

The Contact Lens that Knows Light

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KEY POINTS:

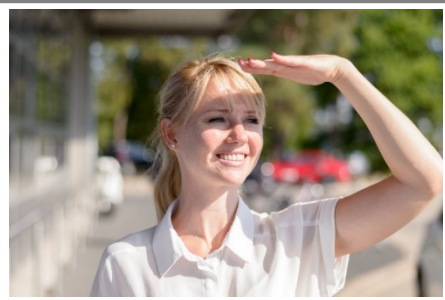
- Nearly two-thirds of patients are bothered by light on a daily basis.¹
- ACUVUE® OASYS with Transitions™ Light Intelligent Technology™ reduces exposure to bright light indoors and outdoors, including filtering blue light,* and blocking harmful UV rays.^{2,3}
- The lens begins to darken as soon as it is exposed to sunlight, is dark in 45 seconds, and fades back within 90 seconds.² It delivers consistent performance irrespective of ambient temperature.²
- In objective measures of functional vision ACUVUE® OASYS with Transitions™ has been shown to deliver significant improvements in both the partially activated (outdoor state) and inactivated states (indoor state) over the leading reusable contact lens.⁴
- In subjective clinical evaluations, ACUVUE® OASYS with Transitions™ has been shown to be superior in multiple indoors and outdoors performance metrics over the leading reusable contact lens.⁵

Introduction

Light is both essential for sight, and yet can be challenging for the visual system to cope with. In a recent review, Hammond *et al* (2019) highlighted the wide range of visual intensities humans are exposed to over the course of an average day; the impact light has on visual performance, and how spectral filtering has been shown to improve functional vision in a number of situations relatable to real-world experience.⁶

It has become increasingly apparent that a significant proportion of patients have problems coping with bright light. Nearly two-thirds (64%) admit to being bothered by harsh or bright lighting conditions on a daily basis.¹ This is not an insignificant issue. The coping mechanisms adopted when light becomes troublesome include shading or averting the eyes, turning down the brightness of digital devices and turning off room lights (Figure 1).¹

Figure 1: Example of compensating behaviour employed to help reduce the uncomfortable effects of bright light



Actions which are certainly inconvenient, and for some behaviours such as squinting, have the potential to cause visual discomfort and fatigue.^{7,8}

Recently, a first-of-its-kind⁹ contact lens has been launched. ACUVUE® OASYS with Transitions™ Light Intelligent Technology™ seamlessly adapts to changing light to provide all day soothing vision.^{†2,4,9} This article reviews the technology which makes it possible, and presents results from a number of studies which demonstrate how the lens performs in situations relevant to the real-world.

Introducing ACUVUE® OASYS with Transitions™

ACUVUE® OASYS with Transitions™ is a first-of-its-kind⁹ intelligent light-responsive contact lens.² Ten years in development, it combines the proven senofilcon A material with a photochromic additive co-polymerized homogeneously throughout the lens matrix.² The fact that the photochromic compound is embedded in the lens means that its light adaptive qualities run from edge to edge and that, unlike spectacle lenses, its performance is consistent irrespective of ambient temperature.

ACUVUE® OASYS with Transitions™ seamlessly adapts to balance the amount of indoor and outdoor light entering the eye, including filtering blue light* and blocking UV rays.^{2,3} 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.*² The lens blocks up to 15% of light indoors, including the high energy visible (HEV) range,*² and up to 70% of visible light at full activation.² It begins to darken as soon as it is exposed to sunlight, is dark in 45 seconds, and fades back within 90 seconds.²

The amount of photochromic additive included in ACUVUE® OASYS with Transitions™ is the result of carefully considered consumer insight. The balance had to be found between how dark the lens goes outside, and the acceptability of the cosmetic appearance when worn on a wide variety of iris colours. When ACUVUE® OASYS with Transitions™ was tried by 121 US consumers for two weeks, only 12% of subjects said that the appearance of the lens outdoors bothered them, and of that group, only 7% said they would not buy the lens.¹⁰ Given that the majority of patients agree they are bothered by light daily,¹ this suggests the subjects who had tried the lens were receiving appreciable day-to-day benefits that they wanted to continue enjoying.

