation, due to the limited accuracy of microkeratomes, (standard deviation of 30µm). Intraoperative measurement of the stromal bed thickness can prevent iatrogenic keratectasia but is rarely undertaken.

There is a minute risk of retinal haemorrhages due to occlusion of the central retinal artery in high myopes with compromised retinal circulation, if the suction ring remains in place for more than three minutes. The risk of other vitreoretinal complications in high myopes does not appear to be significantly greater following LASIK, (Arevalo *et al.*, 2000).

4.4 **Potential Long-term Consequences Of Photoablation**

Since photoablation is a relatively new technique, the long-term side effects are as yet unknown. There appear to be no adverse effects on the corneal endothelium, (Ehlers and Hjortdal, 1992; Amano *et al.*, 1993; Cannamo *et al.*, 1997). Normal corneal sensitivity is restored by 3 months although the recovery may take longer following the correction of high myopia, (Campos *et al.*, 1992; Tervo *et al.*, 1994).

Since the wavelength emitted by the ArF laser is in the Ultraviolet C range, mutagenesis and carcinogenesis are a potential worry. However, Nuss and colleagues (Nuss *et al.*, 1987) found no difference in the unscheduled DNA synthesis, (a measure of the tissue repair mechanism), between the laser and a gemstone knife, suggesting that mutagenesis is not a problem. Extensive animal studies have not detected the development of epithelial or connective tissue neoplasms resulting from exposure to the laser. One study detected the presence of short-term changes in the aqueous humour and prolonged biochemical changes in the crystalline lens of rabbit eyes, which may be the precursor to cataractogenic changes, (Costagliola *et al.*, 1996). In another study, no significant elevation of MDA (malondialdehyde) levels, (a possible indicator of oxidative effects), was seen following PRK on rabbits, although levels were two to three times higher in the LASIK group than the PRK or control groups, implicating the microkeratome rather than the excimer laser, (Wachtlin *et al.*, 2000). No increase in the incidence of cataract following PRK or LASIK has been noted to date.

4.4.1 *Additional Concerns*

The modified shape of an ablated cornea tends to result in the mis-calculation of the intraocular lens power for those undergoing cataract surgery. Cataract operations are rare among certificated pilots but the operating surgeon needs to be aware of the history of refractive surgery. Unless the pre-operative records are available, a satisfactory refractive outcome is unlikely following intraocular lens implantation.

The change in corneal thickness following corneal refractive surgery has implications for the measurement of intraocular pressure. When using an applanation tonometer, a thinner cornea causes underestimation of the intraocular pressure and vice versa. The removal of Bowman's membrane and the deposition of newly synthesised collagen alter the resistance of the cornea to indentation. A reduction in the apparent intraocular pressure also occurs when using a non-contact tonometer. A mean decrease of 3.1 +/– 2.6 mmHg was found, relating to the degree of myopia treated. Pressure drop (mmHg) = 1.6 – (0.4 * treatment mean spherical error (dioptres), (Chatterjee *et al.*, 1997).

4.5 **Treatment Of Astigmatism And Hyperopia**

The treatment of astigmatism using PRK or LASIK is less satisfactory than for spherical procedures since axis alignment is critical, with a 10° error leading to correction of only 65% of the astigmatic error, (Stevens and McG Steele, 1993). Higher degrees of initial astigmatism are unlikely to achieve $^{6}/_{6}$ unaided and only a limited number achieve $^{6}/_{12}$. There is also an increased risk of losing best corrected visual acuity with increasing astigmatism, resulting from induced irregularity. The risks associated with a small ablation zone are greater following astigmatic treatments, since the zone is often no more than 4.5mm in diameter in one meridian, (Ficker *et al.*, 1995).

The treatment for hyperopia using PRK or LASIK is still in its infancy**.** It is more difficult to induce controlled steepening of the central cornea than to flatten the tissue. The amount of flattening of the peripheral cornea is proportional to the degree of steepening of the central cornea (Dierick and Missotten, 1996). The ring-shaped ablation zone used for hyperopic correction has a relatively narrow width and the natural healing of the wound post-surgery has a tendency to fill in this region causing regression. Therefore refractive change is not proportional to the ablation depth and laser nomograms are still being modified to overcome this problem. The greatest problem is undercorrection. As with myopia treatment, the results for lower degrees of refractive error tend to be more predictable and stablise quicker. At 1 year, PRK treatments for low-moderate hyperopia (< +6.00D) achieve a refractive error within +/–1.00D of emmetropia in 40% of eyes, but only 17% for high hyperopia (>+6.25), indicating poor accuracy compared to myopic treatments. At 12 months, 67% of low-moderate hyperopes and only 8% in the high group achieve 6/12 or better. Low hyperopes stabilise by 6 months but high hyperopes continue to regress (Corones *et al.*, 1999). Following PRK for hyperopia, a slight loss of BCVA is expected due to the loss of some spectacle magnification. Hyperopic treatments appear to be less successful in cases >+5.00D (Knorz *et al.*, 1998). LASIK for hyperopia has been used with some success but the algorithms still require modification. An unacceptably high percentage of patients over +4.00D lose 2 or more lines of best corrected acuity, (7.3%) (Ditzen *et al.*, 1998).

4.6 **Technological Developments**

4.6.1 *Customised Ablations For PRK And LASIK*

The latest scanning lasers allow customised ablations up to 10mm in diameter and in principle lead to the possibility of reducing higher order irregular aberrations of the eye. Designing the ideal ablation profile to eliminate all optical aberrations for all retinal locations is impossible and so a balance must be found. To determine the ideal shape of the cornea needed to eliminate the aberrations at the most critical point on the retina, (the fovea), the aberrations of the whole eye must be considered since corneal aberrations are often partially neutralised by lenticular aberrations.

The first step towards customised ablations has been the development of topography-assisted ablations. Although this process does not attempt to treat the whole eye aberrations, it does have the potential to treat the corneal irregularities that occur in 40% of eyes. Large degrees of irregularity have been treated with some success, (Dausch *et al.*, 2000) but treating small degrees of irregularity is proving more difficult. Wiesinger-Jendritza and colleagues (Wiesinger-Jendritza *et al.*, 1998) used corneal topography to analyse the corneal surface and design the laser ablation. Seventy percent of eyes were partially corrected but only 19.4% achieved their full correction. One possible source of error is the inaccuracy of the topographical measurements due to errors in the proprietary algorithms and the incorrect assumption that the cornea is spherical.

4.6.2 *Alternative Technology*

The outcome of PRK and LASIK procedures continues to improve as the technology develops, allowing smoother ablations and larger optic zones with the minimum of tissue removal. Broad-beam lasers are still in use in some clinics in the United Kingdom but patients are likely to get a better outcome if treated with a 2nd and 3rd generation scanning slit or scanning spot laser. Since the microkeratome blade degrades rapidly with repeated use, developments to allow the flap to be cut using intrastromal pulses from a Nd:YLF (neodymium: Yttrium Lithum Fluoride) Picosecond laser (Escalon) or supersonic water jet technology (Medijet) are likely to improve the outcome of LASIK.

Intra corneal ring segments (ICRS) are in their infancy but may become a common method of treating low myopia in the future. They consist of half ring segment of perspex that are inserted into the corneal stroma, causing the central cornea to flatten. They possess a number of advantages over PRK and LASIK in that they do not involve the central cornea and are positioned outside the pupil margin. They also maintain the prolate shape of the cornea and are completely reversible. Only low degrees of myopia can be treated. The technique has been proven safe and predictability is improving (Bisantis *et al.*, 1996; Asbell *et al.*, 1999).

Implantable contact lenses such as the Array lens are also increasing in popularity. However, at present, they commonly lead to intraocular inflammation, endothelial damage and an increased risk of secondary glaucoma. They are reserved for treating patients with high refractive errors unsuitable for corneal surgery, and are therefore unlikely to be of concern to the CAA.

4.7 Opinion On Simultaneous Bilateral Refractive Surgery

The guidance of the US Food and Drug Administration suggests waiting 3 months between PRK treatments. This is mainly because of the risk of haze and regression. However, many patients are attracted to LASIK because of the quick visual recovery, the limited pain and the fact that an increasing number of surgeons will undertake bilateral procedures. Waring et al. (Waring *et al.*, 1999) found no statistically significant difference in intraoperative complication rate, loss of best-corrected acuity or accuracy of correction when comparing simultaneous and sequential LASIK surgery groups. Inexplicably, they found a 1.02x increased risk of epithelial ingrow in the simultaneous group. Gimbel and colleagues (Gimbel *et al.*, 1999) also judged simultaneous LASIK surgery to be as safe and effective as sequential LASIK surgery. A gap of a few days between procedures is considered safest by the Royal College of Ophthalmologists (Royal College of Ophthalmologists, 1997).

4.8 Monovision

A number of refractive surgeons advocate monovision for presbyopic patients, allowing them to continue to manage without glasses for the majority of tasks. The dominant eye is corrected to achieve a refractive error close to emmetropia and the non-dominant eye is left with a small myopic undercorrection, usually in the region of about 1.25D. The majority of patients are happy with monovision although some find the imbalance disturbing and opt to have the undercorrected eye retreated – a simple procedure. Wright and colleagues (Wright *et al.*, 1999) examined binocular function in a group of 21 patients with a monovision correction and compared them to a group of patients who had been fully corrected in both eyes. Both groups were treated with PRK. All patient's maintained binocular fusion and some degree of stereopsis. From personal experience, some monovision patients complain of poor contrast acuity at night, probably due to the reduced stimulus to the binocular cortical cells. Those who are most satisfied appear to be those with lower visual expectations.

For more critical visual tasks such as those involved in piloting an aircraft, monovision is unlikely to be suitable, certainly until further investigation has determined the effect of monovision on optic flow and the ability to judge speed and position.

5 SUBJECTS

5.1 Control Group

A total of 53 control subjects were examined, (see table 1). A proportion of these subjects were patients attending the laser clinic for a pre-surgical consultation. As a consequence, the control group exhibited a range of refractive errors similar to the pre-operative errors seen in the two treatment groups. Unfortunately, due to the high "drop-out" rate following consultation and the restrictions imposed by the need to cause minimal disruption to the schedule of the laser clinic, only a very small sub-group of patients were available for re-examination.

Table 1 Control Group Profile

Control Group	Average	Standard Deviation	Range
Age (years)	37.4	+/– 10.2	22 to 69
Mean Spherical Error (MSE)	–3.20D	+/– 2.74	+2.75D to –9.00D
Astigmatism	0.82DC	+/– 0.83	0 to 4.25DC

5.2 LASIK Group

A total of 52 LASIK patients were examined (see table 2).

Table 2 LASIK Group Profile

Control Group	Average	Standard Deviation	Range
Age (years)	39.0	+/– 9.31	20 to 57
Pre-operative MSE	–4.66D	+/– 2.73	+3.25D to –8.75D
Pre-operative Astigmatism	1.05DC	+/– 1.12	0 to 5.50DC
Follow-up period (weeks)	16.25	+/– 28.21	1 to 160
Manifest MSE	–0.00D	+/ 0.53	+1.25 to –1.50D

5.3 PRK Group

A total of 32 PRK patients were examined, (see table 3).

Table 3 PRK Group Profile

Control Group	Average	Standard Deviation	Range
Age (years)	36.9	+/– 8.3	24 to 55
Pre-operative MSE	–4.31D	+/– 2.27	+3.00D to –8.50D
Pre-operative Astigmatism	0.64DC	+/– 0.49	0 to 2.00DC
Follow-up period (weeks)	135.6	+/– 108.8	1 to 339
Manifest MSE	+0.03D	+/– 0.64	+1.50D to –1.00D

The retrospective nature of the study and the considerable time involved in obtaining a full data set for each subject has had a number of consequences. Firstly, there was less control over variables such as follow-up time and age. Secondly there was a reduction in the power to assess the influence of these variables on the data. Thirdly, it was impossible to obtain complete data sets for all subjects and therefore the group characteristics vary slightly between tests.

A detailed history was taken for each patient to allow identification and exclusion of pregnant women and subjects with systemic disease such as diabetes. Ocular health was examined to exclude eyes with any pathology, including lens opacities. All subjects were examined by either the primary investigator, *CMC,* or the Ophthalmologist performing the surgery. All refractive surgery patients were considered by the surgeon to have had a satisfactory outcome.

All subjects underwent a subjective refraction to determine their full distance correction for a working distance of 0.7m. The dominant eye was tested where possible and the non-dominant eye remained patched through the experimental procedure.

6 METHODS

All computer-based tasks were presented on a high resolution Sony 500 series monitor that was fully calibrated for the spectral output and the luminance versus applied voltage relationship for each gun. A program allowing automatic calibration of phosphor luminance was developed and the luminance calibration was carried out every 2 to 3 months. The monitor was allowed to warm up for a minimum of 20 minutes before use. The background lighting was adjusted to a low light level by directing a current regulated spotlight towards a white diffuser on the ceiling above the visual display. Patients were carefully positioned on the chin rest of the infra-red pupillometer system. All subjects underwent a brief trial run of each experiment before the actual measurements were made.

6.1 Assessment of Forward Light Scatter

Intraocular light scatter was measured directly using the City University Computerised Scatter Program based on the direct compensation technique, (Barbur *et al.*, 1995;

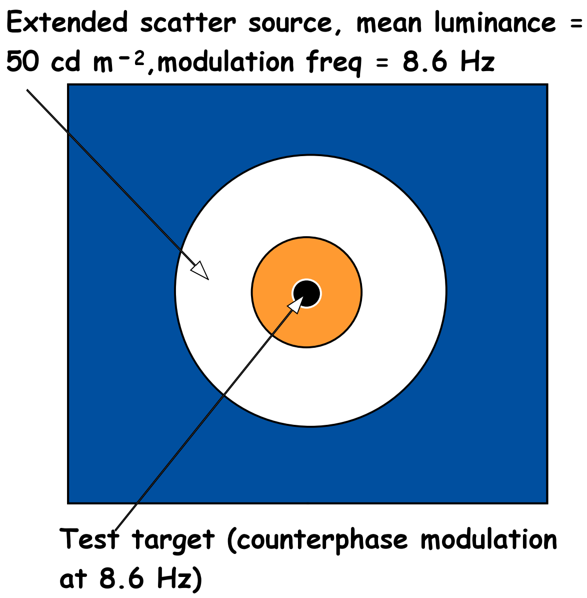


Figure 6 City University Scatter Program

Barbur *et al.*, 1993a; Van Den Berg and Spekreijse, 1987). The system was also calibrated to compensate for internal scatter. The subject fixated the central black target while the luminance of the white scatter annulus was modulated sinusoidally at a frequency of 8.6 Hz, for duration of 0.35s. The subject reported flickering of the central target due to straylight from the annulus, which was superimposed over the retinal image (see figure 6). The luminance of the test target was also modulated sinusoidally but in counterphase to that of the scatter source. The amplitude of the luminance modulation over the test target was modified using a staircase technique (luminance step size 0.15), until the subject identified the point at which the flicker appeared to be neutralised or minimised, giving an estimate of the retinal luminance resulting from the glare annulus at a particular eccentricity. The test was repeated six times for each of five glare angles, allowing the scatter function of the eye to be plotted and the scatter index, n and straylight parameter, k to be calculated.

6.2 Contrast Threshold Measurements

We undertook to design measures of visual performance relevant to the visual tasks involved in piloting an aircraft. Since the bulk of the visual information displayed in the cockpit is located within a small zone surrounding the visual axis, we chose to investigate visual performance over a similarly sized area. Two tests were designed to examine contrast thresholds over a circular field of 10° radius. The stimulus for both contrast threshold experiments consisted of a Landolt ring with an orientation of 45°, (visual angle: diameter 72 mins. of arc, gap 7.7 mins of arc). The subject was required to fixate the central red target and respond to the presentation of a stimulus, flashed up for 250ms duration at one of three, randomly interleaved eccentricities.

6.2.1 *Contrast Thresholds For Detection Program*

This experiment measured the contrast required to detect the target over a range of eccentricities (figure 7). The subject used a two-way forced choice response box (yes/no) to indicate whether or not the target was detected. Target contrast was modified using a random interleaved staircase procedure with an initial step size of 3% reducing to 0.5% for a total of 6 averages.

