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Defence R&D Canada – Toronto
Technical Report
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Canada

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Abstract

Excellent high contrast visual acuity results are achieved after laser refractive eye surgery for low to moderate refractive errors. In the early 1990's, many reports showed a decrease in low contrast acuity after laser surgery. Military aircrew work in many different arenas and have identified situations involving low light and low contrast as being the most visually demanding. Postoperative low contrast acuity has improved with newer laser techniques but there was still concern that vision after laser eye surgery would be not good enough for military aircrew demands. This report was designed to assess the post-laser vision of non-pilot aircrew; measuring both the standard high contrast acuity and low contrast vision with and without glare. This report provides a statistical analysis of contrast sensitivity visual results after laser in situ keratomileusis (LASIK) and reports on the results of a questionnaire designed to assess possible postoperative subjective visual problems. Testing was done on the Stereo Optical Functional Acuity Contrast Test (FACT) at a low light level, with and without glare, and at standard photopic light level. The aircrew subjects who underwent LASIK performed significantly better than matched control subjects on the FACT at all light levels when measured at both 6 and 18 months post-operatively. There was no significant difference between the LASIK group and their controls when tested undilated on the Precision Vision Logarithmic Contrast Sensitivity Charts at 6 months post-operatively. The aircrew at 6 months post-laser performed significantly worse than the control group when each group was dilated with Tropicamide 1%. By 18 months post-LASIK, there was no longer any difference between the LASIK group and their controls on the low contrast letter charts, either dilated or undilated. There was no difference found between the LASIK and control groups on a questionnaire asking about dry eye symptoms, difficulties in low light situations, or with glare. This report lends itself to the recommendation that the CF continue to allow non-pilot aircrew to undergo laser refractive eye surgery and allow them to return to flying duties following satisfactory post-operative visual examination.

R□sum□

La chirurgie oculaire réfractive au laser visant à corriger des vices de réfraction légers ou modérés permet d'obtenir d'excellents résultats sur le plan de l'acuité visuelle à contraste élevé. De nombreux rapports datant du début des années 1990 faisaient état d'une baisse de l'acuité à faible contraste après une chirurgie au laser. Le personnel navigant militaire, qui travaille dans de nombreux contextes différents, a déterminé que les situations les plus exigeantes sur le plan visuel sont celles où la luminance et le contraste sont faibles. Les techniques laser plus récentes ont permis d'améliorer l'acuité à faible contraste, mais on craignait toujours que la vision après une chirurgie oculaire au laser ne réponde pas aux exigences imposées au personnel navigant militaire. Ce rapport visait à évaluer la vision du personnel navigant autre que les pilotes après une chirurgie au laser en mesurant à la fois l'acuité à contraste élevé standard et l'acuité à faible contraste avec et sans éblouissement. Ce rapport présente une analyse statistique de la sensibilité au contraste après une kératomileusie in-situ au laser (LASIK) ainsi que les résultats d'un questionnaire visant à évaluer les problèmes visuels subjectifs pouvant survenir à la suite de l'opération. Les tests ont été faits

au moyen du Functional Acuity Contrast Test (FACT) de Stereo Optical à un niveau de luminance faible, avec et sans éblouissement, et à un niveau de luminance standard. Les sujets membres du personnel navigant qui avaient subi la LASIK ont obtenu au FACT de bien meilleurs résultats, mesurés à 6 mois et à 18 mois après l'opération et à tous les niveaux de luminance, que les sujets témoins auxquels ils avaient été appariés. Aucune différence significative n'a été observée entre les sujets du groupe LASIK et ceux du groupe témoin au test des échelles de sensibilité au contraste à notation logarithmique de Precision Vision subi sans dilatation à 6 mois après l'opération. Le personnel navigant a obtenu des résultats significativement inférieurs à ceux du groupe témoin au test subi 6 mois après l'opération avec dilatation au tropicamide 1 %. À 18 mois après la LASIK, il n'y avait plus aucune différence entre le groupe LASIK et le groupe témoin aux échelles de lettres à faible contraste subi avec ou sans dilatation. Un questionnaire portant sur les symptômes de l'œil sec et sur les difficultés liées aux situations à faible luminance ou aux éblouissements n'a révélé aucune différence entre le groupe LASIK et le groupe témoin. Les auteurs de ce rapport recommandent que les FC continue de permettre au personnel navigant, autre que les pilotes, à subir la chirurgie oculaire réfractive au laser et à leur permettre de résumer leurs fonctions de vol après avoir passé avec succès un examen visuel post-opératoire.

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Executive summary

Laser eye surgery has been shown to correct low to moderate refractive errors with excellent results and long term stability. In Canadian civilian aviation, both Photorefractive Keratectomy (PRK) and Laser in situ keratomileusis (LASIK) have been approved for all classes of licenses providing the clinical outcome is satisfactory and minimum visual requirements are met. In the military, aircrews have more demanding visual requirements, making the decision to allow LRES in military aircrew more difficult. Measurements of contrast sensitivity are more sensitive to changes following laser eye surgery than are the standard high contrast Snellen visual acuity measurements. This report was intended to provide a statistical analysis of ophthalmologic data measuring contrast sensitivity following laser eye surgery (all LASIK) in Canadian non-pilot aircrew. Both the Stereo Optical Functional Acuity Contrast Tests using sine wave patches, the Precision Vision low contrast sensitivity letter charts and a questionnaire were used to compare the contrast sensitivity between a group of aircrew at 6 and 18 months post LASIK to a group of controls. The Ophthalmologist or the Ophthalmic Assistant did all testing at DRDC Toronto. The aircrew subjects who underwent LASIK performed significantly better than matched control subjects when measured on the sine wave tests at both 6 and 18 month post-operatively. On the letter charts, there was no significant difference between the LASIK group at 6 months postop and their controls when tested undilated. The 6-month LASIK subjects did perform significantly worse than the control group when each group was dilated with Tropicamide 1% drops. By 18 months post-operatively, there was no longer any significant difference on letter charts between the LASIK group and their controls whether dilated or undilated. There was no difference found between the two groups on the questionnaire, which asked about dry eye symptoms and difficulties in low light or with glare. This report lends itself to the recommendation that non-pilot aircrew continue to be allowed to undergo laser refractive eye surgery.

Hinton, P., Niall, K., Wainberg, D., Bateman, B., Courchesne, C., Gray, G., Quick, G., Thatcher, B., 2004. A longitudinal study on the effects of laser refractive eye surgery in military aircrew TR 2005-084. Defence R&D Canada - Toronto.

