Visual quality improvement in refractive surgery
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5

STRAIGHTLIGHT BEFORE AND AFTER HYPEROPIC LASIK AND LASEK
ABSTRACT

PURPOSE: To compare straylight values pre-operatively and 3 months post-operatively in hyperopic laser in situ keratomileusis (LASIK) and laser assisted sub-epithelial keratomileusis (LASEK) and analyze the causes of change.

SETTING: Retina, Private refractive surgery clinic, Driebergen, the Netherlands.

METHODS: In 65 eyes undergoing LASIK (39 eyes) or LASEK (26 eyes) straylight was measured pre- and post-operatively with the C-Quant straylight meter, and recorded as log (s).

MAIN OUTCOME MEASURES: Difference in post- versus pre-operative straylight values.

RESULTS: At 3 months post-operatively in LASIK (n=39 eyes) straylight increased slightly with log(s) 0.051 + 0.158 SD, and in LASEK (n=26 eyes) straylight also increased slightly with a mean of 0.031 + 0.146 log(s). Both were not statistically significant, but can be clinically significant in individual cases. In some eyes with increased straylight we found either haze or interface debris. Mean postoperative spherical equivalent refraction was -0.05D + 0.27D.

CONCLUSION: Straylight, by definition the measure for glare disability, increases slightly after hyperopic LASIK and LASEK. The increase in straylight is statistically not significant. In some eyes with increased straylight haze and interface debris were seen. Not in all cases a cause for increased straylight could be found.

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INTRODUCTION

Quality of vision after corneal laser refractive surgery is not always related to Snellen acuity. Contrast acuity and sensitivity, glare, and higher order aberrations play a role in perception of vision.

For visual quality there is no single parameter or test. Forward scatter causes straylight, light that does not come to a focus on the retina, but is scattered in the eye by the ocular structures itself, which is a cause for glare. Retinal straylight by definition corresponds to glare disability. This is a parameter of visual quality that can be dependably and repeatably measured.

The point spread function curve has different domains. The central most 1 degree of arc describes the effect of lower and higher order aberrations, which is the small angle, high intensity domain, and deviations in this domain may cause a decrease in visual acuity and contrast sensitivity. The wider domain beyond 1 degree of arc is the large angle low intensity domain, which is straylight. Clinically straylight corresponds to (disability) glare and haziness of vision.

The C-Quant straylight meter (Oculus Optikgeraete GmbH, Wetzlar, Germany) measures straylight in the eye. It provides information about the optical imperfections as the cause for disability glare. Disability glare is the reduction in visual performance caused by a glare source, which causes retinal contrast degradation secondary to intraocular straylight. The C-Quant determines straylight according to the internationally accepted definition (Commission Internationale d’Éclairage CIE). Straylight is a functional measure for the effect of light spreading over the retina, introduced as the CIE definition for “disability glare”. The amount of straylight is expressed as the straylight parameters.

In corneal laser refractive surgery the assumption has been that straylight may increase after treatment. After corneal laser surgery corneal structure may be altered by changed alignment of the corneal fibrils, which have a precise arrangement essential for optical clarity (like in a crystal), or because of cellular changes and matrix changes after corneal laser surgery, and these changes could induce an increase in straylight post-operatively.

In myopic corneal laser surgery we surprisingly found a statistically significant decrease in straylight overall. In individual cases there may be an increase in straylight, which is related to clinical corneal findings, some of the time. The decrease in straylight in the myopic treatments was found to be strongly correlated to the ablation depth. In hyperopes the deepest ablation profile is more peripheral on the cornea, beyond the pupil opening. Because the central cornea is barely affected by the ablation depth, we do not expect hyperopic treatments to show a decrease in straylight. In order to verify these results and the need to look at the behavior of straylight in hyperopia we compared straylight before and after hyperopic corneal laser surgery.