Performance

The performance of ACUVUE® OASYS with Transitions™ has been assessed in several different situations. In addition to standard clinical trials, the lens has been used to determine how it impacts particular measures of visual performance, both when activated (outdoor state) and in its inactivated (indoor state). It has also been compared to the performance of photochromic spectacle lenses in the important real-world situation of driving. In each of these studies, the control was ACUVUE® OASYS with HYDRACLEAR® PLUS Technology. This was chosen as it is the leading reusable contact lens,¹¹ and has never been beaten in comfort.¹² These studies are summarised below.

Optical bench study with partially activated (outdoor state) and inactivated (indoor state) ACUVUE® OASYS with Transitions™

For the purposes of testing, a photochromic lens can be exposed to a light source to achieve a steady state of activation. This work has been undertaken with photochromic spectacle lenses, with measures of visual function such as response to bright light, photostress recovery and chromatic contrast all showing significant improvements with all photochromic lenses tested compared to clear controls.¹³

The experimental set up to test ACUVUE® OASYS with Transitions™ involved a precise layout on an optical bench. Across the two phases of the

study 123 subjects were enrolled and randomized to contralateral wear of either partially activated (outdoor state) or inactive (indoor state) ACUVUE® OASYS with Transitions™ in one eye, and ACUVUE® OASYS as a control in the other.⁴

Several aspects of visual function were quantified. Temporary impairment of vision due to bright light was measured by recording the light level at which a sine wave grating target disappeared as a surrounding annulus of light was increased in luminosity.

The observation of scatter, starbursts and halos that are typically associated with viewing a bright source of light were also explored. A colored grating target was used to establish chromatic contrast. This aspect of visual function relates to distinguishing between colored objects in a scene, so the experimental set up had a skylight-blue surround with a striped green central target in order to mimic the chromatic borders often seen in nature.¹⁴

Chromatic contrast threshold is the luminance flux of the light source necessary to prevent the subject being able to discern the central area from the surround.

Presenting the visual system with an intentionally bright light for a short period of time will stress the photoreceptors and cause a central target to be obscured. The time taken for the visual system to recover such that the target can be seen again is the photostress recovery time. Finally, a bright light source can induce discomfort, a reaction to which is the squint response, an attempt to try and reduce the uncomfortable amount of

light entering the eye.⁸ In research, this discomfort is assessed by measuring the magnitude of the squint response, which can be quantified by measuring the change in vertical palpebral aperture height.

These variables were carefully chosen and measured using elaborate optics in order to maximize their ecological validity. For example, the measures related to bright light were obtained using white light that matched the noon day sun, the surround for the chromatic testing matched blue sky light (460 nm).⁶ The relevance of all these measures of visual function to everyday life must be considered. As recently summarized,⁶ these aspects of vision measured in a research setting are 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.⁷ A reduction in squint response would suggest vision may feel more comfortable in that situation.

The results from both phases of the study are summarized in Table 1. ACUVUE® OASYS with Transitions™ resulted in significantly improved performance compared to the leading

Table 1: Average improvement in visual performance measures with ACUVUE® OASYS with Transitions™ compared to ACUVUE® OASYS, %⁴

	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.