Sommaire

Il a été établi que la chirurgie oculaire au laser donne d'excellents résultats et assure une stabilité à long terme dans la correction des vices de réfraction faibles ou modérés. Dans l'aviation civile canadienne, la kératectomie photoréfractive (PRK) et la kératomileusie in-situ au laser (LASIK) ont été approuvées pour toutes les classes de licences à condition que les résultats cliniques soient satisfaisants et que les exigences visuelles minimales soient respectées. Comme le secteur militaire impose des exigences visuelles plus strictes à son personnel navigant, il lui est plus difficile d'autoriser la chirurgie oculaire réfractive au laser. Les mesures de la sensibilité au contraste sont plus vulnérables aux changements qui suivent une chirurgie oculaire au laser que les mesures standard de l'acuité visuelle à contraste élevé de l'échelle de Snellen. Ce rapport visait à faire une analyse statistique des données ophthalmologiques mesurant la sensibilité au contraste à la suite d'une chirurgie oculaire au laser (LASIK dans la totalité des cas) chez le personnel navigant autre que les pilotes au Canada. Le Functional Acuity Contrast Test (FACT) de Stereo Optical faisant appel à des grilles d'ondes sinusoïdales, les échelles de lettres à faible contraste de Precision Vision et un questionnaire ont été utilisés pour comparer la sensibilité au contraste entre un groupe formé de personnel navigant à 6 mois et à 18 mois après le LASIK et un groupe témoin. Tous les tests ont été effectués à RDDC Toronto par l'ophthalmologiste ou son assistant. Les sujets membres du personnel navigant qui ont subi la LASIK ont obtenu des résultats largement supérieurs à ceux du groupe témoin auxquels ils avaient été appariés aux grilles d'ondes sinusoïdales à 6 mois et à 18 mois après l'opération. Aucune différence significative n'a été observée entre le groupe LASIK à 6 mois après l'opération et le groupe témoin au test des échelles de lettres effectué sans dilatation. Le groupe LASIK a effectivement obtenu des résultats significativement inférieurs à ceux du groupe témoin au test subi 6 mois après l'opération avec dilatation au tropicamide 1 %. À 18 mois après l'opération, il n'y avait plus aucune différence significative entre le groupe LASIK et le groupe témoin à l'échelle des lettres subie avec ou sans dilatation. Un questionnaire portant sur les symptômes de l'œil sec et sur les difficultés liées aux situations à faible luminance ou aux éblouissements n'a révélé aucune différence entre les deux groupes. Les auteurs de ce rapport recommandent que le personnel navigant autre que les pilotes puisse continuer à subir la chirurgie oculaire réfractive au laser.

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Introduction

Laser Refractive Eye Surgery

Laser Refractive Eye Surgery (LRES) has been shown to correct low to moderate refractive errors with excellent results and long-term stability. At the time of this study, the two most successful Laser Refractive Eye Surgery techniques were Photorefractive Keratectomy (PRK), where the corneal epithelium is removed and the sub-epithelial cornea is reshaped by photo-ablation using an excimer laser, and Laser in situ Keratomileusis (LASIK), which combines the lifting of a corneal flap, then reshaping the cornea with the excimer laser, and replacement of the flap.

By 1999, Transport Canada [1] had approved PRK and LASIK for all classes of licenses in Civilian Aviation, provided that the clinical outcome was satisfactory and that minimum visual requirements were met post-operatively. The Canadian Forces were slower to allow LRES in aircrew because military flying is subject to vastly different environmental stresses. Care needed to be taken to ensure post-LRES vision met a high standard and that the rates of complications were sufficiently low. By 1999, the Canadian Forces [2] allowed LRES only in non-aircrew Military Occupational Categories (MOCs) and in some specific non safety-sensitive aircrew MOCs such as Flight Attendant and Flight Stewart. In July 1999, following a conference of the Central Medical Board regarding laser eye surgery at DRDC Toronto, both PRK and LASIK were approved by the Chief of the Air Staff [3] for entry into all non-pilot aircrew MOCs. This was contingent on certain minimum visual requirements being met post-operatively. Additionally, DRDC was to coordinate a longitudinal study to provide follow-up data of non-pilot aircrew candidates who had undergone LRES (Chief of the Air Staff, 1999) [4]. LRES continued to be disqualifying for either entry into or retention in the pilot MOC.

Contrast Sensitivity

Visual acuity (VA), measured with high contrast Snellen-type charts, has remained the gold standard for assessing visual function since 1862. This is the oldest and most widely used method of testing visual function and population norms are well established. High contrast VA continues to be used to screen applicants in professions requiring keen eyesight. This measure does not provide much information about visual function in low contrast conditions such as flying in clouds or at dusk, which are common military scenarios. Contrast Sensitivity (CS) measures the ability to see details at low contrast levels. As shown in a study by Montes-Mico & Chapman [5], even those who achieved excellent scores on high contrast vision charts can demonstrate a clear disruption of low contrast vision. Many others authors agree that CS testing provides a more comprehensive evaluation of visual function than high contrast visual acuity. Grimson, Schallhorn et al [6] discussed how CS abilities relate directly to complex visual tasks, such as detecting approaching aircraft and identifying tanks and human forms against complex backgrounds. There are many studies looking at the effect of LRES on contrast sensitivity. A comparison of these studies is difficult because of disparities between patient characteristics, the type of lasers and surgical techniques. Reports have shown the

whole spectrum of results, including a loss, no change or improvement of contrast sensitivity following refractive surgery.

Report Rational and Objectives

In January of 2001, the Medical Assessment and Training Section (MAT) section at DRDC Toronto undertook a study to investigate changes in vision following refractive surgery in Canadian aircrew. The purpose of this study was two-fold. First, to compare the standard visual acuity and contrast acuity achieved in post LRES aircrew to a control group who did not have LRES and second to assess the effect of LRES on contrast sensitivity over time. The results of these analyses would contribute to Canadian Forces policy on LRES among Canadian aircrew.

Methods and Findings

Methods

2.1.1 Participants

All Canadian non-pilot aircrew and those seeking entrance into non-pilot MOCs who underwent LRES as of January 2001 were required to participate in this study.

Military aircrew wishing LRES chose their own surgeon, decided on the type of refractive procedure (LASIK or PRK), and paid for the procedure themselves. Military policy limited pre-operative spherical equivalent (SE) refractive errors to less than -7.00 Diopters (D) of myopia, or less than +3.50 D of hyperopia with less than 3.50 D of astigmatism. Subjects were warned that there was a small risk of losing best corrected vision (BCV) after LRES and that they must meet aircrew standards of BCV of 6/6 in one eye and at least 6/9 in the other eye to continue as aircrew.

Between May of 2001 and December 2003, 61 eyes of 31 subjects (25 male and 6 female) who underwent LASIK and 8 eyes of 4 subjects (all male) who underwent PRK were examined. Pre-operatively all LRES subjects had healthy eyes and were myopic (average pre-op SE of –3.28 D. with a range from –1.00D to –6.00D) with astigmatic errors ranging from 0 to 2.50 D. To facilitate comparison, 87 eyes of 48 control subjects (24 male and 24 female) were also examined. Every LRES eye that was not assessed pre-operatively at DRDC was matched to a control eye, which was within one Diopter of the preoperative refraction. Control subjects were recruited from the civilian and military population at DRDC Toronto and compensated as per DRDC Stress Allowance Guidelines. LRES subjects compensated as per Canadian Forces standards for a member traveling for specialist medical services. DRDC Toronto's Human Research Ethics Committee (HREC) approved the protocol and informed consent was obtained from all subjects. Informed consent was obtained from all subjects. Results from each examination were recorded onto a hardcopy (paper) file. These results were then entered into a computer database with a "Subject Identification Number" assigned to each participant. The only demographic variables entered into the database were sex and

age. Thus, confidentiality was assured since it was impossible to link the computer record to any participant's identity given the lack of access to the original hardcopy files.

2.1.2 Experimental Tests

There are many clinical tests for contrast sensitivity but no one test is recognized as the gold standard. The two tests chosen for this study were the Stereo Optical Functional Acuity Test (FACT) developed by Dr Ginsberg [7] and the Precision Vision Logarithmic Contrast Sensitivity Charts (LCSC). These tests were chosen because they were representative of two common CS testing techniques and testing was done at different distances. The FACT sine waves patches were tested at near and the Logarithmic CS letter charts were tested at 6 meters.

The FACT uses sine waves of different spatial frequencies at varying levels of intensity to measure contrast sensitivity. Ginsberg [7] considers sine wave gratings to allow more sensitive testing of CS. The sine wave gratings (FACT) better segregate the effects of acuity (i.e. object discernment) from CS measurement. Spatial frequency is inversely related to the width of the sine wave bars. Low spatial frequencies produce thicker bars, while high spatial frequencies produce thinner bars. Any image can be formed by a pattern of sine waves, where the low spatial frequencies make up the more coarse aspects of an image and the high spatial frequencies develop the finer details such as the edges. Contrast intensity levels vary from high where the bars are dark against the whiter background, to low where the bars are light and very faint against the background. A measure of sine waves of different frequencies and contrast levels provide a comprehensive measure of visual function.