Some forms of hyperopia can be treated with LASIK and LASEK. Many studies pertaining to the visual outcomes, the efficacy and safety are in the literature. Hyperopia is more difficult to treat and does not achieve the same level of efficacy and
STRAYLIGHT IN HYPEROPIC LASIK AND LASEK

safety as in myopic treatments. However, there are no data yet as to the behavior of straylight in hyperopic LASIK and LASEK. We report our data on straylight in hyperopic LASIK and LASEK.

METHODS

Consecutive prospective case series, of 65 eyes, of 33 patients, undergoing hyperopic refractive excimer laser surgery. Enrollment into the study occurred with informed consent. The tenets of the Declaration of Helsinki were followed. All eyes had a full ophthalmologic examination pre-operatively: uncorrected (UDVA) and corrected distance visual acuity (CDVA), manifest and cycloplegic refraction, slit-lamp examination, dilated fundoscopy, topography and pachymetry, wavefront aberrometry, tonometry, mesopic pupilometry by the orbscan, scotopic pupilometry with the NoDIZy zywave (Technolas, Germany), and straylight measurement.

Visual acuity was tested in 3 meter condensed lanes, using the ETDRS chart, noted in metric units. Assignment to LASIK or LASEK was done according to the consensus of the Netherlands’ Society for Refractive Surgery (2006) and patient preference.

Laser in situ keratomileusis was performed using the XP 120 microkeratome (Technolas, Munich, Germany) and the Technolas 100z excimer laser (Technolas, Munich, Germany). Laser assisted subepithelial keratomileusis was performed with a 20% ethanol solution, 30 seconds exposure time and the same laser equipment. The nomogram utilized is the Planoscan standard ablation profile. The optical zone was chosen to be at least 0.7 mm larger than the mesopic pupil. The maximal ablation occurs 1.67 mm peripheral to the optical zone, so at a diameter 3.33 mm larger than the optical zone diameter. Post-operatively LASIK patients were treated with non-preserved hourly sodiumhyaluronic acid eye drops 0.1%, tobramycine 0.3% combined with dexamethasone 0.1% three times daily (tid). The combination drops were stopped after 3 days, artificial tears continued for at least 3 months, but tapered. In LASEK the post-operative treatment consisted of a bandage contact lens for 3 days, with concomitant unpreserved artificial tears, tobramycine 0.3% eye drops tid, and analgesics orally as needed. After the contact lens was removed on post-operative day (POD) 3, the antibiotic was changed for chloramphenicol 0.4% antibiotic ointment four times daily for 4 more days. Fluoromethalone 0.1% eye drops were started on POD 8 twice daily till POD 21. Artificial tears were used hourly and tapered till 3 months. At the three months post-operative visit examination included UDVA, CDVA, keratometry, tonometry, biomicroscopy, and straylight measurement.

Undilated straylight measurements were done twice pre-operatively and twice 3 months post-operatively with the C-Quant straylight meter. The patient performed a test of 2 alternative forced-choices, in which the patient had to choose between the stronger of 2 flickers presented in controlled background lights. The test duration is controlled by presenting a fixed number of stimuli. The straylight test has an internal analysis procedure which yields a reliability estimate called “Expected Standard
Straylight in Hyperopic LASIK and LASEK

Deviation” (ESD). This ESD was developed to control and enhance internal reliability of the test. Only reliable test results with an ESD of less than 0.08 log units were accepted. Each measurement was repeated to arrive at an independent measure of reliability in the study. Measurements were performed under ambient lighting conditions with corrective refraction. The results of the straylight meter is recorded as the “straylight parameter” \( s \), presented on a logarithmic scale as \( \log(s) \). A difference of 0.3 in \( \log(s) \) corresponds to a difference of a factor 2 in the intensity of straylight.

Statistical analysis was done with the SPSS version 16. Significance level was chosen to be 5%. T-tests and the non-parametric sign and Mann-Whitney tests were used, one-sided, and indicated in the results.

RESULTS

In 65 eyes of 33 patients straylight was measured before and after hyperopic LASIK or LASEK.