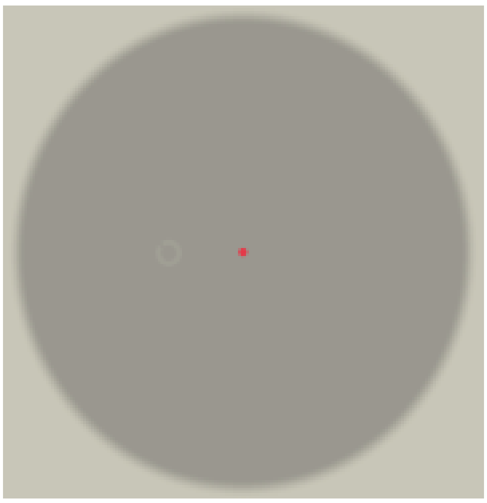


Figure 7 Example stimulus for contrast threshold for detection program

6.2.2 *Contrast Acuity Program*

We also assessed the contrast required to detect the gap in a Landolt ring for a series of eccentricities (figure 8). The set up was almost identical to that for the detection test described above. The subject used a four-choice response box to indicate the orientation of the gap within the target, selecting from one of four oblique positions. Again, target contrast was varied using a random interleaved staircase procedure with step sizes of 3% reducing to 0.5% over 6 averages.

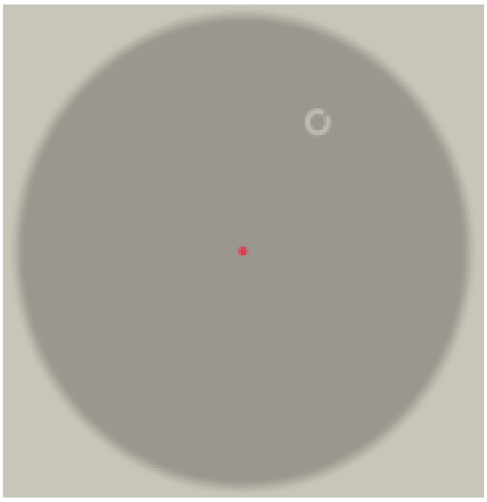


Figure 8 Example stimulus for contrast acuity program

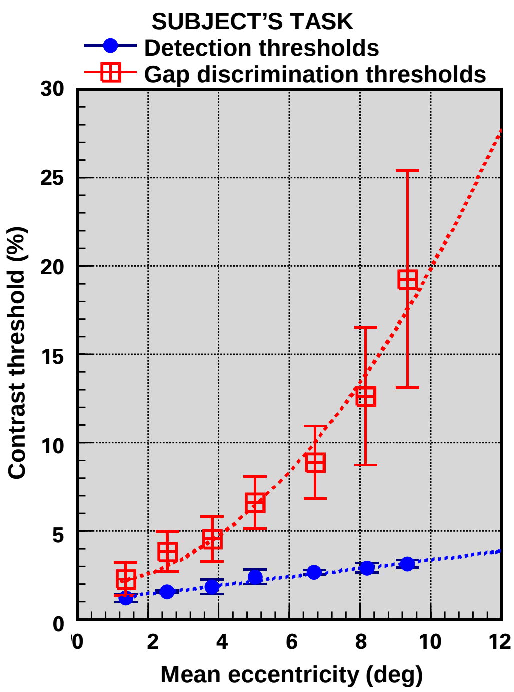


Figure 9 Graph comparing contrast thresholds for detection and discrimination (acuity) for a single subject

6.3 Visual Search Program

The visual search program was designed as a dynamic test of suprathreshold ... ular field of 20° diameter. Both the stimulus and ... olt rings. The subject was required to search the ... ndomly positioned, vertically orientated distractor ... ntated target (figure 10).

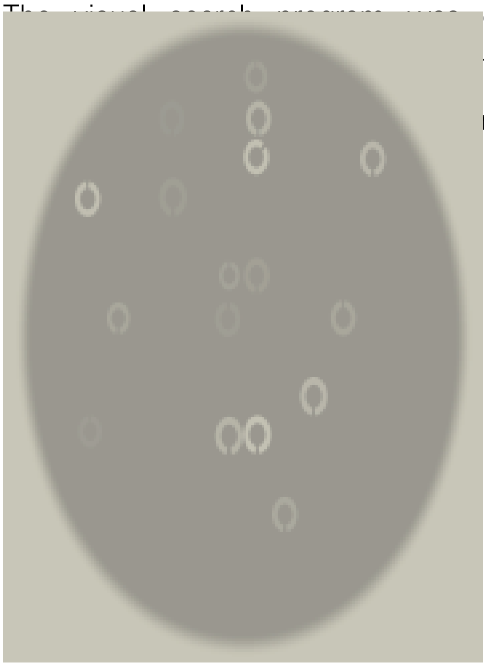
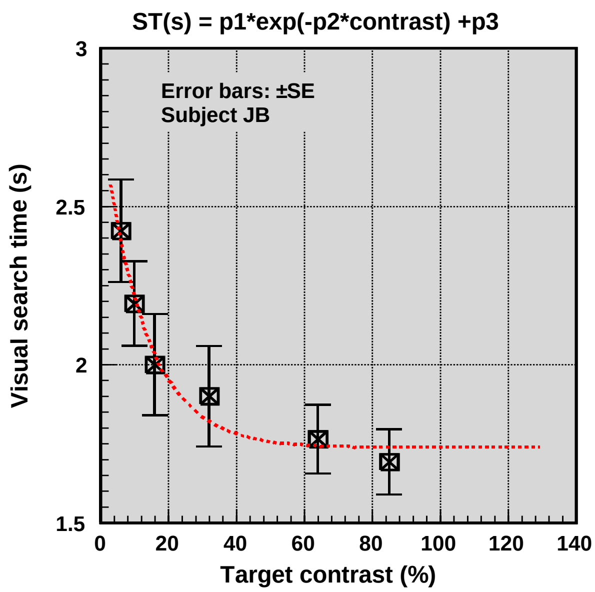


Figure 10 Example of visual search screen with a high contrast target and 15 distractor elements

On finding the target, the subject pressed a response button to indicate identification of the target and allow a measure of search time. A four-choice response box was then used to confirm correct identification of the orientation of the target gap. The distractors varied in contrast between 6–64% and the target was presented at one of 5 pre-selected contrast levels. The targets were randomly interleaved with each repeated an average of 36 times. Mean search time was plotted against the target contrast to obtain the visual search function as shown in figure 11.

Figure 11 Visual Search Function For Subject JB



Single subject data, 64 averages

VS= 1.053*exp(–0.0797*C) + 1.73

Mean glimpse duration = 295ms
SD = 10.4 ms

6.3.1 *Pupil Diameter And Glimpse Duration Measurement*

A 2D pupillometer/infra-red eye tracker system was used to measure the average pupil size and the average glimpse duration during the visual search task. The measurement required the subject to remain very still in order to keep the pupil precisely in focus. Consequently, this data was collected during a separate, short run of the visual search task comprising only 3 target contrasts and 8 averages.

It is useful to know the average pupil diameter at a particular light level when considering the likelihood of visual problems resulting from the pupil overlapping the ablated zone of the cornea. The glimpse duration is defined as the average time taken by the visual system to process the information gained during a single fixation, before moving on to the next location. The glimpse duration is thought to be influenced by the image quality and the filtering out of high spatial frequencies has been shown to increase the glimpse duration.

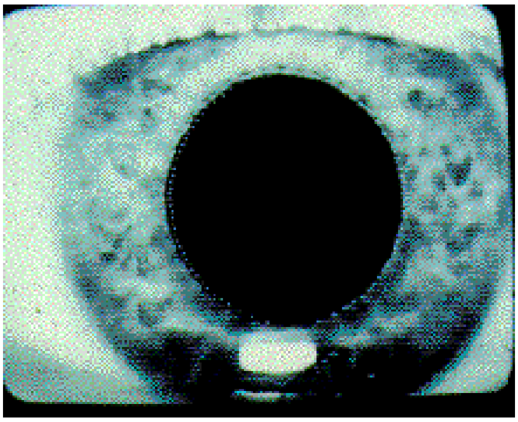


Figure 12 Image of the pupil during a glimpse duration measurement

6.4 Visual Search Modelling

A model of visual search was developed to aid understanding of the multiple factors involved in search performance. When fixating a particular point within the field, the eye is capable of detecting the presence of targets falling inside a lobe centered on a particular point. The size of the lobe is proportional to the contrast of the targets and high contrast targets are associated with a larger lobe. The lobe size can be obtained from the *likelihood of detection rating* taken from the contrast thresholds for detection data. Of greater importance in determining visual search performance is the *likelihood of discrimination rating* obtained from the contrast acuity threshold measurements. Here, the lobe for a particular contrast level corresponds to the area over which the gap in the Landolt ring target should be resolved. The computer model weights the likelihood that the oblique gap in the target will be detected when the eye fixates a particular point within the field. If the target is not detected, the eye moves on to fixate another point and the process starts again. The information gained from the last few fixations can be stored in the pipe memory, so that individual targets are not revisited. The length of the pipe memory varies between individuals. This information is combined with the glimpse duration measurement in order to calculate the search time for a particular contrast level.

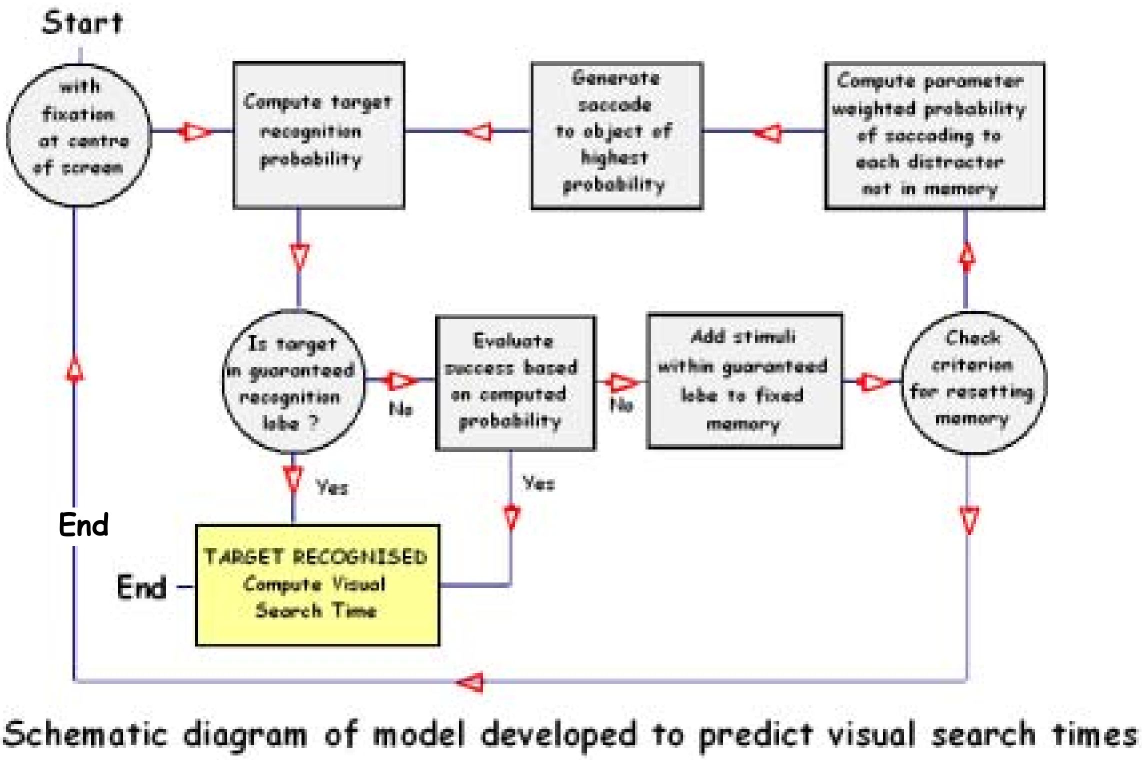


Figure 13

The model was based on previous work (Barbur *et al.*, 1993b), which suggested that the eye moved between fixations analysing the resolvable objects within the discrimination lobe until the target was detected. The position of the next fixation tended to be influenced by the presence of objects identified as having a high chance of being the target or by clusters of Landolt rings. There was also a random element that needed to be taken into account.

In conclusion, despite the obvious importance of target contrast and the quantity of distractor elements in determining the search time, many other factors were involved. This explains the wide inter-subject variability (within groups), in visual search performance. These other factors include a strong learning effect, fatigue, factors relating to the personality and motivation of the subject and the employment of a random or more standardised search pattern.

6.5 LogMAR Acuity Measurements

An Australian Vision logMAR (log Minimum Angle of Resolution) chart was used to assess high (98%) and low (13%) contrast acuity in a proportion of subjects. A logMAR chart has many advantages over the standard Snellen chart, including an equal number of letters on each line, a geometrical size progression between each line and the ability to score for identification of individual letters (figure 14). Average vision (6/6 acuity) indicates that the eye is capable of resolving 1minute of arc. The log of this value of Minimum Angle of Resolution, (logMAR), is therefore scored as 0. Individuals seeing better than average have a logMAR score<0 and those resolving less than average have a logMAR score>0. For each letter incorrectly identified, 0.02 is added to the score. Subjects were examined using both high and low contrast charts at 4 metres while wearing their distance refractive correction.

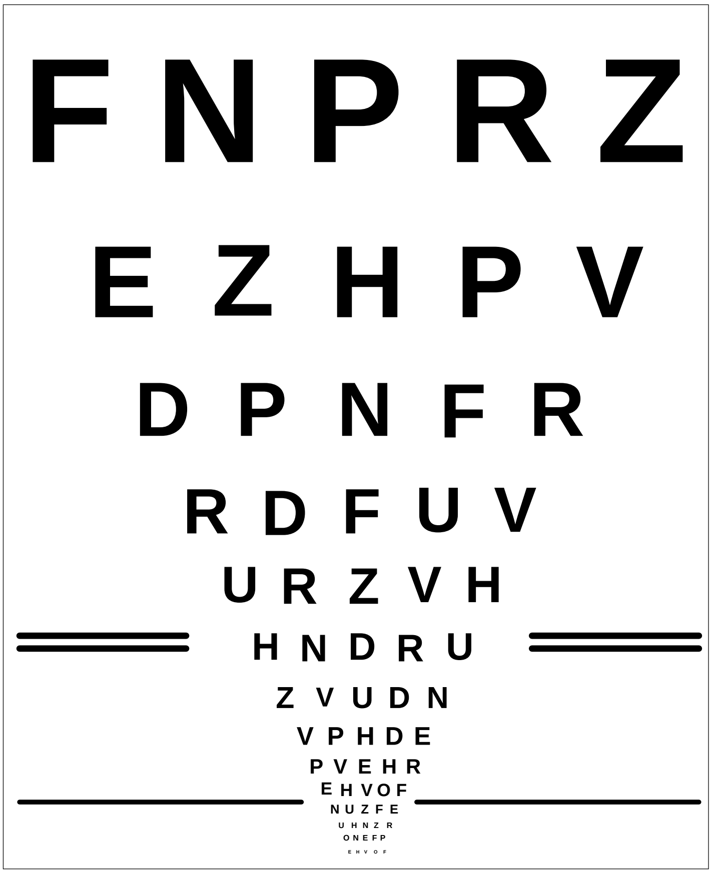


Figure 14 LogMAR Chart

6.6 Statistical Methods

Considerable variations in age, pre-operative refractive error and follow-up time exist within the two refractive surgery groups. In order to precisely assess the influence of each variable on visual performance, a much larger cohort of subjects would be required. An analysis accounting for each of these variables has been performed for all experiments but the results are often influenced by the uneven distribution of subjects within subgroups.

Age

The mean age and standard deviation were very similar for all three groups. Age followed a normal distribution for the LASIK and PRK groups but was not quite normal in the control group. Not all subjects completed the full bank of tests, therefore the age distribution varies slightly between tests.

Age is known to influence visual performance due to a combination of increased intraocular light scatter, reduced retinal illuminance and neuronal degeneration. Few changes occur before the age of 45 years and the greatest reduction tends to occur much later on in life. The subjects in each group were divided into two sections: <45 years and > 45 years due to the known increase in intraocular light scatter after the age of 45 years, (Yager *et al.*, 1992; Whitaker *et al.*, 1993).

A one–way analysis of variance, (ANOVA) was used to examine the effect of age on each experiment, for each of the three subject groups. Very few laser patients were over the age of 45 years since the appeal is reduced by the need to wear reading spectacles. In addition, the average retirement age for a pilot is age 55 and so few subjects above this age were recruited, reducing the power to detect any age effect.