The FACT involves viewing a row of patches of one-dimensional sine wave bars where the level of contrast is decreased in logarithmic steps from left to right. The lowest contrast level where the bars can be detected can be plotted over a range of spatial frequencies to assess CS.

The LCSC uses letter charts made at different levels of contrast to measure contrast sensitivity. The letters decrease in size in logarithmic steps. The number of letters correctly identified at each contrast level is used to measure CS.

A questionnaire was designed to subjectively assess the aircrews' post-LRES vision compared to non-lasered controls. Questions asked about problems with vision in low contrast situations. Questions were also asked about dry eye symptoms and increased glare sensitivity, which can also occur after LRES. The frequency of each symptom was graded on a 1 to 5 scale ranging from "never" (level 1) to "very often" (level 5).

2.1.3 Experimental Design

Originally, experimental subjects were all to have been examined pre-operatively at DRDC and then at 6 and 18 post-operatively. However, many subjects had undergone LRES before the protocol was established, and others were not recruited as aircrew until they had already undergone their LRES. Thus an insufficient number of subjects were examined preoperatively at DRDC. To provide preoperative comparison data, the preoperative refractive errors were obtained from the laser surgeons' records for every eye that was not seen prior to surgery.

This pre-op refraction was matched to a control eye with a similar refractive error, which had not undergone surgery. LRES subjects were not actually matched to a single control subject, but rather each of lasered eyes was matched to two control eyes. In some cases those eyes belonged to the same control subject, while in other cases they belonged to two separate controls. The power of the sphere and power of the cylinder of each control eyes were both within 1.00 D of the pre-operative LRES eye. The average pre-op spherical equivalent (SE) was –3.28 D for the lasered eyes and –3.32 D for the control eyes. The average preoperative astigmatic error was 0.88 D for the lasered eyes and 0.71 D for the controls. Every control subject underwent the same examination as the LRES subjects and this data was then used for comparison purposes. The comparison of experimental subjects to controls was limited in that control subjects were only examined once and therefore, their scores could not be compared over time.

All participants in this study received a complete military ophthalmologic assessment. This included many tests that were not directly pertinent to this study. Only tests directly related to visual acuity and contrast sensitivity were analyzed. Specifically, this included the FACT, the LCSC and the questionnaire results.

2.1.4 The Functional Acuity Contrast Test (FACT)

The FACT chart has 5 rows of sine-wave grating patches with the gratings either tilted 15 degrees to the right, 15 degrees to the left or straight up. The sine-wave grating size decreases from rows A to E. The corresponding spatial frequencies for rows A to E are 1.5 cycles per degree (cpd), 3 cpd, 6 cpd, 12 cpd and 18 cpd respectively. There are 9 numbered columns of patches across each row. The contrast step between each grating patch decreases by 0.15 log units from left to right. This contrast range exceeds the normal population range of contrast sensitivity

Testing was started on the right eye with the light set at a mesopic level (21.5 lux at the chart surface) in the viewing box. The testing distance was 18 inches. Montés-Micó & Charman [8] demonstrated that higher spatial frequencies (i.e. 6 and 12 cpd) are the most useful for assessing visual performance in patients who have undergone LRES; therefore only rows C, D and E (6, 12 and 18 cpd) were tested. This restriction also kept the testing time from being too long. The subject viewed each row from left to right and stated whether the gratings pointed to the LEFT, to the RIGHT or straight UP. If the gratings became too difficult to see, the subject was to say BLANK at that patch number. The subject was then instructed to continue, starting at the BLANK patch, and to guess at the orientation of the sine waves in each patch for the remainder of the row. This whole process was repeated in random order so that each row (C, D and E) was tested twice. The last correct patch before the BLANK was recorded as the functional level of contrast sensitivity in that row (i.e.C5). The number of the last correctly guessed patch, before two consecutive errors, was recorded as the physiological level of contrast sensitivity in that row (i.e. C7). The physiological level is a forced guessing test and less affected by subject motivation. This protocol was then repeated with the left eye at the mesopic light level. Subsequently, subjects were tested at a mesopic light level with a glare light shining from the temporal side and then again at a photopic light level (243 lux at the chart surface).

At the end of testing, the subject had mesopic, mesopic with glare and photopic CS scores for rows C, D and E for each eye. Then each score was converted to a CS equivalent using the FACT Contrast Sensitivity Value Conversion Table (See Table 1). Since each row was tested twice, the mean Contrast score of the two trials was calculated. This mean value was used for statistical analyses.

Table 1. *The Stereo Optical FACT Contrast Sensitivity Value Table*

FACT CONTRAST SENSITIVITY VALUES										
ROW	**CYCLES PER DEGREE**	**COLUMN**								
		1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***
A	1.5	7	9	13	18	25	36	50	71	100
B	3	10	15	20	29	40	57	80	114	160
C	6	12	16	23	33	45	64	90	128	180
D	12	8	11	15	22	30	43	60	85	120
E	18	4	6	8	12	17	23	33	46	65

Table 1: The Stereo Optical FACT Contrast Sensitivity Value Table.

The numbers above are the contrast values for each patch on the FACT chart. Identify the patch by row and column to find the contrast sensitivity value; for example the contrast sensitivity value for patch C4 is 33

2.1.5 The Precision Vision Logarithmic Contrast Sensitivity Charts (LCSC)

The Precision Vision logMAR (logarithm of minimum angle of resolution) Charts used in this study consist of 9 lines of 5 letters decreasing in size on a logarithmic scale. Subjects were tested at 4 levels of contrast: 95%, 5%, 2.5% and 1.25. The contrast values indicate the ratio of illumination between the letters and the white background. The small light box (cat No.914) was used to backlight the charts.

Testing was monocular with the right eye being tested first, with the best-corrected manifest refraction in place. Both eyes were then dilated and cyclopleged with one drop of 1% Tropicamide. After 20 minutes, a cycloplegic refraction was done and the testing was repeated with the best-corrected cycloplegic refraction in place. The testing distance was 3 meters. Subjects began on a line they could easily read on the 95% and 5% chart and on the top line on the 2.5% and 1.25% charts. They then progressed down the chart until the letters were no longer discernable. Subjects were encouraged to wait for a few seconds on a difficult line before giving up since the letters sometimes appear slowly. The number of letters read correctly was recorded as the last line on which at least 3 out of 5 letters were correctly

recognized, adding 1 for each correctly identified letters on the next line and subtracting 1 for any errors on previous lines. For statistical analysis, this was recorded as a log MAR score. Each log MAR score corresponds to a score of visual acuity on a typical Snellen vision chart (see Table 2).

Table 2. *Snellen Equivalent of LogMAR Scores*

LogMAR	SNELLEN ACUITY EQUIVALENT
1.00	20/200
0.90	20/160
0.80	20/125
0.70	20/100
0.60	20/80
0.50	20/63
0.40	20/50
0.30	20/40
0.20	20/32
0.10	20/25
0.00	20/20
-0.10	20/16
-0.20	20/13

Table 2: Snellen equivalent of Precision Vision Low Contrast Letter Charts logMAR scores.

