Title: Effects of Corneal Scars and their Treatment with Rigid Contact Lenses on Quality of Vision

Running Title: Quality of Vision in Corneal Scars and Rigid Contact Lens Treatment

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Abstract

Objectives

34 To study the effects of corneal scars, and the treatment of these scars with rigid gas-
35 permeable (RGP) contact lenses, on quality of vision including straylight. Visual
36 effects were related to scar characteristics such as size and grade.

Methods

38 Straylight and best-corrected visual acuity were measured in 23 patients with corneal
39 scars during and after RGP contact lens wear. Contralateral eyes were used as
40 controls, and age-normal values in case of bilateral scars. Straylight measurements
41 were performed using the compensation comparison method of the Oculus C-Quant
42 instrument.

Results

44 Scarred eye straylight values were 1.53 log(s) without contact lens and 1.60 log(s)
45 with contact lens ($P=0.043$). Healthy eyes without contact lens had a mean straylight
46 value of 1.13 log(s), corresponding to age-normal values. Contact lens wear
47 increased straylight in healthy eyes to 1.26 log(s) ($P<0.001$). Visual acuity improved
48 from 0.66 logMAR to 0.19 logMAR with contact lens wear in eyes with a corneal scar
49 ($P<0.001$).

Conclusions

51 Corneal scars can have a strong effect on quality of vision, by diminishing visual
52 acuity and increasing straylight. The increase in straylight from corneal scars on its
53 own can lead to a serious visual handicap. Contact lens treatment did not improve
54 straylight, but showed a slight worsening. As the recovery of visual acuity with

contact lens wear far exceeded straylight increase, contact lenses remain a clinically useful treatment option in most patients with corneal scars.

Introduction

Corneal scars often result in significant loss of visual function. This can be due to a diminished visual acuity, but corneal scars also frequently cause straylight related complaints.¹ When vision is diminished from straylight in a glare situation this is referred to as disability glare.² Associated complaints include trouble driving at night, hazy vision, and seeing halos around bright lights. While there is only a weak correlation between straylight and visual acuity in the normal population, straylight is still an important factor in experienced quality of vision.³ This is possibly due to the loss of contrast in the immediate environment of glare-inducing light sources.^{4,5} Furthermore, as visual acuity is measured with high contrast tests, subjective complaints due to increased straylight cannot be diagnosed with routine vision tests.⁴

Straylight is known to increase with age due to normal physiological processes especially in the lens.⁶ Several studies have documented straylight increase from opacification in different tissue layers of the cornea.^{3,7,8} However, pathological processes of the ocular structures are also potential causes of increased straylight, which can often be restored by treatment of the underlying condition.^{7,9} In some ocular diseases conservative symptomatic treatment can initially be favored over curative but invasive treatment such as corneal transplantations, as adverse effects such as rejection can be significant. Initial conservative treatment is common for scars of the cornea, a structure that is thought to be responsible for a third of total straylight in healthy eyes.¹⁰ This treatment consists of the use of a rigid gas-permeable (RGP) contact lens, and is primarily aimed at restoring visual acuity by providing a continuous surface with a tear film over the corneal irregularity to correct

refraction.^{11,12} Possible undesirable effects can occur as RGP contact lenses have been found to increase straylight in healthy eyes,¹³ and are not supposed to correct underlying tissue opacity.

The purpose of this study was (a) to describe how corneal scar characteristics affect quality of vision by an increase in straylight as compared to a decrease in visual acuity, and (b) to examine how contact lens use influences the visual quality by documenting the effects on straylight and visual acuity in these patients. Considering the frequent use of RGP contact lens treatment it is beneficial to understand the effects on all factors involved in quality of vision.

Materials and Methods

This nonrandomized contralateral eye study was performed at the Ophthalmology department of the Academic Medical Center in Amsterdam. A total of 23 patients were included in this study (7 male, 16 female). Age was between 11 and 70 years (mean±standard deviation, 45.4±17.7 years). Inclusion criteria for patients were (a) presence of a corneal scar resulting from infectious keratitis, and (b) the use of an RGP contact lens on the scarred eye. Exclusion criteria were (a) any form of clinically significant retinal, lens, or corneal endothelium pathology, (b) other corneal disease such as keratoconus or pellucid marginal degeneration, and (c) any procedures performed on the cornea such as refractive surgery. Informed consent was given by all patients. The study followed the principles of the Declaration of Helsinki and was approved by the local medical ethical committee.