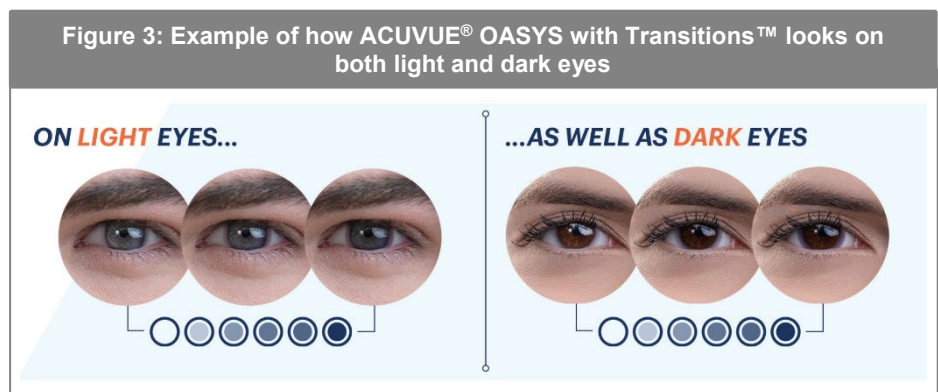
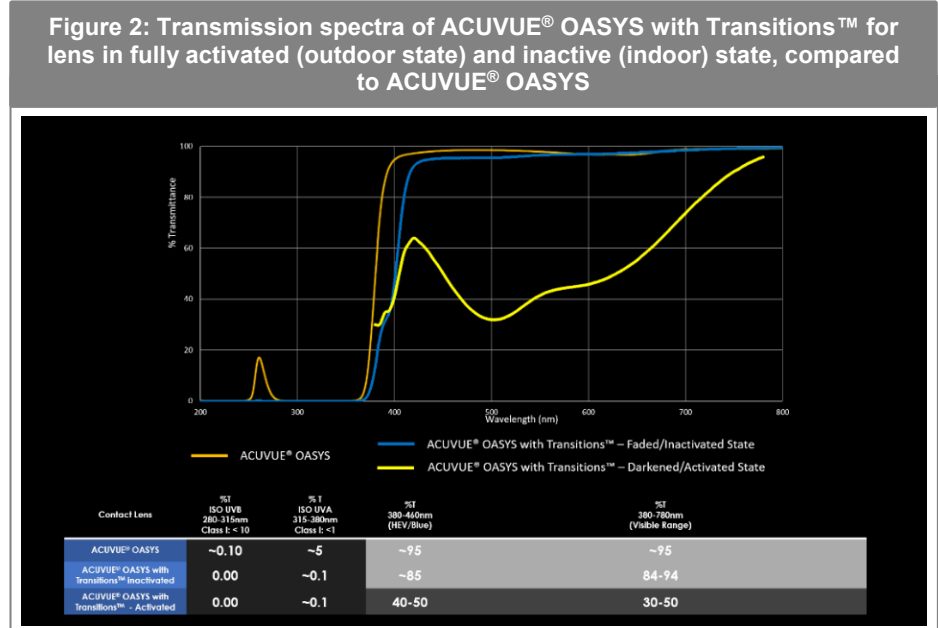
reusable lens for every visual performance metric that was assessed.⁴ For the partially activated condition, this means ACUVUE® OASYS with Transitions™ reduces the stressful impact that light can have on eyes by helping vision recover from bright light up to five seconds faster and reduces squinting by 38% on average.^{†††4}

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.^{†4} The performance of the lens in its inactivated or indoor state is crucial to recognise. Regardless of the lighting conditions some percentage of the photochromic is always absorbing light so it's always on and working, both indoors and out.²

Driving study

To assess the performance of ACUVUE® OASYS with Transitions™ when driving, a study was conducted comparing the lens with two controls: a clear contact lens, and a clear contact lens with plano photochromic spectacles worn over the top. In all three conditions subjects wore a spectacle frame in order to create a comparable visual experience. The study hypothesis was that ACUVUE® OASYS with Transitions™ would be non-inferior to the controls in five metrics of visual, and seven metrics of driving performance.¹⁵

Visual acuity was measured with a LogMAR chart, with subjects viewing both high and low contrast letters. High contrast vision in low luminance was also recorded. Across two more study visits, subjects were randomised to the different visual corrections and then drove a course on a purpose-built driving assessment track in both the day and at night. The driving track consisted of a number of important everyday situations and hazards to allow driving safety to be assessed. These included pedestrian recognition, hazard detection, lane keeping, sign recognition and overall lap times (Figure 4). The results of the individual



hazard and recognition tasks were combined to form an overall driving score.

Twenty-four subjects completed the study. The hypothesis was proved, with no statistical difference between the test and two controls for visual acuity.¹⁵ Further, overall driving scores for ACUVUE® OASYS with Transitions™ were non-inferior to both controls. In one specific situation—sign recognition—ACUVUE® OASYS with Transitions™ showed a statistically significant advantage. In daytime driving conditions ACUVUE® OASYS with Transitions™ enabled signs to be identified 7 metres (23 feet) further away, and for night time driving 17 metres (56 feet) further away.¹⁵ This illustrates once again, how this new technology may make a demonstrable difference for patients in the real-world. Imagine how useful it might be to potentially identify a crucial road sign sooner when driving on an unfamiliar road at night.