2.1.6 The Questionnaire

The vision questionnaire was designed to assess the symptoms of dry eyes, glare and vision in low contrast situations. The dry eye questions asked about the frequency of burning or grittiness in the eyes, fluctuation of vision that clears with blinking, the need for lubricating eye drops and the experience of eyestrain. The questions about glare asked about the frequency of halos around lights at night, glare from instrument panels or computer screens and the need for sunglasses when outside. The questions about low contrast vision asked about seeing details at dusk, and reading in low light. One question asked about difficulty seeing the ball or puck in sports, and a final question asked about the need for corrective lenses. For each question, the subject had to grade the frequency of the symptoms on a scale from 1 never, 2 seldom, 3 sometimes, 4 often and 5 very often.

2.1.7 Limitations

The greatest limitation to this study was the inability to complete the examination of subjects as originally designed. Due to circumstantial factors such as subject availability, it was impossible for the ophthalmologist and ophthalmic assistant to examine every subject pre-operatively and at 6 and 18 months post-operatively. The lack of data at certain time periods limited the number of statistical comparisons that were possible and reduced the chance of detecting small changes.

Results

First, it is important to note that there were no surgical complications reported on the questionnaires sent to each operating surgeons and all LRES subjects corrected to 6/6 or better post-operatively. The remainder of the analyses concerned the contrast sensitivity and the questionnaire results.

2.2.1 Organization of Analyses

Although 4 subjects participating in this study chose the PRK procedure, for the purpose of consistency in the analyses, only subjects who chose LASIK were included in the analyses of variance (ANOVA).

The statistical analyses for both the FACT and the LCSC were broken up into three major components. Two mixed design ANOVAs were completed comparing the LASIK subjects to their matched control eyes. For the FACT, the between-subjects factor was LASIK versus control, and the two within-subjects factors were the 3 light levels and the 3 levels of spatial frequency. For the LCSC, LASIK versus control was the between-subjects factor, and the varying level of contrast was the within-subjects factor. Subjects who completed both a 6-month and 18-month examination were analyzed with repeated measures ANOVAs. For these analyses, a conservative Greenhouse-Geisser correction was applied to correct for non-homoscedasticity.

The first of the two mixed design analyses consisted of matched subjects who had completed the 6-month examination, and the second analysis consisted of matched subjects who had completed the 18-month examination. Inclusion in either of these two analyses was not contingent on completing both a 6 and 18-month examination. The third analysis was between subjects who had completed both the 6-month and 18- month exams to determine if there was any change in contrast sensitivity over time.

FACT Results

It was observed that the means of the FACT raw scores were tied to the variance, so that differences in means might actually be caused by changes in variability. For this reason, and also because the CS scores are already in logarithmic proportion, the logarithm of the raw

scores was taken after adding 1 to each score[1]. Taking the logarithm of the raw scores also returned a distribution of scores that was more nearly normal in distribution.

Matched controls vs. 6-month mixed design ANOVA

The CS scores for the 6-month group were significantly better than their matched controls on both the functional and physiological measures, as shown in Figure 1 [Functional – $F(1,80)=19.42$, MSe=0.62, $p<0.0001$; Physiological – $F(1,80)=23.65$, MSe=0.26, $p<0.00001$].

There was also a significant interaction of light level with group CS scores at the physiological level [$F(2,160)=4.038$, MSe=0.06, $p<0.05$]. Using Scheffe's post-hoc comparison, this interaction was found to be present at the mesopic light level, as shown in Figure 2. The log ratio at this light level was 0.26 [MS=0.04, $p<0.05$].

Matched controls vs. 18-month mixed design ANOVA

The CS scores for the 18-month group were also significantly better than that of their matched controls, on both for the functional and the physiological measures, as shown in Figure 3 [Functional – $F(1,72)=20.19$, MSe=0.43, $p<0.0001$; Physiological – $F(1,72)=10.92$, MSe=0.24, $p<0.01$].

6 vs. 18-month repeated measures ANOVA

No significant differences were found between the 6 and 18-month examination period for either the functional or physiological measure of CS on the FACT [Functional – $F(1,19)=0.23$, NS; Physiological – $F(1,19)=0.41$, NS]

[1] If 1was not added before taking the logarithm, scores of 0 on the FACT would return an undefined value

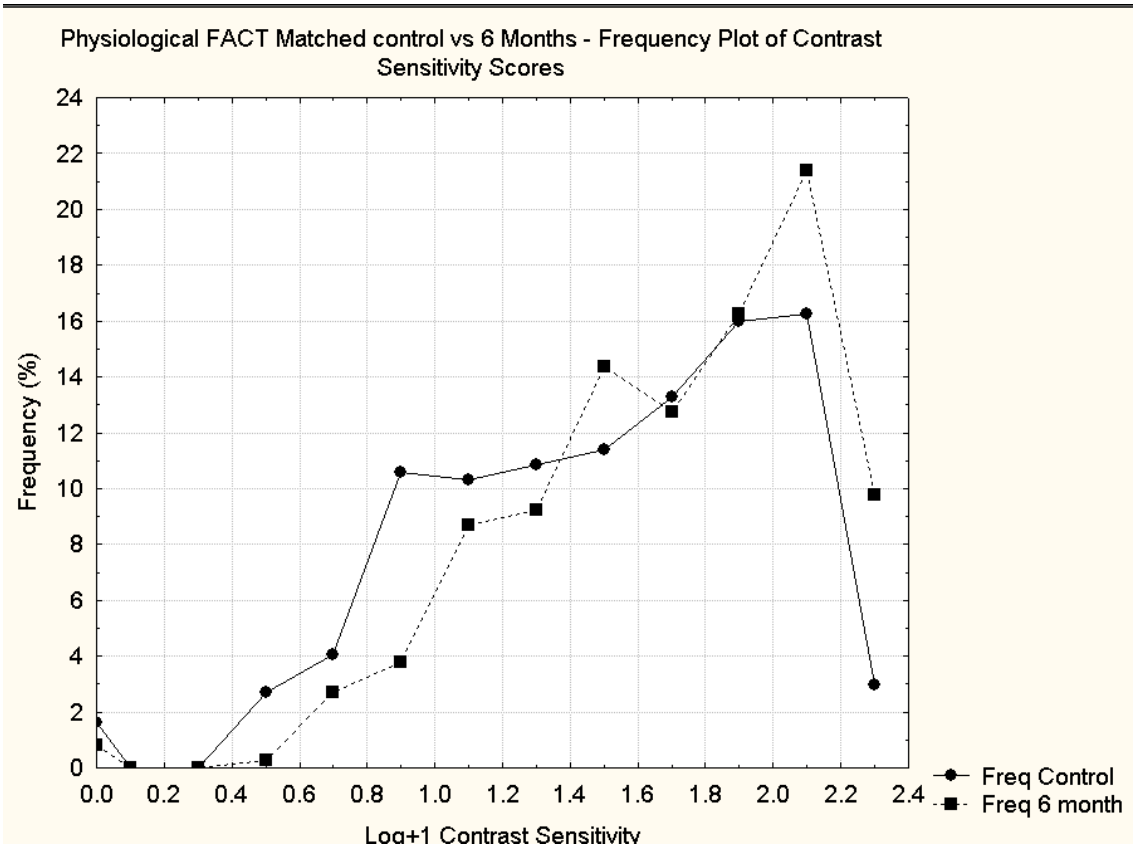

Figure 1. *Control vs. 6-Month Frequency Plot of FACT Contrast Sensitivity Scores*

This graph represents the percent frequency of physiological Log+1 contrast sensitivity scores of matched controls and LASIK subjects at 6 months on the FACT. A solid line with circular points denotes the control group and a dashed line with square points denotes the 6-month LASIK group. Note the greater percentage of LASIK subjects who scored near the higher range of the FACT. This shows a significant increase in contrast sensitivity at 6 months post-LASIK.

