The Contact Lens with Seven Dimensions for Exceptional Visual Performance

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Seven Dimensions for Exceptional Visual Performance[1]

Comfort	**1. Physical comfort[¥,11]**
Light Management	**2. Adaptation to changing light[11]** **3. Active blue light filtering[α,11]** **4. UV protection[†§]**
Vision	**5. Vision in bright light[‡,#,1]** **6. Vision at night[,††,1]** **7. Color contrast[‡,1]**

Additional Key Points

Performance	Amongst those with a preference, preferred nearly 3 to 1 over the leading usable lens[2‡]
Patient communication	Offer a lens that combines "exceptional comfort[¥,11] and vision,[‡,1] with adaptation to light throughout the day"

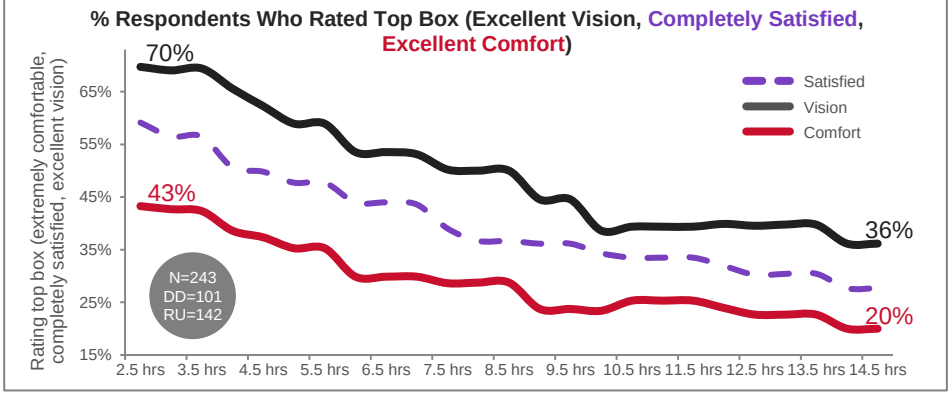
Introduction

Drop out from contact lens wear continues to occur, with dryness, discomfort, visual satisfaction and handling all being cited as contributing reasons.[3-5] Globally, performance issues with contact lenses are reported by more than two-thirds (68%) of dropouts,[6ᵦ] with the majority of dropouts coming from those in reusable contact lenses.[7^]

Contact lens wearers can experience declining overall satisfaction, visual satisfaction and comfort with their lenses over the course of the day.[8] Whilst it is not surprising to see a reduction in comfort (Figure 1), it is significant to appreciate how visual satisfaction deteriorates in a similar way. When it is considered that nearly two-thirds (64%) of people admit to being bothered by harsh or bright lighting conditions on a daily basis,[9] it is possible to appreciate how overall visual performance, a combination of comfort and vision, may be further modulated by management of light levels.

Patients may benefit from experiencing a lens built on a brand that has never been beaten in comfort,[§] and that also delivers exceptional visual performance.[1‡] Recently, a first-of-its-kind contact lens has been launched which does just that. ACUVUE® OASYS with Transitions™ Light Intelligent Technology™ combines the proven comfort and visual performance of ACUVUE®[10] with seamless adaptation to light, day to night.[1,11,12‡] In fact, this one contact lens delivers seven dimensions for exceptional visual performance,[1‡] which fall into the three areas of comfort, light management and vision.

Figure 1: Decline in contact lens satisfaction, comfort and vision over the day, n=243. DD refers to daily disposable wearers and RU to reusable wearers[8]



#1. Physical Comfort

ACUVUE® OASYS with Transitions™ is a first-of-its-kind light-responsive contact lens.[11] Ten years in development, it combines the proven senofilcon A material with a photochromic additive co-polymerised homogeneously throughout the lens matrix.[11] The senofilcon A material, used across the ACUVUE® OASYS family has never been beaten in comfort in fifteen years.[¥] At the time of writing, publicly available data on clinicaltrials.gov recorded 29 clinical trials involving senofilcon A, eleven of which were run by competitor contact lens manufacturers, with a total of more than four thousand patients fit.[§] Physical comfort can be considered the most important first dimension of successful contact lens wear, and the long history of unbeaten comfort[§] gives confidence to recommend this material to patients.