Visual Acuity and Straylight Measurements

Best-corrected visual acuity was measured using the Early Treatment of Diabetic Retinopathy Study (ETDRS) chart, and expressed as the logarithm of the

minimal angle of resolution or logMAR.¹⁴ Measurements were done with RGP contact lens, and after contact lens removal with sphere and cylinder correction.

To quantify the amount of straylight the C-Quant straylight meter based on the compensation comparison method was used.¹⁵ This method entails the forced-choice comparison of flickering strength between two half circles. In one half circle the patient sees straylight resulting from a flickering ring at a mean distance of 7 degrees. In the other half field a counterphase compensation light is added. The goal is to find the compensation value at which both sides are perceived as equally strong in flicker. Output of this measurement is in the form of the logarithm of the ocular straylight value s , where a higher $\log(s)$ corresponds with more straylight and worse quality of vision. This logarithmic conversion is standard procedure in psychophysical functions,¹⁶ and used nowadays often to express visual acuity in the form of the logMAR scale. An increase of 0.3 log units corresponds to a doubling of experienced straylight.

The C-Quant measurement includes a reliability parameter ESD (expected standard deviation). To retain good reliability an upper limit of $ESD=0.1$ log units was enforced, excluding any measurements above this value from analysis. Double measurement series of 25 trials each were taken with the average being used for statistical analysis. Measurements were taken during contact lens wear and after contact lens removal. Contact lenses were worn habitually on day of participation, between 1 and 6 hours. The contact lens was removed at least 30 minutes before the respective measurements as straylight values were found to be elevated directly after removal.¹³ Normal (photopic) room lighting was on during straylight measurements.

Scar Grading and Contact Lens Evaluation

An optometrist specialized in medical contact lens treatment performed both the grading of scars and the evaluation of RGP contact lens characteristics, and was

blind to the straylight measurements. Both assessments involved a slit lamp examination with the use of fluorescein dye as needed. Scar grading consisted of a severity assessment between 3 categories, named nebula, macula, or leucoma.¹⁷ These categories were determined by the depth and degree of opacification of affected corneal tissue. Subepithelial scars corresponded to nebula grades, scars extending to the middle of the stroma to macula grades, and full-stromal scars to leucoma grades. This method was chosen to separate scars in clinically relevant and slit lamp identifiable categories. Scar size, location, and shape were noted independently of scar grade. Scar size was measured by overlaying the slit lamp beam at a right angle to the cornea and using the ruler provided by the slit lamp, while location and shape were noted in a standardized cornea diagram. The percentage of the natural pupil covered by the scar was noted during assessment with indoor lighting, as scarring in the pupillary area would be most likely to cause straylight. Contact lenses were evaluated on fit, wetting, damage, and depositions by a 0 (best) to 4 (worst) grading scheme similar to the Efron grading system.¹⁸ Grading involved visual inspection of possible hydrophobic areas, mobility deficits, and degree of depositions such as proteins, lipids, or calculi.

Results

A total of 46 eyes were measured, of which 25 had a corneal scar and 21 were healthy, due to 2 patients having a corneal scar in both eyes. 22 patients used corneal RGP lenses, and 1 patient used semi-scleral RGP lenses. Of all scars 8 were graded as nebula, 7 as macula, and 10 as leucoma. No scars with active infection were present. Scar age ranged between at least 1 year old up to 30 years.

Visual Acuity

Mean best-corrected visual acuity with RGP contact lens was 0.014 ± 0.06 logMAR for healthy eyes, and 0.193 ± 0.16 logMAR for scarred eyes ($P=0.004$). Best sphere and cylinder corrected acuity for scarred eyes without RGP contact lens was 0.659 ± 0.43 logMAR ($P<0.001$).

Visual acuity loss from a corneal scar was calculated by subtracting healthy eye logMAR values from the scarred eye logMAR values of the same patient. For the 2 patients with bilateral corneal scars 0 logMAR values were used for this comparison (11 and 52 years of age). No statistical effect was found for scar grade on logMAR changes from scarring ($P=0.776$). Neither was there a significant correlation between scar size as percentage of pupillary area and logMAR changes ($P=0.119$).

Straylight

Figure 1 shows reproducibility of the straylight measurements. No learning effect is present, neither for healthy eyes nor for scarred eyes, as there was no significant difference between the first and second measurements, with an overall non-significant mean 0.01 log(s) for the second minus the first measurement. Repeated measures standard deviation was 0.11 log(s).