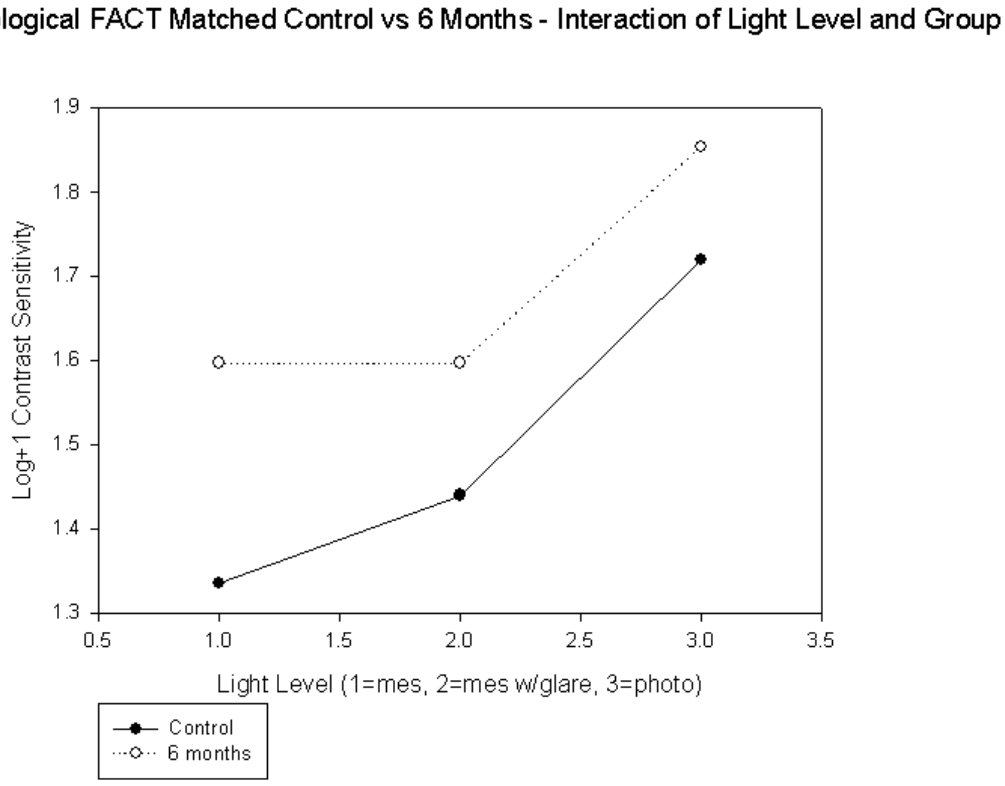

Figure 2. *Control vs. 6-month and Interaction of Light Level*

This graph represents the interaction of light level and group (matched controls vs. LASIK subjects at 6 months) Log+1 contrast sensitivity scores. A solid line with closed circles denotes the control group and a dotted line with open circles denotes the 6-month LASIK group. The 6-month LASIK subjects showed better contrast sensitivity than the controls at each light level. The difference was greatest at the mesopic light level (level 1).

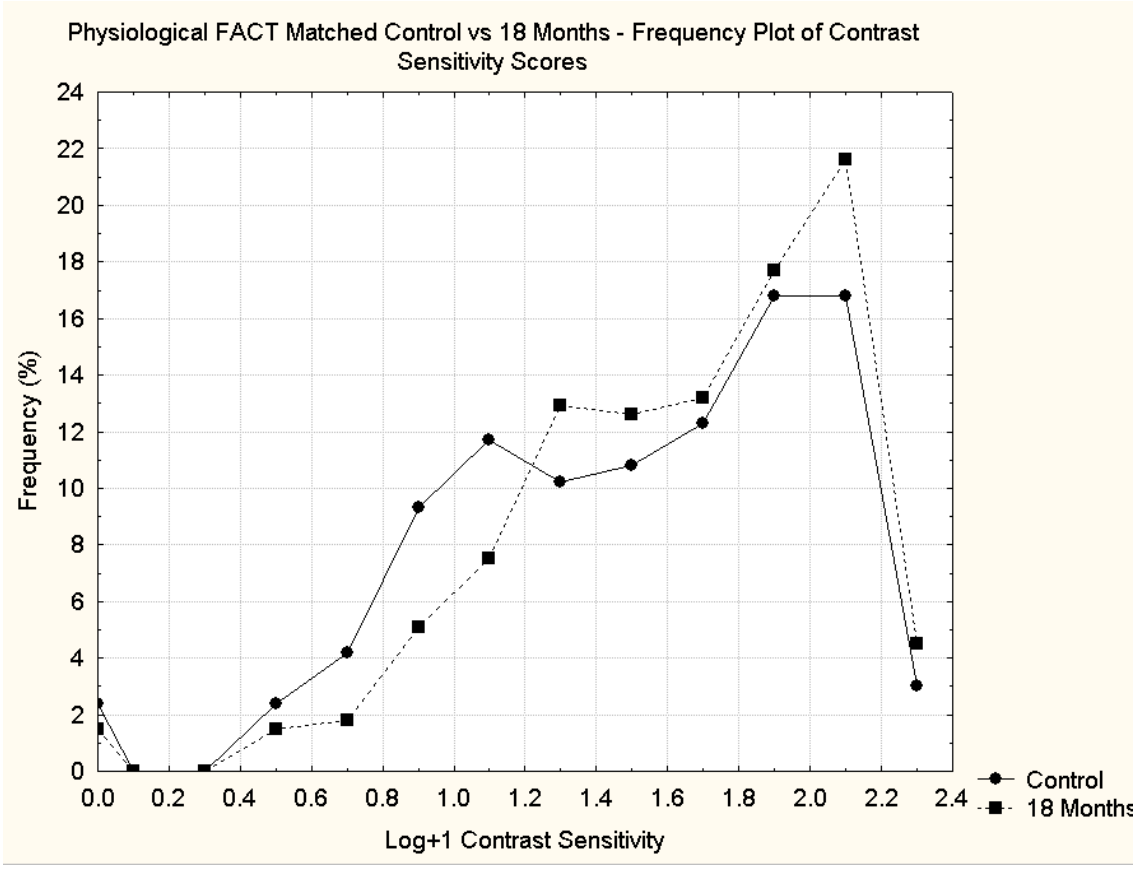

Figure 3. *Control vs.18-Month Frequency Plot of FACT Contrast Sensitivity Scores*

This graph represents the percent frequency of physiological Log+1 contrast sensitivity scores of matched controls and LASIK subjects at 18 months on the FACT. A solid line with circular points denotes the control group and a dashed line with square points denotes the 18-month LASIK group. Note the greater percentage of LASIK subjects who scored in the higher range of the FACT. This shows a significant increase in contrast sensitivity at 18 months post-LASIK. This graph is very similar to the controls vs. the 6-month group shown in figure 1.

LCSC Results

Although most subjects were tested at 4 levels of contrast – 95%, 5%, 2.5% and 1.25%, not all subjects were tested on the 5% chart and therefore the 5% level of contrast was not used in the analyses.

Matched controls vs. 6-month mixed design ANOVA

Mean logMAR scores of the 6-month LASIK group were not significantly different than controls for the non-dilated examination [F(1,80)=2.26, NS]. Scores for the 6-month group were an average of 0.05 logMAR units (2 letters) worse than the controls for the cycloplegic examination as shown in Figure 4. This difference was significant [F(1,80)=5.86, MSe=0.03, $p<0.05$].

Matched controls vs. 18-month mixed design ANOVA

At 18 months, there were no longer any significant differences on mean logMAR scores between experimental subjects and their matched controls for either the non-dilated or cycloplegic exam [Non-Dilated – F(1,72)=0.02, NS, Cycloplegic – F(1,72)=3.662, NS].