Manifest Refractive Error (control group only)

For each experiment, the influence of the patient's manifest refractive error was examined using a one-way ANOVA. The mean spherical errors (MSE) demonstrated a normal distribution and were subdivided into: hypermetropia (mean spherical error > +0.25D), emmetropia (MSE =0), low myopia (–0.25 to –5.00D), medium myopia (–5.25 to –8.00D) and high myopia (–8.25 and above). Astigmatism was also classified as >1.00DC.

Refractive error did not appear to significantly influence the data for any of the experiments. Because the effect of refractive error may have been hidden by the strong effect of age seen for some tests, a two-way analysis of refractive error with age was also undertaken. This analysis came to the same conclusion that the manifest refractive error was not a factor.

This made it very unlikely that the small, post-operative refractive errors exhibited by the refractive surgery patients would influence the analysis in anyway. Consequently the post-operative refractive error was discounted as a possible variable.

Influence Of Pre-Operative Refractive Error

Neither the pre-operative mean spherical error (MSE) nor the astigmatism followed a normal distribution for either of the two refractive surgery groups, although the means and standard deviations were comparable. Again, MSE was subdivided for analysis into: hypermetropia (mean spherical error > +0.25D), emmetropia (MSE =0), low myopia (–0.25 to –5.00D), medium myopia (–5.25 to –8.00D) and high myopia (–8.25 and above). Astigmatism was classified as >1.00DC.

Very few patients who had been treated for hypermetropia were available, partly because long-sight is less visually debilitating than myopia and also because the techniques for correcting hypermetropia are still in the developmental stage. Cases of high astigmatism were also rare. The majority of subjects were distributed evenly across the myopic range. A subdivision limit of –5.00D was chosen based on the present Civil Aviation Authority policy on refractive surgery which limits acceptance to those treated for –5.00D or less, (originating from the poor success rate for radial keratotomy for more than –5.00D). In addition, the limit was close to that chosen by a number of published studies that reported the effect of PRK for myopia above and below –6.00D.

The effect of pre-operative refraction (mean spherical error and astigmatism) was examined using both a one-way ANOVA and a two-way ANOVA (combined with age). The pre-operative refraction is strongly correlated with the amount of treatment received by an eye and may therefore influence the visual outcome.

Influence Of Follow-Up Time

The follow-up times were not normally distributed in either refractive surgery group. There was also a significant difference between the mean and standard deviation of the two groups since the subjects were recruited from different sources. The LASIK subjects were recruited during their 1–6 month follow-up appointments with the refractive surgeon, whereas PRK patients were referred from another clinic, often more than a year after surgery. The subdivisions for follow-up time were less than 5 weeks, 5 to 10 weeks, 10 to 20 weeks, 20 to 40 weeks and 40 to 1000 weeks. This non-linear classification was chosen because of the healing response in the early post-operative period is rapid and evidence suggests that both PRK and LASIK stabilise by about 6 months. Because of the strong influence of age, the effect of post-operative follow-up time was examined taking into account the age effect by using a two-way ANOVA.

6.7 Distribution Of The Data

An Anderson-Darling test was used to examine the distribution of the data for each individual experiment. Generally the data did not demonstrate a normal distributed and in fact tended to be skewed to the right, (i.e. outliers tended to perform worse than average). For consistency, the method chosen for identification of the outliers assumed a non-normal distribution for all tests. Individuals whose results fell outside 1.5x (inter-quartile range) above the upper quartile were identified and removed from the group average before any statistical analysis was performed. In general, the degree of normality improved significantly on removal of the outliers.

6.8 Statistical Tests

The means were corrected for the effects of age, refractive error and follow-up time, to overcome the differences between groups for each of these variables. A three-way ANOVA was used to compare the corrected means of the three groups for each experiment. The hypothesis in each case was that the corrected means were the same for all three data sets. The level of significance was set at 5% for all tests ($p=0.05$ or less). In some cases, a further two-way analysis was needed to identify which particular set of data was significantly different from the other two.

By correcting the means for each of these factors, the potential for error introduced by the differing refractive error and follow-up distributions was reduced.

7 RESULTS

7.1 Intraocular Light Scatter

If θ is the angle between a point glare source and a point of interest on the retina, the luminance of the scattered light at the point of interest, $L_s(\theta)$, is calculated using the empirical glare formula: $\mathbf{L_s(\theta) = Ek\theta^{-n}}$

where E is the illuminance in the plane of the pupil, and the parameters n and k are determined by the scattering properties of the eye, (Stiles, 1929). The scatter index, n, describes the distribution of scattered light across the retina. The stray light parameter, k, describes the quantity of stray light at a point on the retina. The parameters n and k are not independent and their variability within the normal population is considerable. Previous direct measurements of light scatter have incorrectly assumed that n=2, resulting in some inaccuracy in estimating the quantity of straylight. A more useful method of describing the scatter function is the integrated straylight parameter, k' (integration of the area beneath the curve between 2 and infinity). The higher the value of k', the greater the overall quantity of straylight. The parameter k' shows less variability in the normal population and correlates well with measures of visual performance (Barbur *et al.*, 1995). It is known to increase with age, in the presence of media changes such as cataract, corneal dystrophies etc. Since the values of n, k and k' are derived from the scatter function, a valid method of analysing the difference between the scatter functions is to compare n, k and k' values.

LASIK

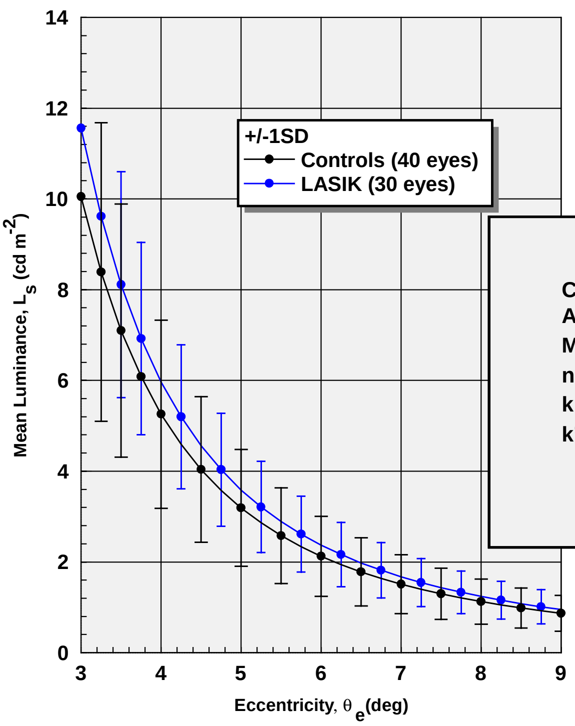


Figure 15 Scatter functions for LASIK and control subjects

Summary Statistics

Controls Subjects	LASIK Subjects
Ave. age 37.3 sd 10.91	Ave. age 38.3 sd 7.63
MSE -3.10D sd 2.71	MSE -0.08D sd 0.43
n = 2.25, sd 0.25	n = 2.28, sd 0.23
k = 35.38, sd 14.85	k = 38.86, sd 14.84
k' = 10.32, sd 3.29	k' = 10.74, sd 2.97
	Ave. follow-up 21.6w sd=34.5
	Pre-op MSE: -5.21D sd=2.48

PRK

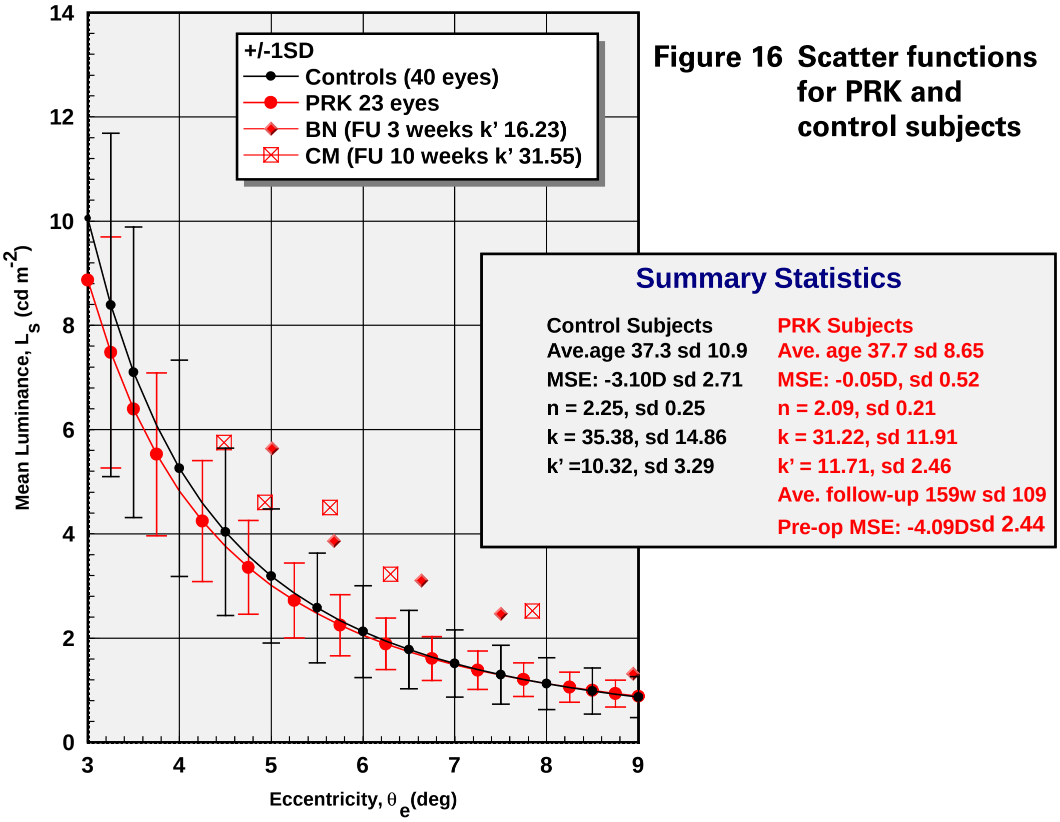


Figure 16 Scatter functions for PRK and control subjects

Analysis

Following the removal of outliers, the data were normally distributed for the parameters n, k and k' in all three groups, (excluding the scatter index, n in the LASIK group).

Table 4 3-way ANOVA (Corrected Means and Statistical Significance)

	Corrected Means (Scatter function)			**Statistical Significance**	
Subject Group	**Controls**	**LASIK**	**PRK**	**p value**	**Significant?**
Scatter Index, n	2.25	2.27	**2.12**	**0.0054**	**Yes**
Straylight Parameter, k	35.53	40.00	31.09	0.0805	No
Integrated Straylight Parameter, k'	10.440	10.770	11.49	0.1702	No

Scatter index, n: A p value of 0.0054 for the analysis of the corrected scatter indices indicated a difference between the corrected means of the three groups, (see table 4). Examining the corrected means, the scatter index for the PRK data was significantly lower than for either the LASIK or control groups. This low value indicates that the straylight had a limited spread across the retina in the PRK group.

Straylight parameter, k: A p value of 0.0805 for the straylight parameter analysis indicates that there was a small but statistically insignificant difference between the k value means of the three data sets. This could be because the corrected means for the PRK and control group lie either side of the LASIK mean. However, a two-way analysis comparing the k means of the LASIK and the PRK groups alone produced a p value of 0.895, confirming that there was no difference between the quantity of straylight in the three groups.

Integrated Straylight parameter, k': A p value of 0.1702 clearly indicates that there was no significant difference between the mean overall light scatter levels (k' values) of the three groups.

7.1.1 *Effect Of Age*

For both the control and LASIK groups, age did not appear to influence the distribution of scattered light, (scatter index, n), the quantity of scattered light, (straylight parameter, k), or the overall quantity of scattered light, (straylight parameter, k'). For the PRK group, the overall quantity of straylight, k' did increase with age, (p=0.048). This is consistent with the literature on light scatter and the apparent lack of any age effect for the control and LASIK groups is likely to be due to the distribution of ages with very few subjects over 45 years.

7.1.2 *Effect Of Pre-operative Refractive Error*

Both a one-way ANOVA (refractive error alone), and a two-way ANOVA (refractive error taking into account the effect of age), indicated that the pre-operative refractive error did not influence intraocular light scatter for either refractive surgery group.

7.1.3 *Effect Of Follow-up Time*

Both a one-way ANOVA (follow-up time alone) and a two-way ANOVA (follow-up time taking into account the effect of age), indicated that light scatter was not significantly influenced by follow-up time after PRK or LASIK.

7.1.4 *Outliers*

Table 5 Intraocular Light Scatter

Subject	**Group**	**Possible Explanation for Outlier Status**
BN	PRK	Follow-up 3 weeks post-PRK. Stromal haze grade 1
CM	PRK	Follow-up 10 weeks. Stromal haze grade 2.5

7.1.5 *Summary*

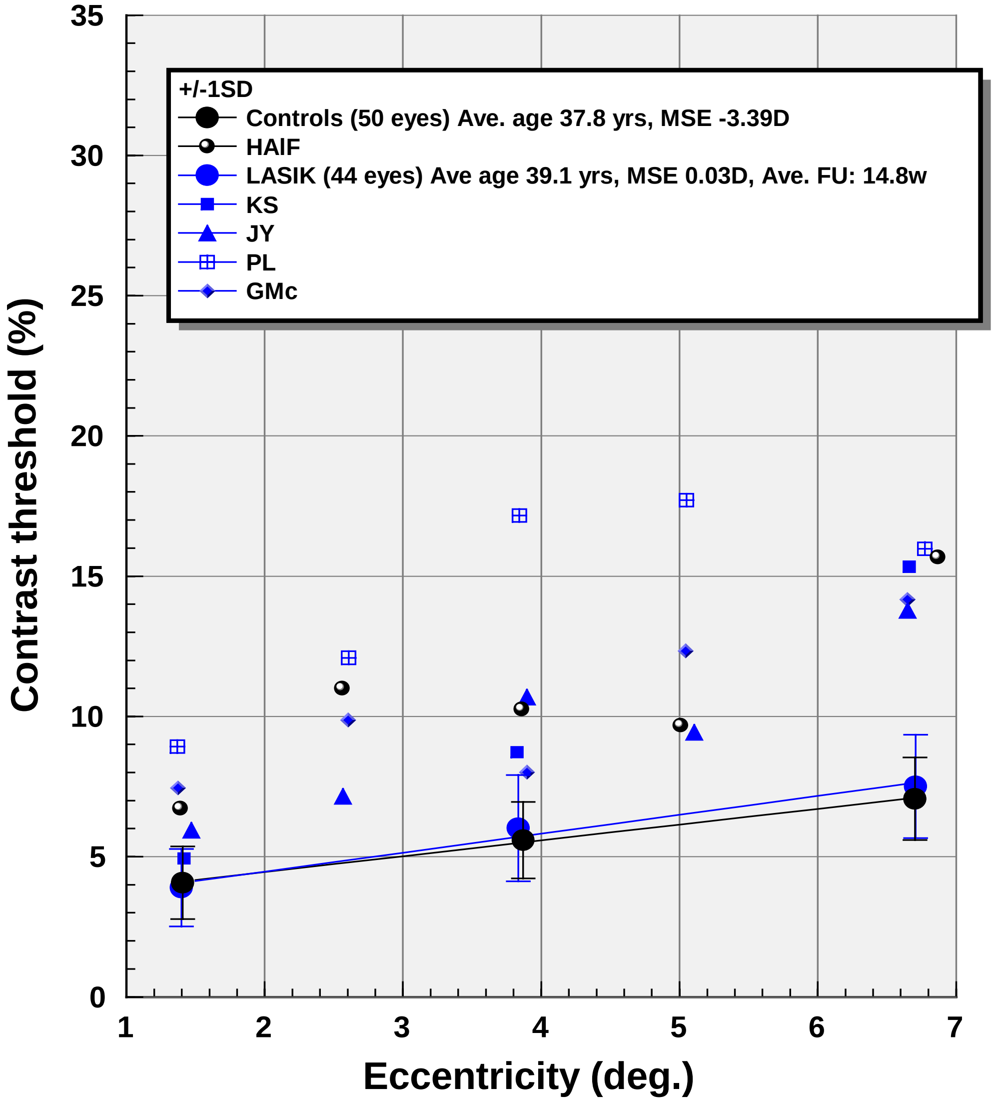
The statistical analysis suggests that the angular distribution of straylight may have been affected by PRK surgery, but there was no statistically significant increase in the quantity of intraocular light scatter. For the subjects examined, LASIK surgery did not appear to increase the intraocular light scatter.