Visual acuity outcomes

In the LASIK group:

Thirty nine eyes of 20 patients had LASIK. Demographic data is in table 1. Mean pre-operative Uncorrected Distance Visual Acuity (UDVA) was 0.71, corrected distance visual acuity (CDVA) was 1.06. Mean ablation depth was 56.3 \( \mu \) (range 16-116 \( \mu \)) in the periphery of the ablation zone, and 3.65 \( \mu \) centrally (range 2-23 \( \mu \)).

At 3 months in 39 eyes post-operative mean spherical equivalent refraction (SE) was -0.05D ± 0.27 D (range -1.00D to +0.63 D). Mean UDVA was 1.12, and mean CDVA was 1.18. Efficacy was 1.06 and safety was 1.11. (Table 1) At 6 months post-operatively

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<thead>
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<th>Table 1: Demographic data of the treatment groups</th>
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<td>LASIK</td>
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<td>Mean pre-operative cylinder (range)</td>
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<td>Mean post-operative UDVA at 3 months</td>
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* Total 33 patients, because 1 patient had LASIK in OD and LASEK in OS due to flap cutting problems.
in 19 eyes the mean SE was $+0.04 \pm 0.24$ D (range -1.00 to +0.75). Mean UDVA was 1.10 and mean CDVA was 1.19. Efficacy was 1.04 and safety was 1.13.

**In the LASEK group:**
Twenty six eyes of 14 patients had LASEK. Again the demographic data is shown in table 1. Mean pre-operative UDVA was 0.45, while CDVA was 1.04. Mean ablation depth was 57.79 (range 23-119) micron peripherally, and 3.8 micron centrally (range 2-20 micron).

At 3 months in 26 eyes post-operative SE was $+0.15 \pm 0.11$ D (range -0.25 to +1.25D). Mean UDVA was 0.99 and mean CDVA was 1.07. Efficacy was 0.95 and safety 1.03. (see table 1) At 6 months follow up data are available on 20 eyes: mean SE is $+0.08 \pm 0.32$ D (range -0.875 to +1.25 D). Mean UDVA 1.0 and CDVA is 1.02. Efficacy is 0.96 and safety is 0.98.

For both LASIK and LASEK groups the lines gained or lost at 3 months are summarized in figure 1.

The difference in postoperative UDVA and CDVA between the LASIK and LASEK group was statistically significant (Students t-test, 1-tailed, unequal variance, p = 0.03).

**Straylight outcomes**
Pre-operatively straylight was found to be increased by 0.005 log units (not statistically significant, p>0.05) compared to the normal population. In LASIK straylight increased 3 months post-operatively by log (s) 0.051 ± 0.158. This increase was statistically not significant (p>0.05). In 50% of eyes the straylight values increased, and in 50% of eyes the straylight values decreased. (Figure 2) In the LASEK group the straylight increased on average by 0.031 log (s) ± 0.146. This was also not statistically significant (p>0.05). Here in 54 % of eyes the straylight values increased, while in 46% of eyes the straylight values decreased (improved). (Figure 3)

![Figure 1: In this figure we show the percentages of eyes that lost or gained lines from pre-operative CDVA to post-operative UDVA. Most of the patients that lost lines were due to undercorrections. In 1 eye in the LASEK group significant haze was thought to be the cause of loss of lines. In all but 1 eye, these lines were regained on re-treatment.](image-url)
Figure 2: The graph shows the comparison between the post- and pre-operative straylight levels in hyperopic LASIK. The diagonal lines are the y=x line ± 0.20 log units. The error bars correspond with 0.05 log units, as these data points are averages over 2 measurements with a repeated measure SD of 0.07 log units. The mean straylight values are increased by 0.051 log (s) postoperatively. This is not statistically significant, but there are some individual cases with significant increase.