6 vs. 18-month repeated measures ANOVA

Mean scores of subjects at 18 months in the non-dilated condition were an average of 0.04 logMAR units (2 letters) better than at 6 months, as shown in Figure 5. This difference was statistically significant [F(1,20)=7.22, MSe=0.009, $p<0.05$]. Mean logMAR scores for the dilated exam improved only slightly, an average 0.02 logMAR units (1 letter), between the 6 and 18-month examinations [F(1,20)=2.44, NS]. This change was not significant.

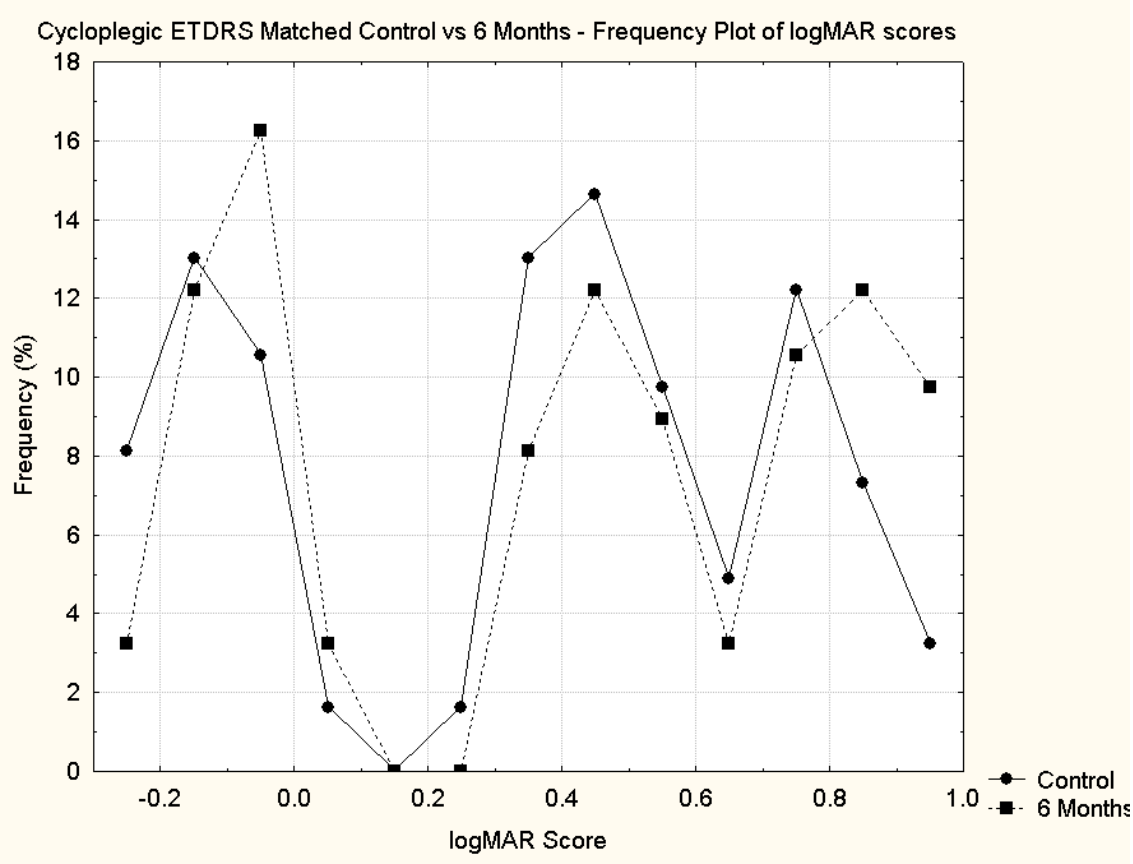

Figure 4. *Dilated Control vs. 6-month Frequency Plot of LogMAR Scores*

This graph represents the percent frequency of LogMAR scores of matched controls and LASIK subjects at 6 months on the Logarithmic Contrast Sensitivity Charts (LCSC). (These charts are referred to as EDTRS charts in the graph title). Both groups were dilated with Tropicamide 1%. A solid line with circular points denotes the control group and a dashed line with square points denotes the LASIK group. The first peak shows results from the 95% CS chart, the middle peak from the 2.5% CS chart and the third peak show the 1.25% CS results. Note the greater percentage of LASIK subjects who had scores approaching 1.0 (low CS). This shows a small but significant decrease in CS at 6 months post-LASIK. This difference had disappeared by 18 months post-LASIK.

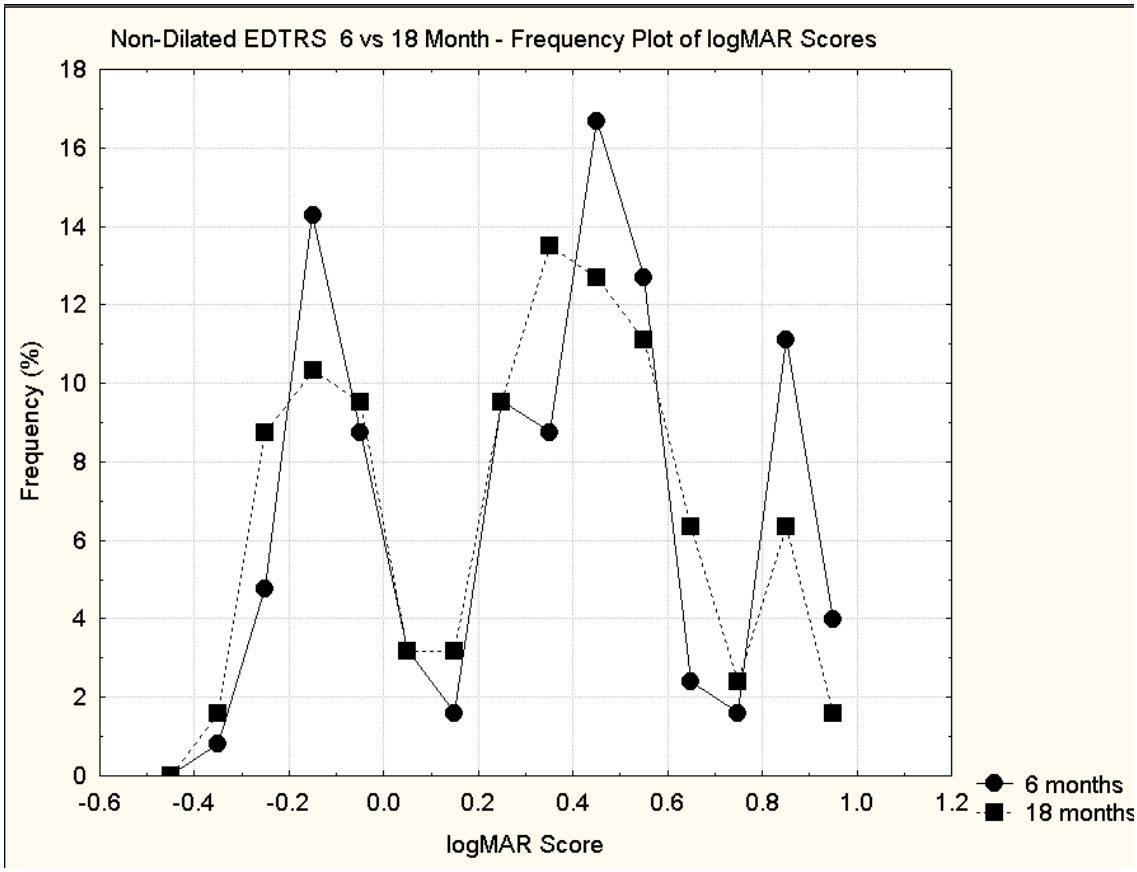

Figure 5. *Undilated 6 vs 18-Month Frequency Plot of LogMAR Scores*

This graph represents the percent frequency of LogMAR scores of undilated LASIK groups at 6 and 18 months on the LCSC (referred to as EDTRS charts in the graph title). A solid line with circular points denotes the 6-month LASIK group and a dashed line with square points denotes the 18-month LASIK group. The first peak shows results from the 95% CS chart, the middle peak from the 2.5% CS chart and the third peak show the 1.25% CS results. Note the 18-month LASIK group showed a slight shift towards higher visual acuities [logMAR (-0.3) – (-0.2)]. This shows a small but significant improvement in overall contrast sensitivity between 6 and 18 months post-LASIK.