The effect of age on intraocular light scatter was only detectable in the PRK group, probably due to the limited number of subjects over the age of 45 years. Neither the pre-operative refractive error nor the follow-up time, were shown to significantly influence the intraocular light scatter.

Two outliers were identified both of whom had recently undergone PRK and exhibited grade 1 or more corneal haze, (see table 5).

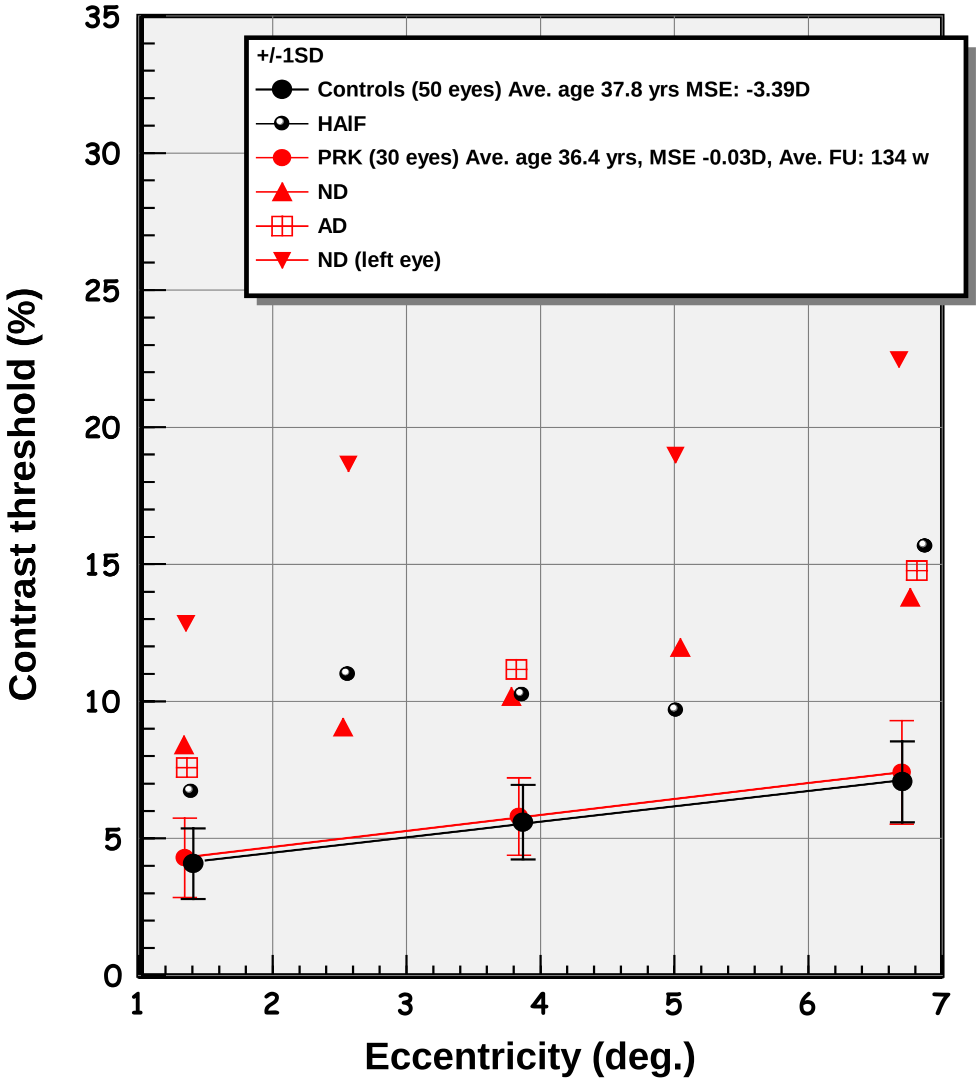
7.2 Results: Contrast Detection Thresholds

LASIK (Figure 17)



The contrast required to detect the presence of a Landolt ring target increased linearly with eccentricity (figure 17). The inter-subject variability was slightly greater in the LASIK group than the control group. A number of outliers were identified, mostly from the LASIK group.

PRK (Figure 18)



The contrast required to detect the presence of a Landolt ring target increased linearly with eccentricity (figure 18). The inter-subject variability was slightly greater in the PRK group than the control group. A number of outliers were identified, mostly from the PRK group.

7.2.1 *Analysis*

Table 6 3-way ANOVA (Corrected Means and Statistical Significance)

	Corrected Means (Contrast Detection Thresholds)			**Statistical Significance**	
Subject Group Eccentricity	**Controls**	**LASIK**	**PRK**	**p value**	**Significant?**
1.4°	4.04	3.84	4.28	0.5778	No
3.6°	5.56	5.93	5.82	0.3895	No
6.8°	7.04	7.37	7.28	0.4470	No

There was no statistically significant difference between the corrected means of the three groups at any eccentricity, (see table 6). At an eccentricity of 1.4°, the even spacing of the three means required a further two-way analysis that detected a statistically significant difference between the LASIK and the PRK means, ($p=0.037$). This suggests that PRK caused an increase in contrast thresholds for detection compared to LASIK, but only at the smallest eccentricity.

7.2.2 *Effect of Age*

A strong age effect was seen in the control data with p values of 0.015 or less for all three eccentricities. This indicates that contrast thresholds for detection increased with age.

The effect was not visible for the LASIK data except at eccentricities of 6.8° and above, ($p= 0.044$). A slight age effect was seen for the PRK group at 3.6° (statistically insignificant, $p=0.066$) with a stronger, more significant effect at 6.8°, ($p=0.014$).

7.2.3 *Effect of Pre-operative Refractive Error*

The influence of pre-operative refractive error was examined alone (one-way ANOVA) and in association with age (two-way ANOVA). No effect was seen for either refractive group when the refractive error alone was considered. For the LASIK contrast detection threshold data, the pre-operative refractive error with age did not appear to affect the results. The degree of influence on the PRK group was less clear with a statistically significant effect shown at 1.4° ($p=0.012$) but not at the higher eccentricities.

7.2.4 *Effect of Follow-up Time*

The influence of follow-up time alone and in association with age were examined using the appropriate ANOVA. No effect was seen for either test in the LASIK group. A statistically significant effect was noted for eccentricities above 6.8° in the PRK group when both follow-up time and age were considered.

7.2.5 *Outliers*

Table 7 Contrast Thresholds for Detection

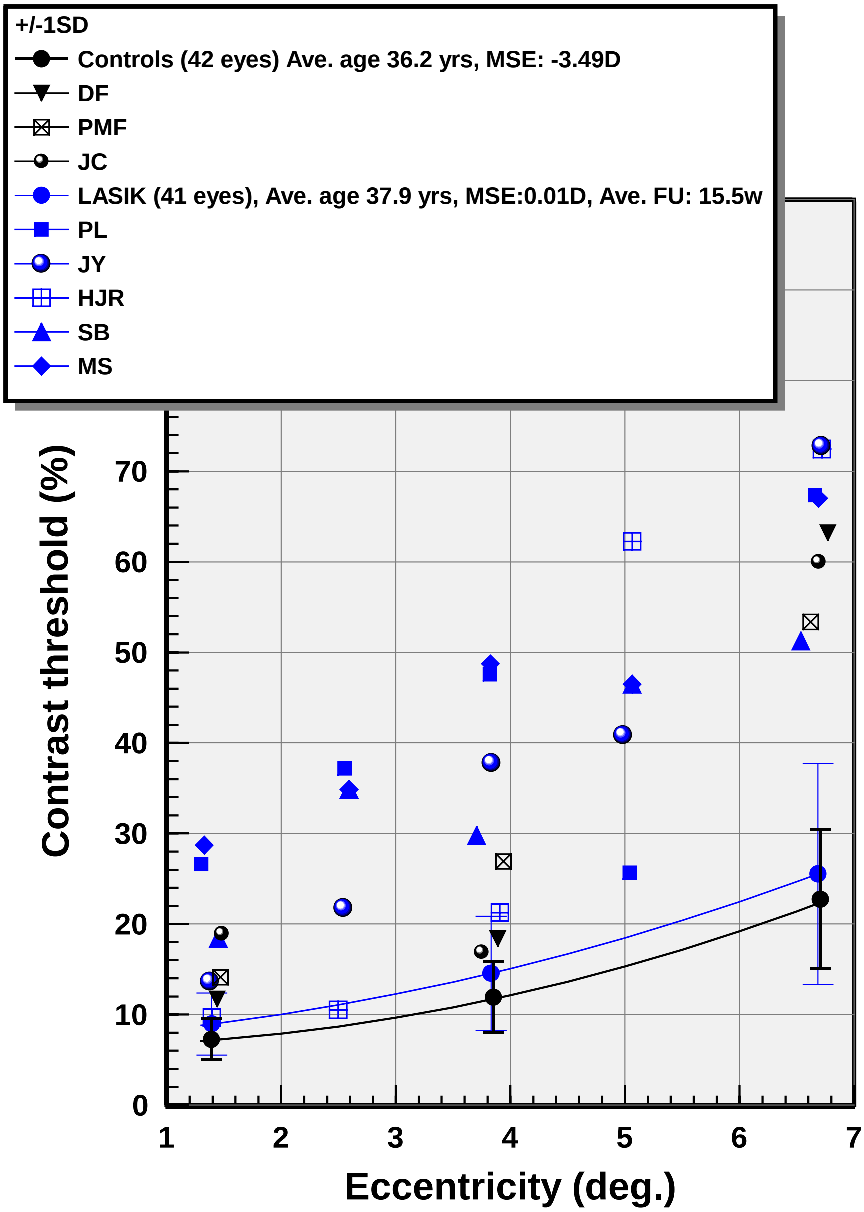
Subject	Group	Possible Explanation for Outlier Status
HalF	Control	Large pupil (increased aberrations?)
KS	LASIK	Pre-op –8.00D (more likely to induce aberrations)
JY	LASIK	Treated for high astigmatism. Can lead to irregularity
PL	LASIK	Retreated due to irregularity and regression. Remained symptomatic
GMcP	LASIK	Examined at 1 week post-surgery. Flap still oedematous
AD	PRK	Large pupil
ND (R&L eyes)	PRK	Zone < pupil diameter. Some irregularity?

7.2.6 *Summary*

For the stimulus parameters employed in this test, there is no increase in contrast thresholds for target detection following either PRK or LASIK. The analysis indicated that thresholds increased with age, although the strength of the effect may have been masked to some extent by the uneven distribution of ages within the refractive surgery groups. The analyses relating to the influence of both pre-operative refractive and follow-up time were inconclusive with a single eccentricity showing significance in some groups. A number of outliers were identified in all three groups, (see table 7).

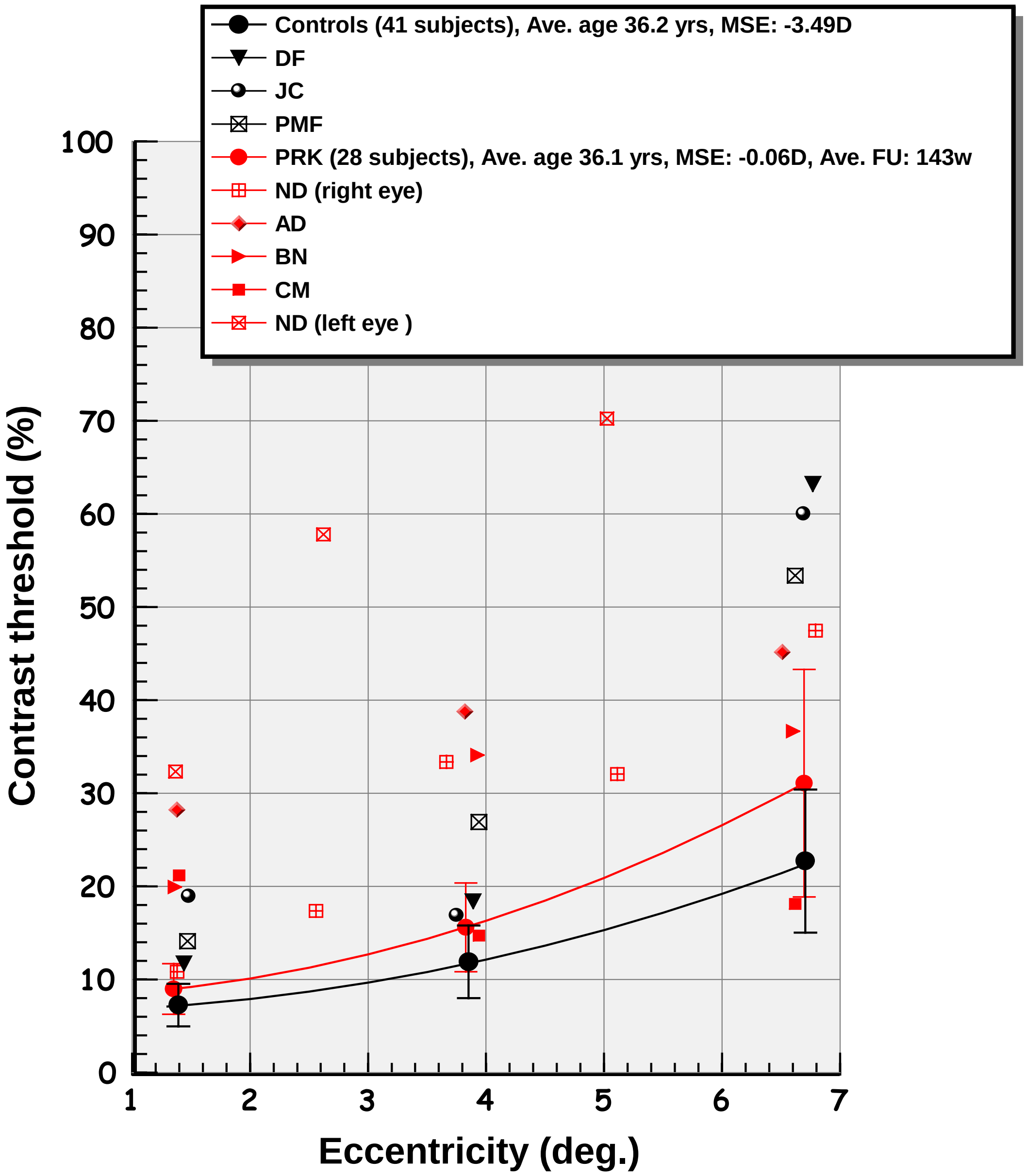
7.3 **Results: Contrast Acuity Thresholds**

LASIK (Figure 19)



The contrast required to identify the gap in the target increased with eccentricity, as did the standard deviation (figure 19). Again, greater inter-subject variability was seen in the LASIK group than the control group. A number of outliers were identified in both groups.

PRK (Figure 20)



The contrast required to detect the gap in the target increased with eccentricity in a similar manner to that seen in the control group (figure 20). Again, a larger inter-subject variability was seen in the PRK group. A number of outliers were identified in both the PRK and control groups.

7.3.1 *Analysis*

Table 8 3-way ANOVA (Corrected Means and Statistical Significance)

	Corrected Means (Contrast Acuity)			Statistical Significance	
Subject Group Eccentricity	**Controls**	**LASIK**	**PRK**	**p value**	**Significant?**
1.4°	**7.30**	8.92	8.85	**0.0176**	**Yes**
3.6°	**12.42**	15.16	16.39	**0.0329**	**Yes**
6.8°	23.63	25.99	**30.10**	**0.0123**	**Yes**

Eccentricity 1.4°
A p value of 0.0176 indicates that there was a statistically significant difference between the corrected means of the three groups, (see table 8). Examination of the data confirms that the control mean was significantly lower than the means for PRK or LASIK.

Eccentricity 3.6°
A p value of 0.0329 indicates that there was a statistically significant difference between the corrected means. Again, the control mean was lower than the means for PRK and LASIK.

Eccentricity 6.8°
A p value of 0.0123 indicates a statistically significant difference between the corrected means. In this case it was the PRK mean that was significantly higher than the control or LASIK means. The LASIK mean showed a small but statistically insignificant increase in contrast acuity threshold compared to the control group.

7.3.2 *Effect of Age*

For the control group, age had a statistically significant effect on the contrast acuity thresholds at all three eccentricities ($p<0.043$), indicating that contrast acuity thresholds increased with age. No age effect was apparent for either the LASIK or the PRK groups, perhaps due to the distribution of ages within these groups.

7.3.3 *Effect of Pre-operative Refractive Error*

A small effect was seen at two eccentricities for the LASIK group when a two-way ANOVA was used to examine the effect of pre-operative refractive error in combination with age. Only one eccentricity showed statistical significance for the PRK data.

