Contact Lens & Anterior Eye 37 (2014) 144–148

Contents lists available at ScienceDirect

Contact Lens & Anterior Eye

journal homepage: www.elsevier.com/locate/clae

Long-term changes in straylight induced by corneal refractive therapy: A pilot study

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ARTICLE INFO

Article history:
Received 25 January 2013
Received in revised form 18 August 2013
Accepted 16 September 2013

Keywords:
Cornea
Intraocular straylight
Corneal refractive therapy

ABSTRACT

Purpose: To assess long-term intraocular straylight changes induced by corneal refractive therapy (CRT) and to determine whether these changes persist after cessation of CRT lens wear.
Methods: A single-center, prospective, longitudinal study was performed in 22 subjects (group 1) undergoing overnight corneal refractive therapy for 1 year. Ten right eyes of 10 subjects (group 2) with emmetropia served as controls. In each subject, high contrast visual acuity (HCVA), manifest refraction and intraocular straylight were determined at several time points during treatment and 1 month after discontinuing treatment. Straylight was measured using the van den Berg straylight meter (third generation). EDTRS charts (logMAR units) were used to assess HCVA. For both groups, only data for the right eyes were analyzed.
Results: Straylight (mean ± standard deviation) significantly fell from baseline (0.98 ± 0.13) to values recorded after 1 month (0.88 ± 0.13, $p = 0.011$), 3 months (0.88 ± 0.13, $p = 0.004$), 6 months (0.88 ± 0.13, $p = 0.000$) and 12 months (0.76 ± 0.12, $p = 0.003$) of treatment. One month after discontinuing CRT lens wear, straylight was still significantly lower than baseline (0.89 ± 0.13, $p = 0.003$). No correlations were observed between intraocular straylight and HCVA.
Conclusions: Good refractive outcomes and reductions in straylight were observed in response to corneal refractive therapy for myopia. The reduction in straylight observed after discontinuing CRT warrents further investigation.

1. Introduction

Corneal refractive therapy (CRT), also known as overnight orthokeratology or corneal reshaping, is a non-surgical procedure designed to achieve a transient reduction in refractive error and improve unaided vision, especially in patients with low to moderate myopia. The main benefit of CRT for myopic subjects is an independence from optical aids during waking hours [1]. The simplicity of new fitting systems [2] along with predictable and safe outcomes [3,4] have led to mounting interest in CRT, with its added advantage of reversibility [5].

The success of CRT has been accompanied by a need to address the factors that affect the corneal response to treatment. Recent research has examined the use of CRT in humans, evaluating its effects on corneal topography, visual acuity, contrast sensitivity, the optical quality of the eye (ocular aberrations) [6–13], and its biomechanical properties [14–17]. In a recent study, the effects of CRT on the cell density of the corneal layers were addressed [18].

When light reaches the eye, some of this light is scattered forwards and backwards and the rest forms the image on the retina. Any back-scattered light does not affect the retinal image. However, light that is forward scattered projects a veil of light over the retinal image, which reduces the contrast of the image produced and thus diminishes vision quality. This veil of light is called straylight [19–21]. In effect, it has been well established that disability glare is a consequence of intraocular straylight [19–21]. In the normal eye, the main contributing factors to the total amount of straylight are the cornea, iris and sclera, crystalline lens and fundus. Intraocular light scattering increases with age and this effect is much greater in subjects with cataracts [22,23]. With CRT, the cornea changes its morphologic and anatomic structure so it is possible that forward light scatter, or straylight, could change in response to this mode of therapy.

Previous studies have shown that light scattering by the cornea also changes after refractive surgery [24–27]. Even when visual acuity is 20/20 after refractive surgery, corneal light scattering can be a cause of dissatisfaction for the patient, with most discomfort

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http://dx.doi.org/10.1016/j.clae.2013.09.003

experienced at night especially while driving. Night-vision disturbances such as glare, halos and starbursts occur frequently and their incidence is highly variable [28]. Fan-Paul et al. [29] reported that a certain percentage of patients complain of glare at night after undergoing a refractive surgical procedure. When patients speak of glare they are, technically, describing a decrease in quality of vision secondary to glare disability, decreased contrast sensitivity, and image degradations.

Van den Berg designed an instrument, the straylight meter, which measures forward light scatter and provides direct information on optical imperfections as the cause of disability glare [30,31]. The use of this device to measure straylight has been reported after laser in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) [25–27], after cataract surgery and lens extraction [23], and in subjects wearing contact lenses [32,33] or implanted with intraocular lenses [34,35].

In prior work, Lorente et al. [25] were able to show reduced intraocular straylight 15 days after refractive surgery. This gradual improvement in straylight was confirmed by Nieto et al. [27] after six months of surgery. Lapiz-Gortzak et al. [36] observed straylight values that were slightly reduced from baseline three months after LASIK and laser-assisted subepithelial keratectomy, LASEK. Rozema et al. [37] noted a significant reduction in forward light scatter six months after LASEK.