Questionnaire results

There was a significant difference between the subjects and controls on the one question asking how frequently corrective lenses were needed. The controls obviously required corrective lenses “often” and the post LASIK subjects “never”. Otherwise there were no significant differences found between the post-LASIK subjects and controls results. The LASIK subjects were all aircrew who were coming off their temporary status and there have

been a reluctance to report any symptoms. Regardless of this possible bias, it was encouraging to find no differences between the controls and LASIK subjects on the questions concerning dry eye symptoms, or problems with glare or in low contrast situations.

2.3 Discussion

Laser eye surgery has proven to be an effective treatment for refractive errors in the civilian world. However, Canadian aircrew are subject to vastly different environmental stresses than the civilian population generally encounters. Therefore, care must be taken to ensure post-operative vision meets a high standard and that rates of complications are sufficiently low. This study was undertaken in order to contribute to the Canadian Forces policy on LRES. Clinical outcomes following LRES in this study were favourable, with no surgical complications reported. All aircrew eyes achieved a best-corrected vision of 6/6 or better post-LASIK.

At 6 months, the LASIK subjects performed significantly better than matched controls on the contrast grating test (FACT) at both the functional and physiological levels. This improvement was greatest at the mesopic light level, with less change at the mesopic light level without glare and the photopic light level. At 18 months, the LASIK group again achieved significantly better results than the control group on the FACT chart at both functional and physiological levels. This result was intuitive given the lack of change in the LASIK group between 6 and 18 months.

The FACT chart is tested at 18 inches, which could introduce a presbyopic bias if there was any difference in age between the groups. The average age of the control group was 33.2 years (SD 1.2 years), the 6-month group had an average age of 33.4years (SD 1.5 years) and the 18-month group had an average of 34.2 years (SD 1.5 years). There was no significant difference in age between these groups.

Previous studies assessing post-laser CS have shown variable results. A study by Montes-Mico [9] demonstrated no loss of photopic CS at 6 months post-LASIK in a group of moderate myopes, but found a significant loss of mesopic CS at high spatial frequencies (12 and 18 c/deg) at 6 months post-op. Conversely, Hoffman et al [10] reported an improvement in mesopic CS (3cd/m2) at 1, 3 and 6 months in 40 patients with preoperative refractions between +2.5 and -13.00 D. Our study also showed an improvement in post-LASIK contrast sensitivity on the FACT charts and somewhat surprisingly, this improvement was most significant at mesopic light levels (21.5 lux). As military aircrew may have to read charts in dimly lit conditions, this finding of better CS in low light was encouraging.

On the 2.5% and 1.25% Logarithmic Contrast Sensitivity Charts used in this study, the 6-month LASIK group did not perform as well as their controls in either the non-dilated or dilated state. While the non-dilated difference was not significant, the decrease in CS levels in the dilated LASIK group was significant.

By 18 months, contrast sensitivity had improved in the LASIK group on the LCSC. There was a small improvement in the LASIK subjects' undilated results and a significant 1-letter

improvement found between the dilated 6 and 18-month LASIK groups ($p<0.05$). By 18 months there was no longer any significant difference in CS noted between the LASIK and their controls, either dilated or undilated. It is impossible to say if this small improvement in the LASIK group was due to a learning effect, as the LASIK group had been tested twice and the control group only once.

Oshika et al [11] showed that an increase in pupil size causes an increase in higher order spherical aberrations and that the LASIK procedure itself can increase higher order aberrations. A dilated pupil would make any postoperative increase in optical aberrations more significant. Larger pupils are associated with increased visual disturbances post LASIK as shown by Chalita, Chavala et al [12]. All the LASIK subjects in this study were treated in 2000 or later with the newer generation lasers using large surgical optical zones. When widely dilated with drops however, the pupil margin could still open beyond the inner edge of the surgical optical zone causing some visual aberration. All these factors could explain why there was a significant decrease in contrast sensitivity at 6 months post-LASIK when the subjects were dilated, while the slight decrease in CS when undilated was not significant.

The best level of contrast for testing on letter charts is controversial. Our use of only the 2.5% and 1.25% low CS letter charts may be limited as testing variability is higher at very low contrast levels. Unfortunately our 5% CS data would not be analyzed, as not all experimental subjects were tested on this chart.

Most reports show a decrease in contrast sensitivity in the early post-op period, followed by a relatively rapid recovery. In 2001, Montes-Mico and Charman [5] found a loss of contrast sensitivity across a broad spectrum of spatial frequencies at 1 month postoperative that returned to preoperative levels at 6 and 12 months. In 2002, Chan et al [13] found that CS was decreased over a broad range (0.3 to 20.5 cpd) at 1 week. 1,3, and 6 months postoperative and had returned to baseline at 1 year post-op. As all aircrew are grounded for 6 months post LRES, the earliest testing in our study was done at 6 months postoperative when the temporary flying restriction could be lifted. By 6 months, subjects were performing better on the FACT charts and showed no significant difference on the letter charts except when dilated with drops. As aircrews are not pharmacologically dilated, it seems reasonable to continue the policy of return to flying at 6 months. This study did not address the question of whether aircrew could return to flying earlier than 6 months after laser correction.

By 18 months the LASIK subjects were unchanged from controls on the LCSC and were still performing better on the FACT charts. Over all there was no change over the year, except for a small improvement on the LCSC charts. This is not surprising given the well documented rapid recovery times, and stability following LASIK surgery.

In the study by Chan et al [13] the reduction in CS was greater for higher amounts of myopia. Other studies confirm this trend of the higher loss of CS showing in patients with higher pre-op refractive errors. Nakamura and assoc [14] found a loss of CS following LASIK that normalized by the third postoperative month in eyes with less than 6 D of myopia. However, patients with greater than 6 D of myopia had a persistent decrease in intermediate and low contrast visual acuity at all post-op visits. However, not all studies find this loss of CS in higher myopes. Mutyala and colleagues [16] found that LASIK had very little effect on CS in myopes between –1.25 and –13.75 D by 3 months postoperative. Our subjects were all

moderate myopes with an average pre-op SE of –3.28 Diopters. The limiting of pre-operative refractive errors was a factor in explaining our good results.

There were an insufficient number of PRK eyes for analysis as only four subjects chose PRK over LASIK. As reported by Ninomiya et al [17], most recent studies show no difference in visual acuity or contrast sensitivity results between PRK and LASIK. Although not addressed in this study, the literature suggests that aircrew can chose the type of refractive procedure according to their personal preference, their vocational demands and their surgeon's advice.

Refractive surgery techniques are constantly improving. Presently, wavefront guided (WFG) and other custom laser techniques can correct higher order optical aberrations, producing even better postoperative results. Mrochen and assoc [18] found that WFG LASIK improved low contrast vision by at least 1 line in 25.8% of patients at 3 months postop. More recently Kaiserman et al [19] demonstrated an 88% improvement in contrast acuity in a WFG LASIK group compared to a 40% improvement in a standard LASIK group at one month postop. These studies support the theory that decreases in contrast acuity after LASIK can result from laser-induced increases in higher order optical aberrations and that postoperative contrast sensitivity can be improved by wavefront and other custom laser technology.