7.3.4 *Effect of Follow-up Time*

Whether considered alone or in combination with age, follow-up time was not found to influence the contrast threshold acuity data for either refractive surgery group.

7.3.5 *Outliers*

Table 9 Contrast Acuity Thresholds

Subject	Group	Possible Explanation for Outlier Status
PMF	Control	Age 69, normal age changes
DF	Control	–9.00D image minification by spectacles. Stretched retina?
JC	Control	High Astigmatism
JY	LASIK	Treated for high astigmatism. More likely to cause irregularity than spherical treatment.
PL	LASIK	Retreated due to irregularity and regression. Remained symptomatic.
HJR	LASIK	Night vision problems. Aberrations? Pupil>zone
SB	LASIK	Pre-op –8.50D More likely to suffer induced aberrations
MS	LASIK	Hyperopic treatment therefore induced irregularity more likely. Seen at 1 week post-surgery. Flap still slightly oedematous
AD	PRK	Large pupil.
ND (R&L eyes)	PRK	Zone < pupil diameter. Some irregularity?
BN	PRK	Follow-up 3 weeks post-PRK. Haze grade 1, raised scatter
CM	PRK	Follow-up 10 weeks. Haze grade 2.5, raised scatter

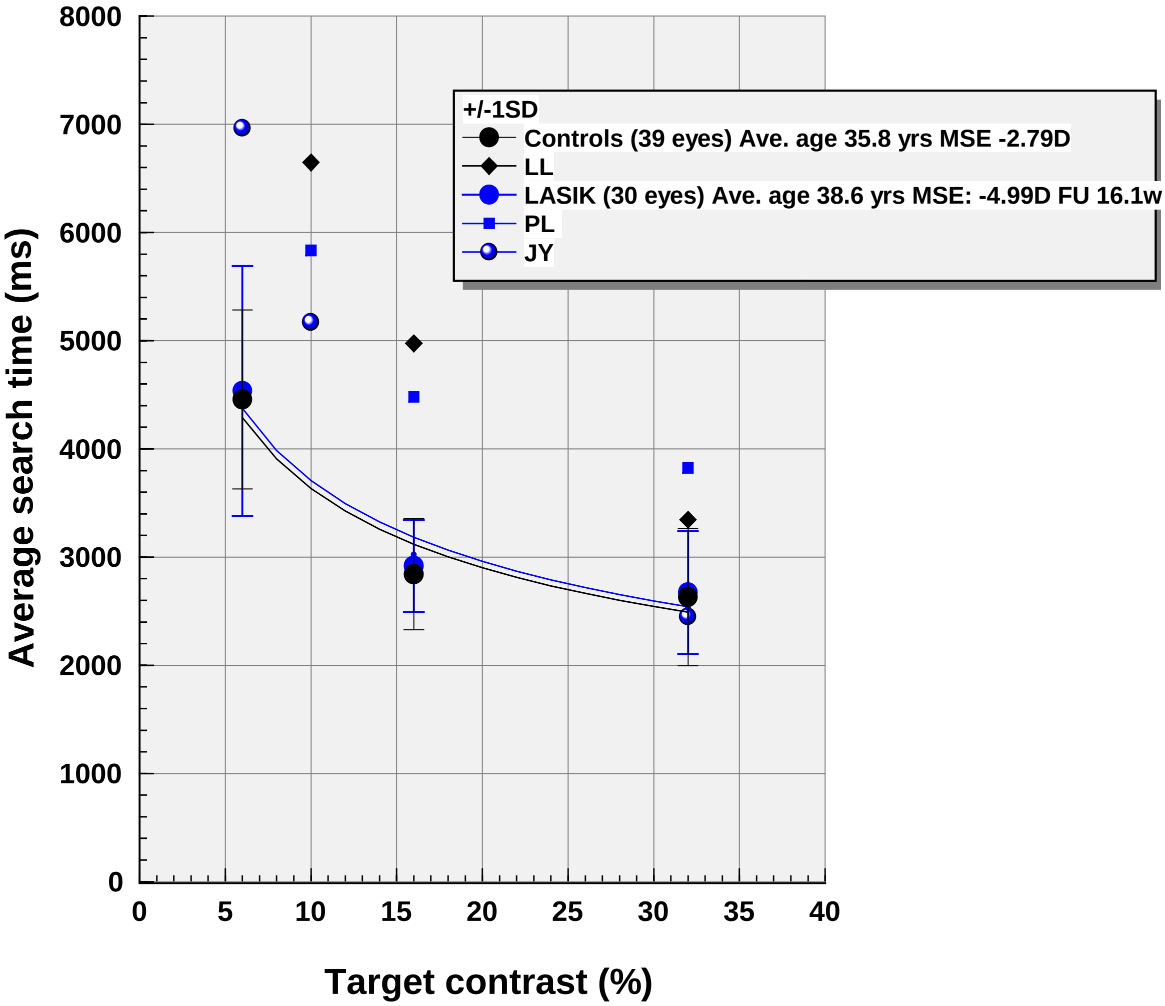
7.3.6 *Summary*

The contrast acuity thresholds were significantly higher for the PRK group than the control group, at all eccentricities. A similar effect was seen for the LASIK group although the increase in contrast acuity was not statistically significant for the highest eccentricity, probably due to the large inter-subject variability at this eccentricity. A number of outliers were identified from all three subject groups, (see table 9).

Age was associated with a significant increase in contrast thresholds in the control group. For the two refractive surgery groups, the presence of other variables and the less homogeneous distribution of age may have masked this effect. There was some suggestion that higher levels of treatment resulted in a higher contrast acuity threshold, although the data were rather inconclusive. Follow-up time did not appear to influence the results.

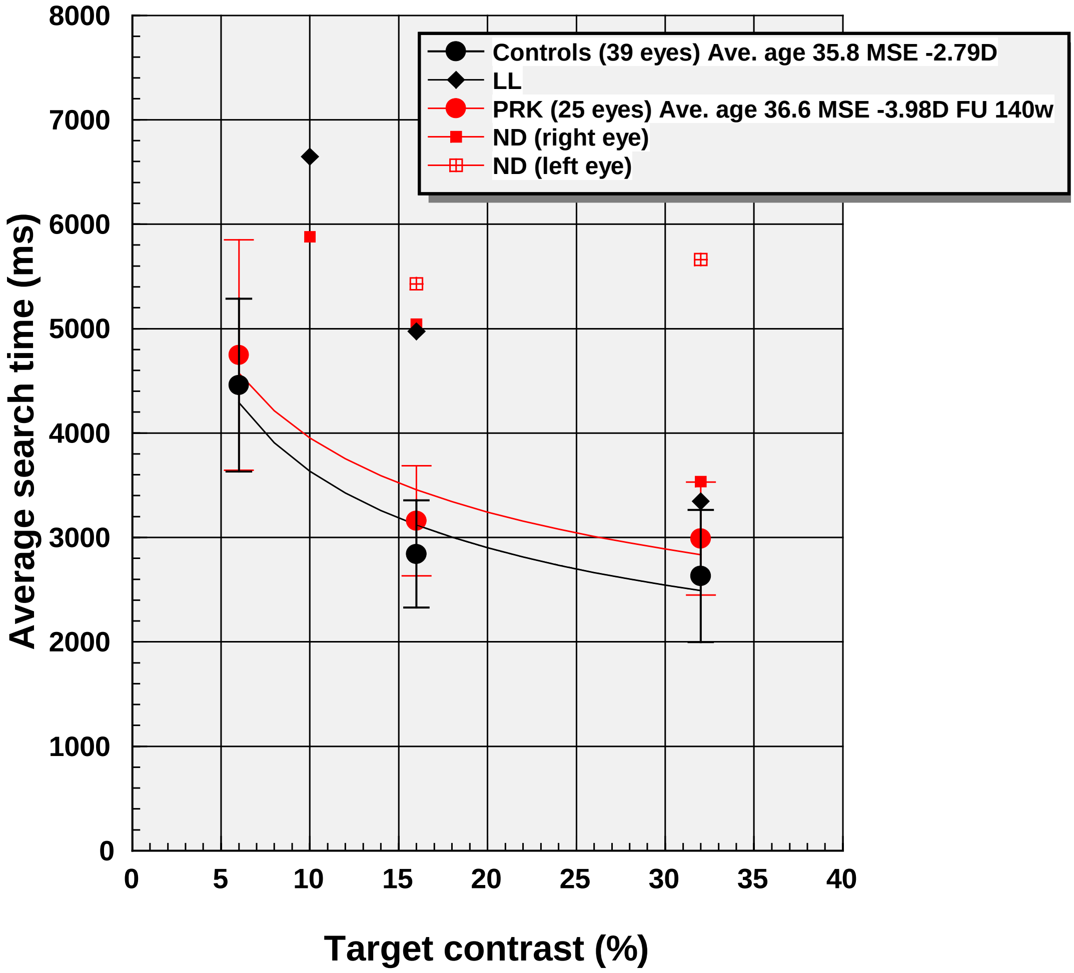
7.4 **Visual Search Task**

LASIK (Figure 21)



As the target contrast increases, the mean search time decreases (see figure 21).

PRK (Figure 22)



As the target contrast increases, the mean search time decreases (see figure 22).

7.4.1 *Analysis*

Table 10 3-way ANOVA (Corrected Means and Statistical Significance)

	Corrected Means (search time, ms)			**Statistical Significance**	
Subject Group Target Contrast	**Controls**	**LASIK**	**PRK**	**p value**	**Significant?**
6%	4458	4534	4747	0.5471	No
16%	**3193**	3596	3883	**0.0196**	**Yes**
32%	2648	2708	**2957**	**0.0350**	**Yes**

6% Contrast: A small but statistically insignificant increase in mean search times was found for the two refractive surgery groups, (see table 10).

16% Contrast: A p value of 0.0196 indicates that there was a significantly lower mean search time for the control group compared to the two treated groups.

32% Contrast: A p value of 0.035 indicates that there was a significant increase in search time for the PRK group compared to the control and LASIK group. The increase in mean search time for the LASIK group compared to the control group, did not reach statistical significance.

7.4.2 *Effect of Age*

No statistically significant effect was detected for any of the three subject groups.

7.4.3 *Effect of Pre-operative Refractive Error*

Analysis of the influence of refraction (one-way) and refraction with age (two-way) indicated no statistically significant effect in any group.

7.4.4 *Effect of Follow-up Time*

Analysis of the influence of follow-up time (one-way) or follow-up time in combination with age (two-way),.indicated no statistically significant effect in any group.

7.4.5 *Outliers*

Table 11 Visual Search Task

Subject	**Group**	**Possible Explanation for Outlier Status**
LL	Control	Large Pupil, shallow learning curve? Fatigue?
PL	LASIK	Retreated due to irregularity and regression. Remained symptomatic.
ND (R&L eyes)	PRK	Zone < pupil diameter. Increase in irregular aberrations?

7.4.6 *Summary*

The data indicate that search times were longer in the PRK group compared to the control group, with the effect reaching statistical significance at 16% and 32% contrast. The insignificant effect at 6% contrast was probably due to the particularly large standard deviation at this contrast level. The effect of LASIK on visual search performance was less clear: although an increase in search times occurred at all eccentricities, the effect was only significant at 16% contrast.

Age, pre-operative refractive error and follow-up time did not appear to influence the outcome of the visual search task.

Very few outliers were detected by the visual search task, (see table 11). The two refractive surgery patients that showed poor search performance were both extreme outliers in other experiments.

7.5 **Glimpse duration**

Table 12 3-way ANOVA (Corrected Means and Statistical Significance)

	Corrected Means (glimpse duration, ms)			**Statistical Significance**	
Subject Group	**Controls**	**LASIK**	**PRK**	**p value**	**Significant?**
Glimpse Duration	0.360	0.354	0.375	0.4900	No

There was no statistically significant difference between the mean glimpse duration measurements of the three groups, (see table 12)

7.5.1 *Effect of Age*

A one-way ANOVA revealed no statistically significant link between glimpse duration and age.

7.5.2 *Effect of Pre-operative Refractive Error*

Both one and two-way (including age) ANOVA’s suggested that pre-operative refractive error did not influence glimpse duration, for either refractive surgery group.

7.5.3 *Effect of Follow-up Time*

Both one and two-way (including age) ANOVA’s indicated that follow-up time did not influence glimpse duration for either refractive surgery group.

7.5.4 *Outliers*

Table 13 Glimpse Duration

Subject	Group	Possible Explanation for Outlier Status
PMF	Control	Age 69, normal age changes
GMcP	LASIK	Follow-up 1 week, sub-clinical flap oedema.
ND (R&L eyes)	PRK	Pupil>zone, irregular aberrations?

7.5.5 *Summary*

Neither PRK nor LASIK caused a significant increase in glimpse duration compared to the control group. Age, pre-operative refractive error and follow-up time did not appear to influence the glimpse duration.

7.6 **Low Contrast Acuity Results**

Table 14 LogMAR Acuity Results

	Control	LASIK	PRK
Number of eyes	24	36	7
Mean Age	39.3 years (SD=9.72)	38.0 years (SD=9.16)	31.57 years (SD=10.0)
Mean Spherical Error (manifest)	–4.03D (SD=2.59)	+0.06D (SD=0.49)	–0.29D (SD=0.44)
Mean Follow-up Time	–	16.06 weeks (SD=29.87)	52.43 weeks (SD=72.10)
Mean Pre-operative Spherical Error	–	–4.59D (SD=2.20)	–4.04D (SD=1.48)
High Contrast logMAR	0.06 (SD=0.12)	0.06 (SD=0.11)	0.09 (SD=0.07)
Low Contrast logMAR	0.29 (SD=0.13)	0.32 (SD=0.10)	0.35 (SD=0.14)
T test	–	HCVA p=0.993 LCVA p=0.391	HCVA p=0.605 LCVA p=0.354

The age and follow-up time distributions of subgroup for whom logMAR acuity measurements were available, differed significantly from that of the main subject groups. A two-tailed Student t-test revealed no statistically significant difference between the three groups for either high contrast acuity or low contrast acuity. There were no outliers for logMAR acuity measurements.

7.7 **Comparison Of Pre-operative And Post-operative Data**

Since the PRK subjects were recruited some time after their surgery, no pre-operative data was available for this group. A small number of LASIK subjects were examined pre-operatively but the limited number available both pre and post surgery precludes the use of any valid statistical analysis.

Intraocular light scatter: seven subjects were examined both before and after surgery. A wide range of ages, pre-operative refractions and follow-up times meant that meaningful conclusions could not be drawn from the data. The scatter functions and n, k, and k' values appeared to suggest no change in scatter at an average of 4 weeks post-LASIK.

Contrast detection thresholds: Ten subjects were examined both prior to and an average of 5 week post-LASIK. Examination of the contrast detection functions suggested that there was no change following LASIK surgery.

Contrast acuity thresholds: Eight subjects were examined before and an average of 4.25 weeks after LASIK. Examination of the contrast acuity functions suggested that LASIK did not influence contrast acuity.

Visual Search: Only three subjects were able to complete the visual search program both before and an average of 2 weeks post-LASIK. The data suggested no difference between the pre and post measurements. Glimpse duration measurements also remained virtually unchanged for this small group.

Three subjects were available for examination on more than one occasion following surgery. Their data appear to show a general trend towards improved visual performance over time.

Subject AM age 42, pre-operative MSE –6.50D
There appears to be a recovery of both contrast detection and contrast acuity thresholds from 1 week to 5 weeks post-LASIK (figures 23 and 24). Irregularity and sub-clinical flap oedema would still be present at 1 week post-surgery.