Light Management

#2. Adaptation to changing light

ACUVUE® OASYS with Transitions™ seamlessly adapts to balance the amount of indoor and outdoor light entering the eye.[11] Beyond obvious situations such as bright sunlight outdoors where sunglasses are recommended to protect a wider area of the anterior eye, there are many examples of everyday situations where sunglasses may not be to hand, or more particularly, they may be too dark. Examples of this include quick trips from

‡Compared to ACUVUE® OASYS with HYDRACLEAR® PLUS. ᵅCalculated per ISO-8980-3 for 380-460nm (Blue Light Hazard Function, B(lambda)). ᵝLens performance issues include comfort & wearability, insertion & removal. ^Contact lenses are defined as soft clear contact lenses. †Helps protect against transmission of harmful UV radiation to the cornea & into the eye. ¥ www.clinicaltrials.gov is a website maintained by the NIH. The 29 clinical studies evaluated subjective comfort as a primary or secondary endpoint for ACUVUE OASYS Brand 2-Weekly Family and for ACUVUE OASYS 1-Day with HydraLuxe Technology. Review conducted as of April 25, 2021.

††Clinical trials have shown those aged 40-65 may be more likely to experience this benefit in the inactivated ACUVUE® OASYS with Transitions™ lens. § All ACUVUE® Brand Contact Lenses have Class 1 or Class 2 UV-blocking to help provide protection against transmission of harmful UV radiation to the cornea and into the eye. UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area.

indoors to outdoors, outdoor sports, and bright light coming through windows when indoors.‡ This product seamlessly adapts between these different and changing environments. They also continue to work by filtering light in low light levels such as night driving.[11] Overall ACUVUE® OASYS with Transitions™ is a contact lens that can adapt to and cope with the dynamic lighting challenges of modern everyday living.

#3. Active blue light filtering

ACUVUE® OASYS with Transitions™ actively filters blue light.[11**] The transmission curves for the lens, in comparison to ACUVUE® OASYS are shown in Figure 2. Both the transmission of the fully activated (outdoor state) and inactive (indoor state) lens are shown. In its indoor state there are differences in light transmission compared to a clear contact lens. This means that even when the lens appears clear, some of the photochromic molecules are activated, allowing the lens to continue filtering light across the visible spectrum.[11**] The lens blocks between 5% and 15% of light indoors, mostly the high energy visible (HEV) range,[11**] and up to 70% of visible light at full activation, including 55% HEV light, where you need it most.[11**] It begins to darken as soon as it is exposed to sunlight, is dark in 45 seconds, and fades back within 90 seconds.[11]

#4. UV protection

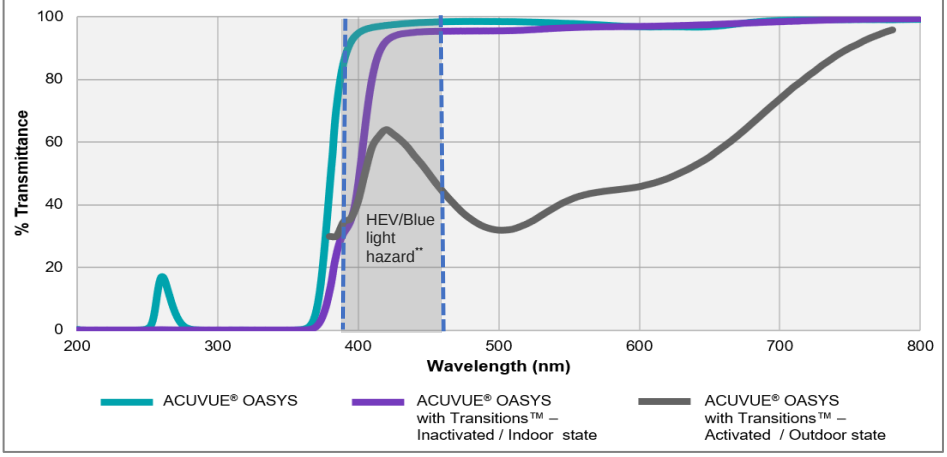
Even in the inactivated or indoor state, ACUVUE® OASYS with Transitions™ blocks more UV and HEV light than clear ACUVUE® OASYS.[11] In fact, it has the highest level of UV protection in a contact lens, with 100% blocking of UVB and above 99% of UVA across the parameter range.[11,13†‡] This is the fourth dimension for exceptional visual performance.[1‡]

Assessment of visual performance

Our world presents a continually changing dynamic set of conditions to our eyes throughout each and every day. This means the assessment of overall visual performance encompasses much more than measures of high contrast visual acuity alone.