Performance in clinical trial

The most relevant test of any new product is to allow people to wear it during their daily lives, thus allowing them to see how it performs across the range of demanding daily visual tasks and varying light conditions they experience. Clinical trials have been conducted comparing the subjective performance and preference of ACUVUE® OASYS with Transitions™ to the leading reusable contact lens, ACUVUE® OASYS with HYDRACLEAR® PLUS Technology. The studies were randomized, partially-subject masked, crossover, dispensing trials with two-weeks wear of each lens. With regard to contact lens fundamentals: fit, acuity, physiological response, and subjective comfort, vision and handling, there was no significant difference between the two lenses.^{5†} 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 230 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 5). These included both outdoors (nearly 6 to 1) and indoor (4 to 1), plus driving during the day (5 to 1) and driving at night (nearly 4 to 1).⁵ 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.^{5†}

Figure 4: Examples of sign detection tasks on the driving test track



Footnotes

*Calculated per ISO-8980-3 for 380-460nm [Blue Light Hazard Function, B(λ)].

†Ability to see comfortably in bright light

††Clinical trials have shown those with dark irises may be more likely to experience this benefit in the activated ACUVUE® OASYS with Transitions™ lens.

‡Compared to ACUVUE® OASYS with HYDRACLEAR® PLUS.

Figure 5: Among those with a preference, ACUVUE® OASYS with Transitions™ was preferred over the leading reusable lens*

JJV Data on File 2018: ACUVUE® OASYS with Transitions™ Subjective Clinical Evaluation of two silicone hydrogel reusable contact lenses. 6-week dispensing evaluation, n=230 soft CL wearers in the U.S. * Compared to ACUVUE® OASYS with HYDRACLEAR® PLUS

Nearly **6x** TO



FOR OUTDOORS

5x TO 1



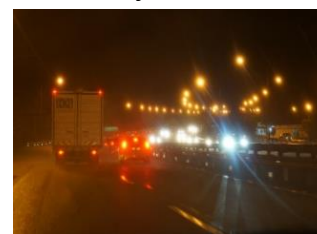
FOR DRIVING DURING THE DAY

4x TO 1



FOR INDOORS

Nearly **4x** TO 1



FOR DRIVING AT NIGHT

CONCLUSIONS

Although light is essential for sight, bright light causes problems for nearly two-thirds of patients on a daily basis, with almost all of this group adopting compensating behaviours to try and cope better with harsh light conditions.¹ Spectral filtering of light has been shown to help with important aspects of functional vision.¹³

ACUVUE® OASYS with Transitions™ is a first-of-its-kind⁹ intelligent light-responsive contact lens.² It seamlessly adapts to balance the amount of indoor and outdoor light entering the eye, including filtering blue light* and blocking harmful UV rays.^{2,3} It has been shown to be comparable to both photochromic spectacle lenses and clear contact lenses for daytime and nighttime driving;¹⁵ to deliver significant differences in visual performance in both its activated (outdoor state) and inactive (indoor state),⁴ and finally, it has been shown to deliver superior overall quality of vision over the leading reusable contact lens.^{5†} Parameters available at launch are shown in Figure 6.

Ask your patients about moments that they are bothered by light, understand what their difficulties are, and know that with ACUVUE® OASYS with Transitions™ there is now a contact lens which can be offered to them to help provide all-day soothing vision.^{†4}

Figure 6: Parameters for ACUVUE® OASYS with Transitions™

Lens material	senofilcon A silicone hydrogel
Technology	HYDRACLEAR® Plus Technology Transitions™ Light Intelligent Technology™
Base curve, mm	8.4 / 8.8
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, including plano)
Dk/t (edge-corrected)	121 x 10 ⁻⁹
Water content	38%
Modulus (MPa)	0.69
UV blocker^{**}	Class 1
Visible light transmission (380-780nm)	Up to 94% (inactivated) Up to 41% (activated)
Center thickness at -3.00D (mm)	0.085
Inside-out mark	Yes
Packaging solution	Optimized to help mimic the electrolyte concentration of natural tears for comfort on insertion

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*Dr. Billy R. Hammond is a paid consultant to Johnson & Johnson Vision Care, Inc.

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

ACUVUE® Brand 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. Lenses should not be prescribed if patients have any eye infection, or experience eye discomfort, excessive tearing, vision changes, redness or other eye problems. Consult the package insert for complete information. Complete information is also available from Johnson & Johnson Vision Care, Inc., by calling 1-800-843-2020, or by visiting www.acuvueprofessional.com.

*Helps protect against transmission of harmful UV radiation to the cornea & into the eye.

** WARNING: 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. You should continue to use UV-absorbing eyewear as directed. NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

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