International multi-centre study of potential benefits of ultraviolet radiation protection using contact lenses

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ABSTRACT

Purpose: To examine the effects of long-term ultraviolet radiation (UVR) blocking wearing contact lenses on ocular surface health, eye focus and macular pigment.

Method: 210 pre-presbyopic patients were recruited from Birmingham UK, Brisbane Australia, Hong Kong China, Houston USA and Waterloo Canada (n = 42 at each site). All patients had worn contact lenses for ≥ 5 years, half (test group) of a material incorporating a UVR-blocking filter. Ocular health was assessed using slit-lamp biomicroscopy and UV autofluorescence. Accommodation was measured subjectively with a push-up test and overcoming lens-induced defocus. Objective stimulus response and dynamic measures of the accommodative response were quantified with an open-field aberrometer. Macular pigment optical density (MPOD) was assessed using heterochromatic flicker photometry (MPS II).

Results: The two groups of participants were matched for age, sex, race, body-mass-index, diet, lifestyle, UVR exposure, refractive error and visual acuity. Limbal (p = 0.035), but not bulbar conjunctival redness (p = 0.903) was lower in eyes that had worn UVR-blocking contact lenses compared to controls. The subjective (8.0 ± 3.7D vs 7.3 ± 3.3D; p = 0.125) and objective (F = 1.255, p = 0.285) accommodative response was higher in the test group, but the differences did not reach significance. However, the accommodative latency was shorter in eyes that had worn UVR-blocking contact lenses (p = 0.003). There was no significant different in MPOD with UVR filtration (p = 0.869).

Conclusions: Blocking the transmission of UVR is beneficial in maintaining the eye’s ability to focus, suggesting that presbyopia maybe delayed in long-term UVR-blocking contact lenses wearers. These lenses also provide protection to the critical limbal region.

1. Introduction

The risk of damage to the skin from ultraviolet radiation (UVR) exposure is well known and there is strong evidence that blocking is beneficial [1,2]. However, there is comparatively little evidence on the ocular benefits of UVR shielding. While exposure to UVR in small quantities can be beneficial to human health in some instances, such as in synthesis of vitamin D [3], there are many associated health risks from both acute and chronic exposure. While the anterior ocular structures absorb most UVR [4], research into the penetration to internal ocular structures is limited. Pterygium, a wing shaped thickening of the conjunctiva and cornea, has been shown to be related to prolonged UVR exposure [5,6]. Ascorbate is an antioxidant in the aqueous humour which has protective effects on the crystalline lens. Levels of ascorbate

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can be affected by extended UVR exposure and may have implications in cataractogenesis [7]. There is some controversy regarding the link between sun exposure and age-related macular degeneration (AMD). Although it has been suggested that UVR is a risk factor in AMD, epidemiological studies have not shown a significant association [8-12].

Soft contact lenses with a UVR filter can offer protection to the cornea, limbus, some of the bulbar conjunctiva and internal ocular structures because of their large diameter, movement with the eye and position against the ocular surface. Incorporating a UVR-blocker into a soft contact lens has been shown to help protect the eye from the peripheral light focusing effect at the nasal limbus, with protection given from all angles of light incidence. Hence, UVR-blocking soft lenses may help reduce the prevalence of ocular conditions, such as pterygium and early cortical cataract [13]. Stem cells are important in the maintenance of tissue integrity and as a result tend to be found in protected areas in the body. Following injury to the corneal epithelium, limbal stem cell division is upregulated in order to replace lost cells [14]. It is thought that the limbal shielding afforded by contact lenses can help to protect the reservoirs of limbal stem cells from UVR damage, especially from tangential and temporal sources of UVR rays [15]. In a recent study, UVR-blocking contact lenses were found to have a protective effect in preventing short-term UV-B-induced limbal stem cell damage and inflammation compared to lenses without a UVR-blocker, and it was suggested that these lenses may be particularly useful in certain situations, such as after limbal stem cell transplantation or following pterygium surgery [16].

Exposure to UV-B causes cell death in the cornea and the use of UVR-blocking contact lenses have been shown to reduce levels of cell death compared to a minimal UVR-blocking contact lenses [7]. In addition, changes in epithelial, stromal and endothelial cells have been observed between eyes wearing standard hydrogel lenses and those wearing UVR-blocking lenses. [17] Trauma to keratocytes and endothelial cells can result in permanent damage to the cornea [18,19] thus UVR protection is imperative.

The level of protection given by a soft contact lens is dependent upon the transmittance characteristics of the lens material, with UVR absorption levels varying between brands [20]. Contact lens light transmittance is reported to change with contact lens wear and this is most likely due to the formation of biofilms on the lens surface, however this was not found to affect the UVR-blocking properties of the lens [21]. The level of UVR protection provided by a contact lens has been shown to be dependent upon its power, and therefore centre thickness [22]. Class I lenses must block at least 90% of UV-A and at least 95% of UV-B, and class II must block at least 50% of UV-A and at least 95% of UV-B [23].

Although there is strong evidence that shielding the skin from UVR is beneficial, there is little direct evidence for the eyes. This multi-site study examined the effects of wearing UVR-blocking contact lenses for at least five years on eye health, ocular accommodation, and macular pigment across five developed countries.

2. Methods

The study was approved by the Research Ethics Committees in each site location and conformed to the tenets of the Declaration of Helsinki. The variability (95% confidence interval) of the push up test is ± 1.43 D [24], so to detect a 0.6 D change (80% power, 0.05 significance level) a minimum of 20 participants in each study arm for non-parametric comparison (G*Power v3.1.9.4) was required. The variability of defocus curves is not known, but the variability of subjective acuity measurement at each level of defocus is ± 0.08 logMAR [25,26], so to detect a 2 letter (0.04 logMAR) change would require at least 14 participants. The variability of Aston aberrometer measures of accommodation has been shown to be 0.2 D [27], so to detect a 0.10 D difference required at least 14 participants. The variability of MPS 900 macular pigment densiometry has been shown to be 0.04 [28] so to detect a 0.02 MPOD change would require 14 participants. Therefore 21 participants were enrolled for each group at each site to allow for some invalid data. Once written informed consent had been obtained after explanation of the nature and possible consequences of the study, 42 participants aged 18 to 50 years were assessed at each of the five sites across the world (Birmingham (United Kingdom), Houston (USA), Brisbane (Australia), Waterloo (Canada) and Hong Kong SAR (China); n = 210 in total). Recruitment was stratified with 7 participants in each of the 18–28 year old, 29–39 year old and 40–50 year old age ranges in both the UVR and minimal UVR-blocking contact lens groups.

The average temperature and UVR indices of each region are represented in Table 1. The UVR index is a standardised way of measuring the strength of UVR reaching the earth’s surface at any given time and location. It was first released in 1995, with an updated version published in 2002 [28]. The index is based on the thickness of the ozone layer in the upper atmosphere, the angle of the sun and the amount of cloud cover. The scale ranges from lows of zero to highs of 11 or more in tropical countries, and can be grouped into five levels of risk: low (0–2), moderate (3–5), high (6–7), very high (8–10) and extreme (11+) [29].

Participants were required to have worn contact lenses for a minimum of five days per week for the previous five years or more and to have been a resident of that country during the same period. Additionally, participants were required to have a best corrected visual acuity of 6/7.5 or better in each eye, have no previous history of eye surgery and not to be on any medication known to affect accommodation. Twenty-one participants from each site (n = 105 in total) had worn contact lens materials with UVR-blocking for at least five years and the 21 controls (n = 105 in total) had worn a contact lens material with minimal UVR-blocking properties for the same period. Participants reported the brand of their contact lenses; these were checked against clinical records where available and the UVR-blocking properties against published spectral profiles.Investigators were masked to the participant’s contact lens history.

Participant demographics of age, sex, ethnicity, height and weight (to calculate body mass index = height × weight (BMI)), general health (including smoking) and medication were recorded. Bulbar conjunctival and limbal redness were graded through a slit lamp biomicroscope using an Efron scale to one decimal place from 0.0 to 4.0, and the presence of any pinguecula and pterygium noted.

All research data was collected by the same researchers at all sites, on the same equipment. Ocular accommodation was assessed subjectively whilst wearing prescription optimized contact lenses by averaging three repeats of the push-up test [30], as well as from minus-to-blur testing: increasingly minus powered lenses were held in front of the participants distance corrected eye monocularly, as they viewed a distance letter chart. Participants attempted to minimise the resulting defocus by accommodating, reading the smallest letters they could see (randomized between lenses), so that the dioptric power at which they could no longer hold their best visual acuity line in clear focus (allowing for lens minification) could be identified [31,32]. Objective stimulus response and dynamic measures of the accommodative response were quantified with an open-field aberrometer [27]. The stimulus response curve for accommodation and pupil size was measured using a high contrast Maltese cross at 0.0D, 0.5D, 1.0D, 2.0D, 3.0D, 4.0D and 5.0D of accommodative demand (in a Badal optical system). The dynamics of accommodation were assessed by rotating a Maltese cross at 3.0D accommodative stimulus into and out of the line of sight of a second Maltese cross positioned at optical infinity, at 5 s intervals (servo motor transverse cut < 0.05 s). The 0.5 Hz dynamic recording of the Aston aberrometer [27] was captured by a personal computer which also controlled the stepper motor rotating the Maltese cross, so the speed of accommodation, response amplitude, latency and speed of disaccommodation could be evaluated from three repeated accommodation and relaxation cycles.

Macular pigment optical density (MPOD) was determined using the MPS II 9000 (Elektron eye technology, Cambridge, UK) that employs the psychophysical technique of heterochromatic flicker photometry [33].
The test eye was fully corrected with full aperture trial lenses position in a trial frame to avoid any bias from the light transmission of the contact lens, with the fellow eye occluded to avoid distraction.

UVR autofluorescence images were captured of the nasal and temporal conjunctiva of the right eye using a custom-made attachment mounted to an iPhone camera (4032 × 3024 pixels resolution) incorporating a macro-lens to give 6x magnification. This bespoke device uses a 365 nm wavelength diode positioned 3 cm from the eye that produces non-collimated light to highly damaged cells on the ocular surface [34]. The edges of regions with conjunctival fluorescence were subjectively outlined using ImageJ software (http://rsbweb.nih.gov/ij/) to give an area in pixels. An object of known size was also imaged using the same camera system to obtain a pixel to mm conversion factor from which the area in square millimetres was ascertained.

Participants were asked to complete a lifestyle questionnaire related to their demographics (age and sex), refractive correction wear, lifestyle (self-reported as ‘sun-avoider’, ‘average sun exposure’ or ‘sun-worshipper’, use of sunglasses – worn most of the time outdoors, worn only when sunny, worn sometimes or never worn) and contact lens history (number of years lenses worn, current brand and years worn) [34]. Additionally, participants completed a validated food frequency questionnaire which collected information about average frequency (checking 1 of 9 frequency categories, ranging from “never or less than once per month” to “two or more times per day”) and serving sizes (small, medium, or large) of consumption over the previous year. The selected frequency categories and serving sizes for each food item were converted into an average daily intake of medium servings and the foods items combined into food groups to reduce inter-person variation [35].

3. Statistics

Due to the association between right and left eyes, only data from right eyes were included in the analysis in order to avoid statistical bias. Amplitude of accommodation, minus lens to blur, accommodative dynamics and macular pigment were not significantly different from a normal distribution (one-sample Kolmogorov–Smirnov test p > 0.05) and therefore analysis of variance (with Tukey post-hoc comparison) was conducted for site and material UVR comparison were used. For redness grading and autofluorescence area, independent sample Mann-Whitney U for lens comparison and Kruskal-Wallis for site and material UVR comparison were used. Only two autofluorescence images of the 420 captured (0.5%) could not be analysed due to low quality. Statistical significance was set as p ≤ 0.05.

4. Results

The cohorts of participants who had worn UVR-blocking or minimal UVR-blocking contact lenses were matched for age, sex, race, body-mass-index, diet, lifestyle, refractive error and visual acuity (Table 2). Reported sun exposure differed between sites (all were ‘average’, except Hong Kong, where the median was ‘sun avoider’; p < 0.001). Use of sunglasses was slightly lower in the minimal UVR-blocking cohort (p = 0.050) and differed with site (all were ‘only worn when sunny’, except Hong Kong, where the median was ‘never worn’; p < 0.001).

There was no statistically significant difference in bulbar conjunctival redness (p = 0.903) in eyes that had worn UVR-blocking contact lenses (1.2 median, 0.5–2.9 range) compared to the controls (1.3 median; 0.2–2.3 range), but the median of the USA and Hong Kong cohorts was double that of Canada (p < 0.001; Table 3). Limbal redness was statistically significantly lower (p = 0.035) in eyes that had worn UVR-blocking contact lenses compared to the controls; the median was higher in the UK, USA and Hong Kong compared to Canada and Australia (p < 0.001; Table 3). Pingueculae (UVR: 19 eyes versus minimal UVR-blocking contact lenses: 20 eyes; p = 0.859) or pterygia (UVR: 4 eyes versus minimal UVR-blocking contact lenses: 5 eyes; p = 0.733) did not differ in proportion between eyes that had worn UVR-blocking contact

| City, Country | Average maximum summer month temperature (°C) | Ultraviolet Radiation Index |
|--------------|-----------------------------------------------|-----------------------------|
| Birmingham, UK | 21.8                                          | 5.5                          |
| Houston, USA  | 34.4                                          | 10.4                         |
| Brisbane, Australia | 29.1                               | 10.5                         |
| Waterloo, Canada | 21.0                              | 10.4                         |
| Hong Kong SAR, China | 31.4                             | 8.5                          |

Table 1: Average maximum summer month temperature, monthly Ultraviolet Radiation index and sunshine hours by data collection region. https://www.weather-atlas.com accessed March 2022.
lenses compared to the controls.

Amplitude of accommodation push-up test results were higher, but not statistically significantly, in eyes that had worn UVR-blocking contact lenses (8.0 ± 3.7D) versus those that had worn minimal UVR-blocking contact lenses (7.3 ± 3.3D; p = 0.125); it was lower in Hong Kong compared to the other sites (p < 0.001; Table 3). The maximum accommodative amplitude without debilitating blur was lower in the minimal UVR-blocking lenses compared to those that had worn UVR-blocking contact lenses (p = 0.758), but again was lower in Hong Kong compared to other sites (p = 0.050; Table 3).

Accommodative response increased with accommodative demand (F = 230.289, p < 0.001) (Fig. 1). There was no statistically significant difference in the stimulus response between UVR and minimal UVR-blocking lenses (F = 1.255, p = 0.285) or countries (F = 1.524, p = 0.066).

Accommodative latency was shorter in eyes that had worn UVR-blocking contact lenses compared to eye that had worn lenses with minimal UVR-blocking (p = 0.003). Accommodative latency was shorter in eyes from the USA than all the other countries except Australia (p < 0.001). The speed of accommodation and step size was higher in eyes from the USA than the UK (p = 0.014) and the step size was lower in Australia than the USA or Canada (both p = 0.002, Table 3).

There was no significant difference in UV autofluorescence (nasal: p = 0.786; temporal: p = 0.639) and MPOD (p = 0.869) between eyes that had worn UVR-blocking contact lenses compared to those that had worn contact lenses with minimal UVR-blocking contact lenses (Table 3). However, there was a significant difference among countries (p = 0.031), with wearers in the UK having a lower macular pigment density than those in Hong Kong (p = 0.050).

## 5 Discussion

There are many associated health risks to both the skin and the eye from exposure to UVR. Soft contact lenses with a UVR filter can offer protection to the eye and its structures because of their relatively large diameters and the fact that they move with the eye, ensuring continued protection. There is strong evidence that light filtering spectacles or sunglasses, they are in contact with the ocular surface and move with the eyes and can therefore block peripheral light rays entering through the cornea. Hence, the finding that they reduced limbal, but not conjunctival redness was not surprising. Likewise the higher levels of bulbar and limbal conjunctival redness in Houston USA and Hong Kong SAR China cohorts could reflect the higher temperatures and UVR indices in these regions, but this did not account for the higher level of limbal redness in the UK cohort that was less exposed to these environmental conditions, nor the lower levels of redness in Brisbane Australia, where more harsh environmental conditions are common. UV autofluorescence of the conjunctiva was also not found to differ with UVR blocking of contact lenses in this study, perhaps due to contact lenses not offering much coverage of this area, although protection has been found in other studies [36]. Other factors such as public health messaging around sun exposure in some regions are likely to play a role in mitigating environmental effects.