The post LASIK questionnaire did not identify any increased incidence of dry eye symptoms; glare problems or difficulty in real life mesopic conditions. As the LASIK subjects were all aircrew coming off their restricted category, there may have been a reluctance to report any symptoms. Regardless of this possible bias, it was encouraging to find no symptomatic differences between the controls and LASIK subjects.

3.0 Conclusions

The safety of laser refractive eye surgery was not an issue in this study. Results of analyses showed that those who had undergone LASIK scored significantly better than matched control subjects on the FACT in low light with and without glare and at a standard photopic light level. There was a decrease in post LASIK contrast sensitivity on the low contrast letter charts at 6 months, but this decrease was significant only when the eyes were dilated. Between 6 and 18 months there was a significant improvement on the low contrast letter charts in dilated LASIK group, and by 18 months there was no longer any difference between the LASIK group and their matched controls whether dilated or undilated. There was no change in symptoms of dry eye, glare or mesopic vision between the LASIK subjects and their controls. On average, it is safe to conclude that the contrast sensitivity of those who had undergone LASIK was the same or better than similar persons who have not undergone the procedure. Providing pre-operative refractive limits are set and that post-operative vision meets military standards, this report lends itself to the conclusion that non-pilot military aircrew can continue to undergo laser refractive eye surgery

Caution must be taken before allowing LASIK in pilots. There is concern about LASIK flap stability in ejection from high performance aircraft. Further study is needed but it is likely that PRK, with or without WFG, will be the refractive procedure of choice for military pilots.

4.0 Recommendations

For further studies, a greater effort should be made to assess more subjects pre-operatively. Examining subjects before and after treatment would increase the power of the analyses and the credibility of the design. If pre-op assessment is impossible, then the matched controls should be re-examined at the same intervals as the laser subjects. This would facilitate the detection of any learning effects that might exist due to repeat testing.

Contrast sensitivity is an important measure of visual function and hopefully standardized testing with well established norms will be developed soon. Ideally, future military experiments would assess visual performance based on actual aircrew visual tasks. These tasks could be simulated or be carried out in the field. Although there would be significant expense and many variables to consider in designing vocationally relevant testing for military aircrew, these experiments would be especially meaningful.

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List of symbols/abbreviations/acronyms/initialisms

ANOVA	Analysis of variance
CS	Contrast sensitivity
DND	Department of National Defence
DRDC	Defence Research and Development Canada
EDTRS	Early Diabetic Treatment Study
FACT	Stereo Optical Functional Acuity Contrast Test
LASIK	Laser in situ Keratomileusis
LCSC	Precision Vision Logarithmic Contrast Sensitivity Charts
LogMAR	Logarithm of minimum angle of resolution
LRES	Laser Refractive Eye Surgery
MAT	Medical Assessment & Training Section
MOCs	Military Occupational Categories
PRK	Photorefractive Keratectomy
VA	Visual acuity
WFG	Wavefront Guided

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14. ABSTRACT

(U) Excellent high contrast visual acuity results are achieved after laser refractive eye surgery for low to moderate refractive errors. In the early 1990's, many reports showed a decrease in low contrast acuity after laser surgery. Military aircrew work in many different arenas and have identified situations involving low light and low contrast as being the most visually demanding. Postoperative low contrast acuity has improved with newer laser techniques but there was still concern that vision after laser eye surgery would be not good enough for military aircrew demands. This report was designed to assess the post−laser vision of non−pilot aircrew; measuring both the standard high contrast acuity and low contrast vision with and without glare. This report provides a statistical analysis of contrast sensitivity visual results after laser in situ keratomileusis (LASIK) and reports on the results of a questionnaire designed to assess possible postoperative subjective visual problems. Testing was done on the Stereo Optical Functional Acuity Contrast Test (FACT) at a low light level, with and without glare, and at standard photopic light level. The aircrew subjects who underwent LASIK performed significantly better than matched control subjects on the FACT at all light levels when measured at both 6 and 18 months post−operatively. There was no significant difference between the LASIK group and their controls when tested undilated on the Precision Vision Logarithmic Contrast Sensitivity Charts at 6 months post−operatively. The aircrew at 6 months post−laser performed significantly worse than the control group when each group was dilated with Tropicamide 1%. By 18 months post−LASIK, there was no longer any difference between the LASIK group and their controls on the low contrast letter charts, either dilated or undilated. There was no difference found between the LASIK and control groups on a questionnaire asking about dry eye symptoms, difficulties in low light situations, or with glare. This report lends itself to the recommendation that the CF continue to allow non−pilot aircrew to undergo laser refractive eye surgery and allow them to return to flying duties following satisfactory post−operative visual examination.

(U) La chirurgie oculaire réfractive au laser visant à corriger des vices de réfraction légers ou modérés permet d'obtenir d'excellents résultats sur le plan de l'acuité visuelle à contraste élevé. De nombreux rapports datant du début des années 1990 faisaient état d'une baisse de l'acuité à faible contraste après une chirurgie au laser. Le personnel navigant militaire, qui travaille dans de nombreux contextes différents, a déterminé que les situations les plus exigeantes sur le plan visuel sont celles où la luminance et le contraste sont faibles. Les techniques laser plus récentes ont permis d'améliorer l'acuité à faible contraste, mais on craignait toujours que la vision après une chirurgie oculaire au laser ne réponde pas aux exigences imposées au personnel navigant militaire. Ce rapport visait à évaluer la vision du personnel navigant autre que les pilotes après une chirurgie au laser en mesurant à la fois l'acuité à contraste élevé standard et l'acuité à faible contraste avec et sans éblouissement. Ce rapport présente une analyse statistique de la sensibilité au contraste après une kératomileusie in−situ au laser (LASIK) ainsi que les résultats d'un questionnaire visant à évaluer les problèmes visuels subjectifs pouvant survenir à la suite de l'opération. Les tests ont été faits au moyen du Functional Acuity Contrast Test (FACT) de Stereo Optical à un niveau de luminance faible, avec et sans éblouissement, et à un niveau de luminance standard. Les sujets membres du personnel navigant qui avaient subi la LASIK ont obtenu au FACT de bien meilleurs résultats, mesurés à 6 mois et à 18 mois après l'opération et à tous les niveaux de luminance, que les sujets témoins auxquels ils avaient été appariés. Aucune différence significative n'a été observée entre les sujets du groupe LASIK et ceux du groupe témoin au test des échelles de sensibilité au contraste à notation logarithmique de Precision Vision subi sans dilatation à 6 mois après l'opération. Le personnel navigant a obtenu des résultats significativement inférieurs à ceux du groupe témoin au test subi 6 mois après l'opération avec dilatation au tropicamide 1 %. À 18 mois après la LASIK, il n'y avait plus aucune différence entre le groupe LASIK et le groupe témoin aux échelles de lettres à faible contraste subi avec ou sans dilatation. Un questionnaire portant sur les symptômes de l'œil sec et sur les difficultés liées aux situations à faible luminance ou aux éblouissements n'a révélé aucune différence entre le groupe LASIK et le groupe témoin. Les auteurs de ce rapport recommandent que les FC continue de permettre au personnel navigant, autre que les pilotes, à subir la chirurgie oculaire réfractive au laser et à leur permettre de résumer leurs fonctions de vol après avoir passé avec succès un examen visuel post−opératoire.

15. KEYWORDS, DESCRIPTORS or IDENTIFIERS

(U)

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