Overall effects of corneal scars and aging on the amount of straylight can be seen in Figure 2. Mean straylight values for healthy eyes without RGP contact lens were 1.13 ± 0.14 log(s), and with RGP contact lens 1.26 ± 0.13 log(s) ($P<0.001$). Scarred eye straylight values without RGP contact lens were 1.53 ± 0.36 log(s), and with RGP contact lens 1.60 ± 0.29 log(s) ($P=0.043$). The individual RGP contact lens effects are shown in Figure 3.

The same method used to calculate visual acuity loss was applied to calculate straylight increase from scarring, with substitute values used for the 2 patients with

182 bilateral scars. Values used were 1.05 log(s) at 52 years,³ and 0.88 at age 11, which
183 is slightly below the average straylight value of a young, healthy eye,³ (0.90), but
184 corresponds with the lowest log(s) measured in one of both eyes. Results are shown
185 in Figure 4. The average increase from all corneal scars was 0.43 log(s) ($P<0.001$).
186 Nebula, macula, and leucoma scars increased log(s) by 0.22, 0.33, and 0.66
187 respectively, which was statistically different ($P=0.005$). Average scar sizes were
188 61mm² for nebula, 11mm² for macula, and 23mm² for leucoma ($P=0.034$). Pupillary
189 area scar proportion showed a significant relation with straylight for leucoma only
190 ($P=0.025$, $r^2=0.49$). The correlation between visual acuity loss and straylight increase
191 due to a corneal scar was low but significant, ($P=0.036$, $r^2=0.18$), and is shown in
192 Figure 5.

193 Contact lens characteristics such as depositions, fit, wetting, and age did not
194 statistically influence straylight values and visual acuity of both healthy and scarred
195 eyes. Median grade for depositions, wetting, and damage was 1 (0 = best, 4 = worst).
196 Lens age was between 0 and 24 months, with an average and standard deviation of
197 5.34±5.28 months.

198 A 52-year-old patient with bilateral nebula scars showed a visual acuity
199 difference between OD and OS with glasses, while straylight values were similar (OD
200 1.16 log(s), OS 1.13 log(s)). A corneal topography scan, Figure 6, revealed that
201 besides a nebular haze, the scar on OD presented with surface irregularities. Best-
202 corrected visual acuity with glasses was 0.4 logMAR. The left eye had a similar
203 nebular haze, but no surface irregularities besides astigmatism. The best-corrected
204 visual acuity of OS with glasses was 0 logMAR. Visual acuity in OD could be restored
205 to 0 logMAR with RGP contact lens use.

209 Patients with corneal scars often have complaints of a deteriorated visual
210 quality, which can be due to a decreased visual acuity, but also to increased
211 intraocular light scattering. Straylight has a nearly equal influence on quality of vision
212 as visual acuity.⁹ The primary treatment for corneal scars, *i.e.* rigid gas-permeable
213 contact lens wear, causes a straylight increase in healthy eyes.¹³ It is necessary to
214 understand what effect corneal scars and contact lens use have on the amount of
215 intraocular straylight to determine more completely what the clinical and functional
216 benefits of contact lens treatment are in patients with corneal scars. These findings
217 could help to understand the visual effects of corneal scars and to understand which
218 corneal scar patients might benefit optimally from RGP contact lens treatment. The
219 goals of this study were to understand the effect of corneal scars and contact lens
220 use on visual quality, as measured by straylight and visual acuity.

221 Mean straylight in scarred eyes was 1.53 log(s), which was on average 2.7
222 times worse than straylight in healthy comparison eyes. This is comparable to
223 straylight levels in pre-operative cataract patients.⁹ This amount of straylight is
224 considered as seriously impairing, which is defined as more than 4 times the amount
225 of a young healthy eye, (0.9 log(s)).^{3,9,19} Scar grading performed by slit lamp
226 examination reflected the increase in straylight, but not visual acuity loss. Corneal
227 haze is more obvious during slit lamp examination than surface irregularities, and
228 thus likely of greater importance for scar grade determination. Additionally, while
229 straylight did not correlate with pupillary area scar proportion when all scars were
230 taken into account, it can be seen in Figure 4 that leucoma grade scars increased
231 straylight more as they increased in size. This relation is not seen in nebula grade
232 scars, which mostly presented with a low increase in straylight regardless of scar
233 size. There was only a low correlation between straylight increase and visual acuity

loss from scarring, as has also been found for cataracts.^{3,9} A clinical implication of these findings is that it seems unwise to rely only on the amount of acuity loss in patients with complaints of reduced visual quality. These patients could have a visual handicap due to increased straylight. When straylight measurements cannot be performed, the clinical grade of the scar can give information about straylight levels. A denser scar leads to more straylight, but scar size is only of influence for leucoma grade scars.