For the purposes of testing, a photochromic lens can be exposed to a light source to achieve a steady state of activation, with subjects viewing various different illuminations and targets through that lens. This work has been undertaken with photochromic spectacle lenses,[14] and has more recently been conducted using ACUVUE® OASYS with Transitions™. Across two phases of a study, 112 subjects were enrolled and randomised to contralateral wear of either partially activated (outdoor state) or inactive (not in the presence of an activating light source, for example indoors or outside at night) ACUVUE® OASYS with Transitions™ in one eye, and ACUVUE® OASYS as a control in the other.[15,16]

Figure 2: Transmission spectra of ACUVUE® OASYS with Transitions™ for lens in fully activated (outdoor state) and inactive (indoor) state, compared to ACUVUE® OASYS



Several aspects of visual function were quantified that were designed to explore the kinds of visual challenges encountered in daily life. Temporary impairment of vision due to bright light was examined, the photostress recovery time for the visual system to recover after exposure to a bright light source was established, and the squint response to bright light sources was measured. CL wearers can experience scatter, starbursts and haloes around light sources, so these situations were also assessed, along with chromatic contrast which relates to the ability to distinguish between different coloured objects in a scene.

The relevance of all these measures of visual function to everyday life must be considered, and these aspects of vision, measured in a research setting, must be directly relatable to the real-world. Temporary impairment of vision occurs, and photostress recovery time is impacted, on exposure to a bright light. This could be experienced as the dazzle of headlights whilst driving at night. To increase the threshold at which temporary impairment of vision occurs, and to reduce the recovery time after exposure would intuitively be potentially beneficial for drivers. Likewise, situations where squinting occurs, for example, when out walking on a bright day, can lead to prolonged contraction of the orbicularis oculi which feels uncomfortable.[17] A reduction in squint response would suggest vision may feel more comfortable in that situation.

#5. Vision in bright light

The results from both phases of the study are summarised in Table 1. ACUVUE® OASYS with Transitions™ resulted in significantly improved performance compared to the leading reusable lens for every visual performance metric that was assessed.[15,16‡] For the partially activated condition, this means ACUVUE® OASYS with Transitions™ reduced the stressful impact that light can have on eyes by helping vision recover from bright light up to five seconds faster, and reduced squinting by 38% on average.[15***‡]

It is particularly interesting to note the improvements in visual performance which occurred for the inactivated (indoor state) lens compared to the clear control contact lens. This translates to benefits whilst the lens is worn indoors by reducing impairment of vision due to bright light by up to 20%, and by providing up to 21% enhanced colour contrast.[15,16‡] The performance of the lens in its inactivated i.e. not in the presence of an activating light source, usually indoors or outside at night, is crucial to recognise. Regardless of the lighting conditions some percentage

†Helps protect against transmission of harmful UV radiation to the cornea & into the eye.‡ All ACUVUE® Brand Contact Lenses have Class 1 or Class 2 UV-blocking to help provide protection against transmission of harmful UV radiation to the cornea and into the eye. UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. ‡Compared to ACUVUE® OASYS with HYDRACLEAR® PLUS. ‡Lenses are not a replacement for sunglasses.**Calculated per ISO-8980-3 for 380-460nm (Blue Light Hazard Function, B(λ)) ***Clinical trials have shown those with dark irises may be more likely to experience this benefit in the activated ACUVUE® OASYS with TransitionsTM lens.