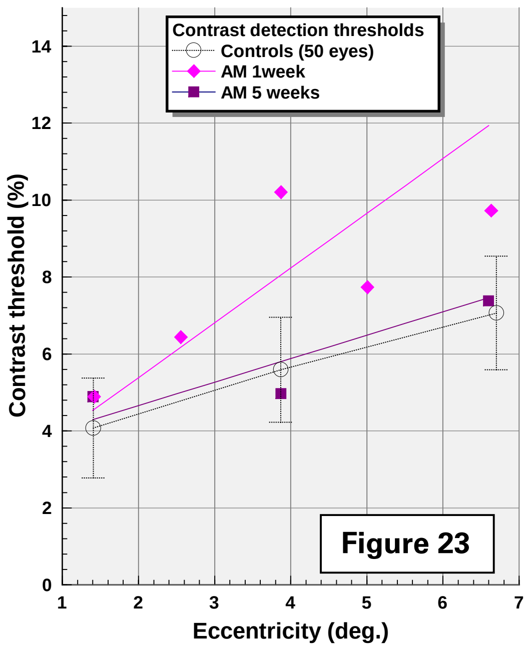


Figure 23

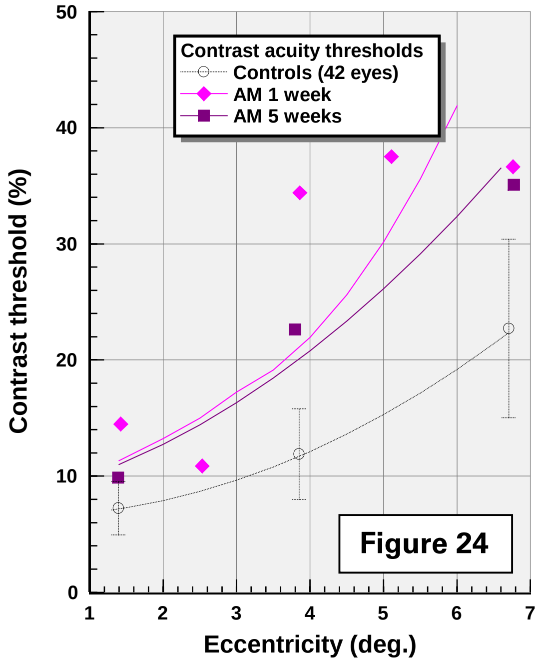


Figure 24

Subject SG age 45, pre-operative MSE –4.50D
Examined pre-operatively, 3 weeks and 12 weeks post-LASIK

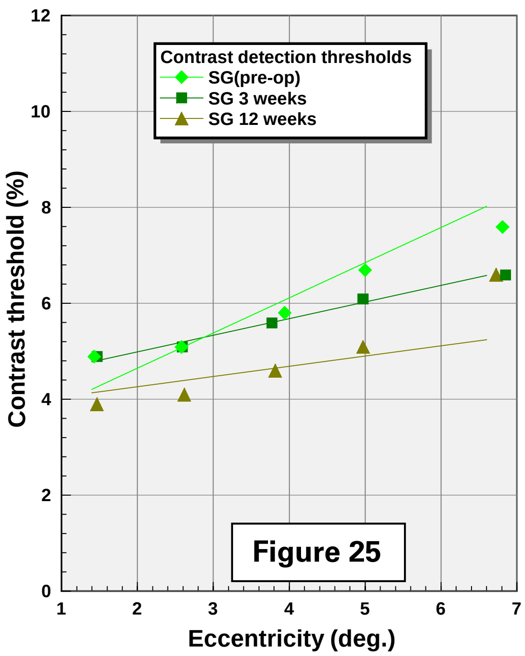


Figure 25

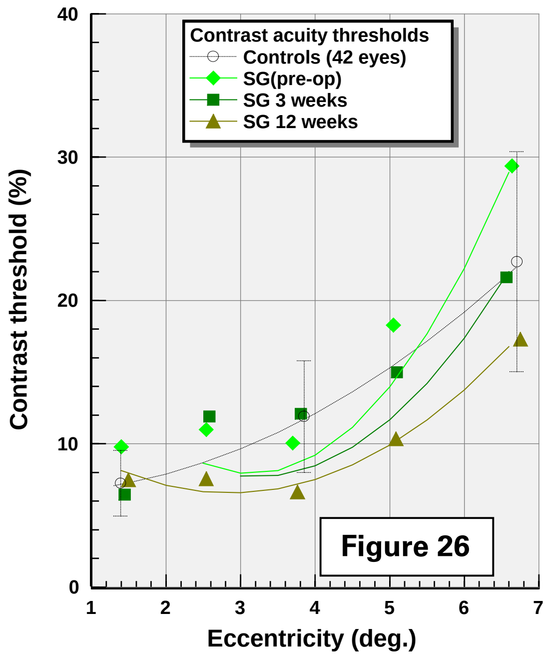


Figure 26

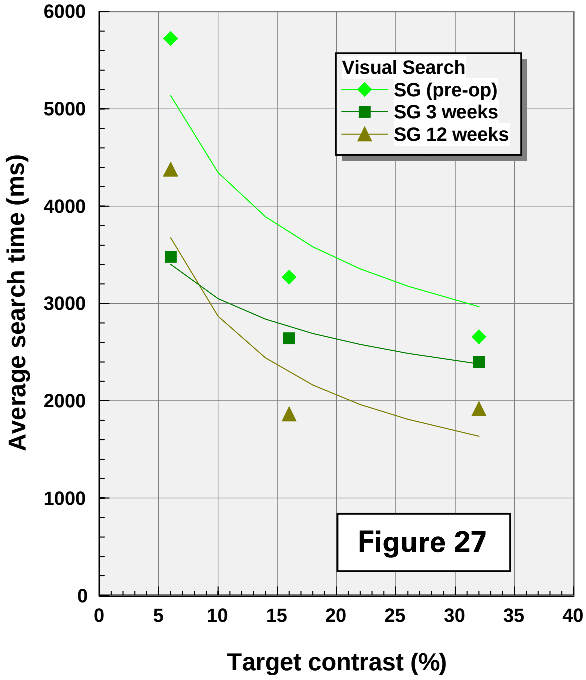


Figure 27

Glimpse duration reduced from 0.408ms pre-operatively to 0.363ms at 12 weeks post-LASIK

LogMAR acuity

Follow-up	**High**	**Low**
3 weeks	0.2	0.4
12 weeks	0.1	0.3

For subject SG, the graphs appear to indicate a gradual improvement in both contrast detection and contrast acuity thresholds following LASIK (see figures 25 and 26). Visual search times and glimpse duration are also seen to reduce and logMAR scores improved (figure 27). There is strong evidence to suggest that LASIK has resulted in enhanced visual performance for this subject, which continues to improve with follow-up time.

Subject: GMcP age 46, pre-operative MSE –7.00D
Examined at 1 week and 26 weeks post-LASIK Sub-clinical flap oedema and irregularity would have been present at 1 week post-surgery.

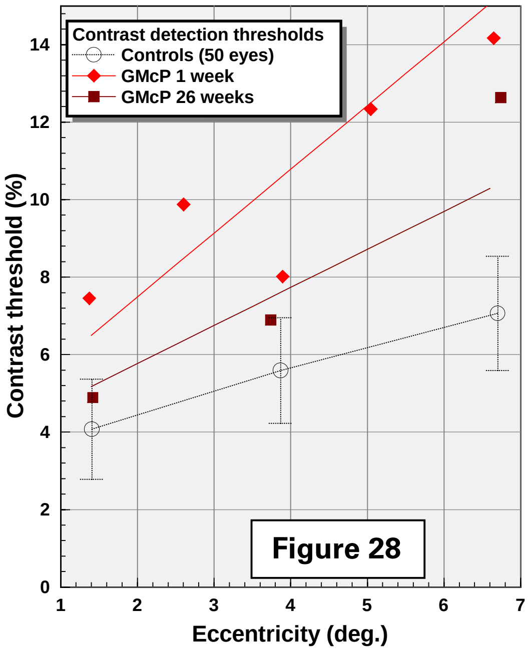


Figure 28

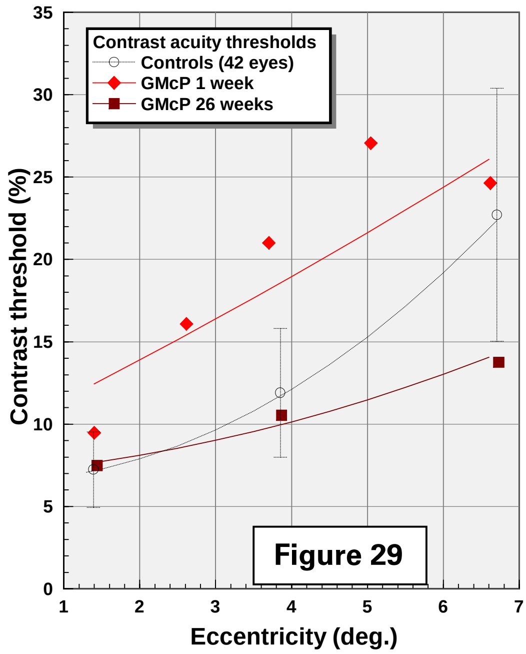


Figure 29

The contrast thresholds for both detection and acuity improved with follow-up time (see figures 28 and 29).

8 DISCUSSION

Intraocular light scatter: for the control group, the corrected means for the parameters n, k and k', differ from published data on intraocular light scatter measurements in normal subjects, (Hennelly, 1997). The most likely explanation for this is the wide range of refractive errors exhibited by the control group in this study, compared to the near emmetropic prescriptions of subjects examined by Hennelly and co-workers. Consequently many patients had a history of contact lens wear and a large proportion required spectacles to correct significant refractive errors during the experiments, both factors leading to a rise in intraocular light scatter. However, the data may therefore provide a more realistic control group than the data from emmetropic patients.

Visual Search: the visual search test was designed to mimic some of the visual tasks employed in aviation and therefore might be expected to form the most relevant assessment of visual performance in aviation. However, the large inter-subject variability and the influence of additional factors other than the visual determinants made it an insensitive method of detecting reduced visual quality. The degree of fatigue and the gradient of the learning curve varied significantly between individuals. In addition, some subjects maximised their performance by devising a search strategy while others did not. No statistically significant difference was found between the groups at 6% contrast, despite this being the contrast level most likely to be affected by the presence of increased scattered light and aberrations. This is probably to be due to the particularly large inter-subject variability within each group at this contrast level, masking any difference between the groups. Collection of data for a target of 64% contrast was ceased early in the study in an attempt to reduce the duration of the test and hence reduce fatigue, and after a few subjects showed unexpectedly long search times for this target despite its high conspicuity. This was attributed to a tendency for these subjects to selectively ignore the high contrast target, assuming that it could not be the target due to its high conspicuity. The measurement of glimpse duration also appeared to be relatively insensitive to a reduction in visual performance

8.1 **LASIK Summary**

8.1.1 *Intraocular light scatter*

For the scatter index, n, (distribution of straylight) there was no significant difference between the LASIK and the control group. A small but statistically insignificant increase was found in the quantity of scattered light (straylight parameter, k), but there was no increase in the overall quantity of straylight (k'). This is not surprising since the literature suggests that only a limited increase in light scatter takes place in the early post-LASIK period, due to the mild healing response that follows LASIK, (Jain *et al.*, 1995). No outliers were noted, even among the small number of subjects who had recently undergone surgery and were therefore likely to have residual flap oedema and irregularities. Borderline cases may have been hidden by the spread of the data within the groups.

8.1.2 *Contrast thresholds for detection*

The threshold increased with target eccentricity, reflecting the reduced resolving power of the retina away from the fovea and the reduction in the optical quality of the eye away from the visual axis. The LASIK group showed no significant difference from the control group at any eccentricity. The threshold at 1.4° was significantly lower in the LASIK group than the PRK group and it is possible that the 1.4° target was more sensitive than higher eccentricities to the presence of scatter and aberrations due to its lower contrast value. However no such trend was noted for the other two eccentricities and it is more likely that this difference between the means was in fact due to chance. Four individuals demonstrating an increased contrast threshold at one or more eccentricity were identified as outliers from the LASIK group.

8.1.3 *Contrast acuity thresholds*

As for the contrast detection thresholds, the contrast acuity thresholds increased with target eccentricity. Compared to the control group, higher thresholds were seen at all eccentricities but the difference only reached statistical significance at 1.4° and 3.6°, perhaps because the effect of scatter and aberrations is greater for the lower eccentricity values since the target contrast is lower. The corrected mean threshold at 6.8° was not significantly higher than the control group mean but was significantly lower than for the PRK group. Five individuals demonstrating an increased contrast threshold at one or more eccentricity were identified as outliers from the LASIK group.

8.1.4 *Visual Search*

The inter-subject variability within the LASIK group was significant, primarily influenced by the varying ability of subjects to perform such a task. This almost certainly explains why the corrected mean search times for each target contrast provide an inconsistent story. A small increase in mean search time was at all three contrast levels compared to the control group but the difference was only significant for 16% contrast. One symptomatic subject formed the only outlier from the LASIK group.

The mean glimpse duration during visual search was not significantly different from the control group. One LASIK subject was excluded as an outlier for glimpse duration. He was also an outlier for contrast thresholds for detection, probably due to the induced irregularity that exists during the early post-operative period. This may have influenced the speed at which he could take-in and analyse visual information.

8.1.5 *LogMAR acuity measurement*

For high contrast visual acuity, there was no difference between the mean values for the LASIK and control groups. At low contrast, a small but statistically insignificant reduction in acuity was detected. No outliers were identified. The results suggest that high contrast acuity assessment is particularly insensitive to a reduction in visual performance after laser surgery.

8.2 **PRK Summary**

8.2.1 *Intraocular light scatter*

A statistically significant difference in the distribution of scattered light was noted in the PRK group compared to the control and the LASIK groups. The corrected mean scatter index (n) was significantly smaller than for the other two groups, indicating less spreading out of the scattered light across the retina following PRK. This could be explained by the microscopic changes in the stromal structure that are peculiar to PRK (Lohmann *et al.*, 1991). For scatter originating from the object of regard itself, concentration of scattered light close to the retinal image will cause greater degradation of visual performance than if the straylight was more spread out (larger scatter index).

Despite the change in straylight distribution, the overall quantity of intraocular scattered light showed a small but statistically insignificantly difference from the other two groups. Two outliers were identified as having raised scatter, almost certainly related to the short period of time since surgery. Their follow-up times were 3 weeks and 10 weeks with integrated straylight parameters of 16.32 and 31.55 respectively. Stromal haze of grade 1 or more was detectable in both cases.

8.2.2 *Contrast thresholds for detection*

Again an increase in contrast threshold with target eccentricity was noted. No significant difference from the control group was noted at any eccentricity, although the corrected mean for the PRK group was significantly higher than the LASIK mean at an eccentricity of 1.4°, (see 1.12).

8.2.3 *Contrast acuity thresholds*

As with the contrast detection thresholds, the acuity threshold increased with target eccentricity. Compared to the control group, higher thresholds were seen at all eccentricities, reaching statistical significance in all cases. The corrected mean threshold at 6.8° was significantly higher than for the LASIK group. Four individuals demonstrating an increased contrast threshold at one or more eccentricity were identified as outliers from the PRK group.

8.2.4 *Visual Search*

The inter-subject variability within the PRK group was significant, primarily influenced by the varying ability of subjects to perform such a task. Again, the corrected mean search times for each target contrast provided an inconsistent story. The mean search time was elevated compared to the control group and the difference reached statistical significance for the 16% and 32% contrast levels. The mean search time was also significantly higher than the LASIK mean at the 32% contrast level. These data indicate an overall reduction in search performance following PRK, which occurs at both high and low contrast levels. Any effect at the 6% contrast level may be masked by the large inter-subject variability for this target contrast.

Both eyes of one PRK subject formed outliers for this experiment.

The glimpse duration measured during visual search showed no statistically significant difference from the control group. One outlier was identified and excluded. He was also an outlier for all other tests suggesting a significant reduction in the quality of the retinal image. It is not surprising that the time taken to detect and analyse the information within a particular visual lobe was significantly longer than for other subjects.

8.2.5 *LogMAR acuity measurement*

Small but statistically insignificant reductions in both high and low contrast acuity were seen in the PRK group. No outliers were identified although this test was not available for use on the majority of PRK subjects, including two of the more extreme outliers identified by other experiments. This result again suggests that high contrast acuity assessment is insensitive to a reduction in visual performance after laser surgery.

8.3 Summary Of Outliers

Table 15 Control group

Subject	Experiment	Possible Explanation for Outlier Status
HAIF	Contrast thresholds for detection	Large pupil, aberrations?
PMF	Contrast acuity and glimpse duration	Age 69 but no increase in scatter
DF	Contrast acuity	–9.00D, previous contact lens wear. Thick spectacles worn
JC	Contrast acuity	High Astigmatism
LL	Visual search	Shallow learning curve? Fatigue?

The outliers from the control group are summarised in table 15.

Subject HAIF was an outlier in the detection threshold test. At the time of testing, she reported great difficulty in spreading her attention across the whole field. As for all subjects, examination of her eyes had ruled out the presence of any pathology and with a small hyperopic correction, she achieved 6/5 acuity. It is possible that she suffered from larger than average ocular aberrations that in combination with her 6.5mm diameter pupil at 12 cd/m^2, led to a reduction in visual performance. Wave-front analysis would be required to examine this hypothesis.