Treatment with RGP contact lenses showed markedly improved visual acuity in scarred eyes. However, straylight levels slightly worsened. Straylight in healthy eyes was also increased by RGP contact lens wear, in agreement with earlier findings.¹³ The increase in straylight levels from contact lens use was equal between scarred and healthy eyes. An explanation for these findings can be found by the two processes which contribute to corneal scar formation, (a) the development of topographical surface irregularities, and (b) the opacification of the corneal substance, forming the haze of corneal scars. As surface irregularity primarily affects refraction, this seems to be responsible for the decrease in visual acuity. Meanwhile, the haziness of the cornea is the primary cause for an increase in straylight.^{6,7,13} The finding that scarred eyes show the same increase in straylight from contact lens use as healthy eyes complies with these separate effects, assuming that only surface irregularities are corrected by the contact lens, and not the underlying haze. The precise reason why contact lens use increases straylight is unclear as no relation with lens characteristics was found. However, the gain in visual acuity with contact lenses can be expected to outweigh the straylight worsening in visual functioning, making the use of RGP contact lenses still a clinically useful treatment for patients with corneal scars. Patients with complaints of glare could benefit from straylight measurements to manage expectations of lens treatment. Objectifying glare

complaints into a straylight value can help avoid disappointment in individuals that indeed have high straylight levels.

The 52-year-old patient with bilateral corneal scars also illustrates the relative independence between straylight and visual acuity. Straylight levels were still within normal range for both eyes, but the scar resulted in 20/50 (0.4 logMAR) acuity in the right eye, with the left eye retaining normal acuity. This indicated the presence of a corneal surface irregularity in the right eye only, which was confirmed by a corneal topography scan. RGP contact lens treatment in the right eye resulted in 20/20 (0 logMAR) acuity, marking the efficacy of the treatment for surface irregularities.

The categorical scar grading system using clinical judgement could be considered as a limitation in this study. While all scar grading was performed by the same person, there is no firm boundary between grades as observed by slit lamp examination for each scar. This process can amount to some loss in reliability. However, the grading system does correspond to routine clinical practice in which slit lamp examination is the golden standard for patient evaluation.

In conclusion, quality of vision after corneal scarring can be compromised by both straylight and visual acuity due to separate processes which do not always occur together. Overall straylight levels in scarred eyes were high, and in some cases more pronounced than the visual acuity loss. Straylight could be measured reliably, without learning effects, and also in patients with severe corneal scars with the compensation comparison method. The opposing treatment effects of contact lens use for acuity and straylight are acceptable in most corneal scar cases, but should be considered when complaints of disability glare exceed those of visual acuity. Straylight measurements could also be an addition to decide when to switch to keratoplasty as treatment, which is able to improve both visual acuity and straylight.²⁰

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341 **Figure 1.** Reproducibility of Oculus C-Quant straylight measurements, with a mean
 342 difference of 0.011 log(s) and repeated measures standard deviation of 0.108 log(s).

Figure 2. Age and scar effects on straylight, assessed without contact lens. Mean normal values (solid line) and corresponding 95% confidence interval are shown (dashed lines). The low straylight value at 70 is from a pseudophakic eye.

Figure 3. RGP contact lens effects on straylight for healthy and scarred eyes. The dashed line is a prediction of the results if RGP contact lens use would lead to a fixed straylight increase of $s=5$.

Figure 4. Straylight increase in relation to scar grade and size. The colored lines indicate mean straylight increase per scar grade.

Figure 5. The correlation between visual acuity loss and straylight increase from scarring, $r^2 = 0.18$.

Figure 6. Corneal topography of a patient with bilateral nebula grade scars. Both eyes were still within similar, normal range $\log(s)$ values. Surface irregularities can be seen in OD. With sphere and cylinder correction OD acuity was 0.4 logMAR, and OS acuity was 0 logMAR.