Table 1: Average improvement in visual performance measures with ACUVUE® OASYS with Transitions™ compared to ACUVUE® OASYS%‡

	Average % improvement	
	Partially activated (Outdoors state)	Inactivated (Indoors state)
Temporary impairment of vision due to bright light	26.6	16.9
Chromatic contrast threshold	32.3	17.1
Photostress recovery time	43.1	45.4
Squint response	38.4	25.7
Scatter	37.0	18.4
Haloes	48.2	17.9††
Starbursts	41.8	21.7

Note that for photostress recovery time and the squint response the results are not directly comparable as the intensity of the illumination was different in the two studies, being greater with the inactivated lens.

of the photochromic is always absorbing light so it's always on and working, both indoors and out.[11] In the fifth dimension for exceptional visual performance,[1‡] ACUVUE® OASYS with Transitions™ reduces the stressful impact of bright light by reducing squinting and enabling a faster recovery.[15,16‡]

#6. Vision at night

The effect of the lens on the visual perception of scatter, haloes and starbursts is particularly relevant to the experience of wearing the lens at night. To make these assessments, subjects completed the following tests. For scatter, they looked at two points of light that were so close together they appeared as one, and the distance between those two points was increased until they were able to be perceived as separate with a dark area between them. Smaller is better for this measurement. For haloes, a holometer was used to measure the diameter, in a dark room, of the halo around a point source of light. Again, smaller is better. Finally, for starbursts, the diameter of a point source of light's spokes lateral spread was measured where, as for all these metrics, smaller is better.

In comparison to a clear lens control, for both the partially activated and inactivated states of ACUVUE® OASYS with Transitions™, there was a significant improvement in visual response (Table 1).[15‡] Even in the indoors inactivated state a benefit was found, providing further confirmation that the lens is always 'on'. The results shown are means and, of course, there are variations between subjects. For haloes, the lens reduced the effect by 18% on average, with older subjects more likely to experience this benefit.[15‡††] Ocular media changes with age cause increased scatter in the eye,[16,18] which may help to explain the greater effect of the lens seen with age in these specific situations. These results characterise our sixth dimension for exceptional visual performance.

#7. Color contrast

The seventh and final dimension of visual performance relates to chromatic or colour contrast, which was also explored in the study by Hammond.[16] This showed that wearers of partially activated ACUVUE® OASYS with Transitions™ lenses enjoyed significantly better chromatic contrast than ACUVUE® OASYS wearers. A mean improvement of 32% with the lens partially activated was found, with some subjects experiencing up to 38% better chromatic contrast.[15‡] The preponderance of Rayleigh scattered light (seen as "blue haze" and blue sky light) creates a natural situation where many targets are viewed on short-wave (blue) backgrounds. Sky light peaks at the same absorbance peak as used in this experiment, 460 nm, indicating the important ecological validity of this effect. The results of this study are consistent with the possibility that wearing a photochromic contact lens will improve border detection (and hence object perception) in real world scenarios.

Performance compared to the leading reusable contact lens

Clinical studies have compared ACUVUE® OASYS with Transitions™ to ACUVUE® OASYS, illustrating how the seven dimensions of visual performance are experienced by wearers. The studies were randomised, partially subject masked, crossover, dispensing trials with 229 subjects completing two-weeks wear of each lens. There were no physiological differences found between the Test and Control lenses at any visit.[2‡] Overall vision for the test lens was superior to the control. This demonstrates how ACUVUE® OASYS with Transitions™ performs well in comparison to the leading reusable contact lens.

Having experienced lens wear for two-weeks, subjects were able to report on their preference between the two lenses, both for specific daily situations and more generally overall. Meta-analysis was conducted on the response from 239 subjects. Among those with a preference, it was found that ACUVUE® OASYS with Transitions™ was strongly preferred to the clear control in several regularly experienced daily situations (Figure 3). These included both outdoors (5.5 to 1) and indoors (4 to 1), digital device use (3 to 1) plus driving during the day (5 to 1) and driving at night (3.5 to 1).[2] This demonstrates how a lens which can seamlessly adapt to changing light can provide noticeable benefits to a clear contact lens. Given that experience, it is not surprising subjects reported ACUVUE® OASYS with Transitions™ provided superior overall quality of vision over the leading reusable contact lens.[2‡]