Three control subjects were outliers in the contrast acuity test and subject PMF also demonstrated a long glimpse duration. This reduction in performance has been attributed to normal age-related changes to the eye since the patient was 69 years old at the time of testing. Early yellowing of the lens was apparent although no opacities were visible and the scatter function was within the normal range.

Subject DF was a high myope who had previously worn soft contact lenses. A –9.00D spectacle correction was worn throughout the experiments. Her outlier status could be attributed to the minification of the retinal image produced by her spectacles, or microscopic corneal changes resulting from long-term contact lens wear, and/or reduced retinal sensitivity due to greater spacing of the retinal receptors associated with high myopia. She was also close to being an outlier for low contrast acuity measurement.

The cause of reduced performance for subject JC was thought to be her high astigmatism. Although the spectacles worn throughout the experiments corrected her to 6/6 acuity, some minification of the retinal image would take place in one meridian causing a degree of image distortion.

Subject LL was an outlier for the visual search task alone. Her outlier status has been attributed to a very slow learning curve. Despite an initial practice run, her search times continued to improve right up to the end of the test.

Table 16 LASIK group

Subject	**Experiment**	**Possible Explanation for Outlier Status**
KS	Contrast thresholds for detection	Treated for –8.00D. More likely to induce aberrations
JY	Contrast thresholds for detection and contrast acuity	Treated for high astigmatism – more likely to induce irregularity
PL	Contrast thresholds for detection, contrast acuity and visual search	Retreated for irregularity Symptomatic
GMcP	Contrast thresholds for detection and glimpse duration	Follow-up 1 week – flap oedema and irregularity likely at this stage
HJR	Contrast acuity	Night vision problems Pupil>zone
SB	Contrast acuity	Treated for –8.50D. More likely to induce aberrations
MS	Contrast acuity	Hyperopic treatment Follow-up 1 week. Flap oedema and irregularity likely at this stage

The outliers from the LASIK group are summarised in table 16. The majority of outliers demonstrated abnormally high contrast acuity thresholds. Subject KS however, was an outlier for the detection thresholds only. Treatment for a relatively high myopic error such as –8.00D, is more likely to induce greater irregular aberrations. However, a reduction in optical quality would also be detrimental to the contrast acuity thresholds. It is possible that his outlier status was due to a lack of concentration.

Subject GMcP was an outlier for both detection thresholds and glimpse duration at his one week follow-up appointment. At this time, the cornea appeared clear and the eye quiet, but sub-clinical flap oedema and irregularity tends to be present during the early stages post-LASIK. He was not an outlier for any experiment at the 26 week visit.

The outlier status of subject JY for both contrast detection and contrast acuity thresholds, was attributed to her high pre-operative astigmatism, (2.12DC). The treatment of astigmatism is more likely to induce central irregularity due to the difficulty of aligning the laser along the principal meridians and the less predictable healing response seen post-surgery. She was also close to being an outlier for the low contrast acuity measurement.

Poor contrast acuity results were attributed to increased aberrations and a mis-match between the pupil and the ablation zone for subject HJR. He complained of glare at night but exhibited no increase in intraocular light scatter. Aberrations related to the treatment of –8.50D of myopia were also thought to be the cause of increased contrast acuity thresholds for subject SB. Retinal function cannot be ruled out as a factor due to the pre-operative high myopia. Subject MS demonstrated a similar increase in thresholds almost certainly related to the presence of corneal irregularity that is common at only one week post hyperopic surgery.

Subject PL was an outlier for every test except scatter and glimpse duration. He was close to being an outlier for low contrast acuity and to a less extent, high contrast acuity. He was examined 160 weeks after a retreatment operation designed to reduce the corneal irregularity induced by the first LASIK procedure for –8.50D. The residual refractive error was –0.50D, which when corrected, enabled him to achieve 6/9 Snellen acuity. His pupil was smaller than the treated zone but corneal topography measurements revealed a significant degree of induced irregularity. He complained of poor quality vision particularly at low light levels.

Table 17 PRK group

Subject	**Experiment**	**Possible Explanation for Outlier Status**
ND (R&L eyes)	Contrast thresholds for detection and contrast acuity, visual search and glimpse duration	Pupil>zone, Irregularity Treated with broad beam laser more than 5 years previously Left eye symptomatic
AD	Contrast thresholds for detection and contrast acuity	Large pupil, induced aberrations?
BN	Scatter and contrast acuity	Follow-up 3 weeks Haze grade 1
CM	Scatter and contrast acuity	Follow-up 10 weeks, haze grade 2.5

All outliers in the PRK group exhibited poor contrast acuity results. Subject ND had been treated for –8.50D of myopia shortly after PRK was first available. Treatment of a small ablation zone using a broad beam laser was common practice in those days, despite a pupil diameter of 7.4mm under low illumination. He complained of reduced vision in his left eye for low contrast targets although did not suffer from night halos. His scatter function was normal and both corneae were clear. His poor performance for all tests of visual performance was attributed to significant induced irregular aberrations. The increase in contrast thresholds for both detection and acuity would have reduced the size of the lobe over which he could discriminate detail. In combination with the increase in glimpse duration associated with a loss of high spatial frequency information, this could explain his poor performance in the visual search task.

Subject AD exhibited poor performance for both contrast threshold tests. Her large pupil (6.4mm) suggests that induced aberrations may be the cause of her visual degradation. She was asymptomatic although she had never driven at night.

Subjects BN and CM both demonstrated raised contrast acuity thresholds which was attributed to an increase in intraocular light scatter associated with the early healing processes post-PRK.

For all subject groups, the majority of outliers were detected by the contrast acuity threshold test. This is not surprising since it is the most likely task to be degraded by increased scatter or aberrations, since the subject is required to resolve small detail at a low contrast level. Very few subjects performed poorly in the contrast threshold for detection task without also being an outlier for the contrast acuity task.

8.4 Influence Of Age

Scatter: An increase in the overall quantity of straylight (k’) with increasing age was noted for the PRK group although age did not appear to influence the distribution of straylight, (scatter index, n). Age was not shown to influence the scatter function for either the control or the LASIK group. Although an increase in intraocular straylight would be expected (Hemenger, 1984; IJspeert *et al.*, 1990) the lack of any significant effect can be attributed to the small number of subjects over the age of 45 years in all groups.

Contrast thresholds: Detection and acuity thresholds were strongly influenced by age in the control group, but the effect was less consistent for the two refractive surgery groups, showing different levels of significance at each eccentricity. The visual search and glimpse duration measurements showed no relationship to age in any group, although the 69 year old control subject (outlier) showed a very long glimpse duration, perhaps related to slower processing of the visual information.

Visual search and glimpse duration: No age effect was detectable for either measure of visual performance.

It is unlikely that an alternative classification of the age groups would increase the power to detect the influence of age, since the literature suggests that age-related ocular changes have no significant effect on performance before the age of 45 years. An increase in the number of subdivisions would have required a substantial increase in the size of the data sample. A larger number of subjects over the age of 45 years would have increased the power to detect age changes however the proportion of laser patients who fall into this subgroup is very small. In addition, pilots tend to retire by the age of 55 years, making such an exercise somewhat academic.

8.5 Influence Of Pre-Operative Refractive Error

The degree of treatment and hence the amount of tissue removed from the cornea might be expected to influence the visual outcome of the surgery. A strong link between the degree of pre-operative myopia and the predictability and accuracy of outcome has been demonstrated in the literature, with a poorer outcome for the more myopic groups following both PRK and LASIK (Hersh *et al.*, 1996; Kim *et al.*, 1996; Guell and Muller, 1996; Goggin *et al.*, 1997; Tuunanen and Tervo, 1998; Knorz *et al.*, 1998). The percentage risk of reduced best corrected visual acuity increases for higher degrees of pre-operative myopia (Rao *et al.*, 1996; Knorz *et al.*, 1998). The larger ablation depth required to treat high myopia necessitates a smaller ablation zone and consequently night vision problems are more common, both as a result of halos and increased irregular aberrations (Guell and Muller, 1996; Hersh *et al.*, 1996).

Very few subjects underwent either PRK or LASIK for treatment of hyperopia or high astigmatism and hence the power to detect a difference in performance related to these categories is very small. The distribution of refractive errors was fairly even across the range of myopic treatments, however the analyses did not detect any definite relationship between pre-operative refractive error and outcome for any of the experiments employed.

8.6 Influence Of Follow-Up Time

Studies have demonstrated the gradual restoration of visual performance as the eye heals post-surgery (Miller and Schoessler, 1995). The recovery is more rapid following LASIK than PRK (Chen *et al.*, 1996). However, the analyses failed to detect any effect in this study. This is likely to be due to the uneven distribution of follow-up times, particularly in the PRK group, with very few subjects available for examination during the first few weeks post-surgery. A much larger subject sample would be required to investigate this effect further.

9 CONCLUSIONS

There was no overall increase in intraocular light scatter for the average follow-up times stated in either the LASIK or the PRK groups. Two outliers were detected in the PRK group, both of whom exhibited corneal haze associated with a short follow-up time. The increase in light scatter was also associated with a reduction in contrast acuity performance.

Contrast detection thresholds remained unaffected but contrast acuity thresholds appeared to detect a subtle reduction in visual performance for both types of surgery. The reduction in performance was small and is unlikely to be significant in “real-life” situations such as aviation, but the data suggest that a screening test based on this measure may be the most sensitive method of detecting problems after surgery, whether due to increased scatter or aberrations. In addition, all symptomatic patients performed poorly on the contrast acuity test.

The spread of data was considerable within all the groups, but particularly the two refractive surgery groups. This indicates that some subjects suffered a slight reduction in performance (although not significant to make them an outlier) while others showed an improvement in visual performance, as seen in the small subgroup examined both pre and post surgery. Since no increase in intraocular light scatter was detected for either PRK or LASIK, this subtle reduction visual performance was probably related to changes in the optical quality of the post-surgical cornea. The literature suggests that some increase in irregular aberrations occur in virtually all eyes following PRK and LASIK.

Due to the time constraints and the nature of the study, it has not been possible to make recommendations regarding the average length of time before normal visual function returns, nor the upper limited of myopia that should be treated based on the visual performance results. Significantly more subjects would need to be examined and followed-up over time in order to make such decisions.

In summary, both PRK and LASIK appear to be safe for use in commercial aviation, however a quick and simple test is needed to identify the small number of outliers who are often asymptomatic. Poor visual performance may be due to increased intraocular scatter, aberrations or high myopia etc. and there is no particular need to discriminate between the causes. The results of this study suggest that a measure of contrast acuity thresholds based on a visual task analysis of a commercial cockpit, would be the most sensitive method of detecting those individuals whose reduction in visual performance is large enough to make them unsafe to fly. The contrast acuity test would be capable of detecting a reduction in visual performance regardless of the underlying cause. Additional tests could then be used to establish the exact cause if required.

Appendix A – Glare Questionnaire

Subject ID **Age**

1 In general, which aspect of flying do you find the most demanding?

2 What aspects of flying are particularly demanding in terms of your eyes and why?

3 If a pilot suffered from poor colour vision, which tasks would be affected?

4 If a pilot suffered from poor distance vision, which tasks would be affected?

5 If a pilot suffered from poor near vision, which tasks would be affected?

6 If a pilot suffered from poor depth perception, which tasks would be affected?

7 What weather conditions do you find visually demanding when flying?

8 Under what circumstances can glare be a problem to pilots? (Glare is defined as difficulty seeing in the presence of a bright light)

9 For each of the following lighting conditions, indicate the extent of any visual problems experienced :
(1 = no problem, 5 = debilitating problem, circle a number from 1 – 5)

(a)	Sun setting immediately ahead	1	2	3	4	5
(b)	Midday – sun overhead	1	2	3	4	5
(c)	Sun to one side (reflections on the screen etc)	1	2	3	4	5
(d)	Sun reflecting off the cloud below	1	2	3	4	5

10 For each of the following lighting conditions, indicate the extent of any visual problems experienced :
(1 = no problem, 5 = debilitating problem, circle a number from 1 – 5)

(a)	Daylight	1 2 3 4 5
(b)	Twilight	1 2 3 4 5
(c)	Darkness	1 2 3 4 5

11 For each of the following tasks, indicate the extent of any visual problems experienced :
(1 = no problem, 5 = debilitating problem, circle a number from 1 – 5)

(a)	Approach	1 2 3 4 5
(b)	Taxiing	1 2 3 4 5
(c)	Taking off	1 2 3 4 5
(d)	Looking at airport maps	1 2 3 4 5
(e)	Looking at the Flight Management Screen	1 2 3 4 5
(f)	Looking at screens/instruments other than the Flight Management Screen	1 2 3 4 5

12 How do you adjust the cockpit lighting at night for:

Take-off	Up / down
Cruising	Up / down
Approach	Up / down

13 Type of plane flown

14 Correction worn — None / Spectacles / Contact lenses

15 Do you ever wear sunglasses? — Yes / No

Summary of Questionnaire Results

Table 18

Subjects	23
Average age	40.3 years
Type of plane flow Instrumentation	Boeings (7), Airbus (4), Other (12) Digital (12), Analogue (9), Helicopter (2)
Prescription spectacles	5
Sunglasses	20 (4 complained of with reduced colour discrimination when wearing sunglasses)
Most demanding tasks	Approach and landing, (especially in poor weather conditions)
Most visually demanding tasks	Approach (5), low sun (5), night flights (7), reading maps (3)
Good colour vision needed for	Speeds up processing (7), not critical (3)
Good distance vision needed for	Take-off and landing, taxiing, watching traffic, judging distances
Good near vision needed for	Instrumentation and maps (intermediate distance)
Good binocular vision is needed for	Landing especially at night, angled runways, approaching over water, snow etc.
Most visually demanding weather conditions	Poor visibility (rain, mist, fog) (11), direct sun (8), night light levels (1)
Circumstances under which glare is a problem	Rain, flying into setting sun, hazy skies (use blinds). One pilot mentioned approach lights and other vehicle lights on taxiway,
Extent of any visual problems experienced (1 = no problem, 5 = debilitating problem)	
Sun setting immediately ahead	4
Midday sun overhead	1.1
Sun reflecting off instrumentation	2.6
Sun reflecting off cloud below	2.4
Daylight in general	2.4
Twilight in general	2.4
Night in general	2.3
Visual difficulty of the following tasks (1 = no problem, 5 = very difficult)	
Approach	3.4
Taxiing	2.3
Take-off	1.9
Airport maps	2.9
Flight Management System	1.7
Other instrumentation	1.6
Cockpit lighting during take-off	Down (21)
Cockpit lighting during cruise	Up (5), down (18)
Cockpit lighting during approach/landing	Down (21)

Appendix B – Luminance Measurements

Luminance was measured using a LMT 1003 luminance meter with a field of view that varied from 20 mins of arc and 3 degrees. Luminance measurements were not always very accurate, particularly for the alpha-numerics since the reading was averaged over an area larger than the individual characters and was therefore dependent on both the bright targets and the dark background. Values are therefore approximate.

Daylight Luminance Levels:

Overcast winter sky: 730 cd/m^2
Terminal building while on ground: 22–55 cd/m^2
Grey surround of cockpit instrumentation: 3.5 cd/m^2
Black background of LCD screens: 0.2–0.5 cd/m^2
Characters on LCD screens: 10–50 cd/m^2 (only approximately due to fill-in effect).