Reports in the literature of straylight measurement after corneal refractive therapy are scarce. Lorente et al. [38] described a reduction in straylight one month after the start of CRT treatment although these authors admitted the need for longer follow-up times.

Given that overnight corneal refractive therapy is evermore being viewed as an alternative to refractive surgery, this study was designed to measure intraocular straylight in patients undergoing CRT over the course of one year after the start of treatment and one month after its discontinuation. Changes produced in high contrast visual acuity (HCVA) were also examined.

2. Materials and methods

A prospective, longitudinal, single-center study was designed. The study protocol adhered to the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the Hospital Carlos III. The participants were students of the Complutense University of Madrid who had been informed of the protocol and its objectives. Subjects were selected according to a set of inclusion criteria as well as an interest in trying the treatment under study.

The inclusion criteria were: men or women aged 18–30 years, ocular refraction −0.50 to −4.5 D of myopia with up to 1.00 D of astigmatism, and a best-corrected visual acuity of at least 0.04 logMAR in both eyes. The baseline refractive state of each participant was recorded as phoropter-determined manifest refraction at the study outset. Subjects were excluded if they currently used or had in the past used gas permeable contact lenses. Hydrophilic lens wearers were instructed to stop using their contact lenses 4 weeks prior to the start of the study. Subjects were also required to be available for follow-up visits on the established dates: 1, 3, 6 and 12 months after the start the treatment, and one month after its discontinuation. The control untreated group (10 subjects) was used to check for lack of any changes over time in the variables determined. The refractive state of these subjects was in the emmetropic range, and these subjects were required to attend a follow-up appointment 1 and 12 months after the start the treatment and one month after discontinuation. Subjects were excluded: if they were pregnant or intended to have children over the next two years, had any systemic or eye disease, a history of eye surgery, blepharitis, recurrent erosion, dry eye syndrome, neovascularization, or evidence of keratoconus, corneal irregularity, pupils larger than 5.5 mm in photopic conditions, or were participating in another clinical trial.

The study followed a controlled protocol. The methods used were performed according to instructions reported in the literature or by the manufacturers of the instruments. All measurements were made in the same office and at the same time of day within a 2-hour margin after lens removal. In each follow-up session, the same clinical procedures were conducted in the same order by two clinicians.

At each follow-up visit, the subjects underwent a full optometric examination including: high contrast visual acuity (HCVA), manifest subjective refraction, pupillometry and straylight measurements. Visual acuity was assessed using EDTRS LogMAR charts. Measurements 1 month after treatment had been discontinued were taken with best spectacle correction.

The contact lens selected for the study was the 100 HDS Paragon CRT lens (Paragon Vision Sciences) distributed in Spain by Interlenco SA (Madrid, Spain). The adaptation procedure for the lenses was performed according to the manufacturer's protocol as follows: (1) the specifications for the lens were determined using the calculation rule provided by the manufacturer, (2) adequate fitting was assessed with fluorescein, and (3) in a corneal topography acquired after an overnight trial, a satisfactory fit was confirmed by the typical bull's eye pattern. Participants were instructed to wear the CRT lenses in one or both eyes overnight for one year. Only data obtained for the right eye were used for statistical analysis.

2.1. Straylight measurements

A straylight meter (Oculus C-Quant, Oculus GmbH) was used to determine the amount of intraocular straylight. This instrument measures intraocular straylight by compensating for the amount of straylight (induced by a peripheral light source) on a test field, with counterphase flickering of the test field of variable intensity. Thus, the intensity of counterphase flickering required to offset flickering induced by the straylight is a measure of the level of intraocular straylight. The test field is divided into 2 half fields: 1 with and 1 without counterphase compensation light. The patient fixates and states which of the two fields' flicker is stronger. This method is known as compensation comparison [31,39].

The amount of straylight in an eye is expressed as a single figure designated by the straylight variable, s. This variable describes the ratio between "unwanted" scattered light, which causes retinal contrast reduction, and "wanted" non-scattered light, which forms the desired retinal image. For reasons that have to do with the way human light perception works, it is more convenient to use the logarithm of s, denoted as $\log(s)$. This value increases with age from 0.85 in young healthy eyes to 1.4 at 80 years of age [22]. In addition, the device provides a range of straylight values that are normal for a given age range. To assess the reliability of the measure, the device gives a data on the error (esd), for each straylight value. $\log(s)$ values with esd ≤ 0.08 are considered reliable measurement.

The C-Quant straylight meter takes measurements in photopic conditions. Measurements were taken in complete darkness to avoid any light from other sources [32] and with the best correction in place. To really get the best out of the measurement, measurements with esd ≤ 0.08 were considered. Three measurements were made per eye and the average is taken.

2.2. Study population

At the study outset (February 2008), 30 Caucasian subjects (30 right eyes) with low to moderate myopia started corneal refractive therapy using the CRT lenses. In 3 of these subjects, treatment was