Performance compared to spectacles in new contact lens wearers

A further study examined the outcomes of fitting neophytes with ACUVUE® OASYS with Transitions™. It was designed to understand how successfully the lens could be fit in this patient group, and how its performance compared to subjects' habitual spectacles. The study enrolled 127 recently dispensed spectacle wearing subjects at 11 sites in the US, with 105 subjects completing the research. There were 5 visits that involved an initial visit, where lenses were fitted and the subject trained in insertion and removal, and four follow up visits. Lenses were replaced at two

‡Compared to ACUVUE® OASYS with HYDRACLEAR® PLUS. º The average in-vivo light transmission used in this study was ~62% ††Clinical trials have shown those aged 40-65 may be more likely to experience this benefit in the inactivated ACUVUE® OASYS with Transitions™ lens. ††Clinical trials have shown those aged 40-65 may be more likely to experience this benefit in the inactivated ACUVUE® OASYS with Transitions™ lens

Figure 3: Among those with a preference, ACUVUE® OASYS with Transitions™ was preferred over ACUVUE® OASYS‡16

5.5 TO 1
FOR OUTDOORS

5 TO 1
DRIVING DURING THE DAY

4 TO 1
FOR INDOORS

3.5 TO 1
FOR DRIVING AT NIGHT

weeks and the subjects returned to their habitual spectacles at visit four.[19]

In terms of fit success rate, for those subjects who wore lenses at the fourth visit, 100% of lenses were deemed by the practitioners to have an acceptable mechanical fit.[19] After initial fitting, final fit success was based on minimal physiological response, good levels of subjective comfort, acceptable vision and good lens handling. 94% of subjects had their lens fit classified as successful using these criteria.[18] The reasons for unsuccessful fits were typical of normal clinical practice. Of the unsuccessful fits, four were related to difficulties with application and removal and one related to poor vision.

Subjects were asked questions pertaining to the clinical performance of the lenses compared to spectacles. The response options had two levels of agreement and two levels of disagreement. The two levels of agreement (top 2 box) are grouped and displayed in Figure 4. Subjects were extremely positive about the benefits of ACUVUE® OASYS with Transitions™ compared to their habitual spectacles. In fact, more than 9 out of 10 subjects wanted to continue to include ACUVUE® OASYS with Transitions™ in their vision correction choice. Only 8% wanted to continue with clear spectacles alone.[19]

Introducing to patients

How best to convey the seven dimensions for exceptional visual performance to patients?[1‡] The key elements to share are that it is built on the platform that has never beaten in comfort,[§] has high levels of visual performance and is able to adapt to changing light levels throughout the day.[11] Giving examples of where those benefits may impact a patient is helpful. For example, referring to the patient viewing digital devices in the office, driving at night or playing sports outside. No different to any contact lens, the best way to demonstrate the benefits of the lens is to allow the patient to try it. Recommend they use the trial lens in a variety of light levels, and that a comparison back to their spectacles or habitual contact lenses may be helpful to see the difference in visual performance ACUVUE® OASYS with Transitions™ delivers.

Conclusion

ACUVUE® OASYS with Transitions™ is a first-of-its-kind light-responsive contact lens.[11] It seamlessly adapts to balance the amount of indoor and outdoor light entering the eye, including filtering blue light* and blocking harmful UV rays.[11,13] The parameters available at launch are shown in Figure 6.

In fact this one contact lens delivers seven dimensions for exceptional visual performance,[1‡] an important principal when the decline in overall satisfaction and visual performance reported with other contact lenses over the course of a day is considered.[8] The visual benefits the wearer receives when wearing ACUVUE® OASYS with Transitions™ are measurable and translate to real-world situations. The experience of wearers, in comparison to the leading reusable contact lens is strong, with a three to one preference expressed for ACUVUE® OASYS with Transitions™.[2‡] Eye care practitioners can have confidence that they are recommending a contact lens which can deliver a discernable difference in overall visual performance.