Luminance levels at 31,000 feet, 15.10GMT

Directly into sun: 369,000 cd/m^2 (limit of scale)

No direct sunlight on screens:

LCD backgrounds: 0.9–1.5 cd/m^2 (i.e. absorb almost all light)
LCD characters: 10–50 cd/m^2 (approximate)
Grey surround: 4–20 cd/m^2

With direct sun on screens:

LCD backgrounds: 2.7 cd/m^2
Grey surround: 337 cd/m^2

Night-time Luminance Levels:

In general, the LCD luminance is reduced by the pilots. Limited ambient illumination falls on the screens.
Floodlights over airport: 300 cd/m^2
Black background of LCD screens: 0.1–0.2 cd/m^2
Characters on LCD screens: 0.5 cd/m^2 (3.8 cd/m^2 when turned to maximum – approximation only)
Grey surround with local lighting: 0.5 cd/m^2
Blue 0.9 cd/m^2, Brown 0.4 cd/m^2 (on primary flight display)
Maps under local lighting: 0.9 cd/m^2
Luminance in plane of pupil: 0.1 cd/m^2

Appendix C – Normality Testing

Control Group

Anderson-Darling Test of Normality
A p value greater than 0.05 indicates a normal distribution

Table 19 p values for Control Group

Parameter examined	With Outliers	Without Outliers
Age	0.002	N/A
Mean Spherical Error	0.858 Normal	N/A
Astigmatism	0.000	N/A
Scatter index, n	0.366 Normal	0.366 Normal
Straylight parameter, k	0.266 Normal	0.266 Normal
Integrated Straylight parameter, k'	0.917 Normal	0.917 Normal
Detection thresholds 1.4°	0.000	0.000
Detection thresholds 3.9°	0.000	0.001
Detection thresholds 6.8°	0.000	0.001
Contrast Acuity 1.4°	0.000	0.043
Contrast Acuity 3.9°	0.007	0.021
Contrast Acuity 6.8°	0.001	0.677 Normal
Visual Search 6% Contrast	0.217 Normal	0.217 Normal
Visual Search 10% Contrast	0.005	0.195 Normal
Visual Search 16% Contrast	0.152 Normal	0.521 Normal
Visual Search 32% Contrast	0.339 Normal	0.325 Normal
Visual Search 64% Contrast	0.280 Normal	0.280 Normal
Glimpse Duration	0.001	0.900 Normal
High Contrast logMAR	0.101 Normal	0.101 Normal
Low Contrast logMAR	0.896 Normal	0.896 Normal

Removal of the outliers resulted in a normal distribution in all but the detection threshold and contrast acuity tests.

LASIK Group

Anderson-Darling Test of Normality
A p value greater than 0.05 indicates a normal distribution

Table 20 p values for LASIK Group

Parameter examined	With Outliers	Without Outliers
Age	0.370 Normal	N/A
Pre-op Mean Spherical Error	0.080 Normal	N/A
Pre-op Astigmatism	0.000	N/A
Follow-up	0.000	N/A
Post-operative mean spherical error	0.000	N/A
Scatter index, n	0.000	0.000
Straylight parameter, k	0.369 Normal	0.369 Normal
Integrated Straylight parameter, k’	0.369 Normal	0.369 Normal
Detection thresholds 1.4°	0.000	0.000
Detection thresholds 3.9°	0.000	0.000
Detection thresholds 6.8°	0.000	0.000
Contrast Acuity 1.4°	0.000	0.055 Normal
Contrast Acuity 3.9°	0.000	0.007
Contrast Acuity 6.8°	0.003	0.184 Normal
Visual Search 6% Contrast	0.140 Normal	0.140 Normal
Visual Search 10% Contrast	0.821 Normal	0.990 Normal
Visual Search 16% Contrast	0.023	0.154 Normal
Visual Search 32% Contrast	0.005	0.007
Visual Search 64% Contrast	0.004	0.010
Glimpse Duration	0.005	0.029
High Contrast logMAR	0.149 Normal	0.149 Normal
Low Contrast logMAR	0.100 Normal	0.100 Normal

PRK Group

Anderson-Darling Test of Normality
A p value greater than 0.05 indicates a normal distribution

Table 21 p values for PRK Group

Parameter examined	With Outliers	Without Outliers
Age	0.766 Normal	N/A
Pre-op Mean Spherical Error	0.472 Normal	N/A
Pre-op Astigmatism	0.032	N/A
Follow-up	0.020	N/A
Post-operative mean spherical error	0.102 Normal	N/A
Scatter index, n	0.213 Normal	0.856 Normal
Straylight parameter, k	0.360 Normal	0.386 Normal
Integrated Straylight parameter, k'	0.000	0.854 Normal
Detection thresholds 1.4°	0.000	0.008
Detection thresholds 3.9°	0.000	0.001
Detection thresholds 6.8°	0.000	0.002
Contrast Acuity 1.4°	0.000	0.116 Normal
Contrast Acuity 3.9°	0.000	0.689 Normal
Contrast Acuity 6.8°	0.151 Normal	0.564 Normal
Visual Search 6% Contrast	0.942 Normal	0.942 Normal
Visual Search 10% Contrast	0.213 Normal	0.208 Normal
Visual Search 16% Contrast	0.079 Normal	0.947 Normal
Visual Search 32% Contrast	0.142 Normal	0.060 Normal
Visual Search 64% Contrast	0.115 Normal	0.413 Normal
Glimpse Duration	0.024	0.182 Normal
High Contrast logMAR	0.652 Normal	0.652 Normal
Low Contrast logMAR	0.588 Normal	0.588 Normal

Appendix D – Refractive Surgery Policy (Practical Considerations)

Should refractive surgery become acceptable to the Joint Aviation Authority (JAA), a clear policy will be needed as part of the occupational standards for aviation.

Refractive Restrictions

From the information gathered during this research project and from consultation with a number of surgeons, the research group felt that any restrictions on refractive surgery patients should be based on visual performance rather than other factors such as refractive error. The pre-operative refractive error is not the most important factor in determining the visual outcome of either PRK or LASIK.

Within the normal untreated population, certain high myopes may suffer from below average visual performance due to spectacle minification and/or a larger than average separation of the retinal receptors, but still achieve the level of Snellen acuity required to meet the present CAA requirements, (particularly if wearing contact lenses). A test of visual performance would detect such people. An additional concern would be the small increase in the risk of retinal detachment with increasing myopia. However, should a detachment occur during flight, visual loss is rarely immediate and is invariably monocular.

Recovery times

A much longer study with significantly larger subject numbers would have been required to determine the precise effect of follow-up time on visual performance. Since this was not possible during the time allocated for the study, the following advice is based on examination of a number of published studies. The research group felt that a waiting period of 6 months following PRK for myopia below –6.00D, and 3 months following LASIK was necessary to ensure refractive stability in the majority of patients. If refractive stability was demonstrable over consecutive examinations before this time, the cornea is clear and all visual performance tests are performed adequately, candidates could be considered earlier.

Assessment For Medical Certification

An examination to consider the suitability of a refractive surgery patient for certification should include:

1 A slit lamp examination to confirm that the eye has returned to normal and that there is no significant loss of corneal transparency.

2 Refraction, topographic examination and pachymetry to screen for keratectasia. Reassurance should be sought from the operating surgeon regarding the thickness of the residual stromal bed and the nature of any complications that may have occurred during or following the procedure.

3 All candidates should complete the test designed by the Applied Vision Research Centre to detect the minority of post-surgery patients who suffer from increased scattered light

and/or aberrations. Those failing the test could be referred to City University for further investigation

4 Candidates should not be considered until all medication has ceased.

Detection Of Laser Surgery

Applicants to the CAA have been known to try and avoid disclosure of the history of refractive surgery. Those who have had Radial Keratotomy are easily identified since the radial scars are permanent. The detection of those who have undergone Photorefractive Keratectomy is more problematic because corneal signs tend to disappear once the initial stromal haze has subsided. LASIK tends to result in a faint C-shaped ring but this can fade completely in some patients.

Detection Using Pachymetry Or Topography

Possible methods for screening out candidates who have undergone a corneal refractive procedure include pachymetry and topography. Measurements of the central corneal thickness vary significantly within the normal population (Price *et al.*, 1999) with a mean central thickness of 550nm but a range of 472 to 651nm. Since the cornea also thickens to some extent following both PRK and LASIK, pachymetry is a surprisingly insensitive method of identifying those who have undergone refractive surgery.

The use of corneal topography maps to identify cases of refractive surgery has also been considered. Schallhorn et al. (Schallhorn *et al.*, 1998) examined the sensitivity of topography to detect refractive surgery and found that even experienced observers exhibited only 77% sensitivity. Smolek et al. demonstrated a neural network for recognition of corneal topography patterns after myopic refractive surgery and claimed a sensitivity of 99.1%. Similar systems have been developed to detect early keratoconus and have proved very effective. It is likely that topography in combination with a proven neural network would provide a more suitable test for screening candidates but topography alone would be insufficient.

However, if a quick and reliable method was available for detecting reduced visual performance post-refractive surgery, it is debatable whether there would be a need to screen candidates for previous refractive surgery, as long as they met the visual standard.

Advice to candidates

It is possible that potential candidates may contact the CAA and express the wish to undergo surgery in order to meet the visual standards for commercial aviation. In such an event, the following points should be made clear:

1 The CAA takes no responsibility for the outcome of surgery and cannot guarantee, even after a supposedly uncomplicated procedure, that the applicant will have a good enough visual outcome to achieve medical certification. In a small proportion of cases, a PRK or LASIK procedure will result in a complication such as epithelial ingrowth or decentration of the ablation. If well managed by the surgeon, such complications are considered minor and of little visual significance to the average patient. However, those involved in visually demanding occupations, may find such complications more problematic. It should be

noted that it is not routine procedure for refractive surgeons to analyse visual symptoms other than a loss in high contrast acuity.

2 It is the responsibility of the potential applicant to choose an experienced surgeon who uses the most up to date technology, in order to increase the chances of a good outcome. The development of aberration-reducing technology is likely to decrease the risk of night vision problems.

3 Those with pupils over 6mm are at a high risk of suffering night problems. An ablation with a large optic zone is essential for all prospective pilots but individuals with 6.5mm pupils should avoid laser treatment until technological advances have occurred.

4 Patients will still need to wear spectacles for reading once they reach presbyopia. Some surgeons advocate monovision (one eye is left slightly under-corrected), but this is not considered suitable for occupations such as aviation, in which depth perception and optic flow are important.

5 Most refractive surgeons suggest that myopia below –4.00D can be treated either with PRK or LASIK, myopia between –4.00 and –10.00D is treated with LASIK and astigmatism up to about 4.00DC can be corrected using either technique. At this point in time, the treatment of hyperopia is experimental and further work is required to improve the laser nomograms. PRK and LASIK have good predictability and accuracy for the ranges stated and the risk of compromising visual performance is small. The upper limit of myopic treatments varies from patient to patient – those with thicker corneas will be able to have a large enough optic zone to prevent night problems. Those with thin corneas will have to accept a compromise and choose between partial correction or a small optic zone.

Glossary of Terms

Aberrations: a deviation in power of the optical components of the eye, (either individually or in combination), from the ideal system that would produce a perfect point image on the retina. Low order aberrations include spherical defocus and astigmatism, both of which can be corrected with spectacles. Higher order aberrations include spherical aberration and coma, which are found to a degree in all eyes and can not be corrected with spectacles. Spherical aberration results in light rays that pass through the peripheral pupil focussing at a point either in front (positive) or behind (negative) the focal point of the axial and paraxial rays. Coma results in peripheral rays focussing at a point laterally displaced from the focal point of the paraxial rays, due to alterations in refractive power of the eye across the pupil. Aberrations have the effect of reducing retinal image contrast and hence visual performance. Both spherical aberration and coma increase with increasing pupil size. The aberrations induced by refractive surgery are best described as irregular aberrations but some studies tend to refer to them as being most similar to spherical aberration and coma.

Accuracy: generally defined as the percentage of patients whose post-operative refractive error falls within +/–1.00D of emmetropia at a point in time.

ACAS: Airborne Collision Avoidance System

ANOVA: Analysis of Variance (statistical technique).

ALK: Automated Lamellar Keratectomy involves the use of a microkeratome to cut a cap of corneal tissue and reshape it to treat myopia.

Astigmatism: the optics of the eye (cornea and lens) are stronger in one meridian than the other, leading to distortion of the retinal image.

Back scatter: the scattering of light by particles within the ocular media in the direction of the observer. Back scatter allows the observation of opacities such as stromal haze within the ocular media, but is only weakly related to forward light scatter and visual performance.

Best Corrected Visual Acuity (BCVA): the vision obtained when any residual refractive error is corrected. Loss of 2 or more lines of BCVA is considered significant following refractive surgery.

Blur circle: the blurred retinal image of a point object formed as a result of spherical refractive error

CAA: Civil Aviation Authority

Contrast Sensitivity: the lowest contrast at which a particular spatial frequency can be resolved. The peak of the average contrast sensitivity function falls between 2 and 5 cycles per degree.

Corneal asphericity: the cornea has a prolate shape, (ellipse which is steeper centrally and flattens in the periphery). Corneal refractive surgery tends to produce an oblate cornea (flatter centrally than peripherally), resulting in an increase in positive spherical aberration.

Corneal melt: a rare condition resulting in destruction of a region of corneal tissue, which may lead to perforation. It has been known to occur following LASIK surgery when epithelial cells and debris become trapped beneath the corneal flap. The processes are thought to be immune-related.

CRT: Cathode ray tube

Forward scatter: the scattering of light by particles within the ocular media in the direction of the retina. Forward light scatter reduces the contrast of the retinal image and hence reduces visual performance.

GPWS: Ground Proximity Warning System

Hypermetropia (hyperopia or long-sight): the optics of the eye are too weak for the axial length of the eyeball, resulting in the image focussing behind the retina and therefore leading to a blurred retinal image. Distance vision can be good if enough accommodation is available to overcome the refractive error but near vision tends to be less clear.

JAA: Joint Aviation Authorities of Europe

Illuminance: the quantity of light reaching a surface measured in lux. Retinal illuminance (intensity of light reaching the retina) is also dependent on pupil size.

Keratectasia: thinning of the cornea resulting in distortion and the development of significant irregular astigmatism. The condition tends to be progressive and often requires a corneal graft to restore reasonable visual quality. Ectasia can be caused by LASIK surgery if too much corneal tissue is removed.

Laser Assisted In-Situ Keratomileusis (LASIK): a thin flap of corneal tissue is cut using a microkeratome and reflected back. The underlying stroma is ablated using an excimer laser to treat refractive error and the flap is repositioned.

LCD: Liquid Crystal Display

LogMAR: logarithm of the minimum angle of resolution

Luminance: the quantity of light emitted by a source/surface per unit area, (dependent on the light incident on the surface and the reflective properties of the surface). Luminance is measured in candelas per metre squared (cd/m^2)

Mesopic range: range of low light levels over which both the cones and rods function. The limits of the mesopic range vary between individuals.

MSE: mean spherical error – average spherical refractive error taking into account half the astigmatic component where present.

Modulation Transfer Function (MTF): the ratio of the image to object contrast over a range of spatial frequencies and therefore a measure of the optical quality of a system. In the eye, the MTF can be assessed by measuring the contrast sensitivity function.

Myopia (short-sight): the optics of the eye are too strong for the axial length of the eyeball, resulting in the image focussing in front of the retina and therefore leading to a blurred retinal image. Distance vision is blurred but near vision generally remains good within a particular range.

Optic Flow: the perception of peripheral motion emanating from a central point, which helps to determine the direction of heading of the individual. Optic flow is thought to be important in depth perception and motion perception.

PERK: Prospective Evaluation of Radial Keratotomy – extensive study undertaken in the USA in the 1980's to examine radial keratotomy.

Photopic range: in use under the majority of lighting conditions. Cone function predominates allowing good visual acuity and colour discrimination.

Photorefractive Keratectomy (PRK): following removal of the corneal epithelium, the underlying stroma is ablated using an excimer laser to reshape the surface to treat refractive error. The epithelium regrows across the treated zone within 5–7 days.

Predictability: generally defined as the percentage of patients achieving 6/12 Snellen vision or better at a point in time (uncorrected).

Presbyopia: reduced near function requiring the need for reading glasses to overcome the reduction of accommodation with age. Accommodation tends to reach a critical level (<4.00D) about the age of 45 years.

Radial Keratotomy (RK): a micrometer diamond blade is used to make radial incisions through 95% of the corneal thickness, causing weakening and therefore steepening of the peripheral cornea and hence flattening of the central cornea. This results in a reduction in myopia.

Staircase procedure: a experimental procedure for determining threshold. For example, if the parameter is size, the size of the target may be reduced until the target can no longer be detected. The size is then increased until the target is just seen and the procedure repeated a set number of times to obtain threshold. The step size is usually set to reduce with each reversal.

Stiles-Crawford Effect: rays of light entering the eye obliquely are less effective as stimuli than those entering the pupil centrally. This effect has been explained by the orientation of the cone receptors towards the centre of the pupil giving the cones directional sensitivity. This results in cones being less sensitive to scattered light since they do not detect light rays approaching from an oblique angle. Rod receptors exhibit no such effect and therefore are more susceptible to scattered light.

Suprathreshold tests: the subject is presented with targets above the threshold for detection and asked to perform a particular task, such as resolving detail within the object.

Wavefront error: the difference between the ideal wavefront leading to a perfect point image and the actual wavefront leaving the eye. Analysis of the differences allows assessment of the aberrations of the system.

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