Figure 3: This graph shows the comparison between post and pre-operative straylight values in hyperopic LASEK procedures. The diagonal lines are the y=x line ± 0.20 log units. The error bars correspond with 0.05 log units, as these data points are averages over 2 measurements with a repeated measure SD of 0.07 log units. The mean post-operative straylight is increased by 0.031. This is not statistically significant, but can be clinically significant in individual cases.
Correlation of straylight outcomes to clinical and other parameters

Pupil size
The mean mesopic pupil was 3.7 mm in diameter (range 2.2 to 5.8 mm). The mean scotopic pupil was 6.03 mm in diameter (range 3.5 to 7.9 mm). The mean optical zone chosen for treatment was +2.75 mm wider than the mesopic pupil (range +0.7 mm to +4.3 mm) and on average +0.42 mm wider than the scotopic pupil (range -0.9 mm to +2.7 mm). On average the site of deepest ablation was at a diameter of 9.8 mm, which is the sum of mean mesopic pupil of 3.7 mm and the optical zone of +2.75 mm, and the maximal ablation being 3.3 mm in diameter beyond the optical zone diameter. This is well beyond the mesopic as well as scotopic pupil size in all cases.

Clinical findings such as haze, flap striae, and interface debris
In LASIK in 8 eyes (5 patients) with > 0.20 log units increased straylight levels interface debris was found in the flap interface in 3 eyes of 3 patients. Of these, 2 patients had complaints on visual quality. The other 3 patients (5 eyes) were satisfied with the quality of vision. The interface debris was mostly central in the interlamellar space. So, central interface debris seems to be a cause for increased straylight, but is not always correlated to visual complaints in our patients.

No flap striae were seen in any of the eyes. Interface debris was seen in 1 other eye with a log (s) change <0.2, not resulting in clinical complaints.

In LASEK in 4 eyes of 3 patients in which straylight values were > 0.20 log units increased, haze could be seen in 3 eyes. Two of these patients (3 eyes), were dissatisfied with their quality of vision. In 2 eyes of 2 other patients haze grade 1 was seen, with log (s) change <0.2. Both patients had no complaints as to their visual acuity or quality of vision. In all of these eyes the haze was midperipheral at the zone of deepest ablation, and peripheral to the mesopic pupil opening.

Repeatability of the measurements
Although the test employed in the C-Quant (“compensation comparison” paradigm) is designed in such a way that subject bias is impossible, it was considered prudent to check whether a learning effect might be possible. For this purpose in our studies first measurements are repeated, and a comparison is made of second to the first measurements. Moreover such data provide an independent measure of repeatability, to be compared to the ESD values given by the C-quant instrument. Overall, the mean difference was 0.008 log units, and repeated measures standard deviation was 0.078 log units. So, no learning process exists that may upset the sequential comparison.

DISCUSSION
In an earlier study we conducted in myopic treatments we surprisingly found that straylight is as a rule decreased after surgery, except in a few cases, in which we could usually correlate the increase in straylight to findings in the cornea like haze, interface debris or flap striae. A correlation between straylight change and ablation depth was
found, suggesting that a thinner central cornea is beneficial for straylight, although the effect may be very small. As a test for this explanation, the hyperopic group is interesting. Indeed at 3 months post-operatively straylight is on average increased by 0.051 and 0.031 log units respectively in LASIK and LASEK treatments. This increase is statistically and clinically not significant. However, in every population where the mean change is small or not significant for the whole group, individuals may still have an individually significant change from the baseline for which we try to find a clinical explanation.

The ablation profile in hyperopic treatments removes most tissue peripheral to the mesopic pupil opening. Issues like haze, interface debris, and flap striae may be assumed to play the same role in hyperopic treatments as in myopic LASIK and LASEK.\textsuperscript{10, 11} The difference between the two treatments is in the location with respect to the pupil center. In the myopes we found a decrease in straylight, and this effect was related to ablation depth and thinning of the cornea. In hyperopes we found a small and statistically and clinically insignificant increase in straylight, most probably because of the more peripheral ablation of tissue. This finding is consistent with our previous findings, and contrary to our expectation of glare disability being increased after corneal excimer laser surgery.

In the Planoscan nomogram hyperopic ablation profile, the maximal ablation occurs 1.67 mm peripheral to the chosen treatment zone, which is chosen at least 0.7 mm peripheral to the mesopic pupil opening. Tissue changes centrally in the pupillary zone are minimal, and this may be one reason for the lack of change, in most cases after hyperopic treatment. The central area of the cornea, in the pupillary opening, is the area that contributes most in straylight from corneal sources.\textsuperscript{18}

In our myopic population we have found that the baseline straylight measurement was significantly increased by 0.06 log units. This relative elevation disappeared upon surgery. Also Rozema and colleagues\textsuperscript{19} reported straylight elevation in myopes. When trying to explain this phenomenon, contact lens wear must be considered. Reports of contact lens effects on straylight have shown strong results, sometimes including long-term effects, but also variable [review in van der Meulen et al.\textsuperscript{17}]. Our patients were instructed not to wear contact lenses at least 72 hours before the measurement in soft contact lenses, and 4-16 weeks in hard contact lenses. In the present study pre-operatively the straylight values are not significantly increased by 0.005 log units compared to the normal population. Although unlikely, we would not like to rule out the possibility that contact lens use could be on the basis of the difference in baseline measurements between the hyperopes and the myopes. Another issue to be considered is axial length. In myopic eyes light has to travel a longer distance, with potentially more scattering elements. However, this is inconsistent with the reduction upon treatment in myopes. Another effect we explored was pre-operative pachymetry. However there was no significant difference. The mean pachymetry in the hyperopes (thinnest point on the Orbscan) was 539\(\mu\)m, and 530\(\mu\)m in our myopic population (t-test, 2-tailed, p=0.09).
From the literature hyperopic corneal refractive surgery had always lagged in outcomes, compared to myopic treatments. The consensus has been that hyperopic corrections until 4 diopters are safer and more predictable than the higher corrections. Hyperopic treatments have higher rates of regression, but in some instances latent hyperopia may play a role in undercorrection. The hyperopic excimer laser ablation pattern tries to steepen the cornea in the mid-periphery, which is more difficult to achieve. Stromal regrowth and epithelial hyperplasia play a role in these processes. These same processes can be expected to play a role in straylight. In cases of haze and interlamellar debris are particles visible on slitlamp, that probably cause increased straylight in some instances. Also in instances of epithelial ingrowth we have shown that ingrowth over the pupillary opening has much more impact on straylight, than ingrowth that does not reach the pupillary opening.

Clinically there was a correlation between increased straylight and findings in the cornea, like haze and interlamellar debris, but the numbers of these adverse events are low. These findings are often correlated with patients’ dissatisfaction with their vision. In some of the eyes in which straylight was increased, we could clinically find a correlation in the cornea in the form of interface debris in LASIK and haze in LASEK. However, in the group as a whole, the mean increase in straylight is minimal and clinically not significant. We did not specifically administer a questionnaire on glare related issues, which needs to be implemented in our future studies. Also the contribution of tearfilm changes in our population, to complaints of visual dissatisfaction in the outcomes was not researched. In the literature the change in the tearfilm is generally accepted as a reason for decreased visual quality and dissatisfaction with visual quality.

There is no definite evidence based answer to whether LASIK or LASEK is the better treatment of hyperopia. Surface ablations are associated with more post-operative pain, slower visual recovery, and corneal haze. Our visual acuity outcomes are comparable to what has previously been published. El Agha found that nearly 20% of patients who had hyperopic PRK had midperipheral haze. This is comparable to our finding haze in 5 of 26 eyes. Only 3 out of these 5 eyes had post-operatively increased straylight measurements as compared to their pre-operative straylight. This is explained by the fact that the haze is concentrated in the area with the deepest ablation, which is the peripheral cornea, approximately 2 mm from the mesopic pupil.

IN CONCLUSION

In hyperopic LASIK and LASEK straylight levels increase slightly on average postoperatively. This increase is not statistically significant, but in a small percentage of individual cases clinically significant changes may occur. This is consistent with our findings in myopic laser treatments, were there is a small decrease in straylight post-operatively. In some eyes the increase of straylight could be related to findings in the cornea. The reason for the increase could be related with tissue changes, but this has to be studied in more detail.
REFERENCES