Although UVR is recognized as a risk factor for cataract, very little is known about its effect on presbyopia [37]. The comparison of amplitude of accommodation and stimulus response curve did not show a statistically significant difference between participants who had worn UVR-blocking compared to those wearing minimal UVR-blocking contact lenses for the past five years or more. The effect size may have been reduced by the age range of the participants, with some older individuals demonstrating minimal objective accommodation. However, the additional amplitude of those who had worn UVR-blocking lenses was +0.25D measured objectively at 5.0 D of accommodative demand and +0.7D measured subjectively at the average amplitude of accommodation of around 7.5D of demand. As around 80% of the subjective amplitude can be utilised in a sustained task [38], this difference could be considered clinically meaningful in delaying the onset of presbyopia. The amplitude of accommodation measured by push-up or the maximum negative powered lens that distance targets could be resolved through without debilitating blur was lower in the Hong Kong cohort. As the region with the highest UVR exposure of the cohorts examined in this study, this concurs with the high incidence of presbyopia occurring at younger ages that has been reported in countries with high levels of UVR [39,40].

Measurement of the dynamics of accommodation, such as speed of accommodation/ disaccommodation and latency, can be used as an indicator of the state of the accommodative system [41,42] and the development of presbyopia [43-45], in addition to assessment of the amplitude of accommodation [41]. Accommodative latency was found to be shorter in those wearing UVR-blocking contact lenses versus those wearing minimal UVR-blocking lenses, suggesting that UVR exposure has an impact on the presbyopic process. The cohort from Houston USA had a shorter latency, faster speed and higher step size than some of the other regions, which cannot be explained by the other data collected in this study, so warrants further investigation.

There was no difference in MPOD between eyes that had worn UVR-blocking contact lenses compared to those that had worn contact lenses with minimal UVR-blocking contact lenses. This suggests that any epidemiological association between macular degeneration and UVR is unlikely to be through the protection afforded by the macular pigment
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Table 3

Comparison of participants wearing UVR and minimal UVR-blocking contact lenses across five international sites. N = 21 in each cohort. Average ± S.D. or Median [range].

|                  | UVR-Blocking | Minimal UVR-Blocking |
|------------------|--------------|----------------------|
| Limbal ± 4.5     | 0.8 ± 1.5    | 1.2 ± 1.4            |
| 2.3 ± 2.5        | 0.8 ± 0.9    | 1.2 ± 2.2            |
| 2.9 ± 2.6        | 1.3 ± 0.8    | 1.4 ± 1.2            |
| 2.6 ± 2.5        | 0.9 ± 1.1    | 1.3 ± 1.1            |
| 3.4 ± 3.5        | 1.3 ± 0.8    | 1.3 ± 0.7            |
| Macular Pigment  | 0.5 ± 0.2    | 0.6 ± 0.2            |
| 0.2 ± 0.1        | 0.8 ± 0.3    | 1.0 ± 0.3            |

Fig. 1. Change in accommodative response between Ultraviolet Radiation blocking and minimally Ultraviolet Radiation blocking contact lens wearers.

filter. Several studies have shown a higher macular pigment level in south Asians compared to Caucasians eyes [46-49], supporting the observation of the highest levels in the Hong Kong cohort in this study, although other cohorts included native Asian participants.

The limitations of the study were its retrospective nature of eye protection and the confounding effects of lifestyle such as indoor UVR exposure, beyond those that were matched for, that may have influenced UVR exposure between individuals. However, the same masked observers collected the clinical metrics across all sites, using the same instrumentation, allowing the first standardised comparison of the clinical effects of UVR-blocking filters embedded in contact lenses. More protective effects may have been observed for a longer period of ocular UVR protection.

In conclusion, blocking the transmission of UVR through a contact lens seems beneficial in maintaining the eye’s ability to focus, suggesting that presbyopia may be delayed in long-term UVR-blocking contact lens wearers. There is also evidence they provide protection to the critical limbal region.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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