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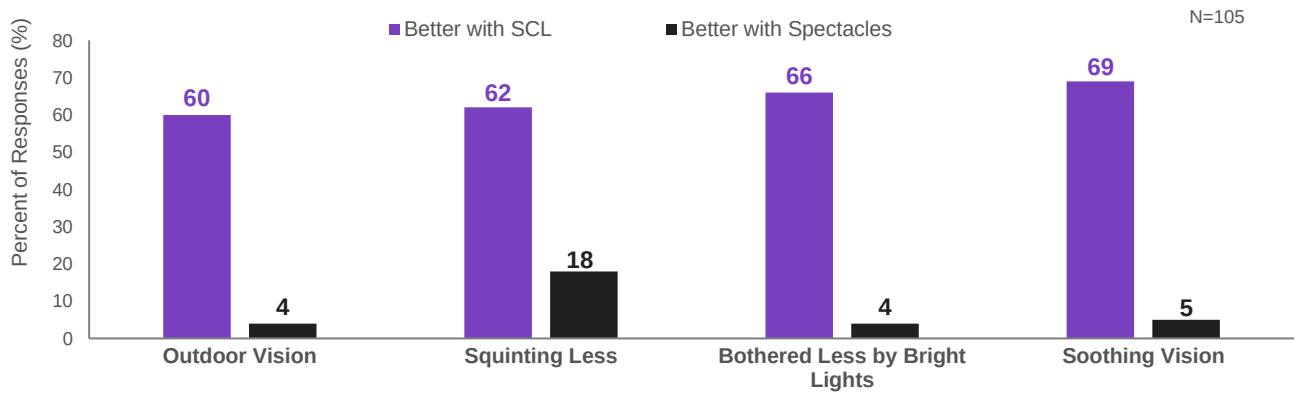
Figure 4: Subjective response to visual experience being better with either ACUVUE® OASYS with Transitions™ or habitual spectacles, n=105



§www.clinicaltrials.gov is a website maintained by the NIH. The 29 clinical studies evaluated subjective comfort as a primary or secondary endpoint for ACUVUE® OASYS Brand 2-Weekly Family and for ACUVUE® OASYS 1-Day with HydraLuxe™ Technology. Review conducted as of April 25, 2021. *Calculated per ISO-8980-3 for 380-460nm (Blue Light Hazard Function, B(λ)) ‡Compared to ACUVUE® OASYS with HYDRACLEAR® PLUS

Figure 6: Parameters for ACUVUE® OASYS with Transitions™

LENS MATERIAL	SENOFILCON A SILICONE HYDROGEL
Lens Material	senofilcon A silicone hydrogel
Technology	HYDRACLEAR® Plus Technology Transitions™ Light Intelligent Technology™
Base curve, mm	8.4
Diameter, mm	14.0
Power range	+8.00 to -12.00D (-6.00D to +6.00D in 0.25D steps; -6.50D to -12.00D in 0.50D steps and +6.50 to +8.00 in 0.50D steps, not including plano)
Dk/t (edge-corrected) ▲	121 x 10^{-9}
Water content	38%
Modulus (MPa)	0.69
UV blocker†‡	Class 1
Center thickness at -3.00D (mm)	0.085
Inside-out mark	Yes
Packaging solution	Optimised to help mimic the electrolyte concentration of natural tears for comfort in insertion

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ACUVUE® OAYSYS Contact Lenses with Transitions™ Light Intelligent Technology™ are not a substitute for sunglasses.

▲ Fatt units (x10-11(cm2/sec)(mlO2/ml x mmHg)) at 35°C, determined via polarographic method. Dk/t for -3.00D lens (x10-9(cm/sec)(ml O2/ml x mmHg)). †Helps protect against transmission of harmful UV radiation to the cornea & into the eye. ‡ All ACUVUE® Brand Contact Lenses have Class 1 or Class 2 UV-blocking to help provide protection against transmission of harmful UV radiation to the cornea and into the eye. UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area.

IMPORTANT SAFETY INFORMATION ACUVUE® Contact Lenses are indicated for vision correction. As with any contact lens, eye problems, including corneal ulcers, can develop. Some wearers may experience mild irritation, itching or discomfort. Contact lenses should not be used in case of eye infections or any other eye conditions. For complete information, including contraindications and precautions, please consult the Instructions for Use or visit our J&J website www.jnjvisioncare.co.uk

^ All ACUVUE® Brand Contact Lenses have Class 1 or Class 2 UV Blocking to help provide protection against transmission of harmful UV radiation to the cornea and into the eye. UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. UV transmission measured with -1